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Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H5216) Submitted to CMS

REPORT HIGHLIGHTS

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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 enrollees being covered.
- To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS. Some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.
- This audit of HumanaChoice (an MA organization administered by Humana, Inc.) is part of a series of audits of 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 HumanaChoice submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements.

- For 178 of the 220 sampled enrollee-years, medical records did not support the diagnosis codes and resulted in $669,237 in overpayments.
- On the basis of our sample results, we estimated that HumanaChoice received at least $130.9 million in overpayments for 2020 and 2021.

As demonstrated by the errors found in our sample, HumanaChoice's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements could be improved.

What OIG Recommends

We made four recommendations, including that Humana, Inc., refund to the Federal Government the $130.9 million of estimated overpayments and determine, for 212 enrollee-years that we did not review in one high-risk group, whether the medical records in each case support the diagnosis for the unrelated condition and refund any resulting overpayments to the Federal Government. We also recommended that Humana, Inc., 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 that it continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that high-risk diagnosis codes comply with Federal requirements and take the necessary steps to enhance those procedures. The full recommendations are in the report.

Humana, Inc., disagreed with some of our findings and all of our recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations based in part on the characteristics of the enrollees being covered. Using a system of risk adjustment, CMS pays MA organizations the anticipated cost of providing Medicare benefits to a given enrollee, depending on such risk factors as the age, 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 56 breast cancer diagnoses into 1 group.) This audit covered HumanaChoice for contract number H5216 and focused on 11 groups of high-risk diagnosis codes for payment years 2020 and 2021.[3, 4]

OBJECTIVE

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

[1] The providers code diagnoses using the International Classification of Diseases (ICD), Clinical Modification (CM), *Official Guidelines for Coding and Reporting* (ICD Coding Guidelines). The ICD is a coding system that is used by physicians and other health care providers to classify and code all diagnoses, symptoms, and procedures.

[2] MA compliance audit reports issued by the Office of Inspector General (OIG) are published on the OIG website.

[3] HumanaChoice is a Medicare Advantage plan administered by Humana, Inc. All subsequent references to "HumanaChoice" in this report refer solely to contract number H5216. We are addressing our recommendations to Humana, Inc.

[4] The 2020 and 2021 payment year data were the most recent data available at the start of the audit.

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 traditional fee-for-service (FFS) program.[5] 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 2024, CMS paid MA organizations $494 billion, which represented 44 percent of all Medicare payments for that year.

Risk Adjustment Program

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

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

- *Base rate*: Before the start of each year, each MA organization submits bids to CMS that reflect the MA organization's estimate of the monthly revenue required to cover an enrollee with an average risk profile.[7] CMS compares each bid to a specific benchmark

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

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

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

amount for each geographic area to determine the base rate that an MA organization is paid for each of its enrollees.[8]

- *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 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).[9] Each HCC has a factor (which is a numerical value) assigned to it for use in each enrollee's risk score.

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

For enrollees who receive diagnoses that map to four or more HCCs, CMS assigns an additional factor that increases the enrollee's risk score. Additionally, for enrollees who have certain combinations of HCCs (which CMS refers to as disease interactions), CMS assigns a separate factor that will also increase the risk score. 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-

[8] 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.

[9] During our audit period, CMS calculated risk scores based on the Version 22 and Version 24 CMS-HCC models.

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.[10] Thus, if the factors used to determine an enrollee's risk score are incorrect, CMS will make an improper payment to an MA organization. Specifically, if medical 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.[11] 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 11 high-risk groups:

- *Acute stroke*: An enrollee received an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on physician claims for one to five dates of service during the service year but did not have an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim.[12] 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 a diagnosis (that mapped to the HCC for Acute Myocardial Infarction) on physician or outpatient claims for one to five dates of service 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

[10] 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. Sequestration was suspended for payment months May 2020 through March 2022, which covered 20 months of our audit period.

[11] 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 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.

[12] For all of the high-risk groups we reviewed for this audit, an enrollee could have had more than one claim (with a diagnosis code that mapped to the HCC under review) on a single date of service.

history of a myocardial infarction (which does not map to an HCC) typically should have been used.

- *Embolism*: An enrollee received a diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease With Complications (Embolism HCCs) on only one date of service 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.

- *Lung cancer*: An enrollee received a lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) on only one date of service 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 a breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one date of service 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 a colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) on only one date of service 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 a prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one date of service 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.

- *Ovarian cancer*: An enrollee received an ovarian cancer diagnosis that mapped to either the HCC for Lymphoma and Other Cancers or to the HCC for Metastatic Cancer and Acute Leukemia (Ovarian Cancer HCCs) on only one date of service during the service year but did not have surgical therapy or chemotherapy drug treatments administered

within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of ovarian cancer (which does not map to an HCC) typically should have been used.

- *Sepsis*: An enrollee received a sepsis diagnosis (that mapped to the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock) on only one date of service on a physician or outpatient claim during the service year but did not have a sepsis diagnosis on a corresponding inpatient hospital claim. A sepsis diagnosis generally results in an inpatient hospital admission.

- *Pressure ulcer*: An enrollee received a pressure ulcer diagnosis[13] that mapped to either the HCC for Pressure Ulcer of Skin With Full Thickness Skin Loss or the HCC for Pressure Ulcer of Skin With Necrosis Through to Muscle, Tendon, or Bone (Pressure Ulcer HCCs) on only one date of service during the service year but did not have a pressure ulcer diagnosis on another inpatient, outpatient, or physician claim for either the calendar year before or the calendar year after the service year. Individuals diagnosed with the most severe types of pressure ulcers generally receive treatment on multiple occasions.

- *Potentially mis-keyed diagnosis codes*: An enrollee received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition (that mapped to a possibly unvalidated HCC). For example, International Classification of Diseases (ICD)-10 diagnosis code E43 (which maps to the HCC for Protein-Calorie Malnutrition) could be mis-keyed as diagnosis code I43 (which maps to the HCC for Congestive Heart Failure and in this example would be unvalidated).[14] Using an analytical tool that we developed, we identified 3,973 scenarios in which diagnosis codes could have been mis-keyed because numbers were transposed, or other data-entry errors occurred that could have resulted in the assignment of an unvalidated HCC.

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

HumanaChoice

Humana, Inc., is an MA organization based in Louisville, Kentucky. HumanaChoice operates as a preferred provider organization that provides coverage to enrollees in multiple States and is administered by Humana, Inc. As of December 2021, HumanaChoice provided coverage under contract number H5216 to 1,730,650 enrollees. For the 2020 and 2021 payment years (audit

[13] Pressure ulcer diagnoses are categorized into five groups according to severity: stages 1, 2, 3, 4, and unstageable. For this audit, we only audited the most severe types of pressure ulcers: stages 3, 4, and unstageable.

[14] See footnote 1 for an explanation of the ICD coding system.

period), CMS paid HumanaChoice approximately $37.8 billion to provide coverage to its enrollees.[15]

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to 1 of the 11 high-risk groups during the 2019 and 2020 service years, for which HumanaChoice received increased risk-adjusted payments for payment years 2020 and 2021, respectively. Because enrollees could be classified into more than one high-risk group or could have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment year, which we refer to as "enrollee-years."

We identified 68,701 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes ($165,672,058). We selected for audit a sample of 220 enrollee-years, which consisted of: (1) a stratified random sample of 200 (out of 68,469) enrollee-years for the first 10 high-risk groups and (2) a nonstatistical sample of 20 (out of 232) enrollee-years for the remaining high-risk group.

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

Table 1: Sampled Enrollee-Years

High-Risk Group	Number of Sampled Enrollee-Years
(1) Acute stroke	20
(2) Acute myocardial infarction	20
(3) Embolism	20
(4) Lung cancer	20
(5) Breast cancer	20
(6) Colon cancer	20
(7) Prostate cancer	20
(8) Ovarian cancer	20
(9) Sepsis	20
(10) Pressure ulcer	20
Total for Stratified Random Sample	**200**
(11) Potentially mis-keyed diagnosis codes	20
Total for All High-Risk Groups	**220**

[15] All of the payment amounts that CMS made to HumanaChoice and the overpayment amounts that we identified in this report reflect the budget sequestration reduction percentages that were in effect during our audit period.

HumanaChoice provided medical records as support for the selected diagnosis codes associated with the 220 sampled enrollee-years. We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. For the HCCs that were not validated, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or if we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

We conducted this performance audit in accordance with generally accepted government auditing standards (GAGAS). 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 B contains our statistical sampling methodology, Appendix C contains our sample results and estimates, and Appendix D contains the Federal regulations regarding MA organizations' compliance programs.

FINDINGS

With respect to the 11 high-risk groups covered by our audit, most of the selected diagnosis codes that HumanaChoice submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 42 of the 220 sampled enrollee-years, the medical records validated the reviewed HCCs. For the remaining 178 enrollee-years, however, the medical records that HumanaChoice provided did not support the diagnosis codes; therefore, the associated HCCs were not validated and resulted in $669,237 in overpayments.

As demonstrated by the errors found in our sample, HumanaChoice'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 HumanaChoice received at least $130.9 million in overpayments for 2020 and 2021.[16, 17]

[16] 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.

[17] Specifically, we estimated that HumanaChoice received at least $130,922,653 of overpayments ($130,868,965 for the statistically sampled enrollee-years plus $53,688 for the nonstatistically sampled enrollee-years associated with the potentially mis-keyed diagnosis codes).

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 ICD, Clinical Modification, *Official Guidelines for Coding and Reporting* (42 CFR § 422.310(d)(1) and 45 CFR §§ 162.1002(c)(2)-(3)). Further, MA organizations must implement procedures to ensure that diagnoses come only from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities, and physicians (the Manual, chap. 7, § 40).

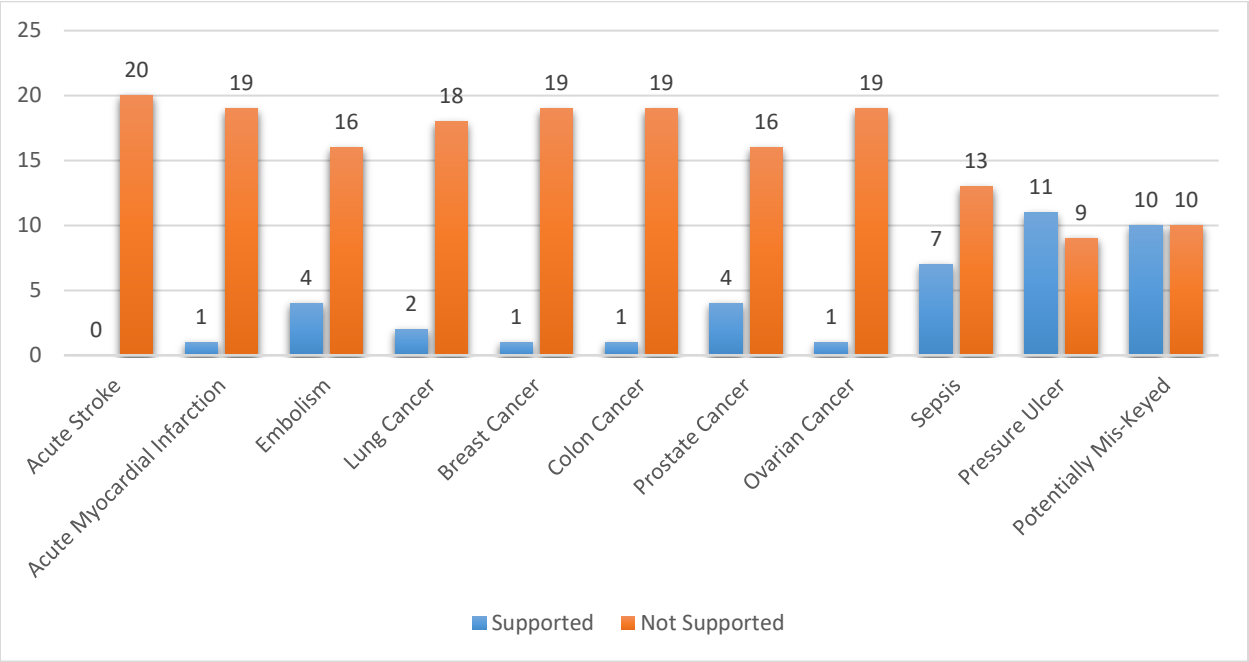
Federal regulations state that MA organizations must monitor the data that they receive from providers and submit to CMS. Federal regulations also state that MA organizations must "adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance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

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

Most of the selected high-risk diagnosis codes that HumanaChoice submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, as shown in the figure on the following page, the medical records for 178 of the 220 sampled

enrollee-years did not support the diagnosis codes. In these instances, HumanaChoice 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

HumanaChoice incorrectly submitted diagnosis codes for acute stroke for all 20 of the sampled enrollee-years. Specifically:

- For 15 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 the assignment of the HCC [for Ischemic or Unspecified Stroke]. There is documentation of a past medical history of a stroke [diagnosis] which does not result in an HCC."

- For the remaining 5 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 "there is no documentation of an acute cerebrovascular accident (CVA) that results in

the assignment of the HCC [for Ischemic or Unspecified Stroke]. There is documentation of a transient ischemic attack (TIA) which does not result in an HCC."[18]

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and HumanaChoice received $42,726 in overpayments for these 20 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Myocardial Infarction

HumanaChoice incorrectly submitted diagnosis codes for acute myocardial infarction for 19 of 20 sampled enrollee-years. Specifically:

- For 10 enrollee-years, the medical records indicated in each case that the individual had previously had an acute myocardial infarction, but the records did not justify an acute myocardial infarction diagnosis at the time of the physician's service.

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

- For 6 enrollee-years, the medical records in each case did not support an acute myocardial infarction 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, HumanaChoice should not have received an increased payment for the acute myocardial infarction diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.[19]

- For the remaining 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 results in the assignment of the HCC [for Acute Myocardial Infarction]. There is documentation of an acute myocardial contusion [diagnosis], as a result of a motor vehicle accident, which does not result in an HCC."

[18] CVA is the medical term for a stroke. A stroke occurs when blood flow to a part of the brain is stopped by either a blockage or the rupture of a blood vessel. A TIA is a temporary period of symptoms similar to those of a stroke.

[19] For 1 of these enrollee-years, we found in CMS's encounter data a diagnosis code submitted by HumanaChoice that mapped to an HCC for a less severe manifestation of the heart attack related-disease group. The less severe HCC had the same numerical factor as the HCC under review, so although we counted this sample item as an error, there was no payment effect.

As a result of these errors, the HCC for Acute Myocardial Infarction was not validated, and HumanaChoice received $30,568 in overpayments for these 19 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

HumanaChoice incorrectly submitted diagnosis codes for embolism for 16 of 20 sampled enrollee-years. Specifically:

- For 9 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 results in the assignment of [an Embolism] HCC. There is documentation of a past medical history of deep vein thrombosis [diagnosis] that does not result in an HCC."[20]

- For 6 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Embolism HCC.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of [an Embolism HCC]."

- For the remaining 1 enrollee-year, the medical record did not justify a diagnosis that mapped to the HCC for Vascular Disease With Complications at the time of the physician's service. However, we identified support for another diagnosis on CMS's systems that mapped to the HCC for Vascular Disease (a less severe manifestation of the related-disease group). Accordingly, HumanaChoice should not have received an increased payment for the embolism with complications diagnosis, but it should have received a lesser increased payment for the other embolism diagnosis identified.

As a result of these errors, the Embolism HCCs were not validated, and HumanaChoice received $47,516 in overpayments for these 16 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

HumanaChoice incorrectly submitted diagnosis codes for lung cancer for 18 of 20 sampled enrollee-years. Specifically:

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

- For 10 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 [for Lung and Other Severe Cancers]. There is documentation of a past medical history of [a] lung cancer [diagnosis] which does not result in an HCC."

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

- For the remaining 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 [for Lung and Other Severe Cancers].

As a result of these errors, the HCC for Lung and Other Severe Cancers was not validated, and HumanaChoice received $140,296 in overpayments for these 18 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

HumanaChoice incorrectly submitted diagnosis codes for breast cancer for 19 of 20 sampled enrollee-years. For all 19 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 [for Breast, Prostate, and Other Cancers and Tumors]. There is documentation of a past medical history of breast cancer [diagnosis] which does not result in an HCC."

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and HumanaChoice received $28,366 in overpayments for these 19 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

HumanaChoice incorrectly submitted diagnosis codes for colon cancer for 19 of 20 sampled enrollee-years. Specifically:

- For 15 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 [for Colorectal, Bladder, and Other Cancers]. There is documentation of a past medical history of [a] colon cancer [diagnosis] which does not result in an HCC."

- For 2 enrollee-years, the medical records in each case did not support a colon cancer diagnosis.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Colorectal, Bladder, and Other Cancers]."

- For the remaining 2 enrollee-years, the medical records in each case did not support the submitted colon cancer diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis on CMS's systems 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, HumanaChoice should not have received an increased payment for the submitted colon cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and HumanaChoice received $54,791 in overpayments for these 19 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

HumanaChoice incorrectly submitted diagnosis codes for prostate cancer for 16 of 20 sampled enrollee-years. Specifically:

- For 12 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

[for Breast, Prostate, and Other Cancers and Tumors]. There is documentation of a past medical history of [a] prostate cancer [diagnosis] which does not result in an HCC."

- For the remaining 4 enrollee-years, the medical records in each case did not support a prostate cancer diagnosis.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Breast, Prostate, and Other Cancers and Tumors]."

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and HumanaChoice received $19,563 in overpayments for these 16 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Ovarian Cancer

HumanaChoice incorrectly submitted diagnosis codes for ovarian cancer for 19 of 20 sampled enrollee-years. Specifically:

- For 13 enrollee-years, the medical records indicated in each case that the individual had previously had ovarian cancer, but the records did not justify an ovarian 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 [an Ovarian Cancer] HCC. There is documentation of a past medical history of [an] ovarian cancer [diagnosis] which does not result in an HCC."

- For 4 enrollee-years, the medical records in each case did not support an ovarian 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 [an Ovarian Cancer] HCC."

- For the remaining 2 enrollee-years, the medical records in each case did not support the submitted ovarian cancer diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis on CMS's systems 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, HumanaChoice should not have received an increased payment for the submitted ovarian cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

As a result of these errors, the Ovarian Cancer HCCs were not validated, and HumanaChoice received $124,924 in overpayments for these 19 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Sepsis

HumanaChoice incorrectly submitted diagnosis codes for sepsis for 13 of 20 sampled enrollee-years. Specifically:

- For 11 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 assignment of the HCC [for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock]."

- 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 justify a sepsis diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock]. There is documentation of a past medical history of [a] 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 HumanaChoice received $47,093 in overpayments for these 13 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Pressure Ulcer

HumanaChoice incorrectly submitted diagnosis codes for pressure ulcer for 9 of 20 sampled enrollee-years. Specifically:

- For 5 enrollee-years, the medical records in each case did not support the submitted pressure ulcer diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to the HCC for Chronic Ulcer of Skin, Except Pressure, which is a less severe manifestation of the related-disease group. Accordingly, HumanaChoice should not have received an increased payment for the submitted pressure ulcer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

- For the remaining 4 enrollee-years, the medical records in each case did not support a pressure ulcer diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Pressure Ulcer of Skin with Full Thickness Skin Loss]."

As a result of these errors, the Pressure Ulcer HCCs were not validated, and HumanaChoice received $79,706 in overpayments for these 9 sampled enrollee-years.

Potentially Mis-keyed Diagnosis Codes

HumanaChoice submitted potentially mis-keyed diagnosis codes for 10 of 20 sampled enrollee-years. In each of these cases, the individuals associated with the enrollee-years received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition. Specifically:

- For 4 enrollee-years, the medical records in each case did not support the diagnosis for the unrelated condition. Because of these errors, HumanaChoice submitted to CMS unsupported diagnosis codes that mapped to unvalidated HCCs.

  For example, for 1 enrollee-year, HumanaChoice submitted five diagnosis codes for malignant neoplasm of prostate[21] (C61) and only one diagnosis code for pneumoconiosis due to asbestos and other mineral fibers[22] (J61). The independent medical review contractor limited its review to the diagnosis code for pneumoconiosis due to asbestos and other mineral fibers, for which it did not find support. The independent medical review contractor noted that "there is no documentation of any condition that results in the assignment of the HCC [for Fibrosis of Lung and Other Chronic Lung Disorders]. Asbestosis is listed in the problem list; however, there is no documentation in the progress note to support that the condition was monitored, evaluated, assessed, or treated."

- For 4 enrollee-years, the medical records indicated in each case that the individual had previously had the unrelated condition, but the records did not justify the unrelated diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, HumanaChoice submitted three diagnosis codes for pneumoconiosis due to asbestos and other mineral fibers (J61) and one diagnosis code for malignant neoplasm of prostate (C61). The independent medical review contractor limited its review to the diagnosis code for malignant neoplasm of prostate, for which it did not find support. The independent medical review contractor noted that "there is no documentation of any condition that results in the assignment of the HCC [for Breast,

[21] Malignant neoplasm of prostate is the medical term for cancer of the prostate.

[22] Pneumoconiosis due to asbestos and other mineral fibers is a lung disease caused by breathing in particles of asbestos (a group of minerals that take the form of tiny fibers).

Prostate, and Other Cancers and Tumors]. There is documentation of a past medical history of prostate cancer [diagnosis] which does not result in an HCC."

- For the remaining 2 enrollee-years, the medical records in each case did not support the diagnosis for the unrelated condition. However, 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, HumanaChoice should not have received an increased payment for the submitted unrelated diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.[23]

Appendix E contains the HCCs that were not validated for the 10 enrollee-years (Table 6) and the HCC for the less severe manifestation of the related-disease group that was supported for the 2 enrollee-years (Table 7).

As a result of these errors, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated, and HumanaChoice received $53,688 of overpayments for these 10 sampled enrollee-years.

Summary of Incorrectly Submitted Diagnosis Codes

In summary, and with respect to the 11 high-risk groups covered by our audit, HumanaChoice received $669,237 in overpayments for 178 of the 220 sampled enrollee-years.

THE POLICIES AND PROCEDURES THAT HUMANACHOICE 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 HumanaChoice 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.

HumanaChoice had compliance procedures in place to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. Specifically, HumanaChoice had preventative techniques in place, including a provider education program designed to promote accurate diagnosis coding. Further, HumanaChoice had provided instructions to providers on the proper coding of several risk adjustment diagnoses, including those in 9 of the 11 high-risk groups reviewed in our audit (acute stroke, acute myocardial infarction, embolism, lung cancer, breast cancer, colon cancer, ovarian cancer, prostate cancer, and pressure ulcer).

[23] For 1 of these enrollee-years, we found in CMS's encounter data a diagnosis code submitted by HumanaChoice that mapped to an HCC for a less severe manifestation of the related-disease group. The less severe HCC had the same numerical factor as the HCC under review, so although we counted this sample item as an error, there was no payment effect.

In addition, HumanaChoice provided guidance to its coders to evaluate diagnosis coding accuracy for several risk adjustment diagnoses, including those in the same nine high-risk groups listed just above. Moreover, HumanaChoice'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 in the associated medical records. However, these 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 HumanaChoice had compliance procedures in place during the audit period that were 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 178 of the 220 sampled enrollee-years were not supported by medical records, we believe that HumanaChoice's compliance procedures to prevent, detect, and correct incorrect high-risk diagnosis codes could be improved.

HUMANACHOICE 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 HumanaChoice received at least $130,922,653 in overpayments for our audit period.

RECOMMENDATIONS

We recommend that Humana, Inc.:

- refund to the Federal Government the $130,922,653 of estimated overpayments;[24]

- determine, for the 212 enrollee-years that we did not review in the potentially mis-keyed diagnosis code high-risk group, whether the medical records in each case support the diagnosis for the unrelated condition and refund any resulting overpayments to the Federal Government;

- 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

[24] 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 CMS's 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 Risk Adjustment Data Validation (RADV) appeals process.

- continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

HUMANA, INC., COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Humana, Inc., responding on behalf of HumanaChoice, disagreed with some of our findings and all of our recommendations.[25] Specifically, Humana did not agree with our findings for 69 of the 187 enrollee-years identified as errors in our draft report and provided additional information for our consideration. (See footnote 26 later in this report.) Humana did not state whether it agreed or disagreed with our findings for the remaining 118 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. Furthermore, Humana said that MA organizations are not required to conduct audits to the standards that we suggest and added that its compliance program satisfies all legal and regulatory requirements.

With respect to our first recommendation, we reviewed Humana's comments and the additional information that it provided and reduced the number of enrollee-years in error from 187 (in our draft report) to 178 and adjusted our calculation of overpayments for this final report. Accordingly, we reduced the recommended refund in our first recommendation from $134,651,888 to $130,922,653. We maintain that our second, third, and fourth recommendations remain valid.

A summary of Humana's comments and our responses follows. Humana's comments appear as Appendix F. We excluded an attachment (which Humana identified as "Appendix A" in its comments) because it contained personally identifiable information. We are separately providing Humana's comments in their entirety to CMS.

[25] HumanaChoice is administered by Humana, Inc.

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

Humana Did Not Agree With OIG's Findings for 69 Sampled Enrollee-Years

Humana Comments

Humana did not agree with our draft report findings for 69 sampled enrollee-years (as shown in Table 2) and requested that we reconsider our findings and modify our estimate of overpayments.[26]

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

High-Risk Group	Number of Sampled Enrollee-Years
Lung Cancer	**11**
Ovarian Cancer	**11**
Acute Stroke	**9**
Embolism	**7**
Colon Cancer	**6**
Potentially Mis-keyed	**6**
Breast Cancer	**5**
Prostate Cancer	**5**
Acute Myocardial Infarction	**4**
Sepsis	**3**
Pressure Ulcer	**2**
Total	**69**

OIG Response

Our independent medical review contractor reviewed the additional information that Humana provided for the 69 enrollee-years.

- For 54 of the 69 enrollee-years, our independent medical review contractor reaffirmed that the HCCs were not validated.

[26] For 68 sampled enrollee-years, Humana did not agree with the findings in our draft report and provided additional information along with its comments on our draft report. During our audit, HumanaChoice submitted a medical record for 1 additional sampled enrollee-year after the medical review period had closed. Although Humana did not specifically disagree with our finding for this enrollee-year in its comments on our draft report, we considered Humana's position on this finding, for purposes of this final report, as a disagreement. In total, therefore, Humana disagreed with our findings for 69 sampled enrollee-years.

- For 9 of the 69 enrollee-years, our contractor found support for the audited HCCs and therefore reversed its original decision and validated the HCCs.[27]

  For example, for 1 enrollee-year from the sepsis high-risk group, Humana cited the medical record's reference to a severe sepsis with septic shock diagnosis that maps to the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock. After reviewing Humana's explanation for this enrollee-year, our contractor reversed its original decision. The contractor stated: "Decision reversed at reconsideration; agree with auditee. There is documentation of a diagnosis of sepsis . . . which results in [the] HCC [for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock]."

- For the remaining 6 enrollee-years, Humana requested that we consider an HCC for a less severe manifestation of the related-disease group. Our draft report calculations already reflected the less severe HCC for 4 of these enrollee-years. For the remaining 2 enrollee-years, the contractor did not validate, and we did not identify support for, another diagnosis on CMS's systems that mapped to the HCC for a less severe manifestation of the related-disease group. Therefore, we did not make any changes for these 6 enrollee-years.

Accordingly, we revised some of our findings and reduced the number of enrollee-years in error from 187 (in our draft report) to 178 for this final report. We also reduced the associated statistical estimates and monetary recommendation.

The independent medical review contractor confirmed that its review of the additional information that Humana gave to us had no impact on the decisions that the contractor had made for the other sampled enrollee-years with which Humana neither agreed nor disagreed.

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." Humana added that "OIG and the MA industry therefore appear to be at an impasse on this critical issue." In this regard, Humana made two related points:

[27] The 9 enrollee-years were in the following high-risk groups: embolism (2), prostate cancer (2), sepsis (1), pressure ulcer (1), lung cancer (1), ovarian cancer (1), and breast cancer (1).

- For the enrollee-years that we sampled, 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 added that "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."

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, as amended, 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 GAGAS, 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 HumanaChoice'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 HumanaChoice could have submitted on behalf of the sampled enrollee-years and (2) enrollee-years for which HumanaChoice 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 B and C, 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 HumanaChoice 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 HumanaChoice submitted to CMS. If our contractor identified a diagnosis code that HumanaChoice 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 GAGAS.

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, it said, 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. Humana stated that 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 added 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 calendar year 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 initiated "an ultimately successful" lawsuit challenging CMS's Final RADV Rule as "arbitrary and capricious." Further, Humana stated that, in its bid to CMS for payment years 2020 and 2021, it notified CMS that it was "relying on CMS's plan to develop and apply an FFSA as part of any RADV process." Humana said, "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 a U.S. District Court vacated and remanded the final rule.[28] 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 statement that it is "misleading, arbitrary and capricious" for us to issue an audit report that both identifies estimated overpayments and

[28] *Humana Inc. v. Becerra, 801 F.Supp.3d 624 (N.D. Tex. 2025)* (accessed on Aug. 25, 2026).

recognizes (based on our awareness of the need for CMS to address statutory requirements) that CMS will make certain determinations regarding an actual overpayment amount. 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, as amended, 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 24.)

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 in the use of our repayment calculation methodologies in our Toolkit[29] and in other audits. Humana noted that we released our Toolkit to enable MA organizations to identify and evaluate high-risk diagnosis codes but said 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 additionally commented that our recently published Medicare Advantage Industry Segment-Specific Compliance Program Guidance[30] "remains voluntary" and "is overly broad and ambiguous, such that Humana and other industry participants are left without actionable guidance."

Humana also stated that although our Toolkit identified eight high-risk groups of diagnosis codes, "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.

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

[30] Medicare Advantage Industry Segment-Specific Compliance Program Guidance, February 2026.

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 B, 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 HumanaChoice at the beginning of the audit.

Moreover, 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.

Similarly, the Medicare Advantage Industry Segment-Specific Compliance Program Guidance serves as OIG's updated and centralized source of voluntary compliance program guidance for the MA program. MA organizations and other entities can use this document to help identify their own risks and implement an effective compliance and quality program to reduce those risks.

Our hope is that MA organizations use the Toolkit and the program guidance as starting points to enhance their compliance programs.

Humana Stated 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 added 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 who can consult a physician to act as a "tiebreaker" in instances when two coders disagree. Humana stated that we 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 said that it believes that the number of HCCs that we determined to be unsubstantiated would be reduced if we followed CMS's coding methodology.

- Humana also stated that "it is unclear what specific diagnosis coding guidance" our independent medical review contractor followed and that 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 standards, 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').[31]

OIG Response

As stated earlier, our audits are intended to provide an independent assessment of HHS programs and operations in accordance with the Inspector General Act of 1978, as amended, 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

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

HumanaChoice that our contractor performed its review to determine whether diagnoses were coded according to applicable ICD Coding Guidelines and the *CMS Medicare Advantage Contract-Specific Risk Adjustment Data Validation Audit Method and Instructions* as of November 14, 2024. MA organizations that contract with CMS must agree to follow CMS's instructions, including the provisions of the Manual.[32] In accordance with the Manual, all submitted diagnosis codes must be documented in the medical record and be documented as a result of a face-to-face encounter. Further, the Manual also requires that diagnoses must be coded according to the ICD Coding Guidelines.[33] Thus, we complied with applicable Federal requirements when conducting our reviews. In addition, as previously stated, our contractor reviewed all medical records that HumanaChoice submitted to determine whether the reviewed HCCs were supported in the medical records. With respect to the "chronic condition" example that Humana cited, our contractor's methodology complied with applicable CMS guidance.

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

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

Humana Comments

Humana disagreed with how we calculated our estimated overpayments. Specifically, Humana stated that we "used the lower limit of a two-sided [90-percent] confidence interval when estimating the total amount of net overpayments" instead of "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. Humana said that therefore, "[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

[32] 42 CFR § 422.504(a).

[33] The Manual, chap. 7, § 40.

valid methodology, not the most precise methodology.[34] 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 HumanaChoice 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,[35] 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 REVIEW AND REFUND OVERPAYMENTS FOR THE 212 ENROLLEE-YEARS IN THE POTENTIALLY MIS-KEYED DIAGNOSIS HIGH-RISK GROUP

Humana Comments

Humana requested that we reconsider our second recommendation. Specifically, Humana stated that we did not "provide which diagnosis codes" we believed were "transposed" and what led us to believe that a potential mis-keying error had occurred.

In addition, Humana stated that although MA organizations are required to monitor data submitted to CMS, neither Federal regulations nor CMS's subregulatory guidance requires MA organizations to replicate audits initiated by OIG or to apply specific methods beyond making "good faith efforts" to ensure data accuracy. Humana also stated that it cannot be expected to replicate our review process for the 212 enrollee-years that we did not review "based on the few examples" provided in our draft report.

OIG Response

We maintain that our second recommendation remains valid. Our audit found errors in 10 of the 20 sampled enrollee-years in this high-risk group, demonstrating a material pattern of incorrect submissions and further supporting the need for Humana to complete its review of the remaining 212 enrollee-years.

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

[35] 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 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).

As defined in the draft report, we identified potentially mis-keyed diagnosis codes in cases when an enrollee received multiple diagnoses for one condition but only a single diagnosis for an unrelated condition that mapped to a possibly unvalidated HCC. Before we issued the draft report, we provided HumanaChoice with detailed enrollee-level information for this high-risk group, including a field identifying the diagnosis codes that met the criteria for potentially mis-keyed entries.

In response to Humana's comments on our draft report, we have supplemented this information by giving HumanaChoice details on additional data fields that specify the diagnosis codes and HCCs associated with the enrollees' documented condition patterns. We have also provided HumanaChoice with the analytical tool we used to identify the 3,973 ICD-10 scenarios in which a mis-keyed or transposed entry could result in assignment of an incorrect HCC, as described in Appendix A.

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 third 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."

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.[36]

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

[36] The OIG guidance to which Humana referred (in footnote 74 of its comments) appeared in 64 Fed. Reg. at 61,900 (Nov. 15, 1999), "*Publication of the OIG's Compliance Program Guidance for Medicare+Choice* [i.e., Medicare Advantage] *Organizations Offering Coordinated Care Plans*."

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 third 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." Humana added that thus, our third recommendation "conflicts with CMS's regulations and guidance" and imposes new regulatory requirements. Humana added that new requirements should 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 statements, we believe that our third recommendation conforms to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (Appendix D)) and, accordingly, does not create a new requirement that would be subject to notice-and-comment rulemaking.

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 HumanaChoice'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 (178 of 220 enrollee-years (Appendix C)) demonstrates that HumanaChoice 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 third 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 fourth 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. According to Humana, our statement that the errors identified in our audit demonstrate that Humana's policies and procedures could be improved imposes a "perfection standard that CMS and OIG have previously recognized is not reasonable to enforce . . . ."

Humana also stated that it is unclear from our recommendations in previous reports 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;" while in a 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 added 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

Our audit focused on diagnosis codes that we determined to be at high risk for being miscoded, and the results revealed substantial issues in these areas. We acknowledge that HumanaChoice had compliance procedures in place to promote the accuracy of diagnosis codes submitted to CMS—including procedures relevant to the high-risk diagnosis codes reviewed.

Although, according to Humana, it has never been informed by CMS of deficiencies in HumanaChoice's compliance program, we continue to believe that the opportunity exists for HumanaChoice to 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 to "[correct] such problems promptly and thoroughly to reduce the potential for recurrence" (42 CFR § 422.503(b)(4)(vi)(G) (Appendix D)). Improvement of HumanaChoice's existing procedures, based on both the results of this audit and the results of HumanaChoice's internal medical reviews, will assist HumanaChoice 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 fourth recommendation is valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid HumanaChoice $37,754,493,932 to provide coverage to its enrollees for 2020 and 2021. We identified 68,701 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2019 and 2020 service years. HumanaChoice received $1,229,361,422 in payments from CMS for these enrollee-years for 2020 and 2021. We selected for audit 220 enrollee-years with payments totaling $4,556,436.

The 220 enrollee-years included 20 acute stroke diagnoses, 20 acute myocardial infarction diagnoses, 20 embolism diagnoses, 20 lung cancer diagnoses, 20 breast cancer diagnoses, 20 colon cancer diagnoses, 20 prostate cancer diagnoses, 20 ovarian cancer diagnoses, 20 sepsis diagnoses, 20 pressure ulcer diagnoses and 20 potentially mis-keyed diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $984,950 for our sample.

Our audit objective did not require an understanding or assessment of HumanaChoice'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 January 2024 through January 2026.

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:

    - 96 diagnosis codes for acute stroke,
    - 16 diagnosis codes for acute myocardial infarction,
    - 74 diagnosis codes for embolism,
    - 17 diagnosis codes for lung cancer,
    - 56 diagnosis codes for breast cancer,

- 10 diagnosis codes for colon cancer,
- 1 diagnosis code for prostate cancer,
- 11 diagnosis codes for ovarian cancer,
- 30 diagnosis codes for sepsis, and
- 50 diagnosis codes for pressure ulcer.

- We developed an analytical tool that identified 3,973 scenarios in which an ICD-10 diagnosis code, when mis-keyed into an electronic claim because of a data transposition or other data-entry error, could result in the assignment of an incorrect HCC to an enrollee's risk score. For each of the 3,973 scenarios, the tool identified a diagnosis code as well as the potentially mis-keyed diagnosis code. Accordingly, we considered the potentially mis-keyed diagnosis codes to be high risk.

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

  - Risk Adjustment Processing System (RAPS)[37] and Encounter Data System (EDS)[38] to identify enrollees who received high-risk diagnosis codes from a physician during the service years,

  - Risk Adjustment System (RAS)[39] to identify enrollees who received an HCC for the high-risk diagnosis codes,

  - Medicare Advantage Prescription Drug System (MARx)[40] to identify enrollees for whom CMS made monthly Medicare payments to HumanaChoice before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix B),

  - EDS[41] to identify enrollees who received specific procedures, and

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

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

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

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

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

- Prescription Drug Event (PDE) file[42] to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.

- We interviewed HumanaChoice officials to gain an understanding of: (1) the policies and procedures that HumanaChoice followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) HumanaChoice's monitoring of those diagnosis codes to detect and correct noncompliance with Federal requirements.

- We identified 68,701 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes for the 2019 and 2020 service years.

- We selected for audit a sample of 220 enrollee-years, which consisted of:

  - a stratified random sample of 200 (out of 68,469) enrollee-years for the first 10 high-risk groups, and

  - a nonstatistical sample of the 20 (out of 232) enrollee-years for the potentially mis-keyed high-risk group (Appendix B).[43]

- We used an independent medical review contractor to perform a coding review for the 220 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.[44]

- The independent medical review contractor's coding review followed a specific process to determine whether there was support for a diagnosis code and the associated HCC:

  - If the first senior coder found support for the diagnosis code on the medical record(s), the HCC was considered validated.

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

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

[43] We selected the 20 enrollee-years that we had identified as some of the most frequently occurring diagnosis codes for the HCCs under review.

[44] 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.

        - 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, the coding supervisor's decision became the final determination. Additionally, at any point in the review process, a senior coder or coding supervisor may have consulted a physician reviewer for additional clarification.

- We used the results of the independent medical review contractor, and CMS's systems, to calculate overpayments or underpayments (if any) for each enrollee-year. Specifically, we calculated:

    - a revised risk score in accordance with CMS's risk adjustment program and

    - the payment that CMS should have made for each enrollee-year.

- We estimated the total overpayment made to HumanaChoice for the high-risk groups included in the sampling frame for recovery purposes.

- We discussed the results of our audit with Humana, Inc., officials.

We conducted this performance audit in accordance with GAGAS. 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: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified HumanaChoice enrollees who: (1) were continuously enrolled in HumanaChoice throughout all of the 2019 or 2020 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 2019 or 2020 or in January of the following year, and (3) received a high-risk diagnosis during 2019 or 2020 that caused an increased payment to HumanaChoice for 2020 or 2021, respectively.

We presented the data for these enrollees to HumanaChoice 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 HumanaChoice. After we performed these steps, our finalized sampling frame consisted of 68,469 enrollee-years.

SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2020 or 2021.

SAMPLE DESIGN AND SAMPLE SIZE

The design for our statistical sample comprised of 10 strata of enrollee-years. For the enrollee-years in each respective stratum, each individual received:

- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on physician claims for one to five dates of service during the service year but did not have an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim (31,137 enrollee-years);

- an acute myocardial infarction diagnosis (that mapped to the HCC for Acute Myocardial Infarction) on physician or outpatient hospital claims for one to five dates of service 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 (14,395 enrollee-years);

- an embolism diagnosis (that mapped to an Embolism HCC) on only one date of service during the service year but did not have an anticoagulant medication dispensed on his or her behalf (2,968 enrollee-years);

- a lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) on only one date of service 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 (1,527 enrollee-years);

- a breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one date of service 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 (6,610 enrollee-years);

- a colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) on only one date of service 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 (2,474 enrollee-years);

- 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 date of service 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 (4,743 enrollee-years);

- an ovarian cancer diagnosis (that mapped to an Ovarian Cancer HCC) on only one date of service during the service year but did not have surgical therapy or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (451 enrollee-years);

- a sepsis diagnosis (that mapped to the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock) on only one date of service on a physician or outpatient claim during the service year but did not have a sepsis diagnosis on a corresponding inpatient hospital claim (3,688 enrollee years); or

- a pressure ulcer diagnosis (that mapped to a Pressure Ulcer HCC) on only one date of service during the service year but did not have a pressure ulcer diagnosis on another inpatient, outpatient, or physician claim for either the calendar year before or the calendar year after the service year (476 enrollee-years).

The specific strata are shown in Table 3 on the following page.

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	31,137	$67,785,211	20
2 – Acute myocardial infarction	14,395	30,483,049	20
3 – Embolism	2,968	8,986,213	20
4 – Lung cancer	1,527	13,049,438	20
5 – Breast cancer	6,610	9,446,073	20
6 – Colon cancer	2,474	6,978,442	20
7 – Prostate cancer	4,743	6,693,470	20
8 – Ovarian cancer	451	2,976,776	20
9 – Sepsis	3,688	13,107,940	20
10 – Pressure ulcer	476	4,955,475	20
Total – First 10 Strata	**68,469**	**$164,462,087**	**200**

After we selected the 200 enrollee-years, we identified an additional group of 232 enrollee-years, from which we nonstatistically selected 20 enrollee-years that represented individuals who received 1 of the 3,973 potentially mis-keyed diagnosis codes (which mapped to a potentially unvalidated HCC) and multiple instances of diagnosis codes for unrelated conditions. Thus, we selected for audit a total of 220 enrollee-years.

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We sorted the items in each stratum by the enrollee-year (a combination of the enrollee identifier and the payment year being reviewed), then consecutively numbered the items in each stratum in the stratified sampling frame. After generating 200 random numbers according to our sample design, we selected the corresponding frame items for review. We also selected a nonstatistical sample of 20 items, which we had identified as some of the most frequently occurring diagnosis codes for the HCCs under review, from the potentially mis-keyed group (footnote 43).

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to estimate the total amount of overpayments in the sampling frame made to HumanaChoice at the lower limit of the two-sided 90-percent

confidence interval (Appendix C). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Details and Results

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	31,137	$67,785,211	20	$42,726	20	$42,726
2 – Acute myocardial infarction	14,395	30,483,049	20	44,001	19*	30,568
3 – Embolism	2,968	8,986,213	20	63,621	16	47,516
4 – Lung cancer	1,527	13,049,438	20	165,993	18	140,296
5 – Breast cancer	6,610	9,446,073	20	29,836	19	28,366
6 – Colon cancer	2,474	6,978,442	20	60,811	19	54,791
7 – Prostate cancer	4,743	6,693,470	20	25,334	16	19,563
8 – Ovarian cancer	451	2,976,776	20	152,238	19	124,924
9 – Sepsis	3,688	13,107,940	20	70,114	13	47,093
10 – Pressure Ulcer	476	4,955,475	20	227,819	9	79,706
Totals for Statistical Sample	**68,469**	**$164,462,087**	**200**	**$882,493**	**168**	**$615,549**
11 – Potentially mis-keyed diagnoses	232	1,209,971	20	102,457	10*	**$53,688**
Totals – All	**68,701**	**$165,672,058**	**220**	**$984,950**	**178**	**$669,237**

* For 1 of these enrollee-years, there was no payment effect.

Table 5: Estimated Overpayments in the Sampling Frame
(Limits Calculated at the 90-Percent Confidence Level)

	Estimated Overpayments for Statistically Sampled High-Risk Groups	Overpayment for Potentially Mis-keyed Diagnosis Group	Total Estimated Overpayments
Point estimate	$140,472,949	$53,688	$140,526,637
Lower limit	130,868,965	53,688	130,922,653
Upper limit	150,076,933	53,688	150,130,621

APPENDIX D: 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 E: BREAKOUT OF POTENTIALLY MIS-KEYED DIAGNOSIS CODES

Table 6: Potentially Mis-keyed Diagnosis Codes and Associated Overpayments

Number of Sampled Enrollee-Years	One Diagnosis for a Condition (Determined To Be Incorrect)		Multiple Diagnoses for a Condition (Not Reviewed)		Overpayments for HCCs That Were Not Validated
	Diagnosis Code	Diagnosis Code Description	Diagnosis Code	Diagnosis Code Description	
2	G10	Huntington's disease	I10	Essential (primary) hypertension	$8,087
2	C61	Malignant neoplasm of prostate	J61	Pneumoconiosis due to asbestos and other mineral fibers	$2,710
1	K739	Chronic hepatitis, unspecified	I739	Peripheral vascular disease, unspecified	$311
1	C7800	Secondary malignant neoplasm of unspecified lung	E7800	Pure hypercholesterolemia, unspecified	$8,523
1	J61	Pneumoconiosis due to asbestos and other mineral fibers	C61	Malignant neoplasm of prostate	$2,033
1	I629	Nontraumatic intracranial hemorrhage, unspecified	G629	Polyneuropathy, unspecified	$0
1	C782	Secondary malignant neoplasm of pleura	E782	Mixed hyperlipidemia	$28,892
1	C184	Malignant neoplasm of transverse colon	N184	Chronic kidney disease, stage 4 (severe)	$3,132
10					**$53,688**

Table 7: Hierarchical Condition Categories (HCCs) That Were Not Validated, However, Support Was Found for a Different HCC

Count of Sampled Enrollee-Years*	More Severe Hierarchical Condition Category That Was Not Validated	Less Severe Hierarchical Condition Category That Was Supported on CMS's Systems
1	Metastatic Cancer and Acute Leukemia	Lung and Other Severe Cancers
1	Cerebral Hemorrhage	Ischemic or Unspecified Stroke

*The 2 enrollee-years identified in Table 7 are a subset of the enrollee-years in Table 6.

APPENDIX F: HUMANA, INC., COMMENTS

Humana.

March 27, 2026

James Barton
Acting Regional Inspector General for Audit Services
Office of Audit Services, Region V
233 North Michigan Avenue, Suite 802
Chicago, IL 60601

VIA EMAIL

RE: Humana's Response to Draft Audit Report No. A-05-24-00010

Dear Mr. Barton:

Humana 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-05-24-00010, entitled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H5216) Submitted to CMS* (the "Draft Report"). As detailed below, Humana respectfully submits that OIG should not finalize the Draft Report's four 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 Humana Health Benefit of Louisiana, (Contract H1951) Submitted to CMS*[1] *and Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS.*[2]

Humana takes great pride in what the Company believes to be its 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 aware, Humana's policies and procedures not only extend to the so-called "high-risk diagnosis

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[1] *See* HHS-OIG, Audit Report No. A-06-21-02001, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes Humana Health Benefit of Louisiana (Contract H1951) Submitted to CMS* (Dec. 2025), *available at* https://oig.hhs.gov/documents/audit/11315/A-06-21-02001.pdf ("Humana HBL Report").

[2] *See* HHS-OIG, Audit Report No. A-05-19-00013 , *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS* (Apr. 2023), *available at* https://oig.hhs.gov/documents/audit/7849/A-05-19-00013-Complete%20Report.pdf.

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 recently published "Medicare Advantage Industry Segment-Specific Compliance Program Guidance" which updates the "last published compliance program guidance for the MA program in 1999."[4] Despite HHS-OIG's efforts to improve its prior compliance program guidance, HHS-OIG's "tool" remains "voluntary [and] nonbinding"—effectively, directing MAOs to identify "their own risk areas."[5] HHS-OIG further instructed MAOs to review existing laws and regulations impacting MA for up-to-date information about their relevant legal obligations, yet simultaneously recognized that "[a]dhering to legal obligations and avoiding pitfalls can present challenges in the complex and evolving MA program."[6]

Moreover, HHS-OIG's updated guidance critically lacks the specificity that MAOs and other industry participants have sought for decades. HHS-OIG identified a number of "potentially fraudulent and abusive conduct" relating to risk adjustment, such as (1) "using chart reviews to identify additional diagnoses that increased risk scores inappropriately" and "failing to remove diagnosis codes previously submitted . . . when chart reviews provide information that those codes were unsupported;" (2) "conducting in-home HRAs to generate additional diagnoses

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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, *Medicare Advantage Industry Segment-Specific Compliance Program Guidance* ("2026 ICPG Guidance") at 7 (Feb. 2026), available at https://oig.hhs.gov/documents/compliance/11464/ma-icpg.pdf (noting that the last guidance published in 1999 "continue[s] to be available . . . as an archived source"); *see also* 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).

[5] 2026 ICPG Guidance at 5.

[6] *Id.* at 6.

that were not considered in the care, treatment, or management of the enrollees or that were otherwise unsupported;" (3) "querying physicians via electronic medical record platforms . . . or otherwise prompting physicians to add risk-adjusting diagnoses that patients did not have;" and (4) "submitting diagnoses that were not supported by the enrollees' medical records to inflate the payments MAOs made" particularly those relating to high-risk diagnosis codes.[7] Merely identifying these practices without substantively tackling the ambiguous, underlying core standards and requirements fails to provide industry participants with actionable guidance. HHS-OIG, for example, provides no clarity on what it means for a chart review to "provide information" that previously submitted diagnosis codes were "unsupported" or "invalid."[8] Similarly, HHS-OIG does not elaborate on what it means for chart reviews to identify additional codes that increase risk scores "inappropriately."[9] OIG itself further caveated these risk areas, warning that its identification of these risk areas is "not intended to imply that the practice or activity is necessarily illegal in all circumstances."[10] OIG's instruction for MAOs to take "appropriate corrective actions" and implement additional oversight steps is overly broad and ambiguous, such that Humana and other industry participants are left without actionable guidance.

As to the high-risk codes, OIG's December 2023 "Toolkit To Help Decrease Improper Payments in Medicare Advantage Through the Identification of High-Risk Diagnosis Codes" ("Toolkit"), similarly lacks the much-needed direction Humana and other industry participants have been seeking for decades.[11] 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."[12] The Toolkit also has significant technical limitations, as further discussed in Section II.4 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.[13] MAOs are instead afforded broad discretion in designing compliance and education programs.[14] Indeed, Humana has several programs in place to enhance the accuracy of risk adjustment data, consistent with MA program requirements and OIG's guidance.[15]

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[7] *Id.* at 20.
[8] *Id.*
[9] *Id.*
[10] *Id.* at 10.
[11] HHS-OIG, Toolkit To Help Decrease Improper Payments in Medicare Advantage Through the Identification of High-Risk Diagnosis Codes ("Toolkit"), at 1 (Dec. 2023).
[12] *Id.* at 2.
[13] 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").
[14] *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.").
[15] *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

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.[16] 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.[17]

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 $134,651,888 in extrapolated estimated overpayments for the 220 sampled enrollee-

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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.").

[16] *See* Draft Report at 4–6.

[17] During Humana's Exit Conference with the OIG auditors for H5216, 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 HBL Report at 19; 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* at 18-20 (Sept. 2024), *available at* https://oig.hhs.gov/documents/audit/10008/A-02-22-01001.pdf ("Humana Health Plan Report"); 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").

years.[18] OIG further recommend that Humana "determine, for the 212 enrollee-years that we did not review in the potentially mis-keyed diagnosis code high-risk group, whether the medical records in each case support the diagnosis for the unrelated condition and refund any resulting overpayments to the Federal Government."[19] 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."[20] Humana has provided OIG with 68 appeals[21] 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, Systemic Inflammatory Response Syndrome/Shock (HCC v22 2), Vascular Disease (HCC v22 108), Metastatic Cancer and Acute Leukemia (HCC v22 8), Lung and Other Severe Cancers (HCC v22 9), Lymphoma and Other Cancers (HCC v22 10), Colorectal, Bladder, and Other Cancers (HCC v22 11), Breast, Prostate, and Other Cancers and Tumors (HCC v22 12), Pressure Ulcer of Skin with Full Thickness Skin Loss (HCC v22 158), and various diagnoses within the Flipped Diagnoses category. 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.[22]

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 repayment amounts.

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[18] Draft Report at 19 .
[19] *Id.*
[20] AHA Coding Clinic, Fourth Quarter 2016, p. 147.
[21] The 68 appeals represent 68 sampled enrollee-years.
[22] *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."); *Section I.A.19*, ICD-10-CMS Official Guidelines for Coding and Reporting – FY 2026 (Oct. 1, 2025), *available at* https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2026/ICD-10-CM-October-2025-Guidelines.pdf (same).

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.[23] 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.[24] 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."[25] Following this approach, OIG determined that "HumanaChoice received at least $134,651,888 in overpayments" in 2020 and 2021 payment years.[26] But Humana was tasked only with supplying medical records to substantiate specific HCCs actually submitted to

[23] 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 $134.6 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.

[24] Humana HBL Report at 20-21; 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.

[25] Draft Report at 24 (Appendix A).

[26] *Id.* at 19.

CMS, not to collect and submit medical records to substantiate all HCCs that *could have been* submitted to CMS (*i.e.*, potential underpayments).[27]

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. 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.[28] 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.[29]

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.[30] 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.[31] The Actuarial Standards of Practice ("ASOPs"), especially ASOP No. 45, necessarily govern these actuarial calculations.[32]

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

[27] 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.
[28] *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)).
[29] *See* Government Auditing Standards; Information Quality Guidelines.
[30] *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i).
[31] *See* 42 U.S.C. §§ 1395w-24(a)(5)(A),(6)(A)(i)-(iii).
[32] 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/.

medical records.[33] 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.[34] Industry experts refer to this error mode as the "Data Inconsistency Issue."[35]

Despite previously acknowledging the need to address the differing documentation standards that are the cause of the Data Inconsistency Issue,[36] 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.[37] Humana then initiated an ultimately successful lawsuit in the United States District Court for the Northern District of Texas to vacate CMS's Final RADV Rule as arbitrary and capricious.[38]

Despite the Final RADV Rule no longer being operative, OIG used the Final RADV Rule's approach to extrapolation here, noting here that it "estimated the total overpayment made to HumanaChoice for the high-risk groups included in the sampling frame for the audit period in accordance with CMS's regulations for the use of extrapolation in Risk Adjustment Data Validation (RADV) audits for recovery purposes."[39] In an earlier audit report where OIG similarly applied extrapolation despite the Northern District of Texas order vacating the Final RADV Rule, OIG commented only that the ruling did not impact OIG's findings or cause OIG to change its recommendations.[40] Specifically, "[i]f CMS deems it appropriate to apply an FFSA,

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[33] *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.

[34] *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.

[35] *See* Wakely Report Section IV.

[36] 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").

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

[38] Humana maintains its position that an FFSA is statutorily required to "ensure actuarial equivalence" in MA payments. 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. *See* 65 Fed. Reg. at 40,268. CMS's Final RADV Rule unlawfully ignores the congressional mandate to "ensure actuarial equivalence" in MA payments because CMS's HCC model continues to rely on unaudited diagnoses contained in administrative claims data (and not medical records) to calculate risk adjustment payment rates. Since Humana's successful vacatur of the Final RADV Rule, the Government has appealed. The case is currently pending appeal at the United States Court of Appeals for the Fifth Circuit.

[39] Draft Report at 24.

[40] Humana HBL Report at 23.

it will, during the audit resolution process, adjust our overpayment finding by whatever amount it determines necessary."[41] In both reports, OIG is applying a vacated CMS extrapolation methodology to estimate its overpayment amounts.

Humana previously notified CMS of the importance of the FFSA and the Data Inconsistency Issue to Humana's bids under H5216 for the years that are the subject of OIG's Draft Report. Specifically, Humana's Calendar Year 2020 and 2021 Actuarial Certifications or bid substantiation documentation for each filed Plan Benefit Package under H5216 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. For example, Humana's Calendar Year 2020 Actuarial Certification states:

> [R]evenue and risk score projections in the bid(s) are based on the assumption that final risk scores will be calculated and payments and overpayments will be determined consistent with the fact that CMS has used diagnoses contained in administrative claims data (and not medical records) to calculate risk coefficients and risk scores for FFS beneficiaries. . . . In the [February 24, 2012 "Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits"] CMS indicated that [] any payment adjustments from risk adjustment data validation audits will be conducted in a manner that maintains consistency between the development of the risk adjustment model and its application. CMS will maintain this consistency by applying a Fee-for-Service Adjuster (FFS Adjuster) to account for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims). However, the actual amount of the FFS adjuster has not been published at this time, and CMS stated that it will be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data.

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

Audits of so-called "high-risk" codes perfectly exemplify the importance of addressing the Data Inconsistency Issue in an actuarially sound manner: such codes are likely to be equally unsubstantiated in the FFS context. For example, OIG found that "[a]lmost all of the selected acute stroke diagnosis codes that physicians submitted to CMS under traditional Medicare . . . did not comply with Federal requirements."[42] 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.[43]

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[41] *Id.* *See also* Humana HBL Report at 23 (OIG "recognize[s] that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program"),

[42] Acute Stroke Audit Report at 6.

[43] *See id.* at 8.

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 and do so following the methodology of a vacated regulation. 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.[44] Recognized industry experts have stated that "[t]his principle applies with equal force irrespective of the type of RADV audit."[45]

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."[46] 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 and where CMS's authority to undertake extrapolated recoveries has been vacated. 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 H5216 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 should reconsider its recommendation because OIG is inconsistent in its use of repayment calculation methodologies applied to different MAOs and in its own "Toolkit."</u>

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.[47]

OIG released the "Toolkit" in December 2023 to "enable [MAOs] to replicate [OIG's] techniques to identify and evaluate high-risk diagnosis codes."[48] 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

[44] *See* Wakely Analysis.
[45] Wakely Report at 33; *see also* Wakely Analysis.
[46] CarePlus Report at 23.
[47] *See* Toolkit.
[48] *Id.* at 1.

expect MAOs to fully "replicate [OIG's] techniques to identify and evaluate high-risk diagnosis codes."[49]

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."[50] 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 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.

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

Humana understands that OIG generally intended the audit described in its Draft Report to follow CMS's procedures.[51] 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.[52] 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."[53] 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

[49] *Id.* at 2.
[50] *Id.* at 47.
[51] Draft Report at 21-24 (Appendix A).
[52] *Id.* at 24 (Appendix A).
[53] 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.

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.[54] 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.[55] 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."[56] To the extent the contractor's review underlying 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.

6. 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,[57] rather than the lower bound of

[54] 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).
[55] Draft Report at 8–18.
[56] *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 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.").
[57] Draft Report at 8, fn. 16.

a 95% or 99% confidence interval.[58] While OIG has defended the use of the 90% confidence interval in other reports,[59] 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[60] and its intention to apply a 90% confidence interval for the PY 2018[61] and PY 2019 audits[62]. 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."[63] It is misleading for OIG to uniformly use the 90% confidence level when CMS has not set a standard confidence level. Humana and other industry participants are now left with little guidance in finalizing their bids. For the foregoing reasons, Humana respectfully requests that OIG reconsider its first recommendation. OIG's inconsistent approach in the Draft Report would further disrupt actuarial equivalence if finalized.

III. HUMANA RESPECTFULLY REQUESTS THAT OIG RECONSIDER ITS SECOND RECOMMENDATION BECAUSE OIG HAS NOT SUPPLIED SUFFICIENT INFORMATION FOR HUMANA TO REPLICATE OIG'S PROCESS.

With respect to the "potential miskeyed diagnosis codes" identified in OIG's draft report, OIG requests that Humana "determine, for the 212 enrollee-years that [OIG] did not review. . . whether the medical records in each case support the diagnosis for the unrelated condition and refund any resulting overpayments to the Federal Government."[64] In connection with this recommendation, OIG did not provide which diagnosis codes they believe were transposed and therefore what led them to believe there was an error.

Additionally, while federal regulations require "MAOs monitor the data they receive from providers and submit to CMS,"[65] those same regulations and existing subregulatory guidance do not require MAOs like Humana to complete audits initiated by regulators such as HHS-OIG. Indeed, CMS has stated that MAOs should use "good faith efforts" to ensure the accuracy of risk adjustment diagnosis code data submitted to CMS, but CMS has not specified particular methods, processes, or programs to satisfy that "good faith" obligation.[66] To that end,

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[58] 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.").

[59] *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").

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

[61] *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.

[62] *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.

[63] *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.

[64] Draft Report at 19.

[65] *Id.* at 9.

[66] 65 Fed. Reg. at 40,268; *see also* 42 C.F.R. § 422.504(l)(2).

Humana cannot be expected to replicate OIG's review process based on the few examples HHS-OIG provided in its Draft Report.[67] To the extent that OIG recommends Humana replicate HHS-OIG's review of "potentially miskeyed diagnosis codes," Humana respectfully requests that OIG reconsider this recommendation.

IV. HUMANA RESPECTFULLY REQUESTS THAT OIG RECONSIDER ITS THIRD 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[.]"[68] 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.[69] CMS implemented the current regulatory regime after acknowledging industry concerns about widespread healthcare provider "mistakes" and "incomplete or inaccurate" provider-generated data.[70] Commenters at the time explained that "it would be unfair and unrealistic to hold [MA] organizations to a '100 percent accuracy' certification standard."[71] 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."[72] 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."[73]

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."[74] 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.[75]

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[67] *Id.* at 17-18.
[68] Draft Report at 19.
[69] 42 C.F.R. § 422.504.
[70] 65 Fed. Reg. at 40,250, 40,268.
[71] *Id.* at 40,268.
[72] *Id.*
[73] *Id.*
[74] 64 Fed. Reg. at 61,900.
[75] *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."[76] 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.[77] 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."[78] 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[79] 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."[80] 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.[81] 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.[82] Accordingly, Humana respectfully requests that OIG reconsider this recommendation.

V. HUMANA RESPECTFULLY REQUESTS THAT OIG RECONSIDER ITS FOURTH 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

[76] Draft Report at 9.
[77] *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.
[78] Draft Report at 9.
[79] *See* Cariten Report at 27.
[80] Draft Report at 19.
[81] *See* Acute Stroke Audit Report at 1.
[82] *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."[83] This exact recommendation came up in connection with OIG's other recent "high-risk" code reports,[84] 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 V.2 and in response to OIG's Policies and Procedures Questionnaire for H6609, Humana has several programs in place to enhance the accuracy of risk adjustment data, consistent with MA program requirements and OIG's guidance,[85] 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."[86] This effectively imposes the perfection standard that CMS and OIG have previously recognized is not reasonable to enforce, as discussed above.[87] 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.[88] 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;[89] 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.[90] Thus, Humana requests that OIG reconsider its

[83] Draft Report at 19-20.
[84] *See* SelectCare Report at 20; *see also* Aetna Report at 17; Presbyterian Health Report at 16.
[85] *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.").
[86] Draft Report at 8, 18-19.
[87] *See* 65 Fed. Reg. at 40,268.
[88] *See* Draft Report at 8.
[89] *See* Anthem Report at 24.
[90] *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.[91] 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.[92] 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 providers on the proper coding of several risk adjustment diagnoses, including those in 9 of the 11 high-risk groups reviewed in our audit."[93] 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."[94] Humana believes these programs satisfy Humana's obligations under applicable MA program requirements.

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[91] *See, e.g.*, Letter from Susan Crowe, Chief Compliance Officer, Humana to Shruti Rajan, Acting Director of the Medicare Plan Payment Group, Centers for Medicare and Medicaid Services (Mar. 17, 2026); 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).

[92] *See* Draft Report at 23 ("[OIG] interviewed HumanaChoice officials to gain an understanding of: (1) the policies and procedures that HumanaChoice followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) HumanaChoice's monitoring of those diagnosis codes to detect and correct noncompliance with Federal requirements.").

[93] *Id.* at 18.

[94] *Id.* at 19.

Despite these findings, OIG's Draft Report concludes that Humana's compliance procedures "could be improved" because Humana's "internal medical reviews did not focus on any specific high-risk diagnosis codes, including those we identified as being higher risk for being miscoded."[95] 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.[96] In the absence of specific CMS-implemented MA program requirements, Humana and other MAOs are afforded broad discretion in designing compliance and education programs.[97]

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.[98]

* * *

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,

Susan Crowe Digitally signed by Susan Crowe Date: 2026.03.27 13:40:15 -04'00'

Susan Crowe
Senior Vice President and Chief Compliance Officer
Enterprise Risk and Compliance Group

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

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[95] *Id.* at 16–17.
[96] *See* Acute Stroke Audit Report at 8.
[97] *See* 65 Fed. Reg. at 40,265.
[98] Draft Report at 20.

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Anyone may request confidentiality. The Privacy Act, the Inspector General Act of 1978, and other applicable laws protect complainants. The Inspector General Act states that the Inspector General shall not disclose the identity of an HHS employee who reports an allegation or provides information without the employee's consent, unless the Inspector General determines that disclosure is unavoidable during the investigation. By law, Federal employees may not take or threaten to take a personnel action because of whistleblowing or the exercise of a lawful appeal, complaint, or grievance right. Non-HHS employees who report allegations may also specifically request confidentiality.

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