

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE
COMPLIANCE AUDIT OF SPECIFIC
DIAGNOSIS CODES THAT
CARITEN HEALTH
PLAN, INC.,
(CONTRACT H4461)
SUBMITTED TO CMS**

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Office of Inspector General

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Report in Brief

Date: July 2022

Report No. A-02-20-01009

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Audit

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations according to a system of risk adjustment that depends on the health status of each enrollee. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources than to healthier enrollees, who would be expected to require fewer health care resources.

To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS. Some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.

For this audit, we reviewed one MA organization, Cariten Health Plan, Inc. (Cariten), and focused on nine groups of high-risk diagnosis codes. Our objective was to determine whether selected diagnosis codes that Cariten submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

How OIG Did This Audit

We sampled 270 unique enrollee-years with the high-risk diagnosis codes for which Cariten received higher payments for 2016 through 2017. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$750,508.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS

What OIG Found

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Cariten submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, for 206 of the 270 enrollee-years, the diagnosis codes that Cariten submitted to CMS were not supported in the medical records and resulted in net overpayments of \$557,250.

These errors occurred because the policies and procedures that Cariten had to detect and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. On the basis of our sample results, we estimated that Cariten received at least \$9.2 million in net overpayments for these high-risk diagnosis codes in 2016 and 2017.

What OIG Recommends and Cariten Comments

We recommend that Cariten (1) refund to the Federal Government the \$9.2 million of net overpayments; (2) identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and (3) examine its existing compliance procedures to identify areas where improvements can be made to ensure diagnosis codes that are at high risk for being miscoded comply with Federal requirements and take the necessary steps to enhance those procedures.

Cariten disagreed with our findings and recommendations. Cariten provided additional information for 12 sampled enrollee-years which, according to Cariten, supported either the reviewed diagnosis code or a related diagnosis code. Cariten also stated that our audit methodology departed from governing statistical and actuarial principles and the statutory requirements of the MA program. Additionally, Cariten disagreed that it should perform audits of high-risk diagnoses and stated that its compliance program satisfies all legal and regulatory requirements. After reviewing Cariten's comments and additional information that it provided, we revised the number of enrollee-years in error from 208 to 206 for this final report. We also revised the amount of our first recommendation from \$9.3 million (in our draft report) to \$9.2 million but made no change to our other recommendations. We followed a reasonable audit methodology and correctly applied applicable Federal requirements underlying the MA program.

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INTRODUCTION

WHY WE DID THIS AUDIT

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations based in part on the characteristics of the enrollees being covered. Using a system of risk adjustment, CMS pays MA organizations the anticipated cost of providing Medicare benefits to a given enrollee, depending on such risk factors as the age, sex, and health status of that individual. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources relative to healthier enrollees, who would be expected to require fewer health care resources. To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS.¹ We are auditing MA organizations because some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS.² Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 29 major depressive disorder diagnoses into 1 group.) This audit covered Cariten Health Plan, Inc. (Cariten),³ for contract number H4461⁴ and focused on nine groups of high-risk diagnosis codes for payment years 2016 and 2017.

OBJECTIVE

Our objective was to determine whether selected diagnosis codes that Cariten submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

¹ The providers code diagnoses using the International Classification of Diseases (ICD), Clinical Modification (CM), *Official Guidelines for Coding and Reporting* (ICD Coding Guidelines). The ICD is a coding system that is used by physicians and other health care providers to classify and code all diagnoses, symptoms, and procedures. Effective October 1, 2015, CMS transitioned from the ninth revision of the ICD Coding Guidelines (ICD-9-CM) to the tenth revision (ICD-10-CM). Each revision includes different diagnosis code sets.

² See Appendix B for a list of related Office of Inspector General reports.

³ Cariten Health Plan, Inc. is a subsidiary of Humana, Inc.

⁴ All subsequent references to "Cariten" in this report refer solely to contract number H4461.

BACKGROUND

Medicare Advantage Program

The MA program offers beneficiaries managed care options by allowing them to enroll in private health care plans rather than having their care covered through Medicare's traditional fee-for-service program.⁵ Beneficiaries who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

Under the MA program, CMS makes advance payments each month to MA organizations for the expected costs of providing health care coverage to enrollees. These payments are not adjusted to reflect the actual costs that the organizations incurred for providing benefits and services. Thus, MA organizations will either realize profits if their actual costs of providing coverage are less than the CMS payments or incur losses if their costs exceed the CMS payments.

For 2019, CMS paid MA organizations \$273.8 billion, which represented 34 percent of all Medicare payments for that year.

Risk Adjustment Program

Federal requirements mandate that payments to MA organizations be based on the anticipated cost of providing Medicare benefits to a given enrollee and, in doing so, also account for variations in the demographic characteristics and health status of each enrollee.⁶

CMS uses two principal components to calculate the risk-adjusted payment that it will make to an MA organization for an enrollee: a base rate that CMS sets using bid amounts received from the MA organization and the risk score for that enrollee. These are described as follows:

- *Base rate:* Before the start of each year, each MA organization submits bids to CMS that reflect the MA organization's estimate of the monthly revenue required to cover an enrollee with an average risk profile.⁷ CMS compares each bid to a specific benchmark amount for each geographic area to determine the base rate that an MA organization is paid for each of its enrollees.⁸

⁵ The Balanced Budget Act of 1997, P.L. No. 105-33, as modified by section 201 of the Medicare Prescription Drug, Improvement, and Modernization Act, P.L. No. 108-173, established the MA program.

⁶ The Social Security Act (the Act) §§ 1853(a)(1)(C) and (a)(3); 42 CFR § 422.308(c).

⁷ The Act § 1854(a)(6); 42 CFR § 422.254 et seq.

⁸ CMS's bid-benchmark comparison also determines whether the MA organization must offer supplemental benefits or must charge a basic beneficiary premium for the benefits.

- *Risk score:* A risk score is a relative measure that reflects the additional or reduced costs that each enrollee is expected to incur compared with the costs incurred by enrollees on average. CMS calculates risk scores based on an enrollee's health status (discussed below) and demographic characteristics (such as the enrollee's age and sex). This process results in an individualized risk score for each enrollee, which CMS calculates annually.

To determine an enrollee's health status for the purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from acceptable data sources, including certain physicians and hospitals. MA organizations collect the diagnosis codes that physicians document on the medical records and submit these codes to CMS. CMS then maps certain diagnosis codes, on the basis of similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs).⁹ Each HCC has a factor (which is a numerical value) assigned to it for use in each enrollee's risk score.

As a part of the risk adjustment program, CMS consolidates certain HCCs into related-disease groups. Within each of these groups, CMS assigns an HCC for only the most severe manifestation of a disease in a related-disease group. Thus, if MA organizations submit diagnosis codes for an enrollee that map to more than one of the HCCs in a related-disease group, only the most severe HCC will be used in determining the enrollee's risk score.

For enrollees who have certain combinations of HCCs, CMS assigns a separate factor that further increases the risk score. CMS refers to these combinations as disease interactions. For example, if MA organizations submit diagnosis codes for an enrollee that map to the HCCs for lung cancer and immune disorders, CMS assigns a separate factor for this disease interaction. By doing so, CMS increases the enrollee's risk score for each of the two HCC factors and by an additional factor for the disease interaction.

The risk adjustment program is prospective. Specifically, CMS uses the diagnosis codes that the enrollee received for 1 calendar year (known as the service year) to determine HCCs and calculate risk scores for the following calendar year (known as the payment year). Thus, an enrollee's risk score does not change for the year in which a diagnosis is made. Instead, the risk score changes for the entirety of the year after the diagnosis has been made. Further, the risk score calculation is an additive process—as HCC factors (and, when applicable, disease interaction factors) accumulate, an enrollee's risk score increases, and the monthly risk-adjusted payment to the MA organization also increases. In this way, the risk adjustment program compensates MA organizations for the additional risk for providing coverage to enrollees expected to require more health care resources.

CMS multiplies the risk scores by the base rates to calculate the total monthly Medicare payment that an MA organization receives for each enrollee before applying the budget

⁹ During our audit period, CMS calculated risk scores based on the Version 22 CMS-HCC model.

sequestration reduction.¹⁰ Miscoded diagnoses submitted to CMS may result in HCCs that are not validated and incorrect enrollee risk scores, which may lead to improper payments (overpayments) from CMS to MA organizations. Conversely, correctly coded diagnoses that MA organizations do not submit to CMS may lead to improper payments (underpayments).

High-Risk Groups of Diagnoses

Using data mining techniques and discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. For this audit, we focused on nine high-risk groups:

- *Acute Stroke*: An enrollee received one acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim. A diagnosis of history of stroke (which does not map to an HCC) typically should have been used.
- *Acute Heart Attack*: An enrollee received one diagnosis that mapped to either the HCC for Acute Myocardial Infarction or to the HCC for Unstable Angina and Other Acute Ischemic Heart Disease (Acute Heart Attack HCCs) on only one physician claim but did not have that diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician's claim). A diagnosis indicating a history of myocardial infarction (which does not map to an HCC) typically should have been used.
- *Embolism*: An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease With Complications (Embolism HCCs) but did not have an anticoagulant medication dispensed on his or her behalf. An anti-coagulant medication is typically used to treat an embolism. A diagnosis of history of embolism (an indication that the provider is evaluating a prior acute embolism diagnosis, which does not map to an HCC) typically should have been used.
- *Vascular Claudication*: An enrollee did not receive a diagnosis related to vascular claudication (that mapped to the HCC for Vascular Disease) for 2 years and then, in the subsequent year, received that diagnosis but had medication dispensed on his or her behalf that is frequently dispensed for a diagnosis of neurogenic claudication.¹¹ In these instances, the vascular claudication diagnoses may not be supported in the medical records.

¹⁰ Budget sequestration refers to automatic spending cuts that occurred through the withdrawal of funding for certain Federal Government programs, including the MA program, as provided in the Budget Control Act of 2011 (BCA) (P.L. No. 112-25 (8-2-2011)). Under the BCA, the sequestration of mandatory spending began in April 2013.

¹¹ Vascular claudication and neurogenic claudication are different diagnoses. Vascular claudication is a condition that can result in leg pain while walking and is caused by insufficient blood flow. Neurogenic claudication is a condition that can also result in leg pain but is caused by damage to the neurological system, namely the spinal cord and nerves.

- *Lung Cancer*: An enrollee received a lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period either before or after the diagnosis. In these instances, a diagnosis of history of lung cancer (which does not map to an HCC) typically should have been used.
- *Breast Cancer*: An enrollee received a breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. A diagnosis of history of breast cancer (which does not map to an HCC) typically should have been used.
- *Colon Cancer*: An enrollee received a colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. A diagnosis of history of colon cancer (which does not map to an HCC) typically should have been used.
- *Prostate Cancer*: An enrollee 74 years old or younger received a prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. A diagnosis of history of prostate cancer (which does not map to an HCC) typically should have been used.
- *Major Depressive Disorder*: An enrollee received a major depressive disorder diagnosis (that mapped to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) during the service year but did not have an antidepressant medication dispensed on his or her behalf. In these instances, the major depressive disorder diagnoses may not be supported in the medical records.

In this report, we refer to the diagnosis codes associated with these groups as “high-risk diagnosis codes.”

Cariten Health Plan, Inc.

Cariten is an MA organization based in Knoxville, Tennessee. As of December 31, 2017, Cariten provided coverage under contract number H4461 to approximately 108,535 enrollees. For the

2016 and 2017 payment years (audit period),¹² CMS paid Cariten approximately \$2.4 billion to provide coverage to its enrollees.¹³

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of the nine high-risk groups during the 2015 and 2016 service years, for which Cariten received increased risk-adjusted payments for payment years 2016 and 2017, respectively. Because enrollees could be classified in more than one high-risk group or have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment year, which we refer to as “enrollee-years.” We identified 5,990 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$14,087,848). We selected for audit a stratified random sample of 270 enrollee-years.

Table 1 details the number of sampled enrollee-years for each high-risk group.

Table 1: Sampled Enrollee-Years

High Risk Group	Number of Sampled Enrollee Years
1. Acute Stroke	30
2. Acute Heart Attack	30
3. Embolism	30
4. Vascular Claudication	30
5. Lung Cancer	30
6. Breast Cancer	30
7. Colon Cancer	30
8. Prostate Cancer	30
9. Major Depressive Disorder	30
Total for All High-Risk Groups	270

Cariten provided medical records as support for the selected diagnosis codes associated with the 270 enrollee-years. We used an independent medical review contractor to review the medical records to determine whether the selected diagnosis codes that Cariten submitted to CMS were supported. If the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

¹² The 2016 and 2017 payment year data were the most recent data available at the start of the audit.

¹³ All of the payment amounts that CMS made to Cariten and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology, Appendix C contains our statistical sampling methodology, and Appendix D contains our sample results and estimates.

FINDINGS

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Cariten submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 64 of the 270 sampled enrollee-years, the medical records supported the diagnosis codes that Cariten submitted to CMS. However, for the remaining 206 enrollee-years, the diagnosis codes were not supported in the medical records.

These errors occurred because the policies and procedures that Cariten had to detect and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. As a result, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Cariten received at least \$9.2 million in net overpayments for 2016 and 2017.¹⁴

FEDERAL REQUIREMENTS

Payments to MA organizations are adjusted for risk factors, including the health status of each enrollee (the Social Security Act (the Act) § 1853(a)). CMS applies a risk factor based on data obtained from the MA organizations (42 CFR § 422.308).

Federal regulations state that MA organizations must follow CMS's instructions and submit to CMS the data necessary to characterize the context and purposes of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner (42 CFR § 422.310(b)). MA organizations must obtain risk adjustment data required by CMS from the provider, supplier, physician, or other practitioner that furnished the item or service (42 CFR § 422.310(d)(3)).

Federal regulations also state that MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes and that such data must conform to all relevant national standards (42 CFR §§ 422.504(l) and 422.310(d)(1)). In addition, MA organizations must contract with CMS and agree to follow

¹⁴ Specifically, we estimated that Cariten received at least \$9,212,531 in net overpayments. To be conservative, we recommend recovery at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

CMS's instructions, including the *Medicare Managed Care Manual* (the Manual) (see 42 CFR § 422.504(a)).

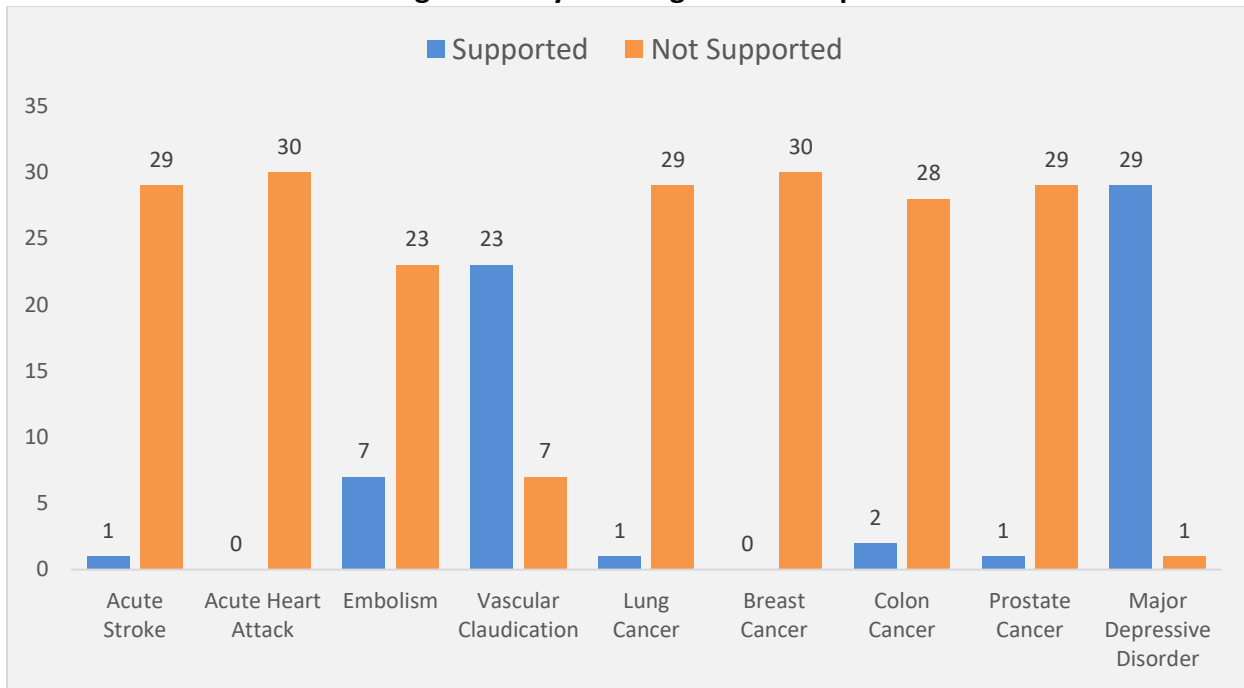
CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap.7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7, § 40). The diagnosis must be coded according to the ICD Coding Guidelines (42 CFR § 422.310(d)(1) and 45 CFR §§ 162.1002(b)(1) and (c)(2)-(3)). Further, the MA organizations must implement procedures to ensure that diagnoses come only from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities, and physicians (the Manual, chap. 7, § 40).

Federal regulations state that MA organizations must monitor the data that they receive from providers and submit to CMS. Federal regulations also state that MA organizations must “adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS’s program requirements” Further, MA organizations must establish and implement an effective system for routine monitoring and identification of compliance risks (42 CFR § 422.503(b)(4)(vi), See Appendix E).

MOST OF THE SELECTED HIGH-RISK DIAGNOSIS CODES THAT CARITEN SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Most of the selected high-risk diagnosis codes that Cariten submitted to CMS for use in CMS’s risk adjustment program did not comply with Federal requirements. As shown in the figure on the following page, the medical records for 206 of the 270 sampled enrollee-years did not support the diagnosis codes. In these instances, Cariten should not have submitted the diagnosis codes to CMS and received the resulting net overpayments.

Figure: Analysis of High-Risk Groups



Incorrectly Submitted Diagnosis Codes for Acute Stroke

Cariten incorrectly submitted diagnosis codes for acute stroke for 29 of 30 sampled enrollee-years. Specifically:

- For 23 enrollee-years, the medical records indicated in each case that the individual had previously had a stroke, but the records did not justify an acute stroke diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the medical record (for a service that occurred in 2016) indicated that the individual had an acute stroke in 2004. The independent medical review contractor noted that “there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC [Ischemic or Unspecified Stroke] or a related HCC. There is mention of a history of a stroke [diagnosis]” The history of stroke diagnosis code does not map to an HCC.

- For 5 enrollee-years, the medical records did not contain sufficient information to support an acute stroke diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC [Ischemic or Unspecified Stroke] or a related HCC.

There is mention of a transient cerebral ischemia [diagnosis]¹⁵ that does not result in an HCC.”

- For the 1 remaining enrollee-year, Cariten submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiparesis¹⁶ (which was supported in the medical records). The independent medical review contractor noted that “there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC [Ischemic or Unspecified Stroke] or a related HCC. There is mention of hemiparesis following a [stroke diagnosis] that results in [the] HCC [for Hemiplegia/Hemiparesis] that should have been assigned instead of the submitted HCC.” This error caused an underpayment.

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and Cariten received \$65,172 in net overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Heart Attack

Cariten incorrectly submitted diagnosis codes for acute heart attack for all 30 sampled enrollee-years. Specifically:

- For 14 enrollee-years, the medical records indicated in each case that the individual had an old myocardial infarction diagnosis but the records did not justify an acute heart attack diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the medical record (for a service that occurred in 2015) indicated that the individual had an acute heart attack in 2003. The independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [the Unstable Angina and Other Acute Ischemic Heart Disease] HCC. There is documentation of a past medical history of myocardial infarction [diagnosis] that does not result in an HCC.”

- For 11 enrollee-years, the medical records did not contain sufficient information to support an acute heart attack diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Acute Myocardial Infarction]. There is documentation of atypical chest pain [diagnosis] that does not result in an HCC.”

¹⁵ Transient cerebral ischemia is a temporary blockage of blood flow to the brain.

¹⁶ Hemiparesis is defined as muscular weakness or partial paralysis restricted to one side of the body.

- For the remaining 5 enrollee-years, we identified support for an unspecified angina pectoris diagnosis¹⁷ that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Cariten should not have received an increased payment for the acute myocardial infarction diagnosis. Rather, it should have received a lesser increased payment for the unspecified angina pectoris diagnosis.

As a result of these errors, the Acute Heart Attack HCCs were not validated, and Cariten received \$62,866 in net overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

Cariten incorrectly submitted diagnosis codes for embolism for 23 of 30 sampled enrollee-years. Specifically:

- For 17 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism but the records did not justify an embolism diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [an Embolism] HCC. There is documentation of a past medical history of a pulmonary embolism¹⁸ [diagnosis] in [2013] that does not result in an HCC.”

- For 5 enrollee-years, the medical records did not contain sufficient information to support an embolism diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [an Embolism] HCC. There is insufficient objective evidence of an active [deep vein thrombosis]¹⁹ as there is no physical findings including left leg signs and no history of pain or swelling. No test results to support the diagnosis.”

- For the 1 remaining enrollee-year, Cariten did not provide a legible copy of a medical record to support the embolism diagnosis; therefore, the Embolism HCC was not validated.

¹⁷ Angina pectoris is defined as a disease marked by brief sudden attacks of chest pain or discomfort caused by deficient oxygenation of the heart muscles, usually due to impaired blood flow to the heart.

¹⁸ Pulmonary embolism is a blockage in one of the pulmonary arteries in the lungs.

¹⁹ Deep vein thrombosis occurs when a blood clot forms in one or more of the deep veins in the body, usually in the legs.

As a result of these errors, the Embolism HCCs were not validated, and Cariten received \$56,623 in overpayments for these 23 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Vascular Claudication

Cariten incorrectly submitted diagnosis codes for vascular claudication for 7 of 30 sampled enrollee-years. Specifically, for the 7 enrollee-years, the medical records did not contain sufficient information to support a vascular claudication diagnosis. For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [the Vascular Disease] HCC.”

As a result of these errors, the HCC for Vascular Disease was not validated, and Cariten received \$16,842 in overpayments for these 7 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

Cariten incorrectly submitted diagnosis codes for lung cancer for 29 of 30 sampled enrollee-years. Specifically:

- For 19 enrollee-years, the medical records indicated in each case that the individual had previously had lung cancer but the records did not justify a lung cancer diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [the Lung Cancer] HCC. There is documentation of a past medical history of lung cancer with no evidence of disease progression [diagnosis] that does not result in an HCC.”

- For 5 enrollee-years, the medical records did not contain sufficient information to support a lung cancer diagnosis.

For example, for 1 enrollee-year, the medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [the Lung Cancer] HCC. There is documentation of left upper lobe lesion²⁰ [diagnosis] that does not result in an HCC.”

- For the remaining 5 enrollee-years, the medical records did not support the submitted lung cancer diagnoses. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to the Breast, Prostate and Other Cancers and Tumors HCC, which is a less severe manifestation of the related-disease group. Accordingly, Cariten should not have received an increased payment for the submitted

²⁰ A left upper lobe lesion is an area of abnormal tissue, which may be benign (not cancer) or malignant (cancer), on the left upper lobe of the lung.

lung cancer diagnoses. Rather, it should have received a lesser increased payment for the other diagnosis identified.

As a result of these errors, the Lung and Other Severe Cancers HCC was not validated, and Cariten received \$212,641 in net overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

Cariten incorrectly submitted diagnosis codes for breast cancer for all 30 sampled enrollee-years. Specifically:

- For 29 enrollee-years, the medical records indicated in each case that the individual had previously had breast cancer but the records did not justify a breast cancer diagnosis at the time of the physician's service.

For example, the medical review contractor noted that "there is no documentation of any condition that will result in the assignment of [the Breast Cancer] HCC. There is documentation of a past medical history of breast cancer with no evidence of recurrence or progression [diagnosis] that does not result in an HCC."

- For the 1 remaining enrollee-year, the medical records did not contain sufficient information to support a breast cancer diagnosis. The medical review contractor noted that "there is no documentation of any condition that will result in the assignment of [the Breast Cancer] HCC."

As a result of these errors, the Breast, Prostate, and Other Cancers and Tumors HCC was not validated, and Cariten received \$40,510 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

Cariten incorrectly submitted diagnosis codes for colon cancer for 28 of 30 sampled enrollee-years. Specifically:

- For 23 enrollee-years, the medical records indicated in each case that the individual had previously had colon cancer but the records did not justify a colon cancer diagnosis at the time of the physician's service.

For example, for 1 enrollee-year, the medical review contractor noted that "there is no documentation of any condition that will result in the assignment of [the Colon Cancer] HCC. There is documentation of a past medical history of colon cancer with no clinical evidence of recurrent disease [diagnosis] that does not result in an HCC."

- For 4 enrollee-years, the medical records did not support the submitted colon cancer diagnoses. However, for each of these enrollee-years, we identified support for another

diagnosis that mapped to the Breast, Prostate and Other Cancers and Tumors HCC, which is a less severe manifestation of the related-disease group. Accordingly, Cariten should not have received an increased payment for the submitted colon cancer diagnoses. Rather, it should have received a lesser increased payment for the other diagnosis identified.

- For the 1 remaining enrollee-year, the medical records did not contain sufficient information to support a colon cancer diagnosis. The medical review contractor noted that “there is no documentation of any condition that will result in assignment of [the Colon Cancer] HCC.”

As a result of these errors, the Colorectal, Bladder, and Other Cancers HCC was not validated, and Cariten received \$64,296 in net overpayments for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

Cariten incorrectly submitted diagnosis codes for prostate cancer for 29 of 30 sampled enrollee-years. Specifically:

- For 27 enrollee-years, the medical records indicated in each case that the individual had previously had prostate cancer but the records did not justify a prostate cancer diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [the Prostate Cancer] HCC. There is documentation of a past medical history of prostate cancer [diagnosis] that does not result in an HCC.”

- For the remaining 2 enrollee-years, the medical records did not contain sufficient information to support a prostate cancer diagnosis.

For example, for 1 enrollee-year, the medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [the Prostate Cancer] HCC. There is no documentation of a diagnosis in the medical record.”

As a result of these errors, the Breast, Prostate, and Other Cancers and Tumors HCC was not validated, and Cariten received \$34,696 in overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder

Cariten incorrectly submitted diagnosis codes for major depressive disorder for 1 of 30 sampled enrollee-years. Specifically, for the 1 enrollee-year, the medical records did not contain

sufficient information to support a major depressive disorder diagnosis.²¹ The independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [the Major Depressive, Bipolar, and Paranoid Disorders] HCC. There is documentation of psychological and behavioral [factors] associated with disorders or diseases classified elsewhere [diagnosis] . . . which [does] not result in an HCC.”

As a result of this error, the HCC for Major Depressive, Bipolar, and Paranoid Disorders was not validated, and Cariten received \$3,604 in overpayments for this 1 sampled enrollee-year.

THE POLICIES AND PROCEDURES THAT CARITEN USED TO DETECT AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS WERE NOT ALWAYS EFFECTIVE

The errors we identified occurred because the policies and procedures that Cariten had to detect and correct noncompliance with CMS’s program requirements, as mandated by Federal regulations (42 CFR § 422.503(b)(4)(vi)), were not always effective.

Cariten had compliance procedures to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. These procedures included a provider education program that was designed to promote accurate diagnosis codes, which provided instructions to its providers on the proper coding of several risk adjustment diagnoses, including those in the nine high-risk groups reviewed in our audit. In addition, Cariten’s compliance procedures included routine internal medical reviews to compare diagnosis codes from a random sample of claims to the diagnoses that were documented on the associated medical records. However, these internal medical reviews did not focus on any specific high-risk diagnosis codes, including those we identified as being at a higher risk for being miscoded. As a result, Cariten’s compliance procedures to prevent and detect incorrect high-risk diagnoses during our audit period were not always effective.

CARITEN RECEIVED NET OVERPAYMENTS

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Cariten received at least \$9,212,531 in net overpayments in 2016 and 2017. (See Appendix D for sample results and estimates).

RECOMMENDATIONS

We recommend that Cariten Health Plan, Inc.:

- refund to the Federal Government the \$9,212,531 of estimated net overpayments;

²¹ For this 1 enrollee-year, the independent medical review contractor identified support for a diagnosis code for a milder form of depression, which does not map to an HCC.

- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
- examine its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

CARITEN COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Cariten, through its parent company, disagreed with our findings and recommendations.²² Although Cariten did not specifically disagree with 196 of the 208 enrollee-years identified in our draft report as not having medical records to support the associated diagnosis codes, Cariten disagreed with our findings for the remaining 12 enrollee-years. For each of the 12 enrollee-years, Cariten provided additional information regarding why it believed that either the associated HCCs were validated or an HCC for a less severe manifestation of the related disease group was validated.

Cariten also stated that our audit methodology departed from governing statistical and actuarial principles, the statutory requirements of the MA program, CMS's Risk Adjustment Data Validation (RADV) processes, and the methodology used in similar OIG audits. Additionally, Cariten did not agree with our overpayment estimation methodology. Lastly, Cariten argued that MA organizations are not required to conduct audits to the standard that OIG suggests and stated that its compliance program satisfies all legal and regulatory requirements.

After reviewing Cariten's comments and the additional information it provided, we reduced the number of enrollee-years in error from 208 to 206 and adjusted our calculation of net overpayments. Accordingly, we reduced our first recommendation from \$9,314,930 to \$9,212,531 for this final report. We made no changes to our second and third recommendations.

A summary of Cariten's comments and our responses follows. Cariten's comments are included as Appendix F.²³

²² As indicated earlier, Cariten is a subsidiary of Humana, Inc.

²³ We excluded an attachment that contained personally identifiable information. We are separately providing Cariten's comments and attachments in their entirety to CMS.

CARITEN DID NOT AGREE WITH OIG’S RECOMMENDATION THAT CARITEN REFUND ESTIMATED NET OVERPAYMENTS

Cariten Did Not Agree With OIG’s Findings for 12 Sampled Enrollee-Years

Cariten Comments

Cariten did not agree with our draft report findings for 12 sampled enrollee-years (as shown in Table 2) and requested that we reconsider our findings and modify our estimate of overpayments.

Table 2: Summary of Enrollee-Years for Which Cariten Disagreed With Our Findings

High Risk Group ²⁴	Number of Sampled Enrollee Years
Acute Heart Attack	1
Embolism	1
Vascular Claudication	1
Lung Cancer	3
Breast Cancer	3
Colon Cancer	1
Prostate Cancer	1
Major Depressive Disorder	1
Total	12

For 11 of the 12 sampled enrollee-years, Cariten provided additional information (including medical records and explanations) supporting its belief that the HCCs for the sampled enrollee-years were validated. For the 1 remaining enrollee-year, Cariten stated there was support for a diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group.²⁵

OIG Response

For the 11 enrollee-years for which Cariten provided additional documentation, our independent medical review contractor reviewed the documentation and reaffirmed that 9 of the 11 HCCs were unvalidated. For example, for 1 enrollee-year from the prostate cancer high-risk group, our contractor upheld its original decision upon reconsideration and noted:

²⁴ In Cariten’s written comments, Cariten refers to the embolism and vascular claudication groups as Vascular Disease conditions. We used information provided in Cariten’s attachment to its comments to categorize the enrollee-years into the appropriate high-risk group.

²⁵ Cariten made this statement in the attachment to its comments.

“[T]here is documentation of a past medical history of prostate cancer with the patient having undergone [radiation therapy] in 2009. . . . The patient was seen for follow-up and treatment of the side effects of the radiation therapy. The patient was scheduled for an annual follow-up visit. . . . The documentation supports follow-up services for a history of prostate cancer with no treatment or active prostate cancer. Past medical history of prostate cancer [diagnosis] should be assigned and does not result in an HCC.”

For the other 2 enrollee-years, our contractor reversed its original decision and stated that the HCCs were validated. As a result, we reduced the number of enrollee-years in error from 208 (as reported in our draft report) to 206.²⁶ We also revised our findings and reduced the associated monetary recommendation.

With respect to the 1 enrollee-year for which Cariten asserted it had support for a diagnosis code that mapped to an HCC for a less severe manifestation of the related-disease group, we agree that the HCC indicated by Cariten in its comments was supported. However, we had considered the financial impact of this HCC when we estimated the recommended refund amount included in our draft report.²⁷ Therefore, we did not need to make any adjustments related to this HCC for the recommended refund amount included in this final report.

Cariten Did Not Agree With How OIG Incorporated Underpayments Into Its Estimates

Cariten Comments

Cariten stated that our estimate of overpayments significantly devalued underpayments and is statistically unsupported. Specifically, Cariten stated that, based on its understanding of our audit procedures and methodology, our findings are “systematically skewed towards identifying overpayments rather than underpayments, [rendering] its results inherently unreliable.” In this regard, Cariten made two related points:

- For OIG’s sampled enrollee-years, Cariten stated that it “was tasked only with supplying medical records to substantiate specific HCCs actually submitted to CMS, not to collect and submit medical records to substantiate all HCCs that *could have been* submitted to CMS (i.e., potential underpayments)” (*emphasis in original*).

²⁶ Our contractor stated that Cariten’s arguments did not impact its decisions related to the 206 sampled enrollee-years found to be in error. The contractor also stated that it found “no systemic quality issues” as part of its review.

²⁷ Specifically, on page 11 of this report we state that for 5 enrollee-years in the acute heart attack group, we identified support for an unspecified angina pectoris diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Therefore, the 5 enrollee-years, including the one Cariten identified in its comments, already reflects the lesser increased payment for the unspecified angina pectoris diagnosis.

- Cariten also stated that “OIG excluded from its sampling frame all non ‘high-risk’ diagnosis codes associated with payment years 2016 and 2017 for [Cariten] enrollees as well as those for which [Cariten] did not submit any risk-adjusting diagnosis codes.” According to Cariten, this exclusion systematically reduced the possibility of identifying underpayments.

Accordingly, Cariten stated that, “[b]ecause OIG’s audit methodology did not conduct a systematic or statistically valid search for substantiated but unsubmitted HCCs, OIG’s extrapolation methodology is statistically unsupported.” In addition, Cariten noted that our net overpayment calculations appear to incorporate the determination that the error for 1 enrollee-year resulted in an underpayment; therefore, we should consider additional “underpayment credits” in the overpayment estimate. Cariten requested that we justify our approach under applicable government auditing standards.

OIG Response

We disagree with Cariten’s statements regarding underpayments. In accordance with the Inspector General Act of 1978, 5 U.S.C. App., our audits are intended to provide an independent assessment of Department of Health and Human Services (HHS) programs and operations. We conduct our audits in accordance with generally accepted government auditing standards, which require that audits be planned and performed so as to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions. Our objective was to determine whether selected high-risk diagnosis codes that Cariten submitted to CMS for use in CMS’s risk adjustment program complied with Federal requirements. In this regard, the identification of (1) all possible diagnosis codes that Cariten could have submitted on behalf of the sampled enrollee-years and (2) enrollee-years for which Cariten did not submit any risk-adjusting diagnosis codes were beyond the scope of our audit.

Cariten’s description of our net overpayment calculations as skewed is not accurate. A valid estimate of net overpayments does not need to take into consideration all potential HCCs or underpayments within the audit period. Our estimate of net overpayments addresses only the portion of payments related to the reviewed HCCs and does not extend to HCCs that were beyond the scope of our audit. In accordance with our objective and as detailed in Appendices C and D, we properly executed a statistically valid sampling methodology in that we defined our sampling frame (enrollee-years with a high-risk diagnosis) and sample unit, randomly selected our sample, applied relevant criteria to evaluate the sample, and used statistical sampling software to apply the correct formulas to estimate the net overpayments in the sampling frame made to Cariten.

Additionally, we asked our independent medical review contractor to review all medical records that Cariten submitted to determine whether the documentation supported any diagnosis codes that mapped to the reviewed HCCs. In this regard, we considered instances in which our contractor found a diagnosis or HCC that should have been used instead of the diagnosis or HCC that Cariten submitted to CMS. If our contractor identified a diagnosis code that Cariten should

have submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC (described by Cariten as “underpayment credits”) in our calculation of net overpayments and the resulting estimate.

Cariten Stated That OIG’s Extrapolation Methodology Did Not Apply Certain CMS Requirements

Cariten Comments

Cariten stated that our extrapolation methodology did not apply certain CMS requirements and thus “improperly equates individual unsubstantiated HCC submissions with overpayments.” Moreover, Cariten stated that our recommendation that it refund estimated overpayments violates a payment principle known as “actuarial equivalence.”

Cariten cited the provision of the Act that mandates that risk-adjusted payments be made in a manner that ensures actuarial equivalence between CMS payments for health care coverage under MA and CMS payments under Medicare’s traditional fee-for-service (FFS) program. According to Cariten, actuarial equivalence “requires risk-adjusted payments to [MA organizations] based on actuarially supportable calculations of the expected cost to CMS if the [MA organizations’] enrollees received their health benefits through the Medicare FFS program.” Cariten asserted that identifying diagnosis codes that were incorrect under MA would create a data inconsistency issue because these diagnosis codes would be subjected to different documentation standards than those that exist under the Medicare FFS program.²⁸ Cariten further stated that “audits of so-called ‘high-risk’ codes perfectly exemplify the importance of addressing the [d]ata [i]nconsistency [i]ssue in an actuarially sound manner: such codes are likely to be equally unsubstantiated in the FFS context.”

Cariten stated that, to address the data inconsistency issue, CMS announced in CY 2012 “that it would determine a contract-level payment error in RADV audits only after applying a Fee-for-Service Adjuster (‘FFSA’) to account for the rate of unsubstantiated diagnosis codes in the Medicare FFS claims data from which CMS’s HCC [factors] were initially derived.” Cariten stated that, in its bid to CMS for payment years 2015 and 2016, it notified CMS that it was “relying on CMS’s plan to develop and apply an FFSA as part of any RADV process.” Further, Cariten stated, “CMS did not respond to this bid certification or otherwise suggest to [Cariten] that [Cariten’s] bid should be modified.” Cariten also cited a November 2018 proposed rule by CMS to eliminate the FFSA. Cariten stated that this was only a proposal; therefore, the RADV methodology (using the FFSA) that CMS introduced in CY 2012 remains operative.

Cariten stated that our draft report does not appear to reference the Act’s actuarial equivalence requirement of applying an FFSA; therefore, we did not appear to take the necessary steps to resolve the data inconsistency issue in our overpayment calculation.

²⁸ Although different diagnosis codes affect payment methodologies in the MA program, they do not have the same effect in the Medicare FFS program.

OIG Response

Our audit methodology correctly applied CMS requirements to properly identify the overpayment amount associated with unsubstantiated HCCs for each sample item. Specifically, we used the results of the independent medical review contractor’s review to determine which HCCs were not substantiated and, in some instances, to identify HCCs that should have been used but were not used in the associated enrollees’ risk score calculations. We followed CMS’s risk adjustment program requirements to determine the payment that CMS should have made for each enrollee and used the overpayments or underpayments to estimate net overpayments.

Regarding Cariten’s statement that we did not consider “actuarial equivalence” in our overpayment calculations, we recognize that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program, including the application of any FFSA. Moreover, CMS has not issued any requirements that compel us to reduce our net overpayment calculations.²⁹ If CMS deems it appropriate to apply an FFSA, it will adjust our overpayment finding by whatever amount it determines necessary. Thus, we believe that our audit methodology provides a reasonable basis for our findings and recommendations, including our estimation of net overpayments.³⁰

Cariten Noted That Similar OIG Audits Used Different Overpayment Calculations

Cariten Comments

Cariten stated that we should reconsider our monetary recommendation because our “use of different calculation methodologies” for other audits of MA organizations is “arbitrary and capricious.” Cariten noted that, as of December 2021, we issued five similar audits of “specific so-called ‘high-risk’ diagnosis codes” submitted by MA organizations to CMS. Cariten stated that these audits focused on different high-risk diagnosis codes, defined the scope of the audited high-risk diagnosis codes differently, and applied different methodologies (judgmental samples without extrapolation for two audits and statistical sampling with extrapolation for three audits) for calculating overpayments. Further, Cariten stated that OIG has not defined what it means for a diagnosis code to be “high-risk.” To these points, Cariten stated that we have “never acknowledged that [our] audit methodology is in constant flux” and must “explain

²⁹ In 2018, CMS proposed to not include an FFSA in any final RADV payment error methodology (Proposed Rule at 83 Fed. Reg. 54982, 55041). To Cariten’s point about CMS’s 2012 statement, we reiterate that CMS has not issued any requirements that compels us to reduce our overpayment calculations.

³⁰ OIG audit findings and recommendations do not represent final determinations by CMS. Action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures. In accordance with 42 CFR § 422.311, which addresses audits conducted by the Secretary (including those conducted by the OIG), if a disallowance is taken, MA organizations have the right to appeal the determination that an overpayment occurred through the Secretary’s RADV appeals process.

why it is justified in adopting dissimilar practices in audits that all purport to cover so-called ‘high-risk’ diagnosis code submissions by MA organizations.”

OIG Response

Our use of statistical sampling to estimate net overpayments is not arbitrary and capricious. As stated earlier, our audits are planned and performed in accordance with generally accepted government auditing standards so as to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions. Accordingly, we designed this audit to determine whether the diagnosis codes that Cariten submitted to CMS for use in the risk adjustment program were adequately supported in the medical records, and thus complied with Federal requirements.

Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.³¹ Although our initial audits of high-risk diagnosis codes only included non-statistical sampling, we determined that the best use of our resources was to transition to statistical sampling and estimation for subsequent audits in this area. As a result, the methodology used in this audit did not mirror the methodology used in the initial audits, nor did it have to.

We also disagree with Cariten’s comment that we did not disclose how a diagnosis code was defined as high-risk. We provided this information multiple times throughout the audit and in our draft report (see page 4 and Appendix C of this final report). Additionally, the methodology and approaches that we have used to identify high-risk diagnosis codes and calculate overpayments for our series of audits of MA organizations have evolved.

Cariten Noted That OIG Did Not Follow CMS’s Established Risk Adjustment Data Validation Methodology

Cariten Comments

Cariten noted that our audit methodology “departs from CMS’s established RADV methodology in several important respects.” Specifically:

- Cariten took exception to our use of a physician (as described in Appendix A) as a “tiebreaker” in instances when two coding reviewers disagree. Cariten stated that, instead of relying on the clinical judgment of a physician to resolve a disagreement between two coders, OIG should use the same method that CMS uses during a RADV audit, which is to consider the code validated as long as one of two coders substantiates

³¹ See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

a diagnosis code for the HCC under review. Cariten stated that “CMS’s approach reflects a true coding analysis, rather than an assessment of clinical support for a particular condition.”

- Cariten stated that the “specific diagnosis coding guidance” that our independent medical review contractor followed was unclear and “does not appear to have complied with the notice-and-comment requirements of *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019).” As an example, Cariten questioned whether we followed CMS’s “2017 RADV Medical Record Reviewer Guidance,” which, according to Cariten, “expressly states that ‘reviewers should evaluate all listed conditions for consistency within the full provider documentation with the understanding that specific management and treatment of every chronic condition is not always going to be clearly documented in the one record submitted to validate the [HCC].’” Moreover, Cariten stated that “to the extent the contractor’s review underlying OIG’s audit findings did not conform to CMS diagnosis coding guidance, the contractor’s approach would have biased OIG’s results and recommendations.”

In addition, Cariten stated that it does not understand the legal basis for our recommendation that it repay funds based on an audit methodology that is inconsistent with the methodology used by CMS in its RADV audits. Cariten stated that holding MA organizations to different risk-adjustment data standards based on whether CMS or OIG conducts the audit would be “arbitrary and capricious under the Administrative Procedure Act (APA).”³²

OIG Response

As stated earlier, our audits are intended to provide an independent assessment of HHS programs and operations in accordance with the Inspector General Act of 1978, 5 U.S.C. App. Although our approach was generally consistent with the methodology CMS uses in its RADV audits, it did not mirror CMS’s approach in all aspects, nor did it have to. Further, we disagree that the differences between our approach and CMS’s approach would hold MA organizations to different risk-adjustment documentation standards that would be considered arbitrary or capricious under the APA. Specifically:

- The independent medical review contractor’s use of senior coders to perform coding reviews, as well as its use of a physician—who was board-certified and did not apply clinical judgment when serving as the final decisionmaker—reflected a reasonable method to determine whether the medical record adequately supported the reported diagnosis codes.

³² The APA governs the process by which Federal agencies develop and issue regulations. It includes requirements for publishing notices of proposed and final rulemaking in the Federal Register and provides opportunities for the public to comment on notices of proposed rulemaking.

- Regarding Cariten’s description of our diagnosis coding guidance as “unclear,” we note that, prior to the issuance of the draft report, we informed Cariten that our independent medical review contractor performed its review to determine whether diagnoses were coded according to the ICD Coding Guidelines and CMS’s 2017 RADV Medical Record Reviewer Guidance. We did not apply any new regulatory requirements that would be subject to notice-and-comment rulemaking. In addition, as previously stated, our contractor reviewed all medical records that Cariten submitted to determine whether the reviewed HCCs were supported in the medical records. With respect to the “chronic condition” example that Cariten cited, our contractor’s methodology complied with applicable CMS guidance and we provided this guidance to Cariten prior to the issuance of the draft report.

Cariten Did Not Agree With OIG’s Use of the 90-Percent Confidence Interval In Estimating Overpayments

Cariten Comments

Cariten disagreed with how we calculated our estimated overpayments. Specifically, Cariten stated that our use of the two-sided 90-percent confidence interval in estimating overpayments is inconsistent with CMS’s practice for RADV audits. Cariten requested that we recalculate the extrapolated overpayment amount using the lower limit of a 99-percent confidence interval to be consistent with CMS’s practice for RADV audits.

OIG Response

OIG is an independent oversight agency; therefore, we are not required to mirror CMS’s estimation methodology. Our policy is to recommend recovery at the lower limit of a two-sided 90-percent confidence interval. The lower limit of a two-sided 90-percent confidence interval provided a reasonably conservative estimate of the total amount overpaid to Cariten for the enrollee-years and time period covered in our sampling frame. Further, we note that this approach, which is routinely used by the HHS for recovery calculations,³³ results in a lower limit (the estimated overpayment amount to refund) that is less than the actual overpayment amount 95 percent of the time. Additionally, the legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise

³³ HHS has used the two-sided 90-percent confidence interval when calculating recoveries in both the Administration for Child and Families and Medicaid programs. See, for example, *New York State Department of Social Services*, DAB No. 1358, 13 (1992); and *Arizona Health Care Cost Containment System*, DAB No. 2981, 4-5 (2019). In addition, HHS contractors rely on the one-sided 90-percent confidence interval, which is less conservative than the two-sided interval, for recoveries arising from Medicare FFS overpayments. See, for example, *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff’d*, 860 F.3d 335 (5th Cir. 2017); and *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 17-18 (E.D.N.Y. 2012).

methodology.³⁴ As detailed in Appendix C, we properly executed a statistically valid sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

Cariten Stated That OIG’s Recommended Recovery is Duplicative of Recoveries Identified by Humana’s Self-Audits

Cariten Comments

Cariten stated that one aspect of its MA compliance program is “regular internal RADV-like [self-audits]” to confirm the accuracy of CMS risk adjusted payments.³⁵ According to Cariten, the self-audits consist of reviews of all HCCs submitted to CMS for a sample of enrollees. Cariten stated that a data correction is submitted for every HCC that Humana determines is not supported and Humana calculates a corresponding payment recovery amount. Humana then applies an “estimated FFSA” to the calculated payment recovery amount to determine the final estimated recovery amount. Cariten asserted that it is duplicative of OIG to recommend refunds of payment amounts other than those found by the self-audits.³⁶

OIG Response

Regarding Cariten’s argument that our recommended recovery amount is duplicative of the recovery amounts identified by the self-audits, Cariten did not provide the information that would be needed to determine if there is duplication. Specifically, Cariten did not indicate whether a self-audit was performed for our audit period nor did Cariten indicate whether it paid CMS estimated recovery amounts calculated using the self-audit results for our audit period. However, we do note that during our audit it came to our attention that Cariten made a data correction for a sampled enrollee-year. Specifically, Cariten determined that the HCC under review for the sampled enrollee-year was not supported in the medical records and Cariten took the necessary steps to remove the unsupported diagnosis code from the risk-adjusted payment calculation. Cariten made this data correction as a result of an internal medical review prior to our sample selection. Therefore, to avoid duplicating recovery of the payment amount associated with this unsupported HCC, we did not include the financial impact of this unsupported HCC in our calculation of net overpayments or the resulting estimate.

³⁴ See *John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at *34-35 (W.D. Pa. 2012), *aff’d* 555 F. App’x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff’d*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

³⁵ The self-audits are conducted by Cariten’s parent company, Humana, Inc.

³⁶ Cariten made these statements in footnote 65 of its comments.

CARITEN DID NOT AGREE WITH OIG’S RECOMMENDATION TO PERFORM ADDITIONAL REVIEWS BEFORE AND AFTER THE AUDIT PERIOD

Cariten Comments

Cariten disagreed with our second recommendation—that Cariten perform additional reviews to determine whether similar instances of high-risk diagnoses occurred before or after the audit period and to refund any overpayments—because, according to Cariten, “[MA] regulations do not require the sort of audits that OIG recommends.” Moreover, Cariten stated that, if it were to identify unsubstantiated diagnosis codes, these would not necessarily be “overpayments.”

Cariten stated that CMS regulations require MA organizations to “take reasonable steps to ensure the ‘accuracy, completeness, and truthfulness’ of the risk adjustment data they submit” but do not impose a requirement of 100 percent accuracy for those data. Moreover, Cariten stated that CMS recognizes that MA organizations receive risk adjustment data from many different sources, which presents “significant verification challenges” and that OIG guidance recognizes that MA organizations’ certification of these data does not constitute an absolute guarantee of accuracy.

In this respect, Cariten stated that our citations of Federal regulations mischaracterize the requirements for MA organizations to monitor the data that they receive from providers and submit to CMS. Cariten stated that these citations imply that MA organizations are responsible for monitoring every piece of risk adjustment data and must “unequivocally guarantee that risk adjustment data are accurate, complete and truthful.” However, according to Cariten, MA regulations afford MA organizations “broad discretion” in designing compliance programs and require only a certification of the accuracy, completeness, and truthfulness of the data that they submit to CMS based on “best knowledge, information and belief.” Thus, according to Cariten, our second recommendation “conflicts with CMS’s regulations and guidance” and imposes new regulatory requirements. Cariten stated that new requirements would be subject to notice-and-comment rulemaking.

Cariten also stated that if it were to conduct the type of review that we recommended, any individual unsubstantiated diagnosis codes that it were to identify would not necessarily constitute “overpayments.” Cariten stated that overpayments could only be calculated using a methodology that applied an FFSA to ensure consistency with the actuarial equivalence requirement.

OIG Response

We do not agree with Cariten’s interpretation of Federal requirements. We recognize that MA organizations have the latitude to design their own federally mandated compliance programs. We also recognize that the requirement that MA organizations certify the data they submit to CMS is based on “best knowledge, information, and belief.” However, contrary to Cariten’s

assertions, we believe that our second recommendation conforms to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (see Appendix E)).

These Federal regulations state that MA organizations must “implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS’ program requirements.” Further, the regulations specify that Cariten’s compliance plan “must, at a minimum, include [certain] core requirements,” such as “an effective system for routine monitoring and identification of compliance risks . . . [including] internal monitoring and audits and, as appropriate, external audits to evaluate . . . compliance with CMS requirements and the overall effectiveness of the compliance program.” These regulations also require MA organizations to implement procedures and a system for 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.” Thus, CMS has, through the issuance of these Federal regulations, assigned the responsibility for dealing with potential compliance issues to the MA organizations, themselves.

In this regard, CMS has provided additional guidance in Chapter 7 § 40 of the Manual, which states:

If upon conducting an internal review of submitted diagnosis codes, the [MA organization] determines that any diagnosis codes that have been submitted do not meet risk adjustment submission requirements, the plan sponsor is responsible for deleting the submitted diagnosis codes as soon as possible. . . . Once CMS calculates the final risk scores for a payment year, [MA organizations] may request a recalculation of payment upon discovering the submission of inaccurate diagnosis codes that CMS used to calculate a final risk score for a previous payment year and that had an impact on the final payment. [MA organizations] must inform CMS immediately upon such a finding.

When an MA organization identifies overpayments, the Overpayment Rule (42 U.S.C. §§ 1301-1320d-8, 1395-1395hhh) requires that, if the MA organization learns a diagnosis it submitted to CMS for payment lacks support in the associated individual’s medical record, the MA organization must refund that payment within 60 days.

Regarding Cariten’s statement about the overpayment calculation, we reiterate that action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures, including applying an FFSA, if applicable.

We believe that the error rates identified in this report demonstrate that Cariten has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope. Accordingly, we maintain that our second recommendation is valid.

CARITEN DID NOT AGREE WITH OIG'S RECOMMENDATION THAT CARITEN ENHANCE ITS EXISTING POLICIES AND PROCEDURES

Cariten Comments

Cariten stated that neither MA program requirements nor OIG guidance offer specific direction related to the high-risk diagnosis codes that are the subject of this audit. Cariten reiterated that MA organizations are instead afforded broad discretion in designing compliance programs. In this respect, Cariten stated that it has designed a risk adjustment compliance program that Cariten believes satisfies its obligations under applicable MA program requirements and that the presence of some data inaccuracies does not indicate a failure in Cariten's policies and procedures. Further, according to Cariten, it has never been informed by CMS of any deficiencies in its risk adjustment compliance program.

Cariten requested that we reconsider our third recommendation—that Cariten take the necessary steps to enhance its procedures for ensuring that diagnosis codes that are at high-risk for being miscoded comply with Federal requirements—because our description of Cariten's policies and procedures as not always effective imposes an unreasonable standard.

OIG Response

We limited our audit to selected diagnoses that we determined to be at high risk for being miscoded. Our audit revealed a significant error rate for some of these high-risk areas. We acknowledge that Cariten had compliance procedures in place to promote the accuracy of diagnosis codes submitted to CMS to calculate risk-adjusted payments, including procedures related to the high-risk diagnosis codes that are the subject of this audit. While, according to Cariten, it has never been informed by CMS of deficiencies in Cariten's compliance program, this does not mean Cariten should not take action to enhance its compliance procedures. Federal regulations require MA organizations to implement procedures for "promptly responding to compliance issues as they are raised" and "[correct] such problems promptly and thoroughly to reduce the potential for recurrence." (42 CFR § 422.503(b)(4)(vi)(G) (see Appendix E)). Improvement of Cariten's existing procedures, based on the results of this audit, as well as the results of Cariten's internal medical reviews, will assist Cariten in attaining better assurance with regard to the "accuracy, completeness and truthfulness" of the risk adjustment data that it submits in the future. Accordingly, we maintain that our third recommendation is valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid Cariten \$2,383,738,611 to provide coverage to its enrollees for 2016 and 2017. We identified a sampling frame of 5,990 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2015 and 2016 service years. Cariten received \$90,526,531 in payments from CMS for these enrollee-years for 2016 and 2017. We selected for audit 270 enrollee-years with payments totaling \$4,144,762.

The 270 enrollee-years included 30 acute stroke diagnoses, 30 acute heart attack diagnoses, 30 embolism diagnoses, 30 vascular claudication diagnoses, 30 lung cancer diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, 30 prostate cancer diagnoses, and 30 major depressive disorder diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$750,508 for our sample.

Our audit objective did not require an understanding or assessment of Cariten's complete internal control structure, and we limited our review of internal controls to those directly related to our objective.

We performed audit work from June 2020 through October 2021.

METHODOLOGY

To accomplish our objective, we performed the following steps:

- We reviewed applicable Federal laws, regulations, and guidance.
- We discussed with CMS program officials the Federal requirements that MA organizations should follow when submitting diagnosis codes to CMS.
- We identified, through data mining and discussions with medical professionals at a Medicare administrative contractor, diagnosis codes and HCCs that were at high risk for noncompliance. We also identified the diagnosis codes that potentially should have been used for cases in which the high-risk diagnoses were miscoded.
- We consolidated the high-risk diagnosis codes into specific groups, which included:
 - 74 diagnosis codes for acute stroke,
 - 38 diagnosis codes for acute heart attack,
 - 85 diagnosis codes for embolism,
 - 4 diagnosis codes for vascular claudication,
 - 24 diagnosis codes for lung cancer,
 - 65 diagnosis codes for breast cancer,

- 20 diagnosis codes for colon cancer,
 - 2 diagnosis codes for prostate cancer, and
 - 29 diagnosis codes for major depressive disorder.
- We used CMS’s systems to identify the enrollee-years on whose behalf providers documented the high-risk diagnosis codes. Specifically, we used extracts from CMS’s:
 - Risk Adjustment Processing System (RAPS)³⁷ to identify enrollees who received high-risk diagnosis codes from a physician during the service years,
 - Risk Adjustment System (RAS)³⁸ to identify enrollees who received an HCC for the high-risk diagnosis codes,
 - Medicare Advantage Prescription Drug System (MARx)³⁹ to identify the total Medicare payments that CMS calculated, before applying the budget sequestration reduction, for Cariten for the payment years,
 - Encounter Data System (EDS)⁴⁰ to identify enrollees who received specific procedures, and
 - Prescription Drug Event (PDE) file⁴¹ to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.
 - We interviewed Cariten officials to gain an understanding of (1) the policies and procedures that Cariten followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Cariten’s monitoring of those diagnosis codes to identify and detect noncompliance with Federal requirements.
 - We selected for audit a stratified random sample of 270 enrollee-years.

³⁷ MA organizations use the RAPS to submit diagnosis codes to CMS.

³⁸ The RAS identifies the HCCs that CMS factors into each enrollee’s risk score calculation.

³⁹ The MARx identifies the payments made to MA organizations.

⁴⁰ The EDS contains information on each item (including procedures) and service provided to enrollees.

⁴¹ The PDE file contains claims with prescription drugs that have been dispensed to enrollees through the Medicare Part D (prescription drug coverage) program.

- We used an independent medical review contractor to perform a coding review for the 270 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.⁴²
- The independent medical review contractor’s coding review followed a specific process to determine whether there was support for a diagnosis code and the associated HCC:
 - If the first senior coder found support for the diagnosis code on the medical record, the HCC was considered validated.
 - If the first senior coder did not find support on the medical record, a second senior coder performed a separate review of the same medical record:
 - If the second senior coder also did not find support, the HCC was considered to be not validated.
 - If the second senior coder found support, then a physician independently reviewed the medical record to make the final determination.
 - If either the first or second senior coder asked a physician for assistance, the physician’s decision became the final determination.
- We used the results of the independent medical review contractor to calculate overpayments or underpayments for each enrollee-year. Specifically, we calculated:
 - a revised risk score in accordance with CMS’s risk adjustment program and
 - the payment that CMS should have made for each enrollee-year.
- We estimated the total net overpayment made to Cariten during the audit period.
- We discussed the results of our audit with Cariten officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

⁴² Our independent medical review contractor used senior coders all of whom possessed one or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS), Certified Coding Specialist – Physician-Based (CCS-P), Certified Professional Coder (CPC), and Certified Risk Coder (CRC). RHITs have completed a 2-year degree program and have passed an American Health Information Management Association (AHIMA) certification exam. The AHIMA also credentials individuals with CCS and CCS-P certifications and the American Academy of Professional Coders credentials both CPCs and CRCs.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health Network (Contract H1961) Submitted to CMS</i>	<u>A-06-18-05002</u>	5/25/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS</i>	<u>A-01-19-00500</u>	2/14/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS</i>	<u>A-07-17-01169</u>	2/3/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS</i>	<u>A-02-18-01029</u>	1/5/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS</i>	<u>A-07-19-01188</u>	11/5/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS</i>	<u>A-07-17-01173</u>	10/28/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS</i>	<u>A-07-19-01187</u>	5/21/2021
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS</i>	<u>A-07-16-01165</u>	4/19/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS</i>	<u>A-02-18-01028</u>	2/24/2021
<i>Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements</i>	<u>A-07-17-01170</u>	4/30/2019

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified Cariten enrollees who (1) were continuously enrolled in Cariten throughout all of the 2015 or 2016 service year and January of the following year, (2) were not classified as being enrolled in hospice or as having end-stage renal disease status at any time during 2015 or 2016 or in January of the following year, and (3) received a high-risk diagnosis during 2015 or 2016 that caused an increased payment to Cariten for 2016 or 2017, respectively.

We presented the data for these enrollees to Cariten for verification and performed an analysis of the data included on CMS's systems to ensure that the high-risk diagnosis codes increased CMS's payments to Cariten. After we performed these steps, our finalized sampling frame consisted of 5,990 enrollee-years.

SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2016 or 2017.

SAMPLE DESIGN

The design for our statistical sample was comprised of nine strata of enrollee-years with either:

- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim (1,622 enrollee-years);
- a diagnosis that mapped to an Acute Heart Attack HCC on only one physician claim but did not have that diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician claim (619 enrollee-years);
- a diagnosis that mapped to an Embolism HCC but for which an anticoagulant medication was not dispensed (325 enrollee-years);
- a vascular claudication diagnosis (that mapped to the HCC for Vascular Disease) on one claim during the service year (and did not occur during the 2 years that preceded the service year), but for which medication was dispensed for neurogenic claudication during the service year (543 enrollee-years);
- a lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) on only one claim but that did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the lung cancer diagnosis administered within a 6-month period before or after the diagnosis (240 enrollee-years);

- a breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one claim but that did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the breast cancer diagnosis administered within a 6-month period before or after the diagnosis (687 enrollee-years);
- a colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) on only one claim but that did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (230 enrollee-years);
- a prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one claim but that did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (642 enrollee-years); or
- a major depressive disorder diagnosis (that mapped to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) on one claim during the service year but for which antidepressant medication was not dispensed (1,082 enrollee-years).

The specific strata are shown in Table 3.

Table 3: Sample Design for Audited High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee- Years	CMS Payment for HCCs in Audited High-Risk Groups*	Sample Size
1 – Acute Stroke	1,622	\$3,601,172	30
2 – Acute Heart Attack	619	1,266,676	30
3 – Embolism	325	863,781	30
4 – Vascular Claudication	543	1,259,619	30
5 – Lung Cancer	240	1,761,639	30
6 – Breast Cancer	687	890,957	30
7 – Colon Cancer	230	588,529	30
8 – Prostate Cancer	642	835,042	30
9 – Major Depressive Disorder	1,082	3,020,432	30
Total	5,990	\$14,087,848⁴³	270

*Rounded to the nearest whole dollar amount.

⁴³ Difference in total is due to rounding.

SOURCE OF RANDOM NUMBERS

We generated the random numbers with the Office of Inspector General (OIG), Office of Audit Services (OAS), statistical software.

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the items in each stratum in the stratified sampling frame. After generating 270 random numbers according to our sample design, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to estimate the total amount of net overpayments to Cariten at the lower limit of the two-sided 90-percent confidence interval (Appendix D). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Details and Results

Audited High-Risk Groups	Frame Size	CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With Incorrect Diagnosis Codes	Net Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)
1 – Acute Stroke	1,622	\$3,601,172	30	\$70,614	29	\$65,172
2 – Acute Heart Attack	619	1,266,676	30	68,256	30	62,866
3 – Embolism	325	863,781	30	75,466	23	56,623
4 – Vascular Claudication	543	1,259,619	30	72,424	7	16,842
5 – Lung Cancer	240	1,761,639	30	222,258	29	212,641
6 – Breast Cancer	687	890,957	30	40,510	30	40,510
7 – Colon Cancer	230	588,529	30	80,319	28	64,296
8 – Prostate Cancer	642	835,042	30	35,932	29	34,696
9 – Major Depressive Disorder	1,082	3,020,432	30	84,730	1	3,604
Totals	5,990	\$14,087,848*	270	\$750,508*	206	\$557,250

* Difference in total is due to rounding.

**Table 5: Estimated Net Overpayments in the Sampling Frame
(Limits Calculated for a 90-Percent Confidence Interval)**

Point Estimate	\$9,733,212
Lower Limit	\$9,212,531
Upper Limit	\$10,253,894

**APPENDIX E: FEDERAL REGULATIONS REGARDING COMPLIANCE PROGRAMS
THAT MEDICARE ADVANTAGE ORGANIZATIONS MUST FOLLOW**

Federal regulations (42 CFR § 422.503(b)) state:

Any entity seeking to contract as an MA organization must

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS's program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

- (1) Articulate the organization's commitment to comply with all applicable Federal and State standards;
- (2) Describe compliance expectations as embodied in the standards of conduct;
- (3) Implement the operation of the compliance program;
- (4) Provide guidance to employees and others on dealing with potential compliance issues;
- (5) Identify how to communicate compliance issues to appropriate compliance personnel;
- (6) Describe how potential compliance issues are investigated and resolved by the organization; and
- (7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials. . . .

- (F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the MA organization, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

- (G) Establishment and implementation of 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 ensure ongoing compliance with CMS requirements.
 - (1) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

 - (2) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.

 - (3) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

APPENDIX F: CARITEN COMMENTS



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December 17, 2021

Brenda M. Tierney
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Audit Services, Region II
Jacob K. Javits Federal Building
26 Federal Plaza, Room 3900
New York, New York 10278

VIA UPS NEXT DAY AIR AND EMAIL

RE: Humana's Response to Draft Audit Report No. A-02-20-01009

Dear Ms. Tierney:

Humana Inc. ("Humana" or "Company") appreciates the opportunity you have provided to respond to the U.S. Department of Health and Human Services, Office of Inspector General's ("OIG's") Draft Audit Report No. A-02-20-01009, entitled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS* (the "Draft Report"). As detailed below, Humana respectfully submits that OIG should not finalize the Draft Report's three recommendations because (1) medical record documentation substantiates certain of the conditions in question, (2) OIG's audit methodology reflects important departures from governing statistical and actuarial principles, the statutory requirements of the Medicare Advantage ("MA") program, and CMS's Risk Adjustment Data Validation ("RADV") processes, (3) Medicare Advantage Organizations ("MAOs") are not required to conduct audits to the standard that OIG suggests, and (4) Humana's risk adjustment compliance program satisfies all legal and regulatory requirements.

Humana takes great pride in what the Company believes to be its industry-leading approach to Medicare risk adjustment ("MRA") compliance. Indeed, Humana has described its MRA compliance program to CMS over the course of many years, and has never received feedback from CMS that its program is deficient in any respect. Humana's policies and procedures not only extend to the so-called "high-risk diagnosis codes" on which the Draft Report focuses, but to *all* diagnosis codes. Humana believes its processes and reviews satisfy all legal requirements, for the reasons explained below.

Seeking repayment of the amounts referenced in the Draft Report would represent a serious departure from the statutory requirements underlying the MA payment model. We therefore request that OIG reconsider its recommendations, and instead work cooperatively with Humana to finalize a report that does not present these issues. Humana stands at the ready to assist OIG and CMS in this regard, as we have conveyed previously to CMS.

I. HUMANA RESPECTFULLY REQUESTS THAT OIG RECONSIDER THE DRAFT REPORT'S FINDINGS THAT MEDICAL RECORDS DO NOT SUBSTANTIATE CERTAIN AUDITED CONDITIONS.

Humana's internal risk adjustment compliance efforts and performance on CMS's RADV audits demonstrate that the vast majority of the risk adjustment data submitted by Humana to CMS meets CMS RADV standards. Considering that risk adjustment data is principally generated by Humana's vast network of medical providers based on the providers' clinical judgment and their implementation of a complex diagnosis coding system, it is not feasible for MAOs to eliminate all risk adjustment data discrepancies, nor is there any legal requirement for them to do so.¹ Humana has several programs in place to enhance the accuracy of risk adjustment data, consistent with MA program requirements and OIG's guidance.² Neither MA program requirements nor OIG guidance, however, offer specific direction related to the so-called "high-risk" diagnosis codes that are the subject of OIG's Draft Report.³ MAOs are instead afforded broad discretion in designing compliance and education programs.⁴

With respect to OIG's medical record determinations as reflected in the Draft Report, Humana believes that the Hierarchical Condition Category ("HCC") substantiation for the sampled-enrollee years would increase if OIG accounted for certain HCCs that Humana believes should be reconsidered by OIG, described more fully in Section II.1 and Appendix A. Given OIG's reliance on an estimation methodology as part of its "overpayment" calculation (discussed in more detail below), it goes without saying that every single HCC subject to review is of critical importance and could greatly affect the outcome of this audit. We would therefore appreciate the opportunity to discuss with OIG the HCCs referenced in the Draft Report in greater detail.⁵ Indeed, setting aside for the moment all other concerns raised in this letter, addressing *only* the HCCs referenced in Appendix A would change the outcome of OIG's review

¹ See Medicare Program; Medicare+Choice Program, 65 Fed. Reg. 40,170, 40,268 (June 29, 2000) (MAOs "cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that HCFA, the OIG, and DoJ believe is reasonable to enforce.").

² See 65 Fed. Reg. at 40,268 (MAOs "will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted."); 42 C.F.R. § 422.504(l); Publication of the OIG's Compliance Program Guidance for Medicare Choice Organizations Offering Coordinated Care Plans, 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999) (MAOs "should ordinarily conduct sample audits and spot checks of this system to verify whether it is yielding accurate information.").

³ CMS recently acknowledged, in fact, that it did not have policies and procedures in place that would have guaranteed so-called "high-risk" diagnosis codes in the Fee-For-Service context, like acute stroke, were always supported by underlying medical record documentation even though those codes ultimately resulted in risk-adjusted payments to MAOs. See HHS OIG, Audit Report No. A-07-17-01176, *Incorrect Acute Stroke Diagnosis Codes Submitted by Traditional Medicare Providers Resulted in Millions of Dollars in Increased Payments to Medicare Advantage Organizations* (Sept. 2020) at 8, available at <https://www.oig.hhs.gov/oas/reports/region7/71701176.pdf> ("*Acute Stroke Audit Report*").

⁴ See 65 Fed. Reg. at 40,265.

⁵ See Draft Report at 9-15.

as those HCCs account for a portion of OIG's overpayment calculation for the sampled enrollees, and would therefore presumably have an impact on OIG's "overpayment" estimate.⁶

II. HUMANA RESPECTFULLY REQUESTS THAT OIG RECONSIDER ITS FIRST RECOMMENDATION BECAUSE OIG'S AUDIT METHODOLOGY REFLECTS IMPORTANT DEPARTURES FROM GOVERNING STATISTICAL AND ACTUARIAL PRINCIPLES, THE STATUTORY REQUIREMENTS OF THE MA PROGRAM, AND CMS'S RADV PROCESSES.

Based on a government contractor's medical record review, OIG concluded that Humana received \$561,435 in net overpayments for the 270 sampled enrollee-years.⁷ OIG then applied an extrapolation methodology to all 2016 and 2017 payments for H4461 based on OIG's sample results and estimated that Cariten "received at least \$9,314,930 in net overpayments in 2016 and 2017," which OIG recommends Cariten return.⁸ For the reasons below, Humana respectfully requests that OIG reconsider its recommendation.

1. OIG's recommended repayment amount is incorrect because some sampled conditions are substantiated by documentation in the relevant medical records.

Humana disagrees with some of OIG's determinations that HCCs for sampled enrollee-years are not substantiated by documentation in the relevant medical records. Specifically, Humana has provided OIG with twelve appeals reflecting instances where, contrary to OIG's determination, the following conditions are substantiated by medical record documentation: Acute Heart Attack, Lung Cancer, Breast Cancer, Colon Cancer, Prostate Cancer, Major Depressive Disorder, and Vascular Disease.⁹

⁶ During Humana's Exit Conference with the OIG auditors for H4461, Humana inquired about the process to submit rebuttals to OIG's medical coding determinations, and Humana was informed that the Company should submit any rebuttals along with Humana's written response to the Draft Report. Failing to incorporate results from OIG's review of additional records would be an arbitrary and capricious departure from the approach OIG took in prior RADV audits. See HHS OIG, Audit Report No. A-07-19-01188, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS* (Nov. 2021) at 22, available at <https://oig.hhs.gov/oas/reports/region7/71901188.pdf>; HHS OIG, Audit Report No. A-07-17-01173, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS* (Oct. 2021) at 18, available at <https://oig.hhs.gov/oas/reports/region7/71701173.pdf>; HHS OIG, Audit Report No. A-07-16-01165, *Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted To CMS* (Apr. 2021) at 13-14, available at <https://oig.hhs.gov/oas/reports/region7/71601165.pdf>; HHS OIG, Audit Report No. A-02-09-01014, *Risk Adjustment Data Validation Of Payments Made To Excellus Health Plan, Inc., For Calendar Year 2007 (Contract H3351)* (Oct. 2012) at 8, available at <https://www.oig.hhs.gov/oas/reports/region2/20901014.pdf>; HHS OIG, Audit Report No. A-05-09-00044, *Risk Adjustment Data Validation Of Payments Made To Paramount Care, Inc., For Calendar Year 2007 (Contract H3653)* (Sept. 2012) at 10-11, available at <https://oig.hhs.gov/oas/reports/region5/50900044.pdf>.

⁷ Draft Report at 24 (Appendix D).

⁸ *Id.* at 15.

⁹ Humana separately submitted these appeals to OIG and has not included the detail of each here due to the Protected Health Information contained in the appeals.

Because these sample enrollee-years are substantiated, Humana asks OIG to reconsider its findings with respect to the corresponding HCCs and modify its recommended estimated and extrapolated repayment amounts.

2. OIG should reconsider its recommendation because OIG’s estimate of “net overpayments” to Humana is statistically unsupported and significantly understates potential “underpayments.”

Based on Humana’s understanding of OIG’s audit procedures and methodology, Humana believes OIG’s findings are systematically skewed towards identifying overpayments rather than underpayments, rendering its results inherently unreliable.¹⁰ OIG explains in its Draft Report that it “used the results of the independent medical review contractor to calculate overpayments or underpayments for each enrollee.”¹¹ Following this approach, OIG determined that “Cariten received at least \$9,314,930 in net overpayments in 2016 and 2017.”¹² But Humana was tasked only with supplying medical records to substantiate specific HCCs actually submitted to CMS, not to collect and submit medical records to substantiate all HCCs that *could have been* submitted to CMS (*i.e.*, potential underpayments).¹³

Based on OIG’s instructions, Humana’s medical record submissions consisted of far less than all records available for the sampled enrollee-years. Thus, OIG’s review could not and does not account for all HCCs that are substantiated but not submitted for the sampled enrollee-years—just as OIG found certain “underpayments” in the records actually subject to review,¹⁴ other records that were never submitted to or reviewed by OIG contain unsubmitted HCCs that would have been found upon review. Moreover, OIG excluded from its sampling frame all non-“high-risk” diagnosis codes associated with payment years 2016 and 2017 for H4461 enrollees as well as those for which Humana did not submit any risk-adjusting diagnosis codes.¹⁵ This

¹⁰ While Humana appreciates the information OIG has shared regarding its audit methodology, OIG has not provided full detail on the extrapolation approach it applied to arrive at its estimate that Humana was overpaid by more than \$9.3 million. This is important because, as leading industry experts have previously described in detail, flaws in a RADV extrapolation methodology can cause substantial bias in the final estimates produced by the methodology. See Wakely Consulting Group, LLC, *Medicare RADV: Review of CMS Sampling and Extrapolation Methodology* (July 2018). Moreover, such full detail is necessary to confirm OIG’s audit methodology conforms to government auditing and actuarial standards. See U.S. Government Accountability Office, *Government Auditing Standards, 2011 Revision* (Dec. 2011) (“Government Auditing Standards”), available at <https://www.gao.gov/assets/590/587281.pdf>; U.S. Dep’t of Health & Human Servs., *HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public*, Part II: HHS Agency Responsibilities and Guidelines, E. Centers for Medicare & Medicaid Services, V. Agency Quality Assurance Policies, Standards and Processes (Oct. 1, 2002) (“Information Quality Guidelines”), available at <https://aspe.hhs.gov/reports/hhs-guidelines-ensuring-maximizing-quality-objectivity-utility-integrity-information-disseminated>.

¹¹ Draft Report at 19 (Appendix A).

¹² *Id.* at 15.

¹³ OIG acknowledged in the Draft Report that “correctly coded diagnoses that MA organizations do not submit to CMS may lead to improper payments (underpayments).” *Id.* at 4.

¹⁴ See *id.* at 10 (concluding for 1 enrollee-year, Cariten submitted an acute stroke diagnosis code where OIG determined an HCC for Hemiplegia/Hemiparesis should have been assigned and that “[t]his error caused an underpayment”).

¹⁵ See *id.* at 17 (Appendix A).

aspect of OIG’s methodology also systematically reduced the probability of identifying underpayments.¹⁶

Because OIG’s audit methodology did not conduct a systematic or statistically valid search for substantiated but unsubmitted HCCs, OIG’s extrapolation methodology is statistically unsupported.¹⁷ In addition, as OIG’s net overpayment calculations for the sampled enrollee-years appears to incorporate OIG’s determination that one error resulted in an underpayment, OIG should also consider additional underpayment credits in its overpayment estimates.¹⁸ Furthermore, because OIG’s auditing methodology and recommendations are skewed towards identifying overpayments rather than underpayments, we respectfully request that OIG justify its approach under applicable government auditing standards, which Humana believes would be implicated if OIG were to finalize the Draft Report in its current form.¹⁹

3. OIG should reconsider its recommendation because OIG’s audit and extrapolation methodology described in the Draft Report improperly equates individual unsubstantiated HCC submissions with overpayments.

The Social Security Act (“Act” or “SSA”) requires risk adjustment payments to MAOs and mandates that those payments be made in a manner that ensures “actuarial equivalence” between CMS payments for healthcare coverage under a Medicare Advantage plan and CMS payments under traditional Medicare FFS.²⁰ Thus, “actuarial equivalence” requires risk-adjusted payments to MAOs based on actuarially supportable calculations of the expected cost to CMS if the MAOs’ enrollees received their health benefits through the Medicare FFS program.²¹ The Actuarial Standards of Practice (“ASOPs”), especially ASOP No. 45, necessarily govern these actuarial calculations.²²

As explained by recognized industry experts, it would violate “an underlying principle of risk adjustment systems” to determine MAO payments by applying (1) coefficients calculated using Medicare FFS diagnosis codes that are *partially unsubstantiated* by medical records, to (2) MAO diagnosis codes that are *fully substantiated* by medical records.²³ Subjecting diagnosis codes from the Medicare FFS and MA programs to different documentation standards

¹⁶ See Matthew G. Mercurio, *Statistical Analysis of Draft Report Number A-07-16-01165* (Dec. 3, 2019).

¹⁷ See *id.*

¹⁸ See Draft Report at 10.

¹⁹ See Government Auditing Standards; Information Quality Guidelines.

²⁰ See 42 U.S.C. § 1395w-23(a)(1)(C)(i).

²¹ See 42 U.S.C. §§ 1395w-24(a)(5)(A), (6)(A)(i)–(iii).

²² Actuarial Standards Board, *Actuarial Standard of Practice No. 45: The Use of Health Status Based Risk Adjustment Methodologies* (Jan. 2012).

²³ See Letter from American Academy of Actuaries to Cheri Rice, Acting Director, Medicare Plan Payment Group (Jan. 21, 2011) (on file with author); see also Wakely Consulting Group, LLC, *Actuarial Report on CMS’ November 1, 2018 Proposed Rule* (Aug. 27, 2019) (“Wakely Report”), Section IV; Avalere Health, *Eliminating the FFS Adjuster from the RADV Methodology May Affect Plan Payment* (March 2019), available at <https://avalere.com/wp-content/uploads/2019/03/20190318-FFS-Adjuster-Analysis-Final-.pdf>; Milliman, *Medicare Advantage RADV FFS Adjuster: White Paper* (Aug. 23, 2019), available at <https://assets.milliman.com/ektron/Medicare Advantage RADV FFS adjuster 8-23-2019.pdf>.

contravenes ASOP No. 45 and disrupts actuarial equivalence in violation of the Act.²⁴ Industry experts refer to this error mode as the “Data Inconsistency Issue.”²⁵

CMS has acknowledged the need to address the differing documentation standards that are the cause of the Data Inconsistency Issue. In its 2012 RADV extrapolation methodology, CMS announced that it would determine a contract-level payment error in RADV audits only after applying a Fee-for-Service Adjuster (“FFSA”) to account for the rate of unsubstantiated diagnosis codes in the Medicare FFS claims data from which CMS’s HCC risk coefficients were initially derived.²⁶ CMS acknowledged that the FFSA was a function of the actuarial requirements of risk-adjusted compensation: “The FFS Adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract’s payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model ([Medicare] FFS Claims).”²⁷ For the reasons explained above, OIG cannot depart from CMS’s methodology in place for the years that are the subject of OIG’s Draft Report.

Humana notified CMS of the importance of the FFSA and the Data Inconsistency Issue to Humana’s bids under H4461 for the years that are the subject of OIG’s Draft Report. Specifically, Humana’s Calendar Year 2015 and 2016 Actuarial Certifications for each filed Plan Benefit Package under H4461 stated explicitly that the Company was relying on CMS’s plan to develop and apply an FFSA as part of any RADV process:

[R]evenue and risk score projections in the bid(s) are based on the assumption that final risk scores will be calculated and payments will be made consistent with the fact that CMS has used diagnoses contained in administrative claims data (and not medical records) to calculate risk coefficients and risk scores for FFS beneficiaries. . . . In the [February 24, 2012 “Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits”] CMS indicated that [] any payment adjustments from risk adjustment data validation audits will be conducted in a manner that maintains

²⁴ See Wakely Consulting Group, LLC, *Actuarial Analysis of OIG’s September 24, 2019 Draft Report Regarding Humana Contract H1036* (Dec. 3, 2019) (“Wakely Analysis”); see also Wakely Report Section IV.

²⁵ See Wakely Report Section IV.

²⁶ See CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audit* (Feb. 24, 2012) (“2012 RADV Audit Notice.”).

²⁷ *Id.* at 4–5. On November 1, 2018, CMS published in proposed rule related to the methodology for Medicare RADV audits in the Federal Register. See Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54982 (Nov. 1, 2018) (“Proposed Rule”). This Proposed Rule is only a proposal; therefore, the RADV methodology that CMS announced in 2012 is still operative for RADV audits of MAO risk adjustment data. See 2012 RADV Audit Notice. In accordance with the notice-and-comment process, Humana has been joined by numerous industry participants and subject-matter experts, including independent actuaries and statisticians, in challenging various aspects of the Proposed Rule, including the proposal to eliminate a FFSA. On October 20, 2021, CMS announced that it extended the deadline for the Final RADV Rule to November 1, 2022. See Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021; Extension of Timeline To Finalize a Rulemaking, 86 Fed. Reg. 58245 (Oct. 21, 2021).

consistency between the development of the risk adjustment model and its application. CMS will maintain this consistency by applying a Fee-for-Service Adjuster (FFS Adjuster) to account for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims). However, the actual amount of the FFS adjuster has not been published at this time, and CMS stated that it will be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data.

CMS did not respond to this bid certification or otherwise suggest to Humana that Humana's bid should be modified.

Additionally, audits of so-called "high-risk" codes perfectly exemplify the importance of addressing the Data Inconsistency Issue in an actuarially sound manner: such codes are likely to be equally unsubstantiated in the FFS context. For example, OIG found that "[a]most all of the selected acute stroke diagnosis codes that physicians submitted to CMS under traditional Medicare . . . did not comply with Federal requirements."²⁸ Further exacerbating this issue is the fact that CMS has not implemented policies or procedures to evaluate whether supposedly "high-risk" codes, like acute stroke and other diagnosis codes examined in OIG's Draft Report, are always supported by underlying medical record documentation in the MA or the FFS program.²⁹

If finalized, the Draft Report's treatment of individual unsubstantiated HCC submissions as overpayments would violate the actuarial equivalence requirement by failing to remedy the Data Inconsistency Issue. The Draft Report implicates the Data Inconsistency Issue because one documentation standard (unaudited data) was used to calibrate the CMS-HCC model while another documentation standard (audited data) was used to measure payment accuracy.³⁰ Recognized industry experts have stated that "[t]his principle applies with equal force irrespective of the type of RADV audit or other documentation-based 'overpayment' analysis."³¹

In short, the Draft Report does not appear to reference in any way the Act's actuarial equivalence requirement. As a result, it appears that OIG did not take the necessary steps to resolve the Data Inconsistency Issue in its "overpayment" calculation underlying the Draft Report's recommendations. If true, OIG's recommendation that Humana refund payments would violate the statutory actuarial equivalence requirement. Moreover, this outcome would directly conflict with the assumption upon which Humana explicitly conditioned its Calendar Year 2015 and 2016 bids for plans under H4461—bids CMS approved, and on which approval Humana relied. Thus, Humana respectfully requests that OIG reconsider its recommendation that Humana refund the amounts identified in the Draft Report.

²⁸ Acute Stroke Audit Report at 6.

²⁹ See *id.* at 8.

³⁰ See Wakely Analysis.

³¹ See Wakely Report at 33; see also Wakely Analysis.

4. OIG should reconsider its recommendation because OIG’s use of different repayment calculation methodologies for different MAOs is arbitrary and capricious.

As of the date of this letter, OIG has released five similar MA compliance audits of specific so-called “high-risk” diagnosis codes.³² In these reports, OIG has focused on different so-called “high-risk” codes, defined the scope of the audited codes differently, and taken differing approaches to calculating the payment error. Neither OIG nor CMS have ever even defined what it means for a diagnosis code to be “high-risk.” And in calculating payment errors associated with these supposedly “high-risk” codes, OIG has applied two completely distinct methodologies, with no rationale supplied to explain these arbitrarily differing approaches. In the first approach, used by OIG in two reports, OIG recommended that the audited MAOs refund to the Federal Government the “net overpayments” based on OIG’s “judgmentally selected” subset of “unique enrollee-years.”³³ In the second approach, used by OIG in its other three reports, OIG calculated “net overpayments” for statistically sampled enrollee-years and then applied an extrapolation methodology to estimate a total net overpayment amount for the sampling frame and recommended audited MAOs refund to the Federal Government the total extrapolated amount.³⁴ OIG has never acknowledged that its audit methodology is in constant flux, or explained why it needs two different methodologies. Here, OIG used the second approach, and so it must, at the very least, acknowledge its departure from prior policy, provide a rationale as to why OIG has selected this approach for this report, and explain why it is justified in adopting such dissimilar practices in audits that all purport to cover so-called “high-risk” diagnosis code submissions by MAOs.³⁵ See 5 U.S.C. § 706(2)(A).

5. OIG’s audit methodology departs from CMS’s established RADV methodology in several important respects.

Humana understands that OIG generally intended the audit described in its Draft Report to follow CMS’s procedures.³⁶ Humana agrees that OIG should not apply an audit methodology

³² See HHS OIG, Audit Report No. A-07-17-01170, *Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements* (Apr. 2019), available at <https://oig.hhs.gov/oas/reports/region7/71701170.pdf> (“Essence Report”); HHS OIG, Audit Report A-02-18-01028, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS* (Feb. 2021), available at <https://oig.hhs.gov/oas/reports/region2/21801028.pdf> (“BCBSM Report”); HHS OIG, Audit Report No. A-07-19-01187, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS* (May 2021), available at <https://www.oig.hhs.gov/oas/reports/region7/71901187.pdf> (“Anthem Report”); HHS OIG, Audit Report No. A-07-17-01173, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS* (Oct. 2021), available at <https://oig.hhs.gov/oas/reports/region7/71701173.pdf> (“Coventry Report”); HHS OIG, Audit Report No. A-07-19-01188, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS* (Nov. 2021), available at <https://oig.hhs.gov/oas/reports/region7/71901188.pdf> (“UPMC Report”).

³³ See Coventry Report at 6, 14; Essence Report at 3–4, 8.

³⁴ See Anthem Report at 14, 31–32; BCBSM Report at 16, 24–25; UPMC Report at 19, 40–41.

³⁵ See Draft Report at 15, 23–25.

³⁶ See Draft Report at 6–7, 17–19 (Appendix A).

that enforces different standards than CMS. Nevertheless, OIG's Draft Report appears to do so in several significant respects:

- First, OIG's audit methodology relies on a physician to act as a "tiebreaker" in situations where two coders disagree regarding whether a medical record substantiates an HCC.³⁷ Per CMS guidance, once a provider has rendered a diagnosis, clinical judgment plays no role in the process of determining or reviewing the appropriateness of any diagnosis code assigned based on that diagnosis.³⁸ Instead of relying on the clinical judgment of a physician to resolve a disagreement between two coders, OIG should use the same method that CMS uses during a RADV audit. Specifically, during a RADV audit, if an HCC appears to be unsubstantiated after the first round of coding, the HCC is escalated to a second coder for "Discrepant Confirmation."³⁹ If the second coder determines that the medical record in question substantiates a diagnosis code that maps to the HCC, then CMS treats the HCC as substantiated without further analysis. CMS's approach reflects a true coding analysis, rather than an assessment of the clinical support for a particular condition, which need not exist in every record to substantiate coding the condition. If OIG were to implement CMS's coding methodology, Humana believes the number of HCCs that OIG determined to be unsubstantiated would be reduced.
- Second, it is unclear what specific diagnosis coding guidance the OIG's contracted reviewer provided to its staff to guide the medical record review.⁴⁰ The standards used by the contractor could have a substantial impact on OIG's findings, and could also explain a number of the issues described further in the Draft Report.⁴¹ For instance, CMS's 2017 RADV Medical Record Reviewer Guidance expressly states that "reviewers should evaluate all listed conditions for consistency within the full provider documentation with the understanding that specific management and treatment of every chronic condition is not always going to be clearly documented in the one record submitted to validate the CMS-HCC."⁴² To the extent the contractor's review underlying

³⁷ See *id.* at 19 (Appendix A).

³⁸ See Centers for Medicare & Medicaid Services & National Center for Health Statistics, *ICD-10-CM Official Guidelines for Coding and Reporting FY 2019*, at 13 (effective Oct. 1, 2018) ("The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient Code assignment is not based on clinical criteria used by the provider to establish the diagnosis.").

³⁹ See CMS, Risk Adjustment Data Validation (RADV) Medical Record Intake Process And Guidance To Coders CY2011 ver. 4.0, at 18-19 (May 8, 2014) ("RADV Guidance").

⁴⁰ While the guidance relied upon is unclear, it does not appear to have complied with the notice-and-comment requirements of *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019).

⁴¹ See Draft Report at 9-15.

⁴² See CMS, Contract-Level Risk Adjustment Data Validation: Medical Record Reviewer Guidance (Sept. 27, 2017), available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/Coders-Guidance.pdf>; see also RADV Guidance at 5 ("Though official coding rules do not change based on the type of audit, the coder should be aware of the background and prospective nature of the RA payment process including its basis on chronic conditions, and dependence on validating chronic conditions for an annual payment on just the review of one record. It is imperative therefore to code all chronic conditions documented by an acceptable provider type during a face to face encounter with the patient, whether or not there was specific treatment mentioned in the one record submitted.

OIG's audit findings did not conform to CMS diagnosis coding guidance, the contractor's approach would have biased OIG's results and recommendations.

Humana does not understand the legal basis for OIG's apparent recommendation that Humana repay funds based on audit methodologies inconsistent with CMS's approach in RADV audits. Surely, OIG does not mean to suggest that the Department of Health and Human Services ("HHS") seeks to hold MAOs to different risk-adjustment data standards based solely on whether CMS or OIG happens to conduct the audit. Such a policy would be, at best, arbitrary and capricious under the Administrative Procedure Act. And it would force MAOs to decide between calibrating their compliance programs to satisfy OIG or CMS.

6. OIG should reconsider its recommendation because OIG's recommended repayment estimate is based on a 90% confidence interval that is inconsistent with CMS RADV audit practice.

The Draft Report states that OIG used the lower limit of a two-sided 90% confidence interval when estimating the total amount of net overpayments,⁴³ rather than the lower bound of a 95% or 99% confidence interval.⁴⁴ CMS announced that it uses the lower bound of a 99% confidence interval when calculating extrapolated repayment amounts for its RADV audits.⁴⁵ Humana believes OIG should be consistent with CMS practice for RADV audits by using the lower bound of a 99% confidence interval. Humana relied upon CMS's approach when making its bids and understood that if the Company were audited, a FFSA and lower bound of a 99% confidence interval would be applied. OIG's inconsistent approach in the Draft Report would further disrupt actuarial equivalence if finalized. Humana respectfully requests that OIG recalculate the extrapolated "overpayment" amount using the lower bound of a 99% confidence interval.

III. HUMANA RESPECTFULLY REQUESTS THAT OIG RECONSIDER ITS SECOND RECOMMENDATION BECAUSE MAOS ARE NOT REQUIRED TO CONDUCT AUDITS TO THE STANDARD THAT OIG SUGGESTS.

OIG recommends that Humana "identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government[.]"⁴⁶ For the reasons described below, Humana respectfully requests that OIG reconsider this recommendation because (1) Medicare Advantage regulations do not require the sort of audits that OIG recommends and

Mention or EMR population of the diagnoses narrative list can be interpreted as management and care for the applicable chronic conditions of the patient once all other coding rules and checks for consistency have been applied. This is where RADV HCC audits may differ in guideline interpretation from fee-for-service, DRG audits or others based on just the payment for one specific encounter.").

⁴³ Draft Report at 23.

⁴⁴ Federal Judicial Center, National Academies Press, Reference Manual on Scientific Evidence 245 (3d ed. 2011) ("The 95% confidence level is the most popular, but some authors use 99%, and 90% is seen on occasion.").

⁴⁵ CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* (Feb. 24, 2012) at 4.

⁴⁶ Draft Report at 16.

(2) even if Humana were to identify unsubstantiated diagnoses codes, instances of individual unsubstantiated codes would not necessarily be “overpayments.”

1. OIG should reconsider its recommendation because Medicare Advantage regulations do not require 100 percent accuracy for risk adjustment data.

Humana, like all MAOs, relies on medical providers to generate large volumes of risk adjustment data based on the providers’ clinical judgment and their implementation of a complex diagnosis coding system. CMS regulations state that MAOs should take reasonable steps to ensure the “accuracy, completeness, and truthfulness” of the risk adjustment data they submit based on “best knowledge, information, and belief,” but do not impose a requirement of 100 percent accuracy.⁴⁷ CMS implemented the current regulatory regime after acknowledging industry concerns about widespread healthcare provider “mistakes” and “incomplete or inaccurate” provider-generated data.⁴⁸ Commenters at the time explained that “it would be unfair and unrealistic to hold [MA] organizations to a ‘100 percent accuracy’ certification standard.”⁴⁹ In response, CMS explicitly recognized that risk adjustment data are submitted to MAOs from many different sources, including healthcare providers, thereby presenting “significant verification challenges.”⁵⁰ As CMS explained, MAOs “cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the OIG, and DoJ believe is reasonable to enforce.”⁵¹

OIG guidance similarly recognizes that “[t]he requirement that the CEO or CFO certify as to the accuracy, completeness and truthfulness of [risk adjustment] data, based on best knowledge, information and belief, does not constitute an absolute guarantee of accuracy.”⁵² In addition, OIG has suggested that MAOs should conduct “sample audits and spot checks” to confirm that their information collection and reporting system is working correctly, but OIG has offered no other specific guidance to the industry in this regard.⁵³

As written, OIG’s Draft Report mischaracterizes these standards in two respects. First, the Draft Report indicates that “[f]ederal regulations state that MA organizations must monitor the data that they receive from providers and submit to CMS.”⁵⁴ This formulation implies that MAOs are responsible to monitor every piece of risk adjustment data. However, that is not the case: MA regulations afford MAOs broad discretion in designing compliance programs and do not required MAOs to adopt any specific oversight measures or confirm the accuracy of all provider submissions. Second, the Draft Report indicates that “[f]ederal regulations also state that MA organizations are responsible for the accuracy, completeness, and truthfulness of the

⁴⁷ 42 C.F.R. § 422.504(l).

⁴⁸ Medicare Program: Medicare+Choice Program, 65 Fed. Reg. 40,169, 40,250, 40,268 (June 29, 2000).

⁴⁹ See *id.* at 40,268.

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² See Publication of the OIG’s Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans, 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999).

⁵³ 64 Fed. Reg. 61,900 (Nov. 15, 1999).

⁵⁴ Draft Report at 8.

data submitted to CMS for payment purposes.”⁵⁵ This formulation implies that MAOs must unequivocally guarantee that risk adjustment data are accurate, complete and truthful. But that is again not the case: MA program requirements impose only a qualified standard of accuracy, completeness and truthfulness based on “best knowledge, information, and belief.”

OIG’s mischaracterizations of MA program requirements in turn influence OIG’s recommendation that Humana “identify . . . similar instances of noncompliance.”⁵⁶ OIG’s recommendation does not align with the requirements of a MA compliance program because the MA program does not compel Humana or other MAOs to conduct audits of specific “high-risk diagnoses.” Despite CMS’s awareness of “several diagnosis codes that are at high risk for inaccurate payments” throughout the MA industry, CMS has not implemented any regulations or guidance to address such issues or require additional compliance measures.⁵⁷ Nor does OIG identify any statutory or regulatory authority that would allow it to unilaterally impose new substantive requirements on Humana, rather than merely identifying non-compliance with duly-promulgated regulations. And, as explained, to the extent OIG’s recommendation conflicts with CMS’s regulations and guidance, it would arbitrarily and capriciously subject Humana to two contradictory regulatory regimes from the same agency. To the extent HHS intends to impose new regulatory requirements on Humana, it must do so through notice-and-comment, under both the Administrative Procedure Act and the SSA.⁵⁸

Accordingly, Humana respectfully requests that OIG reconsider this recommendation.

2. OIG should reconsider its recommendation because individual unsubstantiated codes would not necessarily be overpayments.

In the event Humana were to conduct the type of review recommended by OIG’s Draft Report, any unsubstantiated diagnosis codes that Humana were to identify would not necessarily constitute “overpayments,” as discussed above at Section II.3. Any such overpayment could only be calculated pursuant to a methodology that accounts for diagnosis coding errors in the traditional Medicare program (*e.g.*, a FFSA) in order to ensure consistency with the actuarial requirements of the SSA.

IV. HUMANA RESPECTFULLY REQUESTS THAT OIG RECONSIDER ITS THIRD RECOMMENDATION BECAUSE HUMANA’S RISK ADJUSTMENT COMPLIANCE PROGRAM SATISFIES ALL LEGAL AND REGULATORY REQUIREMENTS.

Despite acknowledging that Cariten had compliance procedures in place designed to promote accuracy in diagnoses coding, including guidance relevant to the so-called “high-risk diagnoses” under review, OIG recommends that Humana “examine its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that

⁵⁵ *Id.* at 7.

⁵⁶ *Id.* at 16.

⁵⁷ See Acute Stroke Audit Report at 1.

⁵⁸ See 5 U.S.C. § 553; 42 U.S.C. § 1395hh(a)(2).

are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures."⁵⁹ For the reasons described below, Humana respectfully requests that OIG reconsider this recommendation.

1. OIG should reconsider its recommendation because the presence of some data inaccuracies does not indicate a failure of Humana's policies and procedures.

As explained in Section IV.2, Humana has several programs in place to enhance the accuracy of risk adjustment data, consistent with MA program requirements and OIG's guidance,⁶⁰ but Humana cannot and does not represent that the risk adjustment data it submits to CMS is free of errors. CMS is capable of modifying MA program requirements as needed on a going forward basis. As for OIG's audit period, however, Humana's risk adjustment compliance programs met or exceeded all applicable MA program requirements.

In the Draft Report, OIG states that the unsubstantiated HCCs for certain so-called high-risk diagnosis codes discovered in the audited sample demonstrate that Humana's policies and procedures to prevent, detect, and correct noncompliance with the relevant regulations "were not always effective."⁶¹ This effectively imposes the perfection standard that CMS and OIG have previously recognized is not reasonable to enforce, as discussed above.⁶² Indeed, none of the authorities cited in the Draft Report support OIG's apparent position that the presence of inaccurate risk adjustment data in an MAO's risk adjustment submissions constitutes *per se* noncompliance with federal requirements.⁶³ To the contrary, as discussed above, the regulatory regime that CMS and OIG have implemented actually presupposes the presence of at least some data inaccuracies. Thus, Humana requests that OIG reconsider its position that Humana's policies and procedures "were not always effective" and its recommendation that Humana "enhance" its current policies and procedures.

2. OIG should reconsider its recommendation because Humana's industry-leading risk adjustment compliance program satisfies all federal requirements.

As noted above, since 2013 Humana has regularly described to CMS the Company's risk adjustment data policies and procedures and the particulars of Humana's MRA compliance program.⁶⁴ To date, Humana has never received a substantive response from CMS related to those communications, nor has CMS ever informed Humana than any aspect of its approach to

⁵⁹ Draft Report at 16.

⁶⁰ See 65 Fed. Reg. at 40,268 ("[MAOs] will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted."); 42 C.F.R. § 422.504(l); Publication of the OIG's Compliance Program Guidance for Medicare Choice Organizations Offering Coordinated Care Plans, 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999) ("[MAOs] should ordinarily conduct sample audits and spot checks of this system to verify whether it is yielding accurate information.")

⁶¹ Draft Report at 15.

⁶² See Medicare Program: Medicare+Choice Program, 65 Fed. Reg. 40,268 (June 29, 2000).

⁶³ See Draft Report at 7-8.

⁶⁴ See, e.g., Letter from Sean J. O'Reilly, Chief Compliance Officer, Humana to Cheri Rice, Acting Deputy Center Director, Centers for Medicare and Medicaid Services (Mar. 4, 2019).

risk adjustment compliance is deficient.⁶⁵ Further, Humana described its risk adjustment data policies and procedures to OIG in connection with the review OIG conducted in support of the Draft Report, including Humana's coding education materials, which include guidance relevant to the so-called "high-risk diagnoses" identified in the Draft Report.⁶⁶ As those communications demonstrate, Humana has for years incurred tremendous expense in implementing numerous MRA audits and compliance measures in reliance on the government methodologies and compliance standards articulated in the regulations and sub-regulatory guidance described herein.

Consistent with the discretion afforded to Humana under MA program requirements, Humana has several programs in place to enhance the accuracy of risk adjustment data, which include but are not limited to, Provider Data Validation reviews, Humana's Risk Adjustment Integrity Unit, Humana-conducted Risk Adjustment Data Validation audits, and Administrative Quality Audits. With regard to the so-called "high-risk diagnoses" OIG has identified, OIG acknowledges that "Cariten had compliance procedures to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct" and these procedures "included a provider education program that was designed to promote accurate diagnosis codes, which provided instructions to its providers on the proper coding of several risk adjustment diagnoses, including those in the nine high-risk groups reviewed in [OIG's] audit."⁶⁷ OIG also acknowledges that Cariten's "compliance procedures included routine internal medical reviews to compare diagnosis codes from a random sample of claims to the diagnoses that were documented on the associated medical records."⁶⁸ Humana believes these programs satisfy Humana's obligations under applicable MA program requirements.

Despite these findings, OIG's Draft Report concludes that Cariten's compliance procedures "were not always effective" because Cariten's "internal medical reviews did not

⁶⁵ One element of Humana's extensive MRA compliance program involves regular internal RADV-like audits that Humana conducts to confirm the accuracy of the risk-adjusted premiums that Humana receives from CMS (called Humana Self Audits). Humana believes that these Self Audits satisfy the Company's legal obligations (contractual, regulatory, or otherwise) with respect to risk adjustment payment accuracy and, therefore, it is duplicative for OIG to recommend that Humana refund premium amounts other than those found by the Company's Self Audits. As discussed with OIG, to administer Self Audits, Humana reviews, in a manner generally consistent with the standards that CMS has applied in its past RADV audits of Humana's contracts, all HCCs submitted to CMS for a sample of members. This includes requesting additional documentation for further review if the initial documentation received from providers does not support an HCC. Consistent with CMS's regulatory guidance and the aforementioned actuarial equivalence requirement, the Self Audit process involves the calculation and comparison of the contract level Self Audit results against an estimated FFSA. Specifically, if Humana determines that an unsubstantiated HCC has been submitted for a sampled member, Humana recalculates the member's risk score and risk adjustment premium to determine any projected payment imprecision related to that member. Humana then calculates each Self Audit contract group's preliminary payment recovery amount and applies an estimated FFSA to determine the final estimated recovery amount from the Self Audit. Humana also submits a corresponding data correction for every HCC that has been selected for Self Audit that is not supported by at least one available medical record.

⁶⁶ See Draft Report at 18 ("[OIG] interviewed Cariten officials to gain an understanding of (1) the policies and procedures that Cariten followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Cariten's monitoring of those diagnosis codes to identify and detect noncompliance with Federal requirements.")

⁶⁷ *Id.* at 15.

⁶⁸ *Id.* at 15.

focus on any specific high-risk diagnosis codes, including those [OIG] identified as being at a higher risk for being miscoded.”⁶⁹ But as Humana explained to CMS at the exit conference, all of Humana’s risk adjustment compliance processes and reviews, by their nature, include such diagnosis codes. Humana disagrees with the notion that existing CMS guidance requires a particular approach to OIG’s unilaterally selected “higher-risk” areas. As explained in Section I, CMS has acknowledged that it does not have policies and procedures in place that would have guaranteed so-called “high-risk” diagnosis codes, like acute stroke, were always supported by underlying medical record documentation.⁷⁰ In the absence of specific CMS-implemented MA program requirements, Humana and other MAOs are afforded broad discretion in designing compliance and education programs.⁷¹

Humana has been in communication with CMS about its compliance efforts and the overall issues with risk adjustment data accuracy for many years and has developed processes, reflected in the Company’s policies and procedures, to enhance broadly the accuracy of diagnosis code data. Each of these programs have been presented in detail to CMS over the course of many years, and CMS has not suggested any revisions thereto. If OIG were to finalize its recommendations as drafted, they would not appropriately account for Humana’s reliance on the CMS guidance that existed during the years subject to OIG’s audit. Humana therefore requests that OIG reconsider its recommendation that the Company “enhance” its risk adjustment policies and procedures.

* * *

As noted above, Humana takes its compliance responsibilities seriously and looks forward to working cooperatively with OIG on revisions to the Draft Report. Please contact me if you have questions, concerns, or would like to discuss further anything described in this letter.

Sincerely,



Sean O’Reilly, JD
Vice President and Chief Compliance Officer
Enterprise Risk & Compliance Group

⁶⁹ *Id.* at 15.

⁷⁰ See Acute Stroke Audit Report at 8.

⁷¹ See 65 Fed. Reg. at 40,265.