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Medicare Advantage Compliance Audit of Specific Diagnosis Codes Humana Health Benefit of Louisiana (Contract H1951) Submitted to CMS

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Why OIG Did This Audit

- Under the Medicare Advantage (MA) program, CMS makes monthly payments to MA organizations based in part on the health status of the enrollees being covered.
- To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from its providers and submit these codes to CMS. Some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.
- This audit of Humana Health Benefit of Louisiana (Humana) is part of a series of audits in which we are reviewing high-risk diagnosis codes that MA organizations submitted to CMS for use in its risk adjustment program.

What OIG Found

Most of the selected diagnosis codes that Humana submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements.

- For 218 of the 240 sampled enrollee-years, medical records did not support the diagnosis codes and resulted in $553,049 in overpayments.
- On the basis of our sample results, we estimated that Humana received at least $10.5 million in overpayments for 2017 and 2018.

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. Due to Federal regulations that limit the use of extrapolation for recovery purposes to 2018 and forward, we limited our recommended recovery to $5.5 million.

What OIG Recommends

We made three recommendations to Humana: that it refund to the Federal Government the $5.5 million of estimated overpayments, identify similar instances of noncompliance that occurred after our audit period and refund any resulting overpayments, and continue to examine its compliance procedures to identify areas where improvements can be made to ensure that diagnoses 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 did not agree with our findings or with our recommendations.

TABLE OF CONTENTS

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 65 breast cancer diagnoses into 1 group.) This audit covered Humana Health Benefit of Louisiana (Humana), for contract number H1951, and focused on eight groups of high-risk diagnosis codes for payment years 2017 and 2018.[3]

OBJECTIVE

Our objective was to determine whether selected diagnosis codes that Humana submitted 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 (CM), *Official Guidelines for Coding and Reporting* (ICD Coding Guidelines). The ICD is a coding system that is used by physicians and other health care providers to classify and code all diagnoses, symptoms, and procedures.

[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 H1951.

traditional fee-for-service (FFS) 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 2023, CMS paid MA organizations $466.7 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

[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.

incorrect, CMS will make an improper payment to an MA organization. Specifically, if medical 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 only one physician or outpatient claim during the service year but did not have a sepsis diagnosis

[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.

on a corresponding inpatient hospital claim. A sepsis diagnosis generally results in an inpatient hospital admission.

- *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 Benefit of Louisiana

Humana is an MA organization based in Louisville, Kentucky. As of December 2018, Humana provided coverage under contract number H1951 to 142,921 enrollees. For the 2017 and 2018

payment years (audit period), CMS paid Humana approximately $3 billion to provide coverage to its enrollees.[11, 12]

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 their condition and the payment year, which we refer to as "enrollee-years."

We identified 6,323 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes ($12,683,846).[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	11	19	30
2. Acute myocardial infarction	12	18	30
3. Embolism	13	17	30
4. Sepsis	20	10	30
5. Lung cancer	15	15	30
6. Breast cancer	11	19	30
7. Colon cancer	20	10	30
8. Prostate cancer	11	19	30
Total for All High-Risk Groups	**113**	**127**	**240**

Humana provided medical records as support for the selected diagnosis codes associated with 238 of the 240 sampled enrollee-years.[14] We used an independent medical review contractor

[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.

[13] The 6,323 unique enrollee-years and associated payments that we reviewed consisted of 3,021 enrollee-years ($6,242,490) for payment year 2017 and 3,302 enrollee-years ($6,441,356) for payment year 2018.

[14] Humana could not locate medical records for the remaining 2 sampled enrollee-years.

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.

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 the selected diagnosis codes that Humana submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 22 of the 240 sampled enrollee-years, the medical records validated the reviewed HCCs. For the remaining 218 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 $553,049 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 $10,565,875 in overpayments for 2017 and 2018.[15] Because of Federal regulations (in effect when we issued our draft audit report) 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

[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.

but are recommending a refund of $5,470,725 in overpayments ($280,578 for the sampled enrollee-years from 2017 and an estimated $5,190,147 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).

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) (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).

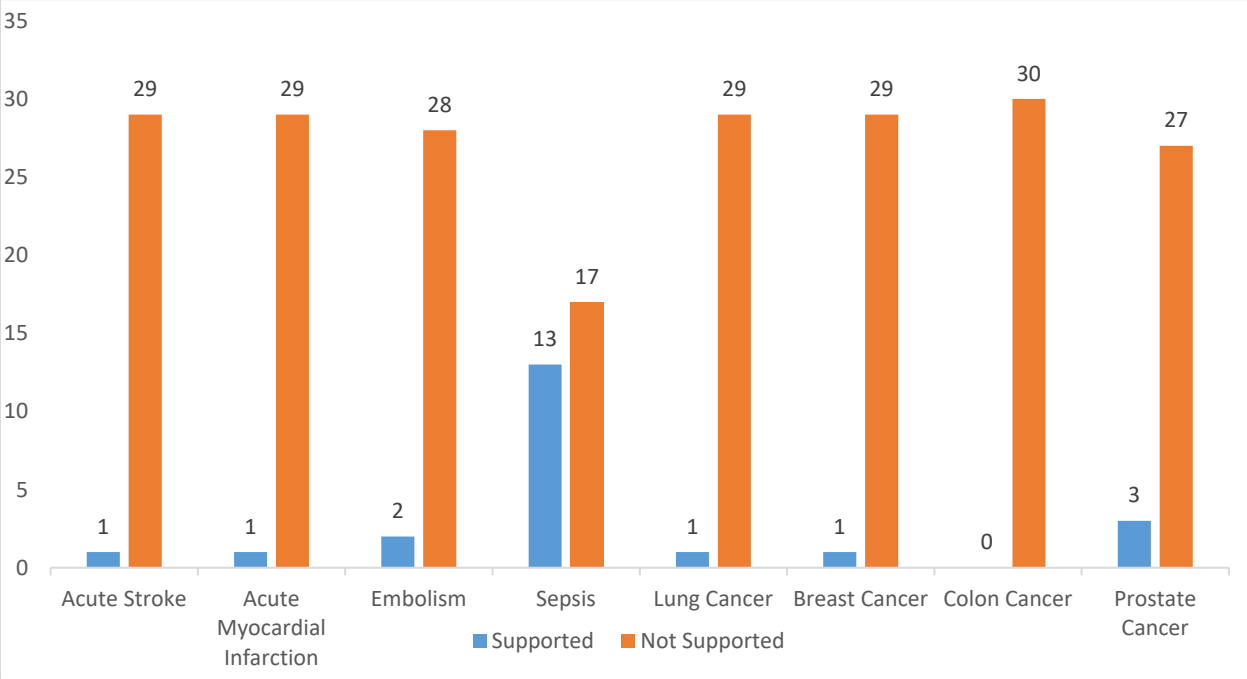
[16] CMS had updated its Federal regulations (The RADV Final Rule, 88 Federal Register 7266 (Feb. 1, 2023) that limit the use of extrapolation in RADV audits to payment years 2018 and forward. These regulations were in place when we conducted this audit and issued our draft report. Therefore, for sampled 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. After Humana commented on our draft report, a U.S. District Court vacated and remanded CMS's RADV Final Rule (*Humana Inc. v. Becerra,* No. 4:23-cv-00909-O (N.D. Tex. Sept. 25, 2025)). Although we received Humana's comments on our recommendation to refund estimated overpayments before the court rendered its decision, we note that OIG audit findings 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. See also footnote 21 later in this report.

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 THE SELECTED HIGH-RISK DIAGNOSIS CODES THAT HUMANA HEALTH BENEFIT OF LOUISIANA SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Most of the selected high-risk diagnosis codes that Humana submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, as shown in the figure below, for 218 of the 240 sampled enrollee-years, either the medical records 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 29 of the 30 sampled enrollee-years. Specifically:

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

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in an HCC. There is documentation of a past medical history of cerebrovascular accident . . . which does not result in an HCC."

- For 4 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "Based on review of the medical record submitted, there is no documentation of an acute cerebrovascular accident (CVA) that results in [the HCC for Ischemic or Unspecified Stroke]. A CVA is listed as a differential diagnosis that is ruled out by the head CT (computed tomography scan). Admitting diagnosis is a transient ischemic attack [diagnosis] which does not result in an HCC."[17]

- For the remaining 1 enrollee-year, the medical record that Humana provided to support the reviewed HCC was a carotid bilateral ultrasound results report signed and credentialed by a diagnostic radiologist who was not on the acceptable provider list. 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 record for this enrollee-year did not meet CMS's requirements for acceptable data sources, we could not validate the reviewed HCC.

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and Humana received $53,846 in overpayments ($20,745 for 2017 and $33,101 for 2018) for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Myocardial Infarction

Humana incorrectly submitted diagnosis codes for acute myocardial infarction for 29 of the 30 sampled enrollee-years. Specifically:

[17] A transient ischemic attack is a temporary period of symptoms similar to those of a stroke.

- For 14 enrollee-years, the medical records indicated in each case that the individual had an old myocardial infarction diagnosis, but the records did not justify an acute myocardial infarction diagnosis at the time of the physician's service.[18]

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in an HCC. There is documentation of a past medical history of myocardial infarction [diagnosis] that does not result in an HCC."

- For 7 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.[19] Accordingly, 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 only medical records that Humana provided to support the reviewed HCCs 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. Because the records for these 5 enrollee-years did not meet CMS's requirements for acceptable data sources, we could not validate the reviewed HCCs.

- For 3 enrollee-years, the medical records in each case did not support an acute myocardial infarction diagnosis.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in [the HCC for Acute Myocardial Infarction]."

As a result of these errors, the HCC for Acute Myocardial Infarction was not validated, and Humana received $39,543 in overpayments ($14,123 for 2017 and $25,420 for 2018) for these 29 sampled enrollee-years.

[18] 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.

[19] 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.

Incorrectly Submitted Diagnosis Codes for Embolism

Humana incorrectly submitted diagnosis codes for embolism for 28 of 30 sampled enrollee-years. Specifically:

- For 14 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not justify 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 will result in the assignment of the HCC under review. There is documentation of a past medical history of other venous thrombosis and embolism [diagnosis] which does not result in an HCC."[20]

- For 11 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 will result in the assignment of the HCC under review."

- For the remaining 3 enrollee-years, the only medical records that Humana provided to support the reviewed HCC were radiology reports signed and credentialed by a diagnostic radiologist who was not on the acceptable provider list. For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources. 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 $70,942 ($28,270 for 2017 and $42,672 for 2018) in overpayments for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Sepsis

Humana incorrectly submitted diagnosis codes for sepsis for 17 of 30 sampled enrollee-years. Specifically:

- For 15 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 under review. The

[20] Venous thrombosis occurs when a blood clot blocks a vein.

medical documentation lists bacterial sepsis [diagnosis] under impression and plan but does not indicate an active treatment to code the diagnosis as a current condition."

- For the remaining 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 under review. There is documentation of a past medical history of sepsis [diagnosis] which does not result in an HCC."

As a result of these errors, the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock was not validated, and Humana received $59,625 in overpayments ($47,115 for 2017 and $12,510 for 2018) for these 17 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

Humana incorrectly submitted diagnosis codes for lung cancer for 29 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 justify 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 under review. There is documentation of [a] past medical history of lung cancer [diagnosis] which does not result in an HCC."

- For 8 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 for another diagnosis on CMS's systems 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.

- For 3 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 under review. There is documentation of suspected lung cancer with the provider

ordering a biopsy for confirmation which would not be coded per outpatient guidelines."

- For the remaining 1 enrollee-year, Humana could not locate any medical records to support the lung cancer diagnosis; therefore, the HCC for Lung and Other Severe Cancers was not validated.

As a result of these errors, the HCC for Lung and Other Severe Cancers was not validated, and Humana received $194,396 in overpayments ($97,960 for 2017 and $96,436 for 2018) for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

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

- For 27 enrollee-years, the medical records indicated in each case that the individual had previously had breast cancer, but the records did not justify a breast 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 under review. There is documentation of a past medical history of breast cancer [diagnosis] which does not result in an HCC."

- For 1 enrollee year, the only medical record that Humana provided to support the reviewed HCC was a radiology report signed and credentialed by a diagnostic radiologist who was not on the acceptable provider list. For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources. Because the record for this enrollee-year 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 a medical record to support the breast cancer diagnosis; therefore, the Breast Cancer HCC 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 $37,643 in overpayments ($18,200 for 2017 and $19,443 for 2018) for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

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

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

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

- For 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.

- For the remaining 1 enrollee-year, the medical records did not support a colon cancer diagnosis. For this enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC under review."

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and Humana received $66,411 in overpayments ($44,034 for 2017 and $22,377 for 2018) for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

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

- For 25 enrollee-years, the medical records indicated in each case that the individual had previously had prostate cancer, but the records did not justify a prostate cancer diagnosis at the time of the physician's service.

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

- For 1 enrollee-year, the medical record did not support a prostate cancer diagnosis.

- For the remaining 1 enrollee-year, the only medical record that Humana provided to support the reviewed HCC was a radiology report signed and credentialed by a diagnostic radiologist who was not on the acceptable provider list. For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources. Because the record for the 1 enrollee-year did not meet CMS's requirements for acceptable data sources, we could not validate the reviewed HCC.

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Humana received $30,643 in overpayments ($10,131 for 2017 and $20,512 for 2018) for these 27 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 $553,049 in overpayments for the 218 sampled enrollee-years ($280,578 for 2017 and $272,471 for 2018).

THE POLICIES AND PROCEDURES HUMANA HEALTH BENEFIT OF LOUISIANA 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 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 218 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 11 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 BENEFIT OF LOUISIANA 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 $10,565,875 in overpayments for our audit period.

Because of Federal regulations (in effect when we issued our draft report) that limit the use of extrapolation in RADV audits for recovery purposes to payment years 2018 and forward,[21] we are reporting the overall estimated overpayment amount, but are recommending a refund of $5,470,725 in overpayments ($280,578 for the sampled enrollee-years from 2017 and an

[21] CMS had updated its Federal regulations (The RADV Final Rule, 88 Fed. Reg. 7266 (Feb. 1, 2023) that limit the use of extrapolation in RADV audits to payment years 2018 and forward. These regulations were in place when we conducted this audit and issued our draft report. RADV audits are conducted to verify that diagnoses submitted by MA organizations for risk-adjusted payment are supported by medical record documentation. After Humana commented on our draft report, a U.S. District Court vacated and remanded CMS's RADV Final Rule (*Humana Inc. v. Becerra,* No. 4:23-cv-00909-O (N.D. Tex. Sept. 25, 2025)). Although we received Humana's comments on our recommendation to refund estimated overpayments before the court decision, we note that OIG audit findings 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.

estimated $5,190,147 for 2018). (See footnote 16 and Appendix D for sample results and estimates.)

RECOMMENDATIONS

We recommend that Humana Health Benefit of Louisiana:

- refund to the Federal Government the $5,470,725 of estimated overpayments;[22]

- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred after our audit period and refund any resulting overpayments to the Federal Government; and

- continue to examine its existing compliance procedures to identify areas where improvements can be made to ensure that diagnoses 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 24 of the 218 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 194 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 standards that OIG suggests and stated that its compliance program satisfies all legal and regulatory requirements.

We reviewed the entirety of Humana's comments and for the reasons detailed below, we maintain that our findings and recommendations are 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.

[22] 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 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.

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

Humana Did Not Agree With OIG's Findings for 24 Sampled Enrollee-Years

Humana Comments

Humana did not agree with our draft report findings for 24 sampled enrollee-years (as shown in Table 2 below) 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
Acute Stroke	5
Acute Myocardial Infarction	2
Lung Cancer	7
Breast Cancer	3
Colon Cancer	5
Prostate Cancer	2
Total	**24**

For each of the 24 sampled enrollee-years, Humana provided either new medical records or explanations supporting its position that previously submitted medical records validated the audited HCCs.

OIG Response

Our independent medical review contractor reviewed the new medical records or the explanations for the 24 sampled enrollee-years and reaffirmed that the HCCs were not validated, thus upholding its original decisions.

For example, for 1 of the enrollee-years (prostate cancer high-risk group), the contractor reviewed Humana's newly submitted medical record and stated that "[t]here is documentation of a past medical history of [a] prostate cancer [diagnosis] which does not result in an HCC. The patient is . . . post prostatectomy with no recurrence or active treatment noted. The provider has documented the prostate cancer as being 'resolved'."

Therefore, we did not need to make any adjustments related to these enrollee-years for 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 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 we modify our "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.

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 Did Not Apply Certain Medicare Advantage Program Requirements and Should Reconsider Its Monetary Recommendation

Humana Comments

Humana stated that we should reconsider our recommendation to refund overpayments because we may have violated statutory requirements. Humana also stated that we have "improperly [equated] 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 (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 claim 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 to measure MA payment accuracy in an audit—audited data—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 defend 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 were identified) to estimate overpayments.

Regarding Humana's statement that we did not consider "actuarial equivalence" in our overpayment calculations in the context of its comment about the Final RADV rule, we note that after Humana commented on our draft report, a U.S. District Court vacated and remanded the final rule.[23] However, this ruling does not impact our findings or cause us to change our recommendations. Notwithstanding this ruling, CMS has not issued any requirements that compel us to reduce our overpayment calculations. If CMS deems it appropriate to apply an FFSA, it will, during the audit resolution process, adjust our overpayment finding by whatever amount it determines necessary.

Further, we do not agree with Humana's assertion that it is "misleading, arbitrary and capricious" for us to issue an audit report that both 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 22.)

Humana Stated That OIG's Recommended Recovery Amount May Be Inflated Due to Data Corrections That Were Previously Submitted to CMS

Humana Comments

Humana stated that our estimated overpayment amount of $5,190,147 for payment year 2018 may be inflated due to the presence of data corrections that Humana submitted to CMS. Humana stated that CMS's recent 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.

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 whether 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

[23] U.S. District Court for the Northern District of Texas ruling can be found at: gov.uscourts.txnd.380836.76.0_2.pdf (accessed on Oct. 1, 2025)

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 we should reconsider our recommendation to refund overpayments to the Federal government because we have not been consistent with our repayment calculation methodologies in our Toolkit[24] and in other audits. Humana noted that we released our Toolkit to enable MA organizations to identify and evaluate high-risk diagnosis codes but noted that our Toolkit "has proven to be merely aspirational" because "CMS program requirements do not compel [MA organizations] to conduct audits of specific diagnosis codes, including so-called 'high-risk' codes." To this point, Humana stated that our Toolkit is "providing little to no guidance to Humana and other industry participants." Humana also noted that our "recent audits" of other MA organizations have identified additional "so-called," "ever-evolving" high-risk diagnosis code groups.

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 discussed this information in detail with 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 their compliance programs.

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

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 coding supervisor 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 that it 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 the guidance "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 data standards based on whether CMS or OIG conducts the audit would be "arbitrary and capricious under the Administrative Procedure Act ('APA')."[25]

[25] 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.

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 data 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 coding supervisor reflected a reasonable method to determine whether the medical record adequately supported the reported diagnosis codes. The contractor's review process allowed a coding supervisor 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 coding supervisor, 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 CMS's instructions, including the provisions of the Manual.[26] 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.[27] 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.

[26] 42 CFR § 422.504(a).

[27] The Manual, chap. 7, § 40.

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 we "used the lower limit of a two-sided [90-percent] confidence interval when estimating the total amount of net overpayments rather than the lower bound of a [95-percent] or [99-percent] confidence interval." Humana also stated that CMS has not clarified the specific confidence interval it intends to use for RADV audits. Therefore, Humana asserts that "[i]t is misleading for OIG to uniformly use the [90-percent] confidence level when CMS has not set a standard confidence level."

OIG Response

We disagree with Humana that it is misleading to use the 90-percent confidence level. The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology. OIG is an independent oversight agency, and our policy is to recommend 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, high-risk groups, and time period covered in our sampling frame. This approach, which is routinely used by HHS for recovery calculations,[28] results in a 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 IDENTIFY SIMILAR INSTANCES OF NONCOMPLIANCE FOR THE HIGH-RISK DIAGNOSES THAT OCCURRED AFTER THE AUDIT PERIOD

Humana Comments

Humana disagreed with our second recommendation—that it identify similar instances of noncompliance for the high-risk diagnoses that occurred 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."

[28] 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).

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 an MA compliance program because the MA program does not compel Humana or other [MA organizations] to conduct audits of specific so-called '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)). 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 (218 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 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.

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 its 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 'higher-risk' areas." Further, according to Humana, it has never been informed by CMS of any deficiencies in its risk adjustment compliance program.

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 high error rates. 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 $3,046,670,560 to provide coverage to its enrollees for 2017 and 2018. We identified a sampling frame of 6,323 unique enrollee-years (footnote 13) on whose behalf providers documented high-risk diagnosis codes during the 2016 and 2017 service years; Humana received $98,302,089 in payments from CMS for these enrollee-years for 2017 and 2018. We selected for audit 240 enrollee-years with payments totaling $4,051,979.

The 240 enrollee-years included 30 acute stroke diagnoses, 30 acute myocardial infarction diagnoses, 30 embolism diagnoses, 30 sepsis diagnoses, 30 lung cancer diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, and 30 prostate cancer diagnoses (Table 1, page 6). We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $640,505 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.

We performed audit work from December 2021 through April 2025.

METHODOLOGY

To accomplish our objective, we performed the following steps:

- We reviewed applicable Federal laws, regulations, and guidance.

- We discussed with CMS program officials the Federal requirements that MA organizations should follow when submitting diagnosis codes to CMS.

- We identified, through data mining and discussions with medical professionals at a Medicare administrative contractor, diagnosis codes and HCCs that were at high risk for noncompliance. We also identified the diagnosis codes that potentially should have been used for cases in which the high-risk diagnoses were miscoded.

- We consolidated the high-risk diagnosis codes into specific groups, which included:

    - 74 diagnosis codes for acute stroke,
    - 40 diagnosis codes for acute myocardial infarction,
    - 85 diagnosis codes for embolism,
    - 40 diagnosis codes for sepsis,
    - 24 diagnosis codes for lung cancer,
    - 65 diagnosis codes for breast cancer,

- 20 diagnosis codes for colon cancer, and
- 2 diagnosis codes for prostate cancer.

- We used CMS's systems to identify the enrollee-years on whose behalf providers documented the high-risk diagnosis codes. Specifically, we used extracts from CMS's:

  - RAPS[29] and the Encounter Data System (EDS)[30] to identify enrollees who received high-risk diagnosis codes from a physician during the service years,

  - Risk Adjustment System (RAS)[31] to identify enrollees who received an HCC for the high-risk diagnosis codes,

  - Medicare Advantage Prescription Drug System (MARx)[32] 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),

  - EDS to identify enrollees who received specific procedures,[33] and

  - Prescription Drug Event (PDE) file[34] to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.

- We communicated with 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).

[29] MA organizations use the RAPS to submit diagnosis codes to CMS.

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

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

[32] The MARx identifies the payments made to MA organizations.

[33] The EDS contains information on each item (including procedures) and service provided to an enrollee.

[34] 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 238[35] enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.[36]

- 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), then the HCC was considered validated.

    - If the first senior coder did not find support on the medical record(s), a second senior coder performed a separate review of the same medical record:

        - If the second senior coder also did not find support, the HCC was considered to be not validated.

        - If the second senior coder found support, then the coding supervisor independently reviewed the medical record(s) to make the final determination.

    - If either the first or second senior coder asked the coding supervisor for assistance, then the coding supervisor's decision became the final determination. In addition, 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.

[35] Humana could not locate medical records for the remaining 2 sampled enrollee-years.

[36] The 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 estimated the total overpayment made to Humana during the audit period.

- We calculated the recommended recovery amount in accordance with CMS's regulations that limit the use of extrapolation in RADV audits for recovery purposes. 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.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health and Life Insurance Company (Contract H1608) Submitted to CMS	A-02-22-01020	6/3/2025
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UCare Minnesota (Contract H2459) Submitted to CMS	A-07-22-01209	12/23/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes Blue Care Network of Michigan (Contract H5883) Submitted to CMS	A-06-20-02000	12/20/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HealthAssurance, Pennsylvania, Inc. (Contract H5522) Submitted to CMS	A-05-22-00020	9/23/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Humana Health Plan, Inc. (Contract H2649) Submitted to CMS	A-02-22-01001	9/23/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Independent Health Association, Inc. (Contract H3362) Submitted to CMS	A-07-19-01194	6/26/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MediGold (Contract H3668) Submitted to CMS	A-07-20-01198	2/16/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That SelectCare of Texas, Inc. (Contract H4506), Submitted to CMS	A-06-19-05002	11/27/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Aetna, Inc. (Contract H5521) Submitted to CMS	A-01-18-00504	10/2/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS	A-07-20-01197	8/3/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS	A-07-20-01202	7/10/2023

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 a high-risk diagnosis 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 6,323 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 (2,441 enrollee-years);

- an acute myocardial infarction 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 (869 enrollee-years);

- an embolism 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 (415 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 (379 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 (178 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 (852 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 (369 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 (820 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	2,441	$4,742,034	30
2 – Acute myocardial infarction	869	1,615,235	30
3 – Embolism	415	986,734	30
4 – Sepsis	379	1,196,024	30
5 – Lung cancer	178	1,250,987	30
6 – Breast cancer	852	1,031,697	30
7 – Colon cancer	369	866,503	30
8 – Prostate cancer	820	994,632	30
Total	**6,323**	**$12,683,846**	**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 the enrollee-year (a combination of the enrollee identifier and the payment year) and then consecutively numbered the items in each stratum in the stratified sampling frame. After generating random numbers according to our sample design, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

Estimated Overpayments

We used the OIG, OAS, statistical software to estimate the total overpayments in the sampling frame made to Humana for payment years 2017 and 2018 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

Because CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward, we calculated the recommended recovery amount in accordance with CMS's regulations (footnote 16). 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	1,129	$2,255,706	11	$20,745	11	$20,745
2 – Acute myocardial infarction	427	807,435	12	16,819	11	14,123
3 – Embolism	208	495,258	13	33,922	11	28,270
4 – Sepsis	186	594,673	20	69,464	13	47,115
5 – Lung cancer	92	661,504	15	114,498	14	97,960
6 – Breast cancer	403	489,314	11	18,200	11	18,200
7 – Colon cancer	190	449,327	20	45,297	20	44,034
8 – Prostate cancer	386	489,273	11	12,584	9	10,131
Total	**3,021**	**$6,242,490**	**113**	**$331,529**	**100**	**$280,578**

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	1,312	$2,486,328	19	$35,008	18	$33,101
2 – Acute myocardial infarction	442	807,800	18	30,889	18	25,420
3 – Embolism	207	491,476	17	42,672	17	42,672
4 – Sepsis	193	601,351	10	32,842	4	12,510
5 – Lung cancer	86	589,483	15	102,090	15	96,436
6 – Breast cancer	449	542,383	19	20,371	18	19,443
7 – Colon cancer	179	417,176	10	23,554	10	22,377
8 – Prostate cancer	434	505,359	19	21,550	18	20,512
Total	**3,302**	**$6,441,356**	**127**	**$308,976**	**118**	**$272,471**

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	2,441	$4,742,034	30	$55,753	29	$53,846
2 – Acute myocardial infarction	869	1,615,235	30	47,708	29	39,543
3 – Embolism	415	986,734	30	76,594	28	70,942
4 – Sepsis	379	1,196,024	30	102,306	17	59,625
5 – Lung cancer	178	1,250,987	30	216,588	29	194,396
6 – Breast cancer	852	1,031,697	30	38,571	29	37,643
7 – Colon cancer	369	866,503	30	68,851	30	66,411
8 – Prostate cancer	820	994,632	30	34,134	27	30,643
Total	**6,323**	**$12,683,846**	**240**	**$640,505**	**218**	**$553,049**

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

Point estimate	$11,138,023
Lower limit	10,565,875
Upper limit	11,710,532

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	$280,578	$5,552,397	$5,832,975
Lower limit	280,578	5,190,147	5,470,725
Upper limit	280,578	5,914,647	6,195,225

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 HEALTH BENEFIT OF LOUISIANA COMMENTS

Humana.

June 20, 2025

Patricia Wheeler
Regional Inspector General for Audit Services
Office of Audit Services, Region VI
1100 Commerce Street, Room 632
Dallas, TX 75242

VIA EMAIL

RE: Humana's Response to Draft Audit Report No. A-06-21-02001

Dear Ms. Wheeler:

Humana Health Benefit Plan of Louisiana, 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-06-21-02001, entitled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Humana Health Benefit of Louisiana, (Contract H1951) 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 standards that OIG suggests, and (4) Humana's risk adjustment compliance program satisfies all legal, contractual and regulatory requirements. These issues should not come as a surprise to OIG as they are substantially the same issues that Humana has explained previously to OIG in connection with its reports entitled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS*[1] and *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Humana Health Plan, Inc., (Contract H2649) Submitted to CMS.*[2]

Humana takes great pride in what the Company believes to be its an 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-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/documents/audit/7849/A-05-19-00013-Complete%20Report.pdf

[2] *See* HHS-OIG, Audit Report No. A-02-22-01001, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Humana Health Plan, Inc., (Contract H2649) Submitted to CMS* (Sept. 2024), *available at* https://oig.hhs.gov/documents/audit/10008/A-02-22-01001.pdf ("Humana Health Plan 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, contractual and regulatory 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 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, contractual or regulatory requirement for them to do so.[3]

Humana is aware of OIG's December 2023 "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, MA program requirements do not prescribe specific activities 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

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[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]

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[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.* 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; 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 H1951, Humana inquired about the process to submit rebuttals to OIG's HCC substantiation 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* Humana Health Plan Report at 18-20; 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), at 21-22, *available at* https://oig.hhs.gov/documents/audit/8264/A-06-19-05002-Complete%20Report.pdf ("SelectCare Report"); HHS-OIG, Audit Report No. A-07-19-01194, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Independent Health Association, Inc. (Contract H3362) Submitted to CMS* (June 2024) at 19-20, *available at* https://oig.hhs.gov/documents/audit/9922/A-07-19-01194.pdf; HHS-OIG, Audit Report No. A-04-19-07082, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That CarePlus Health Plans, Inc. (Contract H1019) Submitted to CMS* (Oct. 2023), at 15-16, *available at* https://oig.hhs.gov/documents/audit/7344/A-04-19-07082-Complete%20Report.pdf ("CarePlus Report"); HHS-OIG, Audit Report No. A-07-19-01188, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS (*Nov. 2021), 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").

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 $553,049 in net overpayments for the 218 sampled enrollee-years.[11] OIG estimated that Humana received at least $10,565,875 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 $5,470,725 in overpayments ($280,578 for the sampled enrollee-years from 2017 and an estimated $5,190,147 for 2018).[13] For the reasons explained 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 Hospital Association ("AHA") Coding Clinic, coding "should be based on provider documentation."[14] Humana has provided OIG with 24 appeals[15] 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), Embolism Diagnosis within Vascular Disease with Complications (HCC v22 107) and/or 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). OIG's findings that these submissions are unsubstantiated despite record documentation implies that OIG's conclusions are based on a standard not found in any relevant diagnosis coding guideline or CMS program requirement.[16]

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[11] Draft Report at 29 (Appendix D).
[12] *Id.* at 7-8.
[13] *Id.*
[14] AHA Coding Clinic, Fourth Quarter 2016, p. 147.
[15] The 24 appeals represent 24 sampled enrollee-years.
[16] *See Section 40—Role and Responsibilities of Plan Sponsors*, Chapter 7, Medicare Managed Care Manual (Sept. 19, 2014), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c07.pdf ("All diagnosis codes submitted must be documented in the medical record and . . . must be coded according to [ICD] Clinical Modification Guidelines for Coding and Reporting."); *Section 6.4.3*, Risk Adjustment Data Technical Assistance Guide (2008), *available at* https://www.csscoperations.com/internet/csscw3_files.nsf/F/CSSCparticipant-guide-publish_052909.pdf/$FILE/participant-guide-publish_052909.pdf ("The coder is cautioned to exactly code only the narrative provided by the physician in the final diagnosis[.]"); *Section I.A.19*, ICD-10-CM Official Guidelines for Coding and Reporting – FY 2025 (Oct. 1, 2024), *available at* https://www.cms.gov/files/document/fy-2025-icd-10-cm-coding-guidelines.pdf ("The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis.").

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

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

Based on Humana's understanding of OIG's audit procedures and methodology, Humana believes OIG's findings are systematically skewed towards identifying overpayments rather than underpayments, rendering its results inherently unreliable.[17] 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.[18] 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."[19] Following this approach, OIG determined that "Humana received at least $10,565,875 in overpayments" in 2017 and 2018.[20] But Humana was tasked only with supplying medical records to substantiate specific HCCs actually submitted to CMS, not to collect and

[17] 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 $10 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.

[18] Humana Health Plan Report at 21-22; 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; 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 H3655) 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; Coventry Report at 27; UPMC Report at 25; *see also* 2021 Humana Report at 16.

[19] Draft Report at 21 (Appendix A).

[20] *Id.* at 17.

submit medical records to substantiate all HCCs that *could have been* submitted to CMS (*i.e.*, potential underpayments).[21]

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 non-"high-risk" diagnosis codes associated with Payment Years ("PY") 2017 and 2018 for H1951 enrollees as well as those for which Humana did not submit any risk-adjusting diagnosis codes.[22] This aspect of OIG's methodology also systematically reduced the probability of identifying underpayments.[23] 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.[24] OIG should consider such underpayment credits in its overpayment estimates. Accordingly, Humana 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.[25]

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.[26] 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.[27] The

[21] 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.
[22] *See id.* at 19 (Appendix A).
[23] *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)).
[24] *See id.*
[25] *See* Government Auditing Standards; Information Quality Guidelines.
[26] *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i).
[27] *See* 42 U.S.C. §§ 1395w-24(a)(5)(A),(6)(A)(i)-(iii).

Actuarial Standards of Practice ("ASOPs"), especially ASOP No. 45, necessarily govern these actuarial calculations.[28]

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.[29] Subjecting diagnosis codes from the Medicare FFS and MA programs to different documentation standards contravenes ASOP No. 45 and disrupts actuarial equivalence in violation of the Act.[30] Industry experts refer to this error mode as the "Data Inconsistency Issue."[31]

Despite previously acknowledging the need to address the differing documentation standards that are the cause of the Data Inconsistency Issue,[32] on February 1, 2023, CMS finalized its rule on Risk Adjustment Data Validation Audits ("Final RADV Rule"), in which CMS eliminated the Fee-for-Service Adjuster ("FFSA") from PY 2018 and beyond.[33] 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") 2025 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.[34] CMS's Final RADV Rule unlawfully ignores the congressional mandate to "ensure actuarial equivalence" in MA payments because

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[28] Actuarial Standards Board, *Actuarial Standard of Practice No. 45: The Use of Health Status Based Risk Adjustment Methodologies* (Jan. 2012), *available at* https://www.actuarialstandardsboard.org/asops/use-health-status-based-risk-adjustment-methodologies-2/.

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

[30] *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.

[31] *See* Wakely Report Section IV.

[32] 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 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 Audits (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 ("February 2012 Notice of Final Payment Error Calculation Methodology").

[33] *See* 88 Fed. Reg. 6643.

[34] *See* 65 Fed. Reg. at 40,268.

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 defend the Final RADV Rule and its principles, instead deferring to CMS on the issue.[35] 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 H1951 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 H1951 subject to this audit stated explicitly that the Company was relying on CMS's plan to develop and apply an FFSA as part of any RADV process:

> [R]evenue and risk score projections in the bid(s) are based on the assumption that final risk scores will be calculated and payments 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 . . .

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[35] 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 (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* Presbyterian Health Report at 19; 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.

did not comply with Federal requirements."[36] 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.[37]

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.[38] Recognized industry experts have stated that "[t]his principle applies with equal force irrespective of the type of RADV audit."[39]

The Draft Report does not appear to reference in any way the Act's actuarial equivalence requirement. As a result, it appears that OIG did not take the necessary steps to resolve the Data Inconsistency Issue in its "overpayment" calculation underlying the Draft Report's recommendations. If true, OIG's recommendation that Humana refund payments would violate the statutory actuarial equivalence requirement.

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."[40] 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 H1951 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. <u>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.</u>

In the Draft Report, OIG reports an "estimated overpayment amount" of $5,190,147 for PY 2018.[41] OIG's estimate could be inflated as it appears to rely on an overstatement of Humana's underlying sampling frame/population due to data corrections that Humana previously submitted to CMS.

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[36] Acute Stroke Audit Report at 6.
[37] *See id.* at 8.
[38] *See* Wakely Analysis.
[39] Wakely Report at 33; *see also* Wakely Analysis.
[40] CarePlus Report at 23.
[41] Draft Report at 7-8.

Humana submits data corrections in the Risk Adjustment Processing System ("RAPS") and Encounter Data Processing System ("EDPS") systems, as applicable, for both open and closed data submission periods. While CMS recently undertook "reruns" of PY 2017 and PY 2018 and recouped related funds from Humana in 2025 related to these data corrections, OIG's report provides no information related to whether these data corrections—either when pending or when included in the CMS "rerun"—were considered in the sampling frame/population or in the extrapolated "estimated overpayment amount" for PY 2018. 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.[42] For this additional reason, Humana respectfully requests OIG reconsider its recommendation.

5. OIG should reconsider its recommendation because OIG is inconsistent in its use of repayment calculation methodologies applied to different MAOs and in its own "Toolkit."

OIG's recent "high-risk" codes "Toolkit" has proven to be merely aspirational, effectively providing little to no guidance to Humana and other industry participants.[43]

OIG released the "Toolkit" in December 2023 to "enable [MAOs] to replicate [OIG's] techniques to identify and evaluate high-risk diagnosis codes."[44] OIG identified eight "high-risk" code groups in the December 2023 Toolkit and yet, in recent audits, has identified additional so-called "high-risk" code groups including sepsis, vascular claudication, and major depressive disorder. Given this ever-evolving characterization of codes as "high-risk," OIG and CMS cannot reasonably expect MAOs to fully "replicate [OIG's] techniques to identify and evaluate high-risk diagnosis codes."[45]

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 interpretated as clarifying MAOs' data accuracy obligations, saying the Toolkit was "not intended to be used to determine compliance with any laws, regulations, or other guidance."[46] 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 reflects 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 HCC model utilized in the toolkit appears outdated—the Toolkit neither implements the most recent

[42] 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").
[43] *See* Toolkit.
[44] *Id.* at 1.
[45] *Id.* at 2.
[46] *Id.* at 47.

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.

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.[47] 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 "coding supervisor" who can consult a physician to act as a "tiebreaker" in situations where two coders disagree regarding whether a medical record substantiates an HCC.[48] 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."[49] 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.[50] 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.[51] 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."[52] To the extent the contractor's review underlying

[47] Draft Report at 19 (Appendix A).
[48] *Id.* at 21 (Appendix A).
[49] 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.
[50] 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).
[51] Draft Report at 8–17.
[52] *See* CMS, Contract-Level Risk Adjustment Data Validation: Medical Record Reviewer Guidance (Sept. 27, 2017), at 41, *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

OIG's audit findings did not conform to CMS diagnosis coding standards, 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 H2649, 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.

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,[53] rather than the lower bound of a 95% or 99% confidence interval.[54] While OIG has defended the use of the 90% confidence interval in other reports,[55] CMS has been inconsistent in the specific confidence interval it intends to use for RADV audits. CMS noted its intention to apply a 99% confidence interval for PY 2011 through PY 2013 audits[56] and its intention to apply a 90% confidence interval for the PY 2018[57] and PY 2019 audits.[58] When was asked whether it intended to apply a particular confidence level to RADV audits, 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."[59] 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

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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 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.").

[53] Draft Report at 26.

[54] Federal Judicial Center, National Academies Press, *Reference Manual on Scientific Evidence* 245 (3d ed. 2011), *available at* https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf ("The 95% confidence level is the most popular, but some authors use 99%, and 90% is seen on occasion.").

[55] *E.g.*, SelectCare Report at 33; Aetna Report at 28; Presbyterian Health Report at 7, n.15; 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), at 24–25, *available at* https://oig.hhs.gov/documents/audit/6506/A-02-20-01009-Complete%20Report.pdf ("Cariten Report").

[56] *See* February 2012 Notice of Final Payment Error Calculation Methodology.

[57] *See* CMS, Payment Year 2018 Medicare Advantage Contract-Specific Risk Adjustment Data Validation (RADV) (Nov. 14, 2024), *available at* https://www.cms.gov/files/document/payment-year-2018-ma-radv-audit-methods-instructions.pdf.

[58] *See* CMS, Payment Year 2019 Medicare Advantage Contract-Specific Risk Adjustment Data Validation (RADV) (June 12, 2025), *available at* https://www.cms.gov/files/document/py2019-radv-audit-methods-and-instructions.pdf.

[59] *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.

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 after [its] audit period and refund any resulting overpayments to the Federal Government[.]"[60] Once again, this recommendation presents issues that Humana and other audited MAOs have addressed with OIG in connection with myriad 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.[61] CMS implemented the current regulatory regime after acknowledging industry concerns about widespread healthcare provider "mistakes" and "incomplete or inaccurate" provider-generated data.[62] Commenters at the time explained that "it would be unfair and unrealistic to hold [MA] organizations to a '100 percent accuracy' certification standard."[63] 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."[64] 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."[65]

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."[66] In addition, OIG has suggested that MAOs conduct "sample audits and spot checks" to confirm that their information collection and reporting systems are working correctly, but OIG has offered no other specific guidance to the industry in this regard.[67]

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[60] Draft Report at 17.
[61] 42 C.F.R. § 422.504.
[62] 65 Fed. Reg. at 40,250, 40,268.
[63] *Id.* at 40,268.
[64] *Id.*
[65] *Id.*
[66] 64 Fed. Reg. at 61,900.
[67] *Id.*

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."[68] 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.[69] 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."[70] This formulation implies that MAOs must unequivocally guarantee that risk adjustment data are accurate, complete and truthful. But that is again not the case: MA program requirements impose only a qualified standard of accuracy, completeness and truthfulness based on "best knowledge, information, and belief." Humana disagrees with OIG's contention[71] 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."[72] 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 so-called "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.[73] 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.[74] 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, CONTRACTUAL 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

[68] Draft Report at 8.
[69] *See* HHS-OIG, *General Compliance Program Guidance*, at 59 (Nov. 2023), *available at* https://oig.hhs.gov/compliance/general-compliance-program-guidance/1135/HHS-OIG-GCPG-2023.pdf.
[70] Draft Report at 8.
[71] *See* Cariten Report at 27.
[72] Draft Report at 17.
[73] *See* Acute Stroke Audit Report at 1.
[74] *See* 5 U.S.C. § 553; 42 U.S.C. § 1395hh(a)(2).

procedures to identify areas where improvements can be made to ensure that diagnoses 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."[75] This exact recommendation came up in connection with OIG's other recent "high-risk" code reports,[76] 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 and in response to OIG's Policies and Procedures Questionnaire for H1951, Humana has several programs in place to enhance the accuracy of risk adjustment data, consistent with MA program requirements and OIG's guidance,[77] 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."[78] This effectively imposes the perfection standard that CMS and OIG have previously recognized is not reasonable to enforce, as discussed above.[79] 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.[80] 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;[81] 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.[82] Thus, Humana requests that OIG reconsider its

[75] Draft Report at 17-18.
[76] *See* SelectCare Report at 20; *see also* Aetna Report at 17; Presbyterian Health Report at 16.
[77] *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); 64 Fed. Reg. at 61,900 ("[MAOs] should ordinarily conduct sample audits and spot checks of this system to verify whether it is yielding accurate information.").
[78] Draft Report at 7, 17-18.
[79] *See* 65 Fed. Reg. at 40,268.
[80] *See* Draft Report at 8.
[81] *See* Anthem Report at 24.
[82] *See* 2021 Humana Report at 13; UPMC Report at 31.

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.[83] 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 to the so-called "high-risk diagnoses" identified in the Draft Report.[84] 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 coding," which "provided instructions to its providers on the proper coding of several risk adjustment diagnoses, including those in six of the eight high-risk groups reviewed in our audit."[85] 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."[86] 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

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[83] *See*, *e.g.*, 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 (Mar. 3, 2025); 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 (Mar. 4, 2024); *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).

[84] *See* Draft Report at 20 ("[OIG] communicated with 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.").

[85] *Id.* at 16.

[86] *Id.*

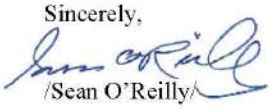
any specific high-risk diagnosis codes, including those we identified as being higher risk for being miscoded."[87] All of Humana's risk adjustment compliance processes and reviews, by their nature, include such diagnosis codes. Humana disagrees with the notion that existing CMS guidance requires a particular approach to OIG's unilaterally selected "higher-risk" areas. As explained in Section I, CMS has acknowledged that it lacks policies and procedures to guarantee that that so-called "high-risk" diagnosis codes, like acute stroke, are supported by underlying medical record documentation.[88] In the absence of specific CMS-implemented MA program requirements, Humana and other MAOs are afforded broad discretion in designing compliance and education programs.[89]

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 used for risk adjustment purposes. 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, OIG would not appropriately account for Humana's reliance on the CMS program requirements that existed during the years subject to OIG's audit. Humana therefore requests that OIG reconsider its recommendation that the Company "enhance" its risk adjustment policies and procedures.[90]

* * *

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

[87] *Id.* at 16–17.
[88] *See* Acute Stroke Audit Report at 8.
[89] *See* 65 Fed. Reg. at 40,265.
[90] Draft Report at 18.

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