

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE
COMPLIANCE AUDIT OF SPECIFIC
DIAGNOSIS CODES THAT
HUMANA HEALTH PLAN, INC.,
(CONTRACT H2649)
SUBMITTED TO CMS**

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Report in Brief

Date: September 2024
Report No. A-02-22-01001

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, Humana Health Plan, Inc. (Humana), and focused on eight groups of high-risk diagnosis codes (high-risk groups). Our objective was to determine whether Humana's submission of selected diagnosis codes to CMS, for use in CMS's risk adjustment program, complied with Federal requirements.

How OIG Did This Audit

We selected a stratified random sample of 240 unique enrollee-years with the high-risk diagnosis codes for which Humana received higher payments for 2017 through 2018. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$642,816.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Humana Health Plan, Inc. (Contract H2649) Submitted to CMS

What OIG Found

For the eight high-risk groups covered by our audit, most of Humana's submissions of the selected diagnosis codes to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, for 202 of the 240 sampled enrollee-years, the diagnosis codes that Humana submitted to CMS were not supported by the medical records and resulted in \$497,225 in overpayments. As demonstrated by the errors found in our sample, Humana's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that Humana received at least \$13.1 million in overpayments for 2017 and 2018. Because of Federal regulations that limit the use of extrapolation in Risk Adjustment Data Validation audits for recovery purposes to payment years 2018 and forward, we are reporting the overall estimated overpayment amount but are recommending a refund of \$6.8 million (\$274,151 for the sampled enrollee-years from 2017 and an estimated \$6,503,234 for 2018).

What OIG Recommends and Humana Comments

We recommend that Humana (1) refund to the Federal Government the \$6.8 million of estimated 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) continue to 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 and take the necessary steps to enhance those procedures.

Humana disagreed with some of our findings and all of our recommendations. Specifically, Humana did not agree with our findings for 33 of the 206 enrollee-years identified as errors in our draft report and provided additional information for our consideration. Additionally, Humana did not agree with our audit methodology or overpayment estimation methodology. After reviewing Humana's comments and additional information that it provided, we reduced the number of enrollee-years identified as errors and revised the amount in our first recommendation. We maintain that our second and third recommendations remain valid.

TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objective	1
Background	1
Medicare Advantage Program	1
Risk Adjustment Program	2
High-Risk Groups of Diagnoses	4
Humana Health Plan, Inc.	5
How We Conducted This Audit.....	6
FINDINGS	7
Federal Requirements	7
Most of Humana Health Plan, Inc.’s Submissions of the Selected High-Risk Diagnosis Codes to CMS Did Not Comply With Federal Requirements.....	8
Incorrectly Submitted Diagnosis Codes for Acute Stroke	9
Incorrectly Submitted Diagnosis Codes for Acute Myocardial Infarction	10
Incorrectly Submitted Diagnosis Codes for Embolism	11
Incorrectly Submitted Diagnosis Codes for Sepsis	12
Incorrectly Submitted Diagnosis Codes for Lung Cancer	13
Incorrectly Submitted Diagnosis Codes for Breast Cancer	14
Incorrectly Submitted Diagnosis Codes for Colon Cancer	14
Incorrectly Submitted Diagnosis Codes for Prostate Cancer	15
Summary of Incorrectly Submitted Diagnosis Codes	16
The Policies and Procedures That Humana Health Plan, Inc., Had to Prevent, Detect, and Correct Noncompliance With Federal Requirements Could Be Improved	16
Humana Health Plan, Inc., Received Overpayments.....	17
RECOMMENDATIONS.....	17

HUMANA COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE	18
Humana Did Not Agree With OIG’s Recommendation That It Refund Estimated Overpayments	18
Humana Did Not Agree With OIG’s Findings for 33 Sampled Enrollee-Years.....	18
Humana Did Not Agree With How OIG Incorporated Underpayments Into Its Estimates.....	20
Humana Stated That OIG’s Extrapolation Methodology Did Not Apply Certain MA Program Requirements.....	22
Humana Stated That OIG’s Recommended Recovery Amount May Be Inflated Due to Data Corrections Not Yet Processed by CMS.....	24
Humana Stated That OIG’s Methodology For Classifying Diagnosis Codes As High-Risk Is Inconsistent With Other OIG Products.....	24
Humana Noted That OIG Did Not Follow CMS’s Established Risk Adjustment Data Validation Methodology.....	25
Humana Did Not Agree With OIG’s Use of the 90-Percent Confidence Interval In Estimating Overpayments.....	27
Humana Did Not Agree With OIG’s Recommendation to Perform Additional Reviews of High-Risk Diagnosis Codes For the Years Before And After The Audit Period.....	28
Humana Did Not Agree With OIG’s Recommendation That Humana Enhance Its Existing Procedures	30

APPENDICES

A: Audit Scope and Methodology.....	32
B: Related Office of Inspector General Reports.....	36
C: Statistical Sampling Methodology.....	37
D: Sample Results and Estimates.....	40
E: Federal Regulations Regarding Compliance Programs That Medicare Advantage Organizations Must Follow.....	44
F: Humana Comments.....	46

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, gender, 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 54 breast cancer diagnoses into 1 group.) This audit covered Humana Health Plan, Inc. (Humana) for contract number H2649 and focused on eight groups of high-risk diagnosis codes for payment years 2017 and 2018.³

OBJECTIVE

Our objective was to determine whether Humana's submission of selected diagnosis codes to CMS, for use in CMS's risk adjustment program, complied with Federal requirements.

BACKGROUND

Medicare Advantage Program

The MA program offers people eligible for Medicare managed care options by allowing them to enroll in private health care plans rather than having their care covered through Medicare's

¹ The providers code diagnoses using the International Classification of Diseases (ICD), Clinical Modification, *Official Guidelines for Coding and Reporting*. 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.

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

³ All subsequent references to "Humana" in this report refer solely to contract number H2649.

traditional fee-for-service program.⁴ Individuals 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 2022, CMS paid MA organizations \$403.3 billion, which represented 45 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.⁵

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.⁶ 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.⁷
- *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 gender). This

⁴ 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.

⁵ The Social Security Act (the Act) §§ 1853(a)(1)(C) and (a)(3); 42 CFR § 422.308(c).

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

⁷ CMS's bid-benchmark comparison also determines whether the MA organization must offer supplemental benefits or must charge a basic enrollee premium for the benefits.

process results in an individualized risk score for each enrollee, which CMS calculates annually.

To determine an enrollee's health status for 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 from providers based on information documented in 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).⁸ 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 one 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 of 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 sequestration reduction.⁹ Thus, if the factors used to determine an enrollee's risk score are incorrect, CMS will make an improper payment to an MA organization. Specifically, if medical

⁸ During our audit period, CMS calculated risk scores based on the Version 22 CMS-HCC model.

⁹ Budget sequestration refers to automatic spending cuts that occurred through the withdrawal of funding for certain Federal programs, including the MA program, as provided in the Budget Control Act of 2011 (BCA) (P.L. No. 112-25 (Aug. 2, 2011)). Under the BCA, the sequestration of mandatory spending began in April 2013.

records do not support the diagnosis codes that an MA organization submitted to CMS, the HCCs are not validated, which causes overstated enrollee risk scores and overpayments from CMS.¹⁰ Conversely, if medical records support the diagnosis codes that an MA organization did not submit to CMS, validated HCCs may not have been included in enrollees' risk scores, which may cause those risk scores to be understated and may result in 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 eight high-risk groups:

- *Acute stroke*: An enrollee received one acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on only one physician claim during the service year but did not have an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim. In these instances, a diagnosis of history of stroke (which does not map to an HCC) typically should have been used.
- *Acute myocardial infarction*: An enrollee received one diagnosis that mapped to the HCC for Acute Myocardial Infarction on only one physician or outpatient claim during the service year but did not have an acute myocardial infarction diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician or outpatient claim). In these instances, 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) on only one claim during the service year but did not have an anticoagulant medication dispensed on his or her behalf. An anticoagulant medication is typically used to treat an embolism. In these instances, 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.
- *Sepsis*: An enrollee received one sepsis diagnosis (that mapped to the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock) on one physician or outpatient claim during the service year but did not have a sepsis diagnosis on a corresponding inpatient hospital claim. A sepsis diagnosis generally results in an inpatient hospital admission.

¹⁰ 42 CFR § 422.310(e) requires MA organizations (when undergoing an audit conducted by the Secretary) to submit "medical records for the validation of risk adjustment data." For purposes of this report, we use the terms "supported" or "not supported" to denote whether or not the reviewed diagnoses were evidenced in the medical records. If our audit determines that the diagnoses are supported or not supported, we accordingly use the terms "validated" or "not validated" with respect to the associated HCC.

- *Lung cancer*: An enrollee received one lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) on only one claim during the service year 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 one breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of breast cancer (which does not map to an HCC) typically should have been used.
- *Colon cancer*: An enrollee received one colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, 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 one prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of prostate cancer (which does not map to an HCC) typically should have been used.

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

HUMANA HEALTH PLAN, INC.

Humana is an MA organization based in Louisville, Kentucky. As of December 2018, Humana provided coverage under contract number H2649 to 247,872 enrollees. For the 2017 and 2018 payment years (audit period), CMS paid Humana approximately \$5 billion to provide coverage to its enrollees.^{11, 12}

¹¹ The 2017 and 2018 payment year data were the most recent data available at the start of the audit.

¹² All of the payment amounts that CMS made to Humana and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of the eight high-risk groups during the 2016 and 2017 service years, for which Humana received increased risk-adjusted payments for payment years 2017 and 2018, respectively. Because enrollees could be classified into more than one high-risk group or could 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 7,637 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$16,294,672).¹³ We selected for audit a stratified random sample of 240 enrollee-years, as shown in Table 1.

**Table 1: Sampled Enrollee-Years
(Strata for Sample Design Based on High-Risk Groups)**

High Risk Group	Number of Sampled Enrollee Years		
	Payment Year 2017	Payment Year 2018	Total
1. Acute stroke	14	16	30
2. Acute myocardial infarction	18	12	30
3. Embolism	15	15	30
4. Sepsis	17	13	30
5. Lung cancer	15	15	30
6. Breast cancer	12	18	30
7. Colon cancer	16	14	30
8. Prostate cancer	15	15	30
Total for All High-Risk Groups	122	118	240

Humana provided medical records as support for the selected diagnosis codes associated with 236 of the 240 enrollee-years.¹⁴ We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. For the HCCs that were not validated, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or if we identified another diagnosis code (on CMS’s systems) that mapped to an HCC in the related-disease group, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

¹³ The 7,637 unique enrollee-years and associated payments that we reviewed consisted of 3,679 enrollee-years (\$7,793,518) for payment year 2017 and 3,958 enrollee-years (\$8,501,154) for payment year 2018.

¹⁴ Humana could not locate medical records for the remaining 4 sampled enrollee-years.

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, Appendix D contains our sample results and estimates, and Appendix E contains the Federal regulations regarding MA organizations' compliance programs.

FINDINGS

With respect to the eight high-risk groups covered by our audit, most of Humana's submissions of the selected diagnosis codes to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 38 of the 240 sampled enrollee-years, the medical records validated the reviewed HCCs. For the remaining 202 enrollee-years, however, either the medical records that Humana provided did not support the diagnosis codes or Humana could not locate the medical records to support the diagnosis codes; therefore, the associated HCCs were not validated and resulted in \$497,225 in overpayments.

As demonstrated by the errors found in our sample, Humana's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that Humana received at least \$13,150,480 in overpayments for 2017 and 2018.¹⁵ Because of Federal regulations that limit the use of extrapolation in Risk Adjustment Data Validation (RADV) audits for recovery purposes to payment year 2018 and forward, we are reporting the overall estimated overpayment amount but are recommending a refund of \$6,777,385 in overpayments (\$274,151 for the sampled enrollee-years from 2017 and an estimated \$6,503,234 for 2018).¹⁶

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).

¹⁵ To be conservative, we estimate overpayments 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.

¹⁶ Federal regulations limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643 (Feb. 1, 2023)). Therefore, for sampled enrollee-years from payment year 2017, we limited our calculation of overpayments to the financial impact associated with these enrollee-years. For sampled enrollee-years from payment year 2018, we used the financial impact associated with the enrollee-years to estimate the total amount of overpayments for that year. (See also footnotes 24 and 42 later in this report.)

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

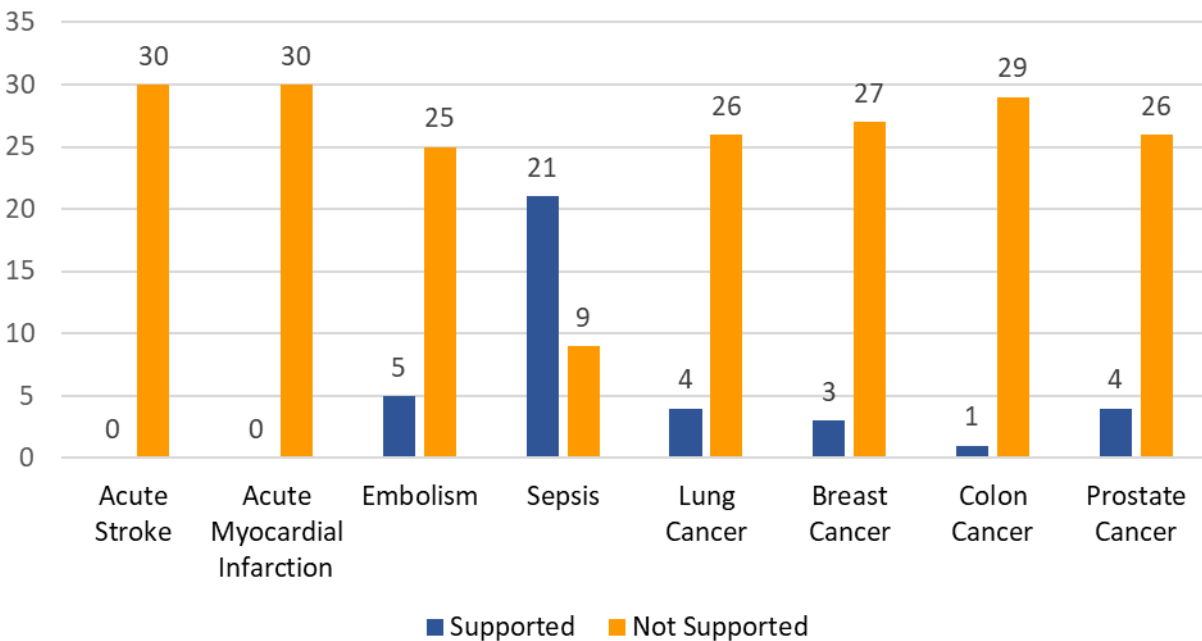
CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap. 7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7, § 40). The diagnosis must be coded according to the International Classification of Diseases, Clinical Modification, *Official Guidelines for Coding and Reporting* (42 CFR § 422.310(d)(1) and 45 CFR §§ 162.1002(c)(2)-(3)). Further, 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’ 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)).

MOST OF HUMANA HEALTH PLAN, INC.’S SUBMISSIONS OF THE SELECTED HIGH-RISK DIAGNOSIS CODES TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Most of Humana’s submissions of the selected high-risk diagnosis codes to CMS for use in CMS’s risk adjustment program did not comply with Federal requirements. Specifically, as shown in the figure on the following page, for 202 of the 240 sampled enrollee-years either the medical records that Humana provided did not support the diagnosis codes or Humana could not locate the medical records to support the diagnosis codes. In these instances, Humana should not have submitted the diagnosis codes to CMS and received the resulting overpayments.

Figure: Analysis of High-Risk Groups



Incorrectly Submitted Diagnosis Codes for Acute Stroke

Humana incorrectly submitted diagnosis codes for acute stroke for all 30 sampled enrollee-years. Specifically:

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

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that results in the assignment of [the HCC for Ischemic or Unspecified Stroke]. There is documentation of a past medical history of stroke with other sequelae of cerebral infarction [diagnosis] which does not result in an HCC.”¹⁷

- For 9 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.
- For 1 enrollee-year, Humana submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for monoplegia (which

¹⁷ Residuals or sequelae are the late effects of an injury that can occur only after the acute phase of the injury or illness has passed.

was supported in the medical records).¹⁸ The independent medical review contractor stated that “there is no evidence of an acute stroke, however the patient has [a] left arm paresis [diagnosis] that results in [the HCC for Monoplegia, Other Paralytic Syndromes] which should have been assigned instead of the submitted HCC.” Accordingly, Humana should not have received an increased payment for the acute stroke diagnosis but should have received a lesser increased payment for the other diagnosis identified.

- For the remaining 1 enrollee-year, Humana could not locate any medical records to support the acute stroke diagnosis; therefore, the HCC for Ischemic or Unspecified Stroke was not validated.

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and Humana received \$60,138 in overpayments (\$27,727 for 2017 and \$32,411 for 2018) for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Myocardial Infarction

Humana incorrectly submitted diagnosis codes for acute myocardial infarction for all 30 sampled enrollee-years. Specifically:

- For 15 enrollee-years, the medical records indicated in each case that the individual had an old myocardial infarction diagnosis, but the records did not support an acute myocardial infarction diagnosis at the time of the physician’s service.¹⁹

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that would result in [the HCC for Acute Myocardial Infarction]. The medical record documentation indicates a past medical history of a previous myocardial infarction occurring in July 2015, but there is no documentation of an acute myocardial infarction in [any medical] record submitted. An old myocardial infarction [diagnosis] can be assigned which does not result in an HCC.”

- For 6 enrollee-years, the medical records did not support an acute myocardial infarction diagnosis, however, for each of these enrollee-years, we identified support on CMS’s systems for the diagnosis of other and unspecified angina pectoris, which mapped to an HCC for a less severe manifestation of the related-disease group.²⁰ Accordingly,

¹⁸ Monoplegia is paralysis affecting a single limb, body part, or group of muscles.

¹⁹ An “old myocardial infarction” is a distinct diagnosis that represents a myocardial infarction that occurred more than 4 weeks previously, has no current symptoms directly associated with that myocardial infarction, and requires no current care.

²⁰ Angina pectoris is 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.

Humana should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the other diagnosis identified.

- For 5 enrollee-years, the medical records in each case did not support an acute myocardial infarction diagnosis.²¹
- For 3 enrollee-years, the medical records that Humana provided to support the reviewed HCC were electrocardiogram test results that were not interpreted by an acceptable provider type. For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources (e.g., a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3)); the Manual, chap. 7, §§ 40 and 120.1)). Because the records for these 3 enrollee-years did not meet CMS's requirements for acceptable data sources, we could not validate the reviewed HCC.
- For the remaining 1 enrollee-year, Humana could not locate any medical records to support the acute myocardial infarction diagnosis; therefore, the HCC for Acute Myocardial Infarction was not validated.

As a result of these errors, the HCC for Acute Myocardial Infarction was not validated, and Humana received \$51,912 in overpayments (\$31,582 for 2017 and \$20,330 for 2018) for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

Humana incorrectly submitted diagnosis codes for embolism for 25 of 30 sampled enrollee-years. Specifically:

- For 13 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not support a diagnosis that mapped to an Embolism HCC at the time of the physician's service.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of [the HCC Vascular Disease with Complications]. There is documentation of a past medical history of pulmonary embolism [diagnosis] which does not result in an HCC."

²¹ For 1 of these enrollee-years, the medical record that Humana provided to support the reviewed HCC did not meet Medicare requirements regarding credentials. For purposes of medical review, services provided or ordered must be authenticated by a signature, and the credentials for the provider must appear on the medical record, in accordance with CMS policies (Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance).

- For 9 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Embolism HCC.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that results in [the HCC for Vascular Disease]. The indication for the doppler [ultrasound exam] was for evaluation of deep vein thrombosis (DVT) however the exam findings clearly indicate no evidence of DVT.”²²

- For the remaining 3 enrollee-years, the medical records that Humana provided to support the reviewed HCC were radiology reports signed and credentialed by radiologists. For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources (e.g., a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3)); the Manual, chap. 7, §§ 40 and 120.1)). Because the records for these 3 enrollee-years did not meet CMS’s requirements for acceptable data sources, we could not validate the reviewed HCC.

As a result of these errors, the Embolism HCCs were not validated, and Humana received \$58,930 in overpayments (\$31,426 for 2017 and \$27,504 for 2018) for these 25 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Sepsis

Humana incorrectly submitted diagnosis codes for sepsis for 9 of 30 sampled enrollee-years. Specifically:

- For 6 enrollee-years, the medical records in each case did not support a sepsis diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that results in [the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock]. Patient was empirically treated with antibiotics for a possible diagnosis of sepsis which was ruled out at discharge and the antibiotics were discontinued.”

- For 2 enrollee-years, the medical records indicated in each case that the individual had previously had sepsis, but the records did not support a sepsis diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that results in the assignment of [the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock]. There is

²² Deep vein thrombosis occurs when a blood clot forms in one or more of the deep veins in the body, usually in the legs.

documentation of a past medical history of sepsis [diagnosis] which does not result in an HCC.”

- For the remaining 1 enrollee-year, Humana could not locate any medical records to support the sepsis diagnosis; therefore, the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock was not validated.

As a result of these errors, the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock was not validated, and Humana received \$28,193 in overpayments (\$12,817 for 2017 and \$15,376 for 2018) for these 9 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

Humana incorrectly submitted diagnosis codes for lung cancer for 26 of 30 sampled enrollee-years. Specifically:

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

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that results in the assignment of [the HCC for Lung and Other Severe Cancers]. There is documentation of a past medical history of lung cancer [diagnosis] which does not result in an HCC.”

- For 5 enrollee-years, the medical records in each case did not support a lung cancer diagnosis. However, for each of these enrollee-years, we identified support on CMS’s systems for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Humana should not have received an increased payment for the lung cancer diagnosis but should have received a lesser increased payment for the other diagnosis identified.²³
- For the remaining 4 enrollee-years, the medical records in each case did not support a lung cancer diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that results in the assignment of [the HCC for Lung and Other Severe Cancers]. The medical documentation includes a pathology report which indicates that the specimen was negative for malignancy. An active lung cancer code cannot be assigned.”

²³ For 1 of these enrollee-years, the medical record that Humana provided to support the reviewed HCC did not meet Medicare requirements regarding credentials. (See footnote 21 for criteria related to signature authentication.)

As a result of these errors, the HCC for Lung and Other Severe Cancers was not validated, and Humana received \$169,675 in overpayments (\$105,135 for 2017 and \$64,540 for 2018) for these 26 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

Humana incorrectly submitted diagnosis codes for breast cancer for 27 of 30 sampled enrollee-years. Specifically:

- For 26 enrollee-years, the medical records indicated in each case that the individual had previously had breast cancer, but the records did not support a breast cancer diagnosis at the time of the physician's service.

For example, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of [the HCC for Breast, Prostate, and Other Cancers and Tumors]. There is documentation of a past medical history of breast cancer [diagnosis] which does not result in an HCC."

- For the remaining 1 enrollee-year, the medical records did not support a breast cancer diagnosis. The independent medical review contractor stated that "there is no documentation of any condition that results in [the HCC for Breast, Prostate, and Other Cancers and Tumors]. There is documentation of a left breast lump [diagnosis] which does not result in an HCC. Provider has documented a possibility that this could be benign. Further diagnostic testing was recommended. A concern for breast mass was noted in the assessment, which in the absence of a confirmed malignancy of the lump on this date of service, is not coded as such."

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Humana received \$31,992 in overpayments (\$12,832 for 2017 and \$19,160 for 2018) for these 27 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

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

- For 24 enrollee-years, the medical records indicated in each case that the individual previously had colon cancer, but the records did not support a colon cancer diagnosis at the time of the physician's service.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of [the HCC for Colorectal, Bladder, and Other Cancers]. There is documentation of a past medical history of colon cancer [diagnosis] which does not result in an HCC."

- For 3 enrollee-years, the medical records in each case did not support a colon cancer diagnosis.
- For the remaining 2 enrollee-years, the medical records in each case did not support the submitted colon cancer diagnosis, however, we identified support on CMS’s systems for another diagnosis that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors, which is a less severe manifestation of the related-disease group. Accordingly, Humana should not have received an increased payment for the submitted colon cancer diagnosis. Rather, it should have received a lesser increased payment for the other diagnosis identified.

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and Humana received \$65,988 in overpayments (\$37,597 for 2017 and \$28,391 for 2018) for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

Humana incorrectly submitted diagnosis codes for prostate cancer for 26 of 30 sampled enrollee-years. Specifically:

- For 22 enrollee-years, the medical records indicated in each case that the individual previously had prostate cancer, but the records did not support a prostate cancer diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that results in the assignment of [the HCC for Breast, Prostate, and Other Cancers and Tumors]. There is documentation of a past medical history of prostate cancer [diagnosis] which does not result in an HCC.”

- For 3 enrollee-years, the medical records in each case did not support a prostate cancer diagnosis.
- For the remaining 1 enrollee-year, Humana could not locate any medical records to support the prostate cancer diagnosis; therefore, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated.

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Humana received \$30,397 in overpayments (\$15,035 for 2017 and \$15,362 for 2018) for these 26 sampled enrollee-years.

Summary of Incorrectly Submitted Diagnosis Codes

In summary and with respect to the eight high-risk groups covered by our audit, Humana received \$497,225 in overpayments for 202 of the 240 sampled enrollee-years (\$274,151 for 2017 and \$223,074 for 2018).

THE POLICIES AND PROCEDURES THAT HUMANA HEALTH PLAN, INC., HAD TO PREVENT, DETECT, AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS COULD BE IMPROVED

As demonstrated by the errors found in our sample, the policies and procedures that Humana had to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations (42 CFR § 422.503(b)(4)(vi)), could be improved.

Humana had compliance procedures to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. Specifically, Humana had preventative techniques, including a provider education program designed to promote accurate diagnosis coding. Further, Humana provided instructions to providers on the proper coding of several risk adjustment diagnoses, including those in six of the eight high-risk groups reviewed in our audit (acute stroke, embolism, lung cancer, breast cancer, colon cancer, and prostate cancer).

In addition, Humana's compliance procedures for detection and correction of incorrectly submitted diagnosis codes included routine internal medical reviews to compare diagnosis codes from a random sample of claims to the diagnoses documented on the associated medical records. Humana provided guidance to its coders to evaluate diagnosis coding accuracy of several risk adjustment diagnoses, including those in seven of the eight high-risk groups reviewed in our audit (acute stroke, acute myocardial infarction, embolism, lung cancer, breast cancer, colon cancer, and prostate cancer). However, the internal medical reviews did not focus on any specific risk adjustment diagnoses, including those we identified as being at a higher risk for being miscoded.

We acknowledge that Humana had compliance procedures designed to ensure that diagnosis codes comply with Federal requirements. However, based on our assessment of the procedures that were in place during our audit period, and because the diagnosis codes for 202 of the 240 sampled enrollee-years were not supported by the medical records, we believe that Humana's compliance procedures to prevent, detect, and correct incorrect high-risk diagnosis codes could be improved.

Humana officials explained that, after our audit period, it modified the filters it applies to the risk adjustment data it submits to CMS through CMS's Risk Adjustment Processing System (RAPS). Specifically, Humana has a process to filter the data it submits to CMS through RAPS to determine whether the data meet CMS risk adjustment data requirements, including the

requirement that the data resulted from a face-to-face encounter with an acceptable provider. However, in calendar year 2020, Humana learned that the filters did not appropriately exclude certain services that may not always be associated with a face-to-face encounter with an acceptable provider (for example, diagnostic radiology services). Humana officials stated that the filters were updated to exclude data associated with these procedure codes from RAPS submissions for service year 2020, thereby preventing errors similar to those we identified for 6 sampled enrollee-years with medical records that were not from acceptable data sources. Humana officials stated that they did not adjust their submission of diagnosis codes associated with these procedure codes that occurred prior to the update of the RAPS filters. Instead, Humana relied on its compliance procedures to identify corrective actions related to these submissions.

HUMANA HEALTH PLAN, INC., RECEIVED 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 Humana received at least \$13,150,480 in overpayments for our audit period.

Because of Federal regulations that limit the use of extrapolation in RADV audits for recovery purposes to payment years 2018 and forward,²⁴ we are reporting the overall estimated overpayment amount, but are recommending a refund of \$6,777,385 in overpayments (\$274,151 for the sampled enrollee-years from 2017 and an estimated \$6,503,234 for 2018). (See footnote 16 and Appendix D for sample results and estimates.)

RECOMMENDATIONS

We recommend that Humana Health Plan, Inc.:

- refund to the Federal Government the \$6,777,385 of estimated overpayments;²⁵
- 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

²⁴ After the start of our audit, CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643 (Feb. 1, 2023)). RADV audits are conducted to verify that diagnoses submitted by MA organizations for risk-adjusted payment are supported by medical record documentation.

²⁵ OIG audit recommendations do not represent final determinations. 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.

- continue to 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.

HUMANA COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Humana disagreed with some of our findings and all of our recommendations. Specifically, Humana did not agree with our findings for 33 of the 206 enrollee-years identified as errors in our draft report and provided additional information for our consideration. Humana did not state whether it agreed or disagreed with our findings for the remaining 173 enrollee-years.

Humana also stated that our audit methodology departed from governing statistical and actuarial principles, the statutory requirements of the MA program, and CMS’s RADV processes. Additionally, Humana did not agree with our overpayment estimation methodology. Lastly, Humana 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 Humana’s comments and the additional information it provided, we reduced the number of enrollee-years identified as in error from 206 to 202 and adjusted our calculation of estimated overpayments. Accordingly, we reduced the recommended refund in our first recommendation from \$6,891,466 to \$6,777,385 for this final report. We maintain that our second and third recommendations remain valid.

A summary of Humana’s comments and our responses follows. Humana’s comments, from which we have removed an attachment that contained personally identifiable information, appear as Appendix F. We are separately providing Humana’s comments in their entirety to CMS.

HUMANA DID NOT AGREE WITH OIG’S RECOMMENDATION THAT IT REFUND ESTIMATED OVERPAYMENTS

Humana Did Not Agree With OIG’s Findings for 33 Sampled Enrollee-Years

Humana Comments

Humana did not agree with our draft report findings for 33 sampled enrollee-years (as shown in Table 2 on the following page) and requested that we reconsider our findings and modify our estimate of overpayments.

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

High Risk Group	Number of Sampled Enrollee Years		
	Payment Year 2017	Payment Year 2018	Total
1. Acute stroke	2	2	4
2. Acute myocardial infarction	2	4	6
3. Embolism	1	4	5
4. Sepsis	2	1	3
5. Lung cancer	3	2	5
6. Breast cancer	0	4	4
7. Colon cancer	2	1	3
8. Prostate cancer	3	0	3
Total for All High-Risk Groups	15	18	33

For 30 of the 33 enrollee-years, Humana provided new medical records and explanations supporting its position that previously submitted medical records validated the audited HCCs. For the remaining 3 enrollee-years, Humana provided new medical records and stated that there was support for a diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group.

OIG Response

For the 30 enrollee-years for which Humana provided additional documentation, our independent medical review contractor reviewed the documentation and reaffirmed that 26 of the 30 HCCs were not validated.²⁶ For example, for 1 enrollee-year from the acute stroke high-risk group, our contractor upheld its original decision upon reconsideration and noted:

“Based on the new medical record provided, the patient was evaluated for intermittent claudication. There was no documentation of any signs or symptoms of an acute stroke. A [stroke syndrome diagnosis] was noted in the assessment and does not result in the assignment of an HCC.”

²⁶ For 1 enrollee-year, the new medical record that Humana provided to support the reviewed HCC was signed by a diagnostic radiologist which is not an acceptable provider type. For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources (e.g., a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3)); the Manual, chap. 7, §§ 40 and 120.1). Because the medical record for this enrollee-year did not meet CMS’s requirements for acceptable data sources, we could not use it to validate the reviewed HCC.

For the remaining 4 enrollee-years, our contractor reversed its original decision and stated that the HCCs were validated.²⁷ Our contractor also completed a quality review of the enrollee-years for which it reversed its original decision based on Humana’s explanations of previously submitted medical records and reported that it did not identify any systemic issues. As a result, we reduced the number of enrollee-years in error from 206 (as reported in our draft report) to 202. We also revised our findings and reduced the associated monetary recommendation.

With respect to the 3 enrollee-years for which Humana 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 HCCs indicated by Humana in its comments were supported. However, we considered the financial impact of these HCCs when we estimated the recommended refund amount included in our draft report.²⁸ Therefore, we did not need to make any adjustments related to these HCCs for the recommended refund amount included in this final report.

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

Humana Comments

Humana stated that our estimate of overpayments significantly understated underpayments and is statistically unsupported. Specifically, Humana stated that, based on its understanding of our audit procedures and methodology, our findings are “systematically skewed towards identifying overpayments rather than underpayments, rendering [our] results inherently unreliable.” Humana stated that “OIG has indeed been clear in the response to comments submitted for related audits that such an analysis of potential underpayments is beyond the scope of OIG’s review. OIG and the MA industry therefore appear to be at an impasse on this critical issue.” In this regard, Humana made two related points:

- For OIG’s sampled enrollee-years, Humana 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).
- Humana stated that “OIG excluded from its sampling frame all non-‘high-risk’ diagnosis codes associated with [payment years] 2017 and 2018 for [Humana] enrollees as well as those for which Humana did not submit any risk-adjusting diagnosis codes.” According

²⁷ The 4 enrollee-years were in the following high-risk groups: sepsis (2), breast cancer (1), and prostate cancer (1).

²⁸ Specifically, on pages 10, 13, and 15 of this report, we state that, for a total of 13 enrollee-years in the acute myocardial infarction (6 enrollee-years), lung cancer (5 enrollee-years), and colon cancer (2 enrollee-years) groups, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. For these 13 enrollee-years, including the 3 enrollee-years that Humana identified in its comments, the associated overpayment amount already reflects the lesser increased payment for the less severe manifestation of the related disease groups.

to Humana, this exclusion systematically reduced the possibility of identifying underpayments.

Accordingly, Humana 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, Humana stated that we should consider such “underpayment credits” in the overpayment estimate. Humana also asked that OIG “modify its recommended estimated repayment amount” and requested that we justify our approach under applicable government auditing standards.

OIG Response

We disagree with Humana’s statements regarding underpayments. In accordance with the Inspector General Act of 1978, 5 U.S.C. ch. 4, 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 Humana’s submission of selected diagnosis codes 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 Humana could have submitted on behalf of the sampled enrollee-years and (2) enrollee-years for which Humana did not submit any risk-adjusting diagnosis codes was beyond the scope of our audit.

Humana’s description of our overpayment calculations as skewed is not accurate. A valid estimate of overpayments, given the objective of our audit, does not need to take into consideration all potential HCCs or underpayments within the audit period; this estimate addressed only the accuracy of the portion of payments related to the reviewed HCCs and did 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 (enrollees 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 overpayments in the sampling frame made to Humana.

Additionally, we asked our independent medical review contractor to review all medical records that Humana submitted to determine whether the documentation supported any diagnosis codes that mapped to the reviewed HCCs. In this regard, we considered instances for which our contractor found a diagnosis or HCC that should have been used instead of the diagnosis or HCC that Humana submitted to CMS. If our contractor identified a diagnosis code that Humana should have submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC (described by Humana as “underpayment credits”) in our calculation of overpayments and the resulting estimate.

As described above, the audit methodology that we followed to estimate the recommended repayment amount for this audit adhered to generally accepting government auditing standards.

Humana Stated That OIG’s Extrapolation Methodology Did Not Apply Certain MA Program Requirements

Humana Comments

Humana stated that our extrapolation methodology did not apply certain statutory requirements of the MA program and thus “improperly equates individual unsubstantiated HCC submissions with risk adjustment data validation audit overpayments.” Moreover, Humana stated that our recommendation that it refund estimated overpayments violates a payment principle known as “actuarial equivalence.”

Humana 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 Humana, 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.” According to Humana, CMS relies on unaudited diagnoses contained in Medicare FFS claims data—and not medical records—to calculate risk adjustment payment rates for the MA program. Humana asserted that using one documentation standard to create the MA payment rates—unaudited data—and another documentation standard—audited data—to measure MA payment accuracy in an audit creates a data inconsistency issue. Humana further stated that “[a]udits 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.”

Humana 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.” Humana noted that on February 1, 2023, CMS finalized its rule on RADV audits (Final RADV Rule), which eliminated the FFSA for RADV audits of payment years 2018 and forward. However, Humana stated that it “maintains its position that an FFSA is statutorily required to ‘ensure actuarial equivalence’ in MA payments.” In this regard, Humana stated that it has initiated a lawsuit “challenging CMS’s Final RADV Rule as arbitrary and capricious.” Further, Humana stated that, in its bid to CMS for payment years 2017 and 2018, it notified CMS that it was “relying on CMS’s plan to develop and apply an FFSA as part of any RADV process.” Humana stated, “CMS did not respond to this bid certification or otherwise suggest to Humana that Humana’s bid should be modified.”

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

Humana also stated that, in prior audits, OIG did not seriously contest the Final RADV Rule and its principles and, instead, deferred to CMS on the issue. Further, Humana referenced related reports that we issued in which we stated, “we recognize that CMS, not OIG, is responsible for making operational and program payment determinations for the MA program” and that “OIG audit findings and recommendations do not represent final determinations by CMS.” Humana stated that “[i]t is misleading, arbitrary and capricious for OIG to issue a report that suggests a certain level of overpayment when OIG is already aware that there are statutory requirements that will need to be addressed by CMS before any actual overpayment can be measured.”

OIG Response

Our audit methodology correctly applied MA program 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-year and used the overpayments and underpayments (if any) to estimate overpayments.

Regarding Humana’s statement that we did not consider “actuarial equivalence” in our overpayment calculations, we note that CMS stated that it “will not apply an [FFSA] in RADV audits,” which Humana acknowledged in its comments.²⁹ Further, we do not agree with Humana’s assertion that it is “misleading, arbitrary and capricious” for us to issue an audit report that identifies estimated overpayments and recognizes that CMS will make certain determinations while we were aware that CMS needed to address statutory requirements. On the contrary, Humana’s statement expresses exactly what we were supposed to do. 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. ch. 4. Thus, we believe that our audit methodology provides a reasonable basis for our findings and recommendations, including our estimation of overpayments. We continue to recognize that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program. (See footnote 25.)

²⁹ 88 Fed. Reg. 6643 (Feb. 1, 2023).

Humana Stated That OIG’s Recommended Recovery Amount May Be Inflated Due to Data Corrections Not Yet Processed by CMS

Humana Comments

Humana stated that our estimated overpayment amount of \$6.6 million for payment year 2018 (as reported in our draft report) may be inflated due to the presence of data corrections that Humana submitted to, but have not yet been processed by, CMS. Humana stated that CMS’s processing of these data corrections could have the effect of removing enrollee-years from this audit’s payment year 2018 sampling frame and result in a lower extrapolated estimated overpayment amount. Humana therefore contends our estimated overpayment amount is inflated because these enrollee-years are included in the sampling frame used to calculate this estimate.

OIG Response

Regarding Humana’s argument that our estimated overpayment amount may be inflated because of unprocessed data corrections, Humana did not provide the information needed to determine if adjustments to our sampling frame or estimated overpayment for payment year 2018 would be appropriate. Specifically, Humana did not indicate whether these data corrections were the result of errors detected by Humana’s compliance program or as a result of this audit. Further, at the beginning of our audit, to ensure an enrollee-year should be included in our sampling frame, we provided Humana with the listing of the enrollee-years in our sampling frame and requested that Humana verify certain data elements—including verification that the diagnosis code under review was submitted to CMS for the date of service shown on CMS’s systems. Humana did not—at this point or at any other point during our audit—notify us that it had made data corrections for any of the enrollee-years in our sampling frame.

Humana Stated That OIG’s Methodology For Classifying Diagnosis Codes As High-Risk Is Inconsistent With Other OIG Products

Humana Comments

Humana stated that our methodology for characterizing diagnosis codes within the high-risk condition categories is inconsistent with other OIG products. Specifically, Humana noted that our Toolkit³⁰ provides guidance for eight high-risk diagnosis code groups but does not mention other diagnosis code groups included in our audits of other MA organizations or the sepsis group included in this audit.

³⁰ *Toolkit To Help Decrease Improper Payments in Medicare Advantage Through the Identification of High-Risk Diagnosis Codes* ([A-07-23-01213](#)), Dec. 14, 2023.

OIG Response

Humana is correct in that we have identified different high-risk groups of diagnosis codes for other audits of MA organizations and for our Toolkit. However, this variation of high-risk groups does not impact this report.

Using data mining techniques, discussions with medical professionals, and the results of our audits, we may identify additional high-risk groups of diagnosis codes for our audits. Not all MA organizations are the same, and we audited the high-risk groups of diagnosis codes applicable for each MA organization. For this audit, as described in Appendix C, our sampling methodology identified specific diagnoses as high risk for being miscoded if they met certain parameters. We also provided this information in detail to Humana at the beginning of the audit.

Finally, we published the Toolkit to offer MA organizations information that will enable them to identify and evaluate diagnosis codes that are at a high risk of being miscoded. The Toolkit does not contain all high-risk groups that we have audited or that we may include in future audits. As stated in the Toolkit, we include only those high-risk groups that were found in our audits to have high error rates as of November 2023. Our hope is that MA organizations use the Toolkit as a starting point to enhance its compliance programs.

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

Humana Comments

Humana stated that “OIG should not apply an audit methodology that enforces different standards than CMS, particularly one that has not been subject to required notice-and-comment rulemaking.” Humana noted that our audit methodology “departs from CMS’s established RADV methodology in several important respects.” Specifically:

- Humana stated that our audit methodology relies on a physician as a “tiebreaker” in instances when two coders disagree. Humana stated that 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 a diagnosis code for the HCC under review. Humana stated that “CMS’s approach reflects a true coding analysis” and believes the number of HCCs that we determined unsubstantiated would be reduced if we followed CMS’s coding methodology.
- Humana stated that “it is unclear what specific diagnosis coding guidance” our independent medical review contractor followed and “it 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, Humana questioned whether we followed CMS’s “2017 RADV Medical Record Reviewer Guidance” which, according to Humana,

“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, Humana stated that “[t]o 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, Humana 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. Humana stated that holding MA organizations to different risk-adjustment standards based on whether CMS or OIG conducts the audit would be “arbitrary and capricious under the Administrative Procedure Act (‘APA’).”³¹

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. ch. 4. 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. No new requirements were imposed and thus there was no need for notice-and-comment rulemaking.

Further, we disagree that the differences between our approach and CMS’s approach would hold MA organizations to different risk-adjustment 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—reflected a reasonable method to determine whether the medical record adequately supported the reported diagnosis codes. The contractor’s review process allowed a physician with expertise in coding requirements to clarify support for a condition in the medical record when there was a difference of opinion between two senior coders. A consensus between two reviewers, either two senior coders or a senior coder and a physician, ensured accurate coding review results.
- Regarding Humana’s statement about the guidance our independent medical review contractor followed, we note that, prior to the issuance of the draft report, we informed Humana that our 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. MA organizations that contract with CMS must agree to follow

³¹ 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.

CMS's instructions, including the provisions of the Manual.³² In accordance with the Manual, all submitted diagnosis codes must be documented in the medical record and be documented as a result of a face-to-face encounter. Further, the Manual also requires that diagnoses must be coded according to the ICD Coding Guidelines.³³ Thus, we complied with applicable Federal requirements when conducting our reviews. In addition, as previously stated, our contractor reviewed all medical records that Humana submitted to determine whether the reviewed HCCs were supported in the medical records. With respect to the "chronic condition" example that Humana cited, our contractor's methodology complied with applicable CMS guidance.

Although our audit methodology differed from CMS's RADV audit methodology, both apply the same Federal requirements with respect to determining whether the diagnosis codes under review were supported by medical records.

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

Humana Comments

Humana disagreed with how we calculated our estimated overpayments. Specifically, Humana stated that our use of the two-sided 90-percent confidence interval in estimating overpayments is inconsistent with CMS's practice for RADV audits. Humana stated that CMS has not clarified the specific confidence interval it intends to use for RADV audits. Therefore, Humana asserts that it is misleading for OIG to uniformly use the 90-percent confidence level when CMS has not set a standard confidence level.

OIG Response

OIG is an independent oversight agency; therefore, our estimation methodology does not need to mirror CMS's estimation methodology. Our policy recommends recovery at the lower limit of a two-sided 90-percent confidence interval. We believe that the lower limit of a two-sided 90-percent confidence interval provides a reasonably conservative estimate of the total amount overpaid to Humana for the enrollee-years and time period covered in our sampling frame. This approach, which is routinely used by HHS for recovery calculations,³⁴ results in a

³² 42 CFR § 422.504(a).

³³ The Manual, chap. 7, § 40.

³⁴ For example, 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 e.g., *New York State Department of Social Services*, HHS Departmental Appeals Board (DAB) No. 1358, 13 (1992); *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 fee-for-service (FFS) overpayments. See e.g., *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, 17-18 (E.D.N.Y. 2012).

lower limit (the estimated overpayment amount) that is designed to be less than the actual overpayment total 95 percent of the time.

HUMANA DID NOT AGREE WITH OIG’S RECOMMENDATION TO PERFORM ADDITIONAL REVIEWS OF HIGH-RISK DIAGNOSIS CODES FOR THE YEARS BEFORE AND AFTER THE AUDIT PERIOD

Humana Comments

Humana disagreed with our second recommendation—that it 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 Humana, “MA regulations do not require the sort of audits that OIG recommends.”

Humana 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, Humana 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, Humana stated that our citations of Federal regulations mischaracterize the requirements for MA organizations to monitor the data they receive from providers and submit to CMS. Humana stated that these citations imply that MA organizations are responsible for monitoring all risk adjustment data and must “unequivocally guarantee that risk adjustment data are accurate, complete and truthful.” However, according to Humana, 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 they submit to CMS based on “best knowledge, information, and belief.”

Further, Humana stated that our recommendation “does not align with the requirements of a MA compliance program because the MA program does not compel Humana or other [MA organizations] to conduct audits of specific ‘high-risk diagnoses’.” According to Humana, although CMS is aware of several high-risk diagnosis codes, “CMS has not implemented any regulations or guidance to address such issues or require additional compliance measures.” Thus, according to Humana, our second recommendation “conflicts with CMS’s regulations and guidance” and imposes new regulatory requirements. Humana stated that new requirements would be subject to notice-and-comment rulemaking.

OIG Response

We do not agree with Humana’s interpretation of Federal requirements. As stated earlier, 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 Humana’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 Humana’s compliance plan “must, at a minimum, include [certain] core requirements,” which include “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.” (42 CFR § 422.503(b)(4)(vi)(G)). Thus, CMS has, through the issuance of these Federal regulations, assigned the responsibility for dealing with potential compliance issues to the MA organizations.

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 [MA organization] 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.

We believe that the error rate identified in our audit (202 of 240 enrollee-years (see Appendix D)) demonstrates that Humana has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope. Further, Humana’s comments implied that we opined on its responsibilities to ensure 100-percent accuracy of all the data it submitted to CMS. That was not our intention or our focus for this audit. We limited our audit and recommendations to certain diagnosis codes that we had determined to be at high risk for being miscoded. Accordingly, we maintain that our second recommendation is valid.

HUMANA DID NOT AGREE WITH OIG’S RECOMMENDATION THAT HUMANA ENHANCE ITS EXISTING PROCEDURES

Humana Comments

Humana stated that MA program requirements do not offer specific direction related to the high-risk diagnosis codes that are the subject of this audit. Humana reiterated that MA organizations are instead afforded broad discretion in designing compliance programs. In this respect, Humana stated that it has designed a risk adjustment compliance program that Humana believes satisfies its obligations under applicable MA program requirements and that the presence of some data inaccuracies does not indicate a failure in Humana’s policies and procedures. Humana stated that all of Humana’s risk adjustment compliance processes and reviews, by their nature, include high-risk diagnosis codes and it “disagrees with the notion that existing CMS guidance requires a particular approach to OIG’s unilaterally selected ‘high-risk’ areas.” Further, according to Humana, it has never been informed by CMS of any deficiencies in its risk adjustment compliance program.

Humana requested that we reconsider our third recommendation—that Humana 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 statement that the errors identified in our audit demonstrate that Humana’s policies and procedures could be improved imposes an unreasonable standard.

Humana stated that it is unclear “from OIG’s recommendations to date what policies and procedures would be acceptable, as OIG arbitrarily and capriciously provides this recommendation to a variety of circumstances: in one report stating that it did not review the full compliance program, but still issuing this same overarching recommendation; in the report for a prior Humana audit, providing this recommendation even with an incredibly high 87 [percent] accuracy rate; and giving this recommendation in two other reports after acknowledging that the plans had already made improvements.”

OIG Response

We limited our audit to selected diagnoses that we determined to be at high risk for being miscoded. Our audit revealed a substantial error rate for some of these high-risk areas. We acknowledge that Humana 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 Humana, it has never been informed by CMS of deficiencies in Humana’s compliance program, this does not mean Humana should not take action to enhance its compliance procedures, especially for areas that we have identified in this report as having errors. 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 Humana’s existing procedures, based on the results of this audit, as well as the results of Humana’s internal medical reviews, will assist Humana in attaining better assurance about 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 Humana \$4,991,800,487 to provide coverage to its enrollees for 2017 and 2018. We identified a sampling frame of 7,637 unique enrollee-years (footnote 13) on whose behalf providers documented high-risk diagnosis codes during the 2016 and 2017 service years; Humana received \$118,233,618 in payments from CMS for these enrollee-years for 2017 and 2018. We selected for audit 240 enrollee-years with payments totaling \$3,737,080.

The 240 enrollee-years included 30 acute stroke diagnoses, 30 acute myocardial infarction diagnoses, 30 sepsis diagnoses, 30 embolism diagnoses, 30 lung cancer diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, and 30 prostate cancer diagnoses (Table 1). We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$642,816 for our sample.

Our audit objective did not require an understanding or assessment of Humana's complete internal control structure, and we limited our review of internal controls to those directly related to our objective. Specifically, we reviewed Humana's controls for preventing, detecting, and correcting noncompliance with CMS's program requirements.

We performed audit work from October 2021 through January 2024.

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:
 - 71 diagnosis codes for acute stroke,
 - 11 diagnosis codes for acute myocardial infarction,
 - 63 diagnosis codes for embolism,
 - 40 diagnosis codes for sepsis,
 - 17 diagnosis codes for lung cancer,

- 54 diagnosis codes for breast cancer,
 - 10 diagnosis codes for colon cancer, and
 - 1 diagnosis code for prostate cancer.
- We used CMS systems to identify the enrollee-years on whose behalf providers documented the high-risk diagnosis codes. Specifically, we used extracts from CMS's:
 - RAPS³⁵ and the Encounter Data System (EDS)³⁶ to identify enrollees who received high-risk diagnosis codes from a physician during the service years,
 - Risk Adjustment System (RAS)³⁷ to identify enrollees who received an HCC for the high-risk diagnosis codes,
 - Medicare Advantage Prescription Drug System (MARx)³⁸ to identify enrollees for whom CMS made monthly Medicare payments to Humana, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C),
 - EDS³⁹ to identify enrollees who received specific procedures, and
 - Prescription Drug Event (PDE) file⁴⁰ to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.
 - We interviewed Humana officials to gain an understanding of: (1) the policies and procedures that Humana followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Humana's monitoring of those diagnosis codes to detect and correct noncompliance with Federal requirements.
 - We selected for audit a stratified random sample of 240 enrollee-years (Appendix C).

³⁵ MA organizations use the RAPS to submit diagnosis codes to CMS.

³⁶ CMS uses the EDS to collect encounter data, including diagnosis codes, from MA organizations.

³⁷ The RAS identifies the HCCs that CMS factors into each enrollee's risk score calculation.

³⁸ The MARx identifies the payments made to MA organizations.

³⁹ The EDS contains information on each item (including procedures) and service provided to enrollees.

⁴⁰ 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 236 enrollee-years (footnote 14) to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.⁴¹
- 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(s), 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(s):
 - 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 the coding supervisor reviewed the medical record(s) to make the final determination.
 - If either the first or second senior coder asked the coding supervisor for assistance, the coding supervisor’s decision became the final determination. Additionally, at any point in the review process, a senior coder or coding supervisor may have consulted a physician reviewer for additional clarification.
- We used the results of the independent medical review contractor, and CMS’s systems, to calculate overpayments or underpayments (if any) 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 overpayment made to Humana during the audit period.

⁴¹ 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 Adjustment 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.

- We calculated the recommended recovery amount in accordance with CMS’s regulations that limit the use of extrapolation in RADV audits for recovery purposes.⁴² Specifically, we calculated the recommended recovery amount as the sum of the overpayments identified for the sampled enrollee-years from payment year 2017 and the estimate of total overpayments made to Humana for the enrollee-years from payment year 2018.
- We discussed the results of our audit with Humana 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 Federal regulations at 42 CFR § 422.311(a) state: “[T]he Secretary annually conducts RADV audits to ensure risk-adjusted payment integrity and accuracy. (1) Recovery of improper payments from MA organizations will be conducted in accordance with the Secretary’s payment error extrapolation and recovery methodologies. (2) CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years” (88 Fed. Reg. 6643, 6655 (Feb. 1, 2023)).

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That SelectCare of Texas, Inc. (Contract H4506), Submitted to CMS</i>	<u>A-06-19-05002</u>	11/27/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Aetna, Inc. (Contract H5521) Submitted to CMS</i>	<u>A-01-18-00504</u>	10/02/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS</i>	<u>A-07-20-01197</u>	8/03/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS</i>	<u>A-07-20-01202</u>	7/10/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. (Contract H3952) Submitted to CMS</i>	<u>A-03-20-00001</u>	5/31/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS</i>	<u>A-05-19-00013</u>	4/04/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring Life & Health Insurance Company, Inc. (Contract H4513) Submitted to CMS</i>	<u>A-07-19-01192</u>	3/28/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS</i>	<u>A-02-20-01008</u>	3/24/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS</i>	<u>A-09-21-03011</u>	3/16/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Cigna-HealthSpring of Tennessee, Inc. (Contract H4454) Submitted to CMS</i>	<u>A-07-19-01193</u>	12/22/2022

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified Humana enrollees who: (1) were continuously enrolled in Humana throughout all of the 2016 or 2017 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 2016 or 2017 or in January of the following year, and (3) received certain high-risk diagnoses during 2016 or 2017 that caused an increased payment to Humana for 2017 or 2018, respectively.

We presented the data for these enrollees to Humana 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 Humana. After we performed these steps, our finalized sampling frame consisted of 7,637 enrollee-years.

SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2017 or 2018.

SAMPLE DESIGN AND SAMPLE SIZE

The design for our statistical sample comprised eight strata of enrollee-years. For the enrollee-years in each respective stratum, each enrollee received:

- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on only one physician claim during the service year but did not have an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim (2,877 enrollee-years);
- a diagnosis that mapped to the HCC for Acute Myocardial Infarction on only one physician or outpatient claim during the service year but did not have an acute myocardial infarction diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician or outpatient claim (1,106 enrollee-years);
- a diagnosis that mapped to an Embolism HCC on only one claim during the service year but did not have an anticoagulant medication dispensed on his or her behalf (605 enrollee-years);
- a sepsis diagnosis (that mapped to the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock) on only one physician or outpatient claim during the service year but did not have a sepsis diagnosis on a corresponding inpatient hospital claim (533 enrollee-years);

- a lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) on only one claim during the service year but 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 (272 enrollee-years);
- a breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one claim during the service year but 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 (985 enrollee-years);
- a colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (467 enrollee-years); or
- a prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors), for an individual 74 years old or younger, on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (792 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	2,877	\$5,648,849	30
2 – Acute myocardial infarction	1,106	2,144,055	30
3 – Embolism	605	1,551,318	30
4 – Sepsis	533	1,794,532	30
5 – Lung cancer	272	1,904,853	30
6 – Breast cancer	985	1,187,012	30
7 – Colon cancer	467	1,120,134	30
8 – Prostate cancer	792	943,919	30
Total	7,637	\$16,294,672	240

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We sorted the items in each stratum by an enrollee identification number and payment year and then consecutively numbered the items in each stratum in the stratified sampling frame. After generating 240 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 overpayments made to Humana at the lower limit of the two-sided 90-percent confidence interval (Appendix D, Table 7). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

Estimated Overpayments for Recommended Recovery

Federal regulations limit the use of extrapolation in RADV audits to payment years 2018 and forward (footnote 42). Therefore, we calculated the recommended recovery amount in accordance with CMS's regulations. Specifically, we calculated the recommended recovery amount as the sum of the overpayments identified for the sampled enrollee-years from payment year 2017 and the estimate of total overpayments made to Humana for the enrollee-years from payment year 2018 (Appendix D, Table 8).

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Details and Results for Payment Year 2017

Audited High-Risk Groups	Frame Size	CMS Payments for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payments for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With HCCs That Were Not Validated	Overpayments for HCCs That Were Not Validated (for Sampled Enrollee-Years)
1 – Acute stroke	1,404	\$2,758,823	14	\$30,947	14	\$27,727
2 – Acute myocardial infarction	534	1,027,433	18	36,571	18	31,582
3 – Embolism	279	715,113	15	38,509	13	31,426
4 – Sepsis	244	814,811	17	58,265	5	12,817
5 – Lung cancer	133	914,383	15	112,232	15	105,135
6 – Breast cancer	492	583,697	12	13,970	11	12,832
7 – Colon cancer	218	534,632	16	39,271	16	37,597
8 – Prostate cancer	375	444,626	15	17,775	13	15,035
Total	3,679	\$7,793,518	122	\$347,540	105	\$274,151

Table 5: Sample Details and Results for Payment Year 2018

Audited High-Risk Groups	Frame Size	CMS Payments for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payments for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With HCCs That Were Not Validated	Overpayments for HCCs That Were Not Validated (for Sampled Enrollee-Years)
1 – Acute stroke	1,473	\$2,890,026	16	\$32,411	16	\$32,411
2 – Acute myocardial infarction	572	1,116,622	12	21,655	12	20,330
3 – Embolism	326	836,205	15	38,120	12	27,504
4 – Sepsis	289	979,721	13	42,263	4	15,376
5 – Lung cancer	139	990,470	15	89,740	11	64,540
6 – Breast cancer	493	603,315	18	21,457	16	19,160
7 – Colon cancer	249	585,502	14	32,027	13	28,391
8 – Prostate cancer	417	499,293	15	17,603	13	15,362
Total	3,958	\$8,501,154	118	\$295,276	97	\$223,074

**Table 6: Sample Details and Results
(Payment Years 2017 and 2018 Combined)**

Audited High-Risk Groups	Frame Size	CMS Payments for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payments for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With HCCs That Were Not Validated	Overpayments for HCCs That Were Not Validated (for Sampled Enrollee-Years)
1 – Acute stroke	2,877	\$5,648,849	30	\$63,358	30	\$60,138
2 – Acute myocardial infarction	1,106	2,144,055	30	58,226	30	51,912
3 – Embolism	605	1,551,318	30	76,629	25	58,930
4 – Sepsis	533	1,794,532	30	100,528	9	28,193
5 – Lung cancer	272	1,904,853	30	201,972	26	169,675
6 – Breast cancer	985	1,187,012	30	35,427	27	31,992
7 – Colon cancer	467	1,120,134	30	71,298	29	65,988
8 – Prostate cancer	792	943,919	30	35,378	26	30,397
Total	7,637	\$16,294,672	240	\$642,816	202	\$497,225

**Table 7: Estimated Overpayments in the Sampling Frame
(Payment Years 2017 and 2018 Combined)
(Limits Calculated for a 90-Percent Confidence Interval)**

Point Estimate	\$13,788,881
Lower Limit	13,150,480
Upper Limit	14,427,281

**Table 8: Total Estimated Overpayments in the Sampling Frame
for Recommended Recovery
(Limits Calculated for a 90-Percent Confidence Interval)**

	Overpayments for Sampled Enrollee-Years for 2017	Estimated Overpayments for Statistical Sample for 2018	Total Estimated Overpayments
Point Estimate	\$274,151	\$6,947,345	\$7,221,496
Lower Limit	274,151	6,503,234	6,777,385
Upper Limit	274,151	7,391,457	7,665,608

**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' 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: HUMANA COMMENTS



March 1, 2024

Jennifer Webb
Regional Inspector General for Audit Services
Office of Audit Services, Region II
Jacob K. Javits Federal Building
26 Federal Plaza, Room 3900
New York, NY 10278

VIA EMAIL

RE: Humana's Response to Draft Audit Report No. A-02-22-01001

Dear Ms. Webb:

Humana Health Plan, Inc. ("Humana" or "Company") appreciates the opportunity you have provided to respond to the U.S. Department of Health and Human Services ("HHS"), Office of Inspector General's ("OIG's") Draft Audit Report No. A-02-22-01001, entitled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Humana Health Plan, Inc., (Contract H2649) 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. These issues should not come as a surprise to OIG as they are the same issues that Humana recently explained to OIG in connection with its report entitled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS*¹ and with its report entitled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS*.²

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. As OIG and CMS are now well

¹ See HHS-OIG, Audit Report No. A-02-20-01009, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS* (July 2022), available at <https://oig.hhs.gov/oas/reports/region2/22001009.pdf> ("Cariten Report").

² See HHS-OIG, Audit Report No. A-05-19-00013, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS* (Apr. 2023), available at <https://oig.hhs.gov/oas/reports/region5/51900013.pdf> ("HumanaChoice Report").



aware, 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 continues to believe its processes and reviews satisfy all legal requirements, for the reasons explained previously to OIG and CMS and reiterated again 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 both agencies.

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 meet 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.³

Humana is aware of OIG’s recently released “Toolkit To Help Decrease Improper Payments in Medicare Advantage Through the Identification of High-Risk Diagnosis Codes” (“Toolkit”) intended “to identify and evaluate high-risk codes to ensure proper payments.”⁴ In the Toolkit, OIG expressed its “hope” that MAOs would use the information to “detect and correct inaccurate diagnosis codes in their own systems” and as a “starting point to identify other diagnosis codes that are at high risk for being miscoded and take appropriate measures to prevent, detect, and correct such errors.”⁵ As a preliminary matter, the release of this Toolkit after OIG initiated this audit did not allow industry participants, such as Humana, to evaluate and implement OIG’s suggestions before the audit. The Toolkit also has significant technical limitations, as further discussed in Section II.5 below. Moreover, the MA program requirements still do not offer specific direction related to the so-called “high-risk” diagnosis codes that are the subject of OIG’s Draft Report.⁶ MAOs are instead afforded broad discretion in designing

³ 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.”).

⁴ HHS-OIG, Toolkit To Help Decrease Improper Payments in Medicare Advantage Through the Identification of High-Risk Diagnosis Codes (“Toolkit”), at 1 (Dec. 2023).

⁵ *Id.* at 2.

⁶ CMS 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”).

compliance and education programs.⁷ Indeed, Humana has several programs in place to enhance the accuracy of risk adjustment data, consistent with MA program requirements and OIG's guidance.⁸

With respect to OIG's medical record determinations as reflected in the Draft Report, Humana believes that the rate of 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.⁹ Indeed, setting aside for a moment all other concerns raised in this letter, addressing only the HCCs referenced in Appendix A would change the outcome of OIG's review 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.¹⁰

⁷ See 65 Fed. Reg. at 40,265 (MAOs "have broad discretion . . . to design their compliance plan structure to meet the unique aspects of each organization.").

⁸ See *id.* (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; 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.").

⁹ See Draft Report at 4–5.

¹⁰ During Humana's Exit Conference with the OIG auditors for H2649, 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> ("UPMC 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) at 18, available at <https://oig.hhs.gov/oas/reports/region7/71701173.pdf> ("Coventry Report"); HHS-OIG, Audit Report No. A-07-16-01165, *Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract 111036) Submitted To CMS* (Apr. 2021) at 13-14, available at <https://oig.hhs.gov/oas/reports/region7/71601165.pdf> ("2021 Humana Report"); 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> ("2021 Excellus Report"); 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> ("Paramount Report").

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 \$507,167 in net overpayments for the 206 sampled enrollee-years.¹¹ OIG estimated that Humana received at least \$13,349,819 in overpayments for the audit period.¹² However, “[b]ecause of Federal regulations that limit the use of extrapolation in RADV audits for recovery purposes to payment years 2018 and forward,” OIG recommended a refund of \$6,891,466 in overpayments (\$279,344 for the sampled enrollee-years from 2017 and an estimated \$6,612,122 for 2018).¹³ 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. Per the American Heart Association (“AHA”) Coding Guidance, coding “should be based on provider documentation.”¹⁴ Humana has provided OIG with 34 appeals¹⁵ reflecting instances where, contrary to OIG’s determination, the following conditions are substantiated by provider medical record documentation: Ischemic or Unspecified Stroke (HCC v22 100), Acute Myocardial Infarction (HCC v22 86), Septicemia, Sepsis and Systemic Inflammatory Response Syndrome/Shock (HCC v22 2), Vascular Disease (HCC v22 108), Lung and Other Severe Cancers (HCC v22 9), Colorectal, Bladder and Other Cancers (HCC v22 11), and Breast, Prostate, and Other Cancers and Tumors (HCC v22 12).

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

¹¹ Draft Report at 29 (Appendix D).

¹² *Id.* at 7, 17.

¹³ *Id.*

¹⁴ AHA Coding Clinic, Fourth Quarter 2016, p. 147.

¹⁵ The 34 appeals represent 33 sampled enrollee-years. Separately, one of the 34 appeals of OIG’s determinations is based upon a revised version of the medical record that was reviewed by OIG but is now inclusive of a Humana Practitioner Assessment Form that was completed on the same date of service and signed by the rendering provider.

underpayments, rendering its results inherently unreliable.¹⁶ OIG has indeed been clear in the response to comments submitted for related audits that such an analysis of potential underpayments is beyond the scope of OIG's review.¹⁷ OIG and the MA industry therefore appear to be at an impasse on this critical issue.

As OIG explains in its Draft Report, it “used the results of the independent medical review contractor, and CMS’s systems, to calculate overpayments or underpayments (if any) for each enrollee-year.”¹⁸ Following this approach, OIG determined that “Humana received at least \$13,349,819 in overpayments” in 2017 and 2018.¹⁹ 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).²⁰

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. Other records that were never submitted to or reviewed by OIG could contain unsubmitted HCCs that would have been found upon review. Moreover, OIG excluded from its sampling frame all

¹⁶ 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 \$13 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/files.gao.gov/assets/gao-12-331g.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/hhs-guidelines-ensuring-maximizing-disseminated-information#main-content>.

¹⁷ HHS-OIG, Audit Report No. A-07-20-01197, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS* (Aug. 2023), at 19, available at <https://oig.hhs.gov/oas/reports/region7/72001197.pdf> (“Presbyterian Health Report”); HHS-OIG, Audit Report No. A-07-20-01202, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS* (July 2023) at 23, available at <https://oig.hhs.gov/oas/reports/region7/72001202.pdf> (“2023 Excellus Report”); HHS-OIG, Audit Report No. A-01-18-00504, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Aetna, Inc. (Contract H5521) Submitted to CMS* (Oct. 2023), at 21, available at <https://oig.hhs.gov/oas/reports/region1/11800504.pdf> (“Aetna 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 113655) Submitted to CMS* (May 2021), at 19, available at <https://www.oig.hhs.gov/oas/reports/region7/71901187.pdf> (“Anthem Report”); HHS-OIG, Audit Report No. A-01-19-00500, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Tufts Health Plan (Contract H2256) Submitted to CMS* (Feb. 2022), at 16, available at <https://oig.hhs.gov/oas/reports/region1/11900500.pdf> (“Tufts Report”); Coventry Report at 27; UPMC Report at 25; see also 2021 Humana Report at 16.

¹⁸ Draft Report at 21 (Appendix A).

¹⁹ *Id.* at 17.

²⁰ OIG acknowledged in the Draft Report that “if medical records support diagnosis codes that an MA organization did not submit to CMS, validated HCCs may not have been included in enrollees’ risk scores, which may cause those risk scores to be understated and may result in underpayments” *Id.* at 4.

non-“high-risk” diagnosis codes associated with Payment Years (“PY”) 2017 and 2018 for H2649 enrollees as well as those for which Humana did not submit any risk-adjusting diagnosis codes.²¹ This aspect of OIG’s methodology also systematically reduced the probability of identifying underpayments.²² 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.²³ OIG should consider such underpayment credits in its overpayment estimates. Accordingly, Humana also asks OIG to modify its recommended estimated repayment amount.

And 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 have been implicated by OIG’s recommendations in other recent reports and would be implicated again if OIG were to finalize the Draft Report in its current form.²⁴

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 risk adjustment data validation audit 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.²⁵ 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.²⁶ The Actuarial Standards of Practice (“ASOPs”), especially ASOP No. 45, necessarily govern these actuarial calculations.²⁷

As industry experts have explained to CMS over the course of many years, 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.²⁸ Subjecting diagnosis codes from the Medicare FFS and MA programs to

²¹ See *id.* at 19 (Appendix A).

²² See 2021 Humana Report at 31, n.10 (citing Matthew G. Mercurio, *Statistical Analysis of Draft Report Number A-07-16-01165* (Dec. 3, 2019)).

²³ See *id.*

²⁴ See Government Auditing Standards; Information Quality Guidelines.

²⁵ See 42 U.S.C. § 1395w-23(a)(1)(C)(i).

²⁶ See 42 U.S.C. §§ 1395w-24(a)(5)(A), (6)(A)(i)-(iii).

²⁷ Actuarial Standards Board, *Actuarial Standard of Practice No. 45: The Use of Health Status Based Risk Adjustment Methodologies* (Jan. 2012), available at <https://oig.hhs.gov/oas/reports/region2/21801029.pdf>.

²⁸ 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”), available at https://downloads.regulations.gov/CMS-2018-0133-0267/attachment_4.pdf; see also Avalere Health, *Eliminating the FFS Adjuster from the RADV Methodology May Affect Plan Payment* (Mar. 2019), available at <https://avalere.com/wp-content/uploads/2019/03/20190318-FFS-Adjuster-Analysis-Final-.pdf>; see also Milliman, *Medicare Advantage*

different documentation standards contravenes ASOP No. 45 and disrupts actuarial equivalence in violation of the Act.²⁹ Industry experts refer to this error mode as the “Data Inconsistency Issue.”³⁰

Despite previously acknowledging the need to address the differing documentation standards that are the cause of the Data Inconsistency Issue,³¹ on February 1, 2023, CMS finalized its rule on Risk Adjustment Data Validation Audits (“Final RADV Rule”), in which CMS eliminated the FFSA from PY 2018 and beyond.³² Humana maintains its position that an FFSA is statutorily required to “ensure actuarial equivalence” in MA payments. To that end, Humana has initiated a lawsuit in the United States District Court for the Northern District of Texas challenging CMS’s Final RADV Rule as arbitrary and capricious. As described in Humana’s complaint and in its Calendar Year (“CY”) 2024 bid, CMS’s Final RADV Rule is unlawful and amounts to a retroactive and unacceptable change, effectively imposing a risk adjustment data perfection standard that CMS and OIG have previously recognized is not reasonable to enforce.³³ CMS’s Final RADV Rule unlawfully ignores the congressional mandate to “ensure actuarial equivalence” in MA payments because CMS’s HCC model continues to rely on unaudited diagnoses contained in administrative claims data (and not medical records) to calculate risk adjustment payment rates.

Keeping in line with previous audits, OIG does not seriously contest the Final RADV Rule and its principles, instead deferring to CMS on the issue.³⁴ However, even before CMS published the Final RADV Rule, Humana notified CMS of the importance of the FFSA and the Data Inconsistency Issue to Humana’s bids under H2649 for the years that are the subject of OIG’s Draft Report. Specifically, Humana’s Calendar Year 2017 and 2018 Actuarial Certifications for each filed Plan Benefit Package under H2649 subject to this audit stated

RADV FFS Adjuster: White Paper (Aug. 23, 2019), available at https://assets.milliman.com/ektron/Medicare_Advantage_RADV_FFS_adjuster_8-23-2019.pdf.

²⁹ See 2021 Humana Report at 32, n.17 (citing 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.

³⁰ See Wakely Report Section IV.

³¹ In CMS’s 2012 RADV extrapolation methodology, it 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. See CMS, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audit (Feb. 24, 2012), available at <https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/recovery-audit-program-parts-c-and-d/other-content-types/radv-docs/radv-methodology.pdf> (“2012 RADV Audit Notice”).

³² See 88 Fed. Reg. 6643.

³³ See 65 Fed. Reg. at 40,268.

³⁴ Presbyterian Health Report at 19 (OIG “recognize[s] that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program and that any OIG audit findings and recommendations do not represent final determinations by CMS.”); see also HHS-OIG, Audit Report No. A-03-20-00001, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. (H3952) Submitted to CMS* (May 2023), at 20, available at <https://oig.hhs.gov/oas/reports/region3/32000001.pdf> (“Keystone Report”); HHS-OIG, Audit Report No. A-09-21-03011, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS* (Mar. 2023), at 27, available at <https://oig.hhs.gov/oas/reports/region9/92103011.pdf> (“Geisinger Report”).

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 and overpayments will be determined 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 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.

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]lmost all of the selected acute stroke diagnosis codes that physicians submitted to CMS under traditional Medicare . . . did not comply with Federal requirements."³⁵ 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.³⁶

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. To reiterate: 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 in an audit context.³⁷ Recognized industry experts have stated that "[t]his principle applies with equal force irrespective of the type of RADV audit."³⁸

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

³⁵ Acute Stroke Audit Report at 6.

³⁶ See *id.* at 8.

³⁷ See Wakely Analysis.

³⁸ Wakely Report at 33; see also Wakely Analysis.

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.

In recent reports on so-called “high-risk” codes, OIG has explained “we recognize that CMS, not OIG, is responsible for making operational and program payment determinations for the MA program” and further, that “OIG audit findings and recommendations do not represent final determinations by CMS.”³⁹ It is misleading, arbitrary and capricious for OIG to issue a report that suggests a certain level of overpayment when OIG is already aware that there are statutory requirements that will need to be addressed by CMS before any actual overpayment can be measured. This is particularly true where, as is the case here, an MAO expressly conditioned its bid on an understanding that an FFSA would be applied before the government measured any overpayments in a risk adjustment data validation audit. CMS approved Humana’s bids for H2649 and Humana relied on this approval. Thus, Humana respectfully requests that OIG reconsider its recommendation that Humana refund the amounts identified in the Draft Report.

4. OIG’s recommended repayment amount may be inflated given the presence of submitted data corrections which CMS has not yet processed that could affect the sampling frame size and extrapolation results.

In the Draft Report, HHS-OIG reports an “estimated overpayment amount” of \$6,612,122 for PY 2018.⁴⁰ OIG’s estimate could be inflated as it relies on an overstatement of Humana’s underlying sampling frame/population due to data corrections that Humana previously submitted to CMS and which CMS has yet to process.

OIG’s recommended repayment amount may be biased upwards given not yet processed data corrections associated with PY 2018 for the HCCs at issue. The processing of these data corrections could have the effect of removing entire enrollee-years from consideration. At minimum, this could change the PY 2018 sampling frame size for one or more strata resulting in a lower extrapolated estimate as the stratum level sample averages would be multiplied by a smaller frame size.⁴¹

Humana submits data corrections in the Risk Adjustment Processing System (“RAPS”) and Encounter Data Processing System (“EDPS”) systems for both open and closed data submission periods. CMS, however, has never rerun PY 2017 or PY 2018, the years at issue in OIG’s audit, to recoup premiums associated with related closed period data corrections. Therefore, the closed period data corrections that Humana has submitted for these years and for the HCCs at issue in OIG’s audit have not yet resulted in payment adjustments to Humana’s premium. The additional members that OIG includes in the sampling frame/population in the Draft Report to calculate its extrapolated overpayment amount for PY 2018 is accordingly

³⁹ HHS-OIG, Audit Report No. A-04-19-07082, *Medicare Advantage Compliance Audit of Diagnosis Codes That CarePlus Health Plans, Inc. (Contract H1019) Submitted to CMS*, at 23 (Jan. 2022), available at <https://oig.hhs.gov/oas/reports/region4/41907082.pdf> (“CarePlus Report”).

⁴⁰ Draft Report at 7.

⁴¹ William G. Cochran, *Sampling Techniques* 89 (John Wiley & Sons, 3rd ed. 1977) (stating that “[t]o obtain the full benefit from stratification, the values of the [stratum frame sizes within the strata] must be known”).

inflated. For this additional reason, Humana respectfully requests OIG reconsider its recommendation.

5. OIG should reconsider its recommendation because OIG is inconsistent with its use of different repayment calculation methodologies for different MAOs and its own Toolkit.

Despite the recent release of the Toolkit, OIG is still inconsistent with its methodology for characterizing diagnosis codes within the “high risk” condition categories. OIG admitted that the Toolkit “includes only those high-risk groups that had high error rates”⁴² but failed to provide further guidance on what constitutes a “high-risk” group outside the eight identified groups in the Toolkit, which include acute stroke, acute heart attack, embolism, lung cancer, breast cancer, colon cancer, prostate cancer, and potentially mis-keyed diagnosis codes.⁴³ In fact, OIG in this Draft Report analyzed the “high risk” group for sepsis, which was not included at all in the Toolkit.⁴⁴ Prior audits have also analyzed different “high-risk” categories, including vascular claudication⁴⁵ and major depressive disorder,⁴⁶ which the Toolkit does not identify as “high-risk” groups. OIG’s changing approach to the conditions under review here evidences a deviation from prior audit methodologies and its own Toolkit.

Moreover, OIG’s aspirations for the use of the Toolkit do not align with the requirements of an MA compliance program because CMS program requirements do not compel MAOs to conduct audits of specific diagnosis codes, including so-called “high-risk” codes. Indeed, OIG made clear that the Toolkit should not be interpreted as clarifying MAOs’ data accuracy requirements, saying the Toolkit was “not intended to be used to determine compliance with any laws, regulations, or other guidance.”⁴⁷ OIG further minimized the utility of its Toolkit, cautioning that “no representation is made that the information included in the toolkit . . . is error free” and that “[c]ompatibility of the toolkit with any user systems is not guaranteed.” Ultimately, while the “toolkit was prepared as a technical resource,” OIG has essentially disclaimed that it has any utility. Furthermore, the Toolkit has significant technical limitations on its face. For instance, the information made available in the toolkit relies on Risk Adjustment Processing System (“RAPS”) submission data that is no longer in use as of PY 2022. Likewise, the Hierarchical Condition Category (“HCC”) model utilized in the toolkit appears outdated—the Toolkit neither implements the most recent risk adjustment model (*i.e.*, the V28 HCC Model for 2023 dates of service forward), nor does it account for changes in other industry code sets over the last several years.

⁴² *Id.* at 2, n.1.

⁴³ *Id.*

⁴⁴ Draft Report at 4.

⁴⁵ *See, e.g.*, HHS-OIG, Audit Report No. A-06-19-05002, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That SelectCare of Texas, Inc. (Contract H4506) Submitted to CMS* (Nov. 2023), available at <https://oig.hhs.gov/oas/reports/region6/61905002.pdf> (“SelectCare of Texas Report”); *see also* Aetna Report.

⁴⁶ *See, e.g., id.*

⁴⁷ Toolkit at 48.

6. 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.⁴⁸ Humana agrees that OIG should not apply an audit methodology that enforces different standards than CMS, particularly one that has not been subject to required notice-and-comment rulemaking. 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.⁴⁹ 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."⁵⁰ 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. 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 interpret, add to, or inform the use of ICD Coding Guidelines that we understand were used to guide the medical record review.⁵¹ 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.⁵² 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."⁵³ To the extent the contractor's review underlying

⁴⁸ Draft Report at 19 (Appendix A).

⁴⁹ *Id.* at 21 (Appendix A).

⁵⁰ CMS, Risk Adjustment Data Validation (RADV) Medical Record Intake Process And Guidance To Coders CY2011 ver. 4.0, at 18–19 (May 8, 2014) ("2014 RADV Guidance"); *see also* CMS, Contract-Level 15 Risk Adjustment Data Validation, Medical Record Reviewer Guidance, ver. 2.0 (Jan. 10, 2020), *available at* <https://www.cms.gov/files/document/medical-record-reviewer-guidance-january-2020.pdf-0> ("2020 RADV Guidance").

⁵¹ 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).

⁵² Draft Report at 8–16.

⁵³ *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* 2014 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. Mention or EMR population of the diagnoses narrative list can be interpreted as management and care for the

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

As we explained in connection with OIG's recent report related to contract H6609, 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 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 ("APA"). And it would force MAOs to decide between calibrating their compliance programs to satisfy OIG or CMS.

7. 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,⁵⁴ rather than the lower bound of a 95% or 99% confidence interval.⁵⁵ While OIG has defended the use of the 90% confidence interval in other reports,⁵⁶ CMS has not clarified the specific confidence interval it intends to use and when asked whether it intends to apply the 99% confidence level stated in the 2012 RADV Rule, CMS circumvented this issue by stating, "it will rely on any statistically valid method for sampling and extrapolation that it determines to be well-suited to a particular audit."⁵⁷ It is misleading for OIG to uniformly use the 90% confidence level when CMS has not set a standard confidence level. Humana and other industry participants are now left with little guidance in finalizing their bids. For the foregoing reasons, Humana respectfully requests that OIG reconsider its first recommendation. OIG's inconsistent approach in the Draft Report would further disrupt actuarial equivalence if finalized.

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[.]"⁵⁸ Once again, this recommendation presents issues that Humana and other audited MAOs have addressed with OIG

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.").

⁵⁴ Draft Report at 26.

⁵⁵ 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.").

⁵⁶ E.g., SelectCare of Texas Report at 33; Aetna Report at 28; Presbyterian Health Report at 7, n.15; Cariten Report at 24-25.

⁵⁷ See CMS, *Frequently Asked Questions: Contract-Level Risk Adjustment Data Validation (RADV) FAQs* (Nov. 2023), available at <https://www.cms.gov/files/document/contract-level-radv-faqs.pdf>.

⁵⁸ Draft Report at 18.

in connection with other recent audits. For the reasons described by Humana and other industry participants, reiterated below, Humana respectfully requests that OIG reconsider this recommendation because MA regulations do not require the sort of audits that OIG recommends.

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.⁵⁹ CMS implemented the current regulatory regime after acknowledging industry concerns about widespread healthcare provider "mistakes" and "incomplete or inaccurate" provider-generated data.⁶⁰ Commenters at the time explained that "it would be unfair and unrealistic to hold [MA] organizations to a '100 percent accuracy' certification standard."⁶¹ 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."⁶² 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."⁶³

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."⁶⁴ 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.⁶⁵

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."⁶⁶ 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 require MAOs to adopt any specific oversight measures or confirm the accuracy of all provider submissions.⁶⁷ Second, the Draft Report indicates that "[f]ederal regulations also state that MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes."⁶⁸ 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,

⁵⁹ 42 C.F.R. § 422.504.

⁶⁰ 65 Fed. Reg. at 40,250; 40,268.

⁶¹ *Id.* at 40,268.

⁶² *Id.*

⁶³ *Id.*

⁶⁴ 64 Fed. Reg. at 61,900.

⁶⁵ *Id.*

⁶⁶ Draft Report at 8.

⁶⁷ See HHS-OIG, General Compliance Program Guidance, at 59 (Nov. 2023), available at <https://oig.hhs.gov/compliance/general-compliance-program-guidance/>.

⁶⁸ Draft Report at 8.

completeness and truthfulness based on “best knowledge, information, and belief.” Humana disagrees with OIG’s contention⁶⁹ that its recommendation is in line with the requirements of the Federal regulations.

OIG’s mischaracterizations of MA program requirements in turn influence OIG’s recommendation that Humana “identify . . . similar instances of noncompliance.”⁷⁰ 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.⁷¹ 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 APA and the SSA.⁷² Accordingly, Humana respectfully requests that OIG reconsider this recommendation.

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 Humana 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 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.”⁷³ This exact recommendation came up in connection with OIG’s other recent “high-risk” code reports,⁷⁴ and again it appears that OIG and the MA industry are at an impasse. For the reasons described below, explained previously to OIG by Humana and other industry participants, 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

⁶⁹ See Cariten Report at 27.

⁷⁰ Draft Report at 18.

⁷¹ See Acute Stroke Audit Report at 1.

⁷² See 5 U.S.C. § 553; 42 U.S.C. § 1395hh(a)(2).

⁷³ Draft Report at 18.

⁷⁴ See SelectCare of Texas Report at 20; see also Actna Report at 17; Presbyterian Health Report at 16.

guidance,⁷⁵ 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 "could be improved."⁷⁶ This effectively imposes the perfection standard that CMS and OIG have previously recognized is not reasonable to enforce, as discussed above.⁷⁷ 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.⁷⁸ 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. Nor is it clear from OIG's recommendations to date what policies and procedures would be acceptable, as OIG arbitrarily and capriciously provides this recommendation to a variety of circumstances: in one report stating that it did not review the full compliance program, but still issuing this same overarching recommendation;⁷⁹ in the report for a prior Humana audit, providing this recommendation even with an incredibly high 87% accuracy rate; and giving this recommendation in two other reports after acknowledging that the plans had already made improvements.⁸⁰ Thus, Humana requests that OIG reconsider its position that Humana's policies and procedures "could be improved" 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.⁸¹ To date, Humana has never received a substantive response from CMS related to those communications, nor has CMS ever informed Humana that any aspect of its approach to risk adjustment compliance is deficient. 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

⁷⁵ 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(1); 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.").

⁷⁶ Draft Report at 7, 17.

⁷⁷ See 65 Fed. Reg. at 40,268.

⁷⁸ See Draft Report at 7–8.

⁷⁹ See Anthem Report at 24.

⁸⁰ See 2021 Humana Report at 13; UPMC Report at 31.

⁸¹ 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); see also Letter from Sean J. O'Reilly, Chief Compliance Officer, Humana to Jennifer R. Shapiro, Director of the Medicare Plan Payment Group, Centers for Medicare and Medicaid Services (Sept. 1, 2023).

to the so-called “high-risk diagnoses” identified in the Draft Report.⁸² 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, and Administrative Quality Audits. With regard to the so-called “high-risk diagnoses” OIG has identified, OIG acknowledges that “Humana 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 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 eight high-risk groups reviewed in our audit.”⁸³ OIG also acknowledges that “Humana’s compliance procedures for detection and correction of incorrectly submitted diagnosis codes included routine internal medical reviews to compare diagnosis codes from a random sample of claims to the diagnoses documented on the associated medical records.”⁸⁴ Humana believes these programs satisfy Humana’s obligations under applicable MA program requirements.

Despite these findings, OIG’s Draft Report concludes that Humana’s compliance procedures “could be improved” because Humana’s “internal medical reviews did not focus on any specific high-risk diagnosis codes, including those we identified as being higher risk for being miscoded.”⁸⁵ 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 documentation⁸⁶ in the absence of specific CMS-implemented MA program requirements. Humana and other MAOs are afforded broad discretion in designing compliance and education programs.⁸⁷

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

⁸² See Draft Report at 20 (“[OIG] interviewed Humana officials to gain an understanding of (1) the policies and procedures that Humana followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Humana’s monitoring of those diagnosis codes to identify and detect noncompliance with Federal requirements.”).

⁸³ *Id.* at 16.

⁸⁴ *Id.*

⁸⁵ *Id.* at 16–17.

⁸⁶ See Acute Stroke Audit Report at 8.

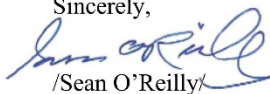
⁸⁷ See 65 Fed. Reg. at 40,265.

the CMS guidance that existed during the years subject to OIG's audit. Humana therefore requests that OIG reconsider in recommendation that the Company "enhance" its risk adjustment policies and procedures.⁸⁸

* * *

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/

Sean O'Reilly, JD
Senior Vice President and Chief Compliance Officer
Enterprise Risk and Compliance Group

Cc: Jane Susott, Associate General Counsel & Vice President of Humana Inc.

⁸⁸ Draft Report at 18.