Department of Health and Human Services

**OFFICE OF INSPECTOR GENERAL**

# MEDICARE ADVANTAGE COMPLIANCE AUDIT OF SPECIFIC DIAGNOSIS CODES THAT HUMANACHOICE (CONTRACT H6609) SUBMITTED TO CMS

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**Report in Brief**
Date: April 2023
Report No. A-05-19-00013

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

# Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS

## Why OIG Did This Audit

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

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

For this audit, we reviewed one MA organization, HumanaChoice (administered by Humana, Inc.), and focused on seven groups of high-risk diagnosis codes. 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.

## How OIG Did This Audit

We sampled 210 unique enrollee-years with the high-risk diagnosis codes for which HumanaChoice received higher payments for 2015 and 2016. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $694,939.

## What OIG Found

With respect to the seven 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 157 of the 210 sampled enrollee-years, the diagnosis codes that HumanaChoice submitted to CMS were not supported in the medical records and resulted in $480,295 of net overpayments for the 210 enrollee-years. These errors occurred because the policies and procedures that HumanaChoice had 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 $27.3 million of net overpayments for 2015 and 2016.

## What OIG Recommends and HumanaChoice Comments

We recommend that HumanaChoice: (1) refund to the Federal Government the $480,295 of net overpayments; (2) identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and (3) examine its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements and take the necessary steps to enhance those procedures.

HumanaChoice disagreed with our findings and recommendations and provided additional information for certain sampled enrollee-years. HumanaChoice disagreed with our audit methodology and how we estimated overpayments. HumanaChoice also stated that our recommendation to identify similar instances of noncompliance does not align with CMS's requirements and that its compliance program satisfies all legal and regulatory requirements.

After reviewing HumanaChoice's comments and the additional information that it provided, we revised the number of enrollee-years in error. After we had issued our draft report, CMS updated regulations for audits in its risk adjustment program to specify that extrapolated overpayments could only be recouped beginning with payment year 2018. Because our audit period covered payment years 2015 and 2016, we changed our first recommendation to specify a refund of only the net overpayments for the sampled enrollee-years. We made no changes to our second and third 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. 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 27 major depressive disorder diagnoses into 1 group.) This audit covered HumanaChoice, for contract number H6609, and focused on seven groups of high-risk diagnosis codes for payment years 2015 and 2016.[2] (See Appendix B for a list of related Office of Inspector General reports on MA organizations.)

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

[2] HumanaChoice is a Medicare Advantage plan administered by Humana, Inc. All subsequent references to "HumanaChoice" in this report refer solely to contract number H6609. We are addressing our recommendations to Humana, Inc.

## BACKGROUND

### Medicare Advantage Program

The MA program offers beneficiaries managed care options by allowing them to enroll in private health care plans rather than having their care covered through Medicare's traditional fee-for-service program.[3] Beneficiaries who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

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

For 2020, CMS paid MA organizations $317.1 billion, which represented 34 percent of all Medicare payments for that year.

### Risk Adjustment Program

Federal requirements mandate that payments to MA organizations be based on the anticipated cost of providing Medicare benefits to a given enrollee and, in doing so, also account for variations in the demographic characteristics and health status of each enrollee.[4]

CMS uses two principal components to calculate the risk-adjusted payment that it will make to an MA organization for an enrollee: (1) a base rate that CMS sets using bid amounts received from the MA organization and (2) 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.[5] CMS compares each bid to a specific benchmark

[3] 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.

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

[5] 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.[6]

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

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

For enrollees who have certain combinations of HCCs (in either the Version 12 model or the Version 22 model), CMS assigns a separate factor that further increases the risk score. CMS refers to these combinations as disease interactions. For example, if MA organizations submit diagnosis codes (in the Version 12 model) for an enrollee that map to the HCCs for acute stroke, acute myocardial infarction, and chronic obstructive pulmonary disease (COPD), CMS assigns a separate factor for this disease interaction. By doing so, CMS increases the enrollee's risk score for each of the three HCC factors and by an additional factor for the disease interaction.

The risk adjustment program is prospective. Specifically, CMS uses the diagnosis codes that the enrollee received for 1 calendar year (known as the service year) to determine HCCs and calculate risk scores for the following calendar year (known as the payment year). Thus, an enrollee's risk score does not change for the year in which a diagnosis is made. Instead, the risk

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

[7] CMS transitioned from one HCC model to another during our audit period. As part of this transition, for 2015, CMS calculated risk scores based on both models. CMS refers to these models as the Version 12 model and the Version 22 model, each of which has unique HCCs. CMS blended the two separate risk scores into a single risk score that it used to calculate a risk-adjusted payment. Accordingly, for 2015, an enrollee's blended risk score is based on the HCCs from both models. For 2016, CMS calculated risk scores based on the Version 22 model.

score changes for the entirety of the year after the diagnosis has been made. Further, the risk score calculation is an additive process: As HCC factors (and, when applicable, disease interaction factors) accumulate, an enrollee's risk score increases, and the monthly risk-adjusted payment to the MA organization also increases. In this way, the risk adjustment program compensates MA organizations for the additional risk of providing coverage to enrollees expected to require more health care resources.

CMS multiplies the risk scores by the base rates to calculate the total Medicare monthly payment that an MA organization receives for each enrollee before applying the budget sequestration reduction.[8] 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 unvalidated, which causes overstated enrollee risk scores and overpayments from CMS.[9] Conversely, 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.

**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 seven high-risk groups:[10]

- *Acute stroke*: An enrollee received one acute stroke diagnosis (that mapped to the HCCs for Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient or outpatient hospital claim. In these instances, a diagnosis of history of stroke (which does not map to an HCC) typically should have been used.

- *Acute heart attack*: An enrollee received one diagnosis that mapped to either the HCC for Acute Myocardial Infarction or to the HCC for Unstable Angina and Other Acute Ischemic Heart Disease (Acute Heart Attack HCCs) on only one physician or outpatient claim during the service year but did not have that diagnosis on a corresponding

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

[9] 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 "unsupported" to denote whether or not the reviewed diagnoses were evidenced in the medical records. If our audit determines that the diagnoses are supported or unsupported, we accordingly use the terms "validated" or "unvalidated" with respect to the associated HCC.

[10] Unless otherwise specified, the HCCs described in this report have the same name under both the Version 12 and Version 22 models.

inpatient hospital claim (either within 60 days before or 60 days after the physician or outpatient claim). In these instances, a diagnosis for a less severe manifestation of a disease in the related-disease group typically should have been used.

- *Acute stroke and acute heart attack combination*: An enrollee met the conditions of both the acute stroke and acute heart attack high-risk groups in the same year.[11]

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

- *Vascular claudication*: An enrollee received one diagnosis related to vascular claudication (that mapped to the HCCs for Vascular Disease) during the service year but had not received one of these diagnoses during the 2 preceding years and had medication dispensed on his or her behalf that is frequently dispensed for a diagnosis of neurogenic claudication.[12] In these instances, the diagnosis related to vascular claudication may not be supported in the medical records.

- *Major depressive disorder*: An enrollee received one major depressive disorder diagnosis (that mapped to the HCCs for Major Depressive, Bipolar, and Paranoid Disorders) during the service year but did not have an antidepressant medication dispensed on his or her behalf. In these instances, the major depressive disorder diagnoses may not be supported in the medical records.

- *Potentially miskeyed diagnosis codes*: An enrollee received multiple diagnoses for a condition but received only one—potentially miskeyed—diagnosis for an unrelated condition (that mapped to a possibly unvalidated HCC). For example, ICD-9 diagnosis code 250.00 (which maps to the HCC for Diabetes Without Complication) could be transposed as diagnosis code 205.00 (which maps to the HCC for Metastatic Cancer and

[11] We combined these enrollees into one group because an individual's risk scores could have been further increased if that enrollee also had a COPD diagnosis (which was not part of our audit). If our audit identified an error that invalidated either the Acute Stroke or Acute Heart Attack HCC, then the disease interaction factor would also be identified as an error. By combining these enrollees in one group, we eliminated the possibility of including the disease interaction factor twice in overpayment calculations (if any).

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

Acute Leukemia and in this example would be unvalidated). Using an analytical tool that we developed, we identified 832 scenarios in which diagnosis codes could have been miskeyed 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**

HumanaChoice is an MA Preferred Provider Organization based in Wisconsin. As of December 31, 2016, HumanaChoice provided coverage under contract number H6609 to approximately 665,000 enrollees. For the 2015 and 2016 payment years (audit period),[13] CMS paid HumanaChoice approximately $14 billion to provide coverage to its enrollees.[14]

## HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of the seven high-risk groups during the 2014 and 2015 service years, for which HumanaChoice received increased risk-adjusted payments for payment years 2015 and 2016, 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 18,483 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes ($47,928,028). We selected for audit a sample of 210 enrollee-years, which comprised: (1) a stratified random sample of 180 (out of 18,453) enrollee-years for the first 6 high-risk groups and (2) a nonstatistical sample of 30 enrollee-years for the remaining high-risk group.

Table 1 on the following page details the number of sampled enrollee-years (of the 210) for each of the 7 high-risk groups.

[13] The 2015 and 2016 payment year data were the most recent data available at the start of the audit.

[14] 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.

**Table 1: Sampled Enrollee-Years for Each High-Risk Group**

| High-Risk Group | Number of Sampled Enrollee-Years |
|---|---|
| 1. Acute stroke | 30 |
| 2. Acute heart attack | 30 |
| 3. Acute stroke/acute heart attack combination | 30 |
| 4. Embolism | 30 |
| 5. Vascular claudication | 30 |
| 6. Major depressive disorder | 30 |
| **Total for Stratified Random Sample** | **180** |
| | |
| 7. Potentially miskeyed diagnosis codes | 30 |
| **Total for All High-Risk Groups** | **210** |

HumanaChoice provided medical records as support for the selected diagnosis codes associated with 208 of the 210 sampled enrollee-years.[15] 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 we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

Appendix A contains the details of our audit scope and methodology, Appendix C contains our statistical sampling methodology, Appendix D contains our sample results and estimates, and Appendix E contains the Federal regulations regarding MA organizations' compliance programs.

## FINDINGS

With respect to the seven 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 53 of the 210 sampled enrollee-years, the medical records validated the reviewed HCCs, or we identified another diagnosis code (on CMS's

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

systems) that mapped to the HCC under review. For the remaining 157 enrollee-years, however, either the medical records that HumanaChoice provided did not support the diagnosis codes or HumanaChoice could not locate the medical records to support the diagnosis codes, and the associated HCCs were therefore not validated. As a result, HumanaChoice received $480,295 in net overpayments.

As demonstrated by the errors we identified, 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 $27,388,180 of net overpayments for 2015 and 2016.[16]

**FEDERAL REQUIREMENTS**

Payments to MA organizations are adjusted for risk factors, including the health status of each enrollee (the Social Security 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 42 CFR § 422.310(d)(1)). In addition, MA organizations must contract with CMS and agree to follow CMS's instructions, including the *Medicare Managed Care Manual* (the Manual) (see 42 CFR § 422.504(a)).

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

[16] Specifically, we estimated that HumanaChoice received at least $27,388,180 of net overpayments ($27,260,354 for the statistically sampled groups plus $127,826 for the group of potentially miskeyed diagnosis codes). To be conservative, we estimate net 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.

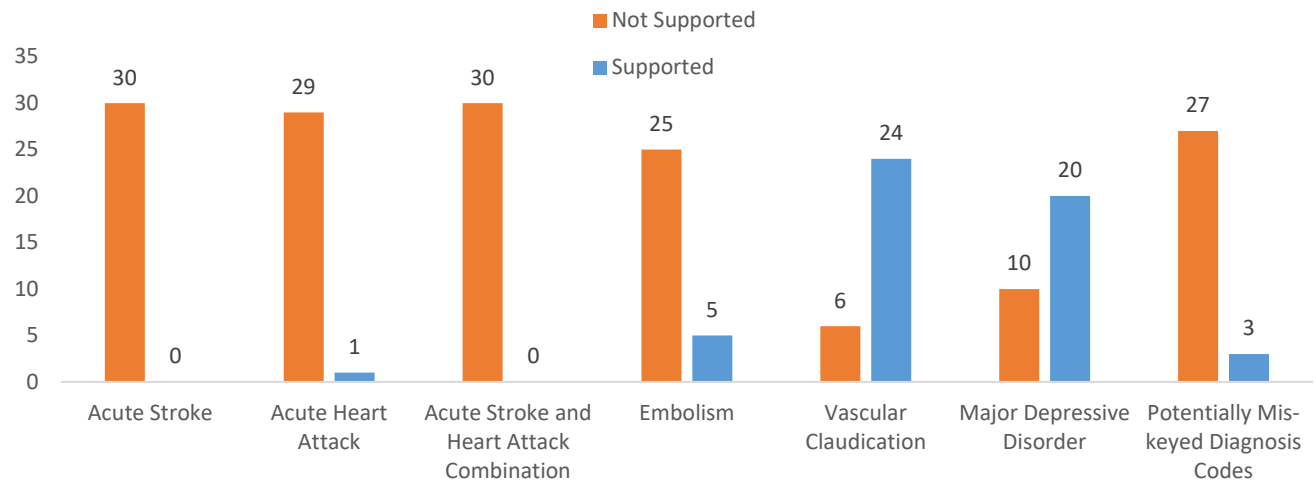
procedures to ensure that diagnoses come only from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities, and physicians (the Manual, ch. 7 § 40).

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. As shown in the figure, the medical records for 157 of the 210 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 30 sampled enrollee-years. Specifically:

- For 16 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 evidence of an acute stroke or any related condition that would result in an assignment of the [reviewed] HCC or a related HCC. There is mention of a history of a stroke [diagnosis] but no description of residuals or sequelae that should be coded."[17]

- For 13 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 evidence of an acute stroke or any related condition that would result in an assignment of the [reviewed] HCC or a related HCC [for Ischemic or Unspecified Stroke]."

- For 1 enrollee-year, HumanaChoice submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiparesis (which was supported in the medical records).[18] This error caused an underpayment.

  For this enrollee-year, the independent medical review contractor did not find support for an acute stroke but noted that ". . . [the] HCC [for Hemiplegia/Hemiparesis] is substantiated based on the assessment of hemiparesis from an old stroke [diagnosis]."

As a result of these errors, the HCCs for Ischemic or Unspecified Stroke were not validated, and HumanaChoice received $70,174 of net overpayments for these 30 sampled enrollee-years.

**Incorrectly Submitted Diagnosis Codes for Acute Heart Attack**

HumanaChoice incorrectly submitted diagnosis codes for acute heart attack for 29 of 30 sampled enrollee-years. Specifically:

- For 17 enrollee-years, the medical records in each case did not support either an acute myocardial infarction diagnosis or a diagnosis of a less severe manifestation of the related-disease group.

[17] Residuals or sequelae are lasting effects after the acute phase of an illness or injury has ended.

[18] Hemiparesis is a mild or partial weakness or loss of strength on one side of the body primarily caused by stroke but can also be caused by injuries or diseases that impact the brain and spinal cord.

For example, for 1 enrollee-year, the independent medical review contractor noted that ". . . there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of HCC [Unstable Angina and Other Acute Ischemic Heart Disease]. There is documentation of chest pain [diagnosis code] which does not result in an HCC."

- For 12 enrollee-years, the medical records in each case did not support an acute myocardial infarction diagnosis. However, we identified support for another diagnosis that should have been included in the enrollee-years' risk scores. In some instances, the diagnosis mapped to a less severe manifestation of the related-disease group as detailed below:

    - For 6 enrollee-years, which occurred in payment year 2015, the old myocardial infarction diagnosis mapped to an HCC for a less severe manifestation of the related-disease group.[19] Accordingly, HumanaChoice should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the old myocardial infarction diagnosis.

      For example, for 1 enrollee-year, the independent medical review contractor noted that ". . . there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of HCC [Unstable Angina and Other Acute Ischemic Heart Disease]. There is documentation of a history of myocardial infarction [diagnosis] which results in HCC [Old Myocardial Infarction] which should have been assigned instead of the submitted HCC."

    - For 4 enrollee-years, which occurred in either payment year 2015 or 2016, we identified support for the diagnosis of other and unspecified angina pectoris, which mapped to an HCC for a less severe manifestation of the related-disease group.[20] Accordingly, HumanaChoice should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the less severe diagnoses.

      For example, for 1 enrollee-year (payment year 2016), the independent medical review contractor noted that ". . . there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of HCC [Unstable Angina and Other Acute Ischemic Heart Disease].

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

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

There is documentation of . . . atherosclerosis of autologous vein coronary artery bypass graft(s) with other forms of angina pectoris [diagnosis code] that results in HCC [Angina Pectoris] which should have been assigned instead of the submitted HCC."[21]

- For 2 enrollee-years, which occurred in payment year 2015, we identified support for both the diagnosis of an old myocardial infarction and the diagnosis of other and unspecified angina pectoris, which 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 should have received a lesser increased payment for the less severe diagnoses.

  For example, for 1 enrollee-year, the independent medical review contractor noted that ". . . there is no documentation of any condition that will result in the assignment of HCC [Unstable Angina and Other Acute Ischemic Heart Disease]." However, we identified both a diagnosis code for an old myocardial infarction and other and unspecified angina pectoris on CMS's systems that mapped to HCC [Angina Pectoris/Old Myocardial Infarction] and HCC [Angina Pectoris] which are less severe manifestations of the related-disease group.

As a result of these errors, the Acute Heart Attack HCCs were not validated, and HumanaChoice received $51,251 of overpayments for these 29 sampled enrollee-years.

**Incorrectly Submitted Diagnosis Codes for Acute Stroke and Acute Heart Attack Combination**

For 30 sampled enrollee-years, HumanaChoice had submitted diagnosis codes in which physicians had documented conditions for both the acute stroke and acute heart attack high-risk groups in the same year (footnote 11). However, we found errors for all 30 of the enrollee-years because the medical records in each case did not support either the acute stroke diagnosis, the acute myocardial infarction diagnosis, or both.

Table 2 on the following page details the findings for the 30 enrollee-years for which the medical records did not support the submitted diagnosis codes.

[21] A coronary artery bypass graft (CABG) is a surgical procedure used to treat coronary heart disease. It diverts blood around narrowed or clogged parts of the major arteries to improve blood flow and oxygen supply to the heart.

**Table 2: Acute Stroke and Acute Heart Attack Combination Findings**

| Count of Enrollee-Years | Acute Stroke HCC | | Acute Heart Attack HCC | |
|---|---|---|---|---|
| | Medical Record Validated HCC | Support for Different HCC Found | Medical Record Validated HCC | Support for Different HCC Found |
| 18 | No | No | No | No |
| 4* | No | No | No | Yes – Old Myocardial Infarction |
| 2** | No | No | No | Yes – Angina Pectoris |
| 1** | No | No | No | Yes – Angina Pectoris/Old Myocardial Infarction (Version 12)/Angina Pectoris (Version 22) |
| 1*** | No | Yes - Cerebral Palsy and Other Paralytic Syndromes (Version 12)/Monoplegia, Other Paralytic Syndromes (Version 22) | No | Yes – Old Myocardial Infarction |
| 1**** | No | Yes - Hemiplegia/Hemiparesis | No | No |
| 2 | Yes | Not Applicable | No | No |
| 1 | No | No | Yes | Not Applicable |

* For these 4 enrollee-years, which occurred in payment year 2015, the old myocardial infarction diagnosis mapped to an HCC for a less severe manifestation of the related-disease group (footnote 19). Accordingly, HumanaChoice should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the old myocardial infarction diagnosis.

** For these 3 enrollee-years, which occurred in either payment year 2015 or 2016, we identified support for the diagnosis of other and unspecified angina pectoris, which mapped to an HCC for a less severe manifestation of the related-disease group (footnote 20). Accordingly, HumanaChoice should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the less severe diagnoses.

*** For this enrollee-year, HumanaChoice submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for history of stroke with weakness of bilateral lower extremities (which was supported in the medical records). Accordingly,

HumanaChoice should not have received an increased payment for the Ischemic or Unspecified Stroke HCCs but should have received increased payments for the HCCs identified in Table 2. In addition, the old myocardial infarction diagnosis, which occurred in payment year 2015, mapped to an HCC for a less severe manifestation of the related-disease group (footnote 19). Accordingly, HumanaChoice should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the old myocardial infarction diagnosis.

**** For this enrollee-year, HumanaChoice submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiparesis resulting in an HCC for Hemiplegia/Hemiparesis (which was supported in the medical records) (footnote 18). This error caused an underpayment.

As a result of these errors, the HCCs for either Ischemic or Unspecified Stroke or Acute Heart Attack, or both, were not validated, and HumanaChoice received $113,962 of net overpayments for these 30 sampled enrollee-years.

**Incorrectly Submitted Diagnosis Codes for Embolism**

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

- For 16 enrollee-years, the medical records in each case did not support an embolism diagnosis.

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

- For 8 enrollee-years, the medical records in each case indicated that the individual had previously had an embolism, but the records did not justify an embolism diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor noted that ". . . there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of [an Embolism] HCC. There is documentation of history of deep vein thrombosis[22] [diagnosis] that does not result in an HCC. . . ."

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

- For 1 enrollee-year, the medical record showed support for a peripheral vascular disease diagnosis,[23] which mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, HumanaChoice should not have received an increased payment for vascular disease with complications diagnosis but should have received a lesser increased payment for the vascular disease diagnosis.

As a result of these errors, the Embolism HCCs were not validated, and HumanaChoice received $76,777 of overpayments for these 25 sampled enrollee-years.

**Incorrectly Submitted Diagnosis Codes for Vascular Claudication**

HumanaChoice incorrectly submitted diagnosis codes for vascular claudication for 6 of 30 sampled enrollee-years. Specifically:

- For 5 enrollee-years, the medical records in each case did not support a vascular claudication diagnosis.

  For example, for 1 enrollee-year, the independent medical review contractor noted that ". . . there is no documentation of any condition that will result in the assignment of [the] HCC [for Vascular Disease]."

- For the 1 remaining enrollee-year, HumanaChoice could not locate any medical records to support the vascular claudication diagnosis; therefore, the HCCs for Vascular Disease were not validated.

As a result of these errors, the HCCs for Vascular Disease were not validated, and HumanaChoice received $15,125 of overpayments for these 6 sampled enrollee-years.

**Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder**

HumanaChoice incorrectly submitted diagnosis codes for major depressive disorder for 10 of 30 sampled enrollee-years. Specifically:

- For 8 enrollee-years, the medical records in each case did not support a major depressive disorder diagnosis.

  For example, for 1 enrollee-year, the independent medical review contractor noted that ". . . there is no documentation of any condition that will result in assignment of [the] HCC [for Major Depression, Bipolar and Paranoid Disorders]. There is documentation of depression [diagnosis] that does not result in an HCC."

[23] Peripheral vascular disease is a circulatory system disorder that causes blood vessels to become narrow, blocked, and spasm.

- For 1 enrollee-year, the medical record in each case indicated that the individual had previously had a major depressive disorder, but the record did not justify a major depressive disorder diagnosis at the time of the physician's service.

- For the 1 remaining enrollee-year, HumanaChoice could not locate any medical records to support the major depressive disorder diagnosis; therefore, the HCCs for Major Depression, Bipolar and Paranoid Disorders were not validated.

As a result of these errors, the HCCs for Major Depressive, Bipolar, and Paranoid Disorders were not validated, and HumanaChoice received $25,180 of overpayments for these 10 sampled enrollee-years.

**Potentially Miskeyed Diagnosis Codes**

HumanaChoice submitted potentially miskeyed diagnosis codes for 27 of 30 sampled enrollee-years. In each of these cases, the beneficiaries associated with these enrollee-years received multiple diagnoses for a condition but received only one—potentially miskeyed—diagnosis for an unrelated condition.

- For 19 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 four diagnosis codes for malignant neoplasm of female breast unspecified site (174.9) and only one diagnosis code for unspecified inflammatory polyarthropathy (714.9), which is a type of arthritis of multiple joints. The independent medical review contractor noted that ". . . there is no documentation of any condition that will result in the assignment of HCC [Rheumatoid Arthritis and Inflammatory Connective Tissue Disease]."

- For 8 enrollee-years, the medical records in each case did not support the diagnosis for the unrelated condition. However, we identified support for another diagnosis, which mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, for 7 of these enrollee-years, HumanaChoice received an overpayment, in that it should not have received an increased payment for the submitted diagnosis but should have received a lesser increased payment for the other diagnosis identified. For the 1 remaining enrollee-year, there was no payment effect.[24]

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

[24] The HCC risk factor for the less severe manifestation is the same as the HCC risk factor for the unrelated condition; therefore, the risk score will not change.

> HCC [for Vascular Disease with Complications]. There is documentation of peripheral vascular disease [diagnosis] that results in [the] HCC [for Vascular Disease], which should have been assigned instead of the submitted HCC."

Appendix F contains the HCCs that were not validated for the 27 enrollee-years (Table 6) and the HCCs for the less severe manifestation of the related-disease group that were supported for the 8 enrollee-years (Table 7).

As a result of these errors, the HCCs associated with the potentially miskeyed diagnosis codes were not validated, and HumanaChoice received $127,826 of overpayments for these 27 sampled enrollee-years.

**Summary of Net Overpayments for Incorrectly Submitted Diagnosis Codes**

In summary and with respect to the 7 high-risk groups covered by our audit, HumanaChoice received $480,295 in net overpayments for the 157 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 we identified, 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 officials stated that HumanaChoice had compliance procedures for determining whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. According to the officials, these procedures included a provider education program that was designed to promote accurate diagnosis codes, which provided instructions to its providers on the proper coding of several risk adjustment diagnoses, including those in the seven high-risk groups reviewed in our audit. In addition, the officials stated that HumanaChoice's compliance procedures included routine internal medical reviews to compare diagnosis codes from a random sample of claims to the diagnoses that were documented on the associated medical records. However, these internal medical reviews did not focus on any specific high-risk diagnosis codes, including those we identified as being at a higher risk for being miscoded. For this reason, HumanaChoice's compliance procedures to prevent, detect, and correct miscoded high-risk diagnoses during our audit period could be improved.

## HUMANACHOICE RECEIVED NET OVERPAYMENTS

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that HumanaChoice received at least $27,388,180 of net overpayments ($27,260,354 for the statistically sampled high-risk

groups plus $127,826 for the high-risk group with the potentially miskeyed diagnosis codes) for 2015 and 2016. (See Appendix D for sample results and estimates.)

Due to Federal regulations that limit the use of extrapolation in Risk Adjustment Data Validation (RADV) audits for recovery purposes, we are reporting the estimated net overpayment amount but are recommending a refund of only the $480,295 in net overpayments that HumanaChoice received for the 157 sampled enrollee-years.[25]

## RECOMMENDATIONS

We recommend that Humana, Inc.:

- refund to the Federal Government the $480,295 of net overpayments;
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
- examine its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

## HUMANACHOICE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, HumanaChoice disagreed with our findings and recommendations. Although HumanaChoice did not specifically disagree with 150 of the 159 enrollee-years identified in our draft report as not having medical records to support the associated diagnosis codes, HumanaChoice disagreed with our findings for the remaining 9 enrollee-years.[26] For each of the 9 enrollee-years, HumanaChoice provided additional information regarding why it believed that either the associated HCCs were validated or an HCC for a less severe manifestation of the related disease group was validated.

HumanaChoice also stated that our audit methodology departed from governing statistical and actuarial principles, the statutory requirements of the MA program, CMS's Risk Adjustment Data Validation (RADV) processes, and the methodology used in similar OIG audits.

[25] After we had issued our draft report, CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643, (Feb. 1, 2023)).

[26] HumanaChoice identified what it referred to as 12 "appeals" or disagreements with our determinations. These 12 "appeals" included 1 enrollee-year with 2 HCCs in the acute stroke and acute heart attack combination high-risk group, 2 enrollee-years that were not identified as errors in our draft report and therefore did not impact our audit results, and 9 enrollee-years for which HumanaChoice believed the HCCs should have been validated.

Additionally, HumanaChoice did not agree with our overpayment estimation methodology. Lastly, HumanaChoice stated that our recommendation to identify similar instances of noncompliance does not align with CMS's requirements and that its compliance program satisfies all legal and regulatory requirements.

After reviewing HumanaChoice's comments and the additional information it provided, we reduced the number of enrollee-years in error from 159 to 157. After we had issued our draft report, CMS updated Federal regulations for RADV audits to specify that extrapolated overpayments could only be recouped beginning with payment year 2018. Because our audit period covered payment years 2015 and 2016, we changed our first recommendation to specify a refund of only the net overpayments of $480,295 that HumanaChoice received for the 157 sampled enrollee-years. We made no changes to our second and third recommendations.

A summary of HumanaChoice's comments and our responses follows. HumanaChoice's comments are included as Appendix G.[27]

## HUMANACHOICE DID NOT AGREE WITH OIG'S RECOMMENDATION THAT HUMANACHOICE REFUND ESTIMATED OVERPAYMENTS

### HumanaChoice Did Not Agree With OIG's Findings for 9 Sampled Enrollee-Years

*HumanaChoice Comments*

HumanaChoice did not agree with our draft report findings for 9 sampled enrollee-years (as shown in Table 3 on the following page) and requested that we reconsider our findings and modify our estimate of overpayments.

**Table 3: Summary of Enrollee-Years for Which HumanaChoice Disagreed With Our Findings**

| High-Risk Group | Number of Sampled Enrollee-Years |
|---|---|
| (1) Major depressive disorder | 2 |
| (2) Acute stroke | 2 |
| (3) Acute heart attack | 3 |
| (4) Acute stroke and acute heart attack combination | 1 |
| (5) Embolism | 1 |
| **Total for All High-Risk Groups** | **9** |

[27] We excluded an attachment that contained personally identifiable information. We are separately providing HumanaChoice's comments and attachments in their entirety to CMS.

For the 9 sampled enrollee-years, HumanaChoice provided additional information (including medical records and explanations) supporting its belief that the HCCs for the sampled enrollee-years were validated. For 1 of the 9 enrollee-years, HumanaChoice stated that there was support for a diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group.[28]

*Office of Inspector General Response*

Our independent medical review contractor reviewed the additional information that HumanaChoice referred to in its comments for the 9 enrollee-years and confirmed that the HCCs for 6 of the 9 enrollee-years were not validated.

For example, for 1 enrollee-year from the acute stroke high-risk group, our contractor upheld its original decision upon reconsideration and noted:

> Although there is notation of an assessment of a cerebrovascular accident (CVA) prior to CT scan, the provider clearly documented the diagnosis as a differential diagnosis. The ICD-9-CM Official Guidelines for Coding and Reporting indicates that uncertain diagnoses are not to be coded for outpatient services. A differential diagnosis is a suspected, but unconfirmed, diagnosis and therefore not to be reported as an established condition on outpatient records. The physician documented a final impression of Paresthesia [diagnosis] and a Transient Ischemic Attack (TIA) [diagnosis]. Neither of these diagnoses result in assignment of [the] HCC [for Ischemic or Unspecified Stroke].

For 2 enrollee-years, our contractor reversed its original decision as follows:

- For 1 enrollee-year, our contractor found support for a diagnosis of major depressive affective disorder, single episode, unspecified, reversed its original decision, and validated the HCC for Major Depressive Disorder.

- For 1 enrollee-year, our contractor found support for a diagnosis of other pulmonary embolism and infarction, reversed its original decision, and validated the HCC for Embolism.

For the remaining enrollee-year in the acute stroke and acute heart attack combination high-risk group, our contractor found support for a diagnosis of cerebral artery occlusion unspecified with cerebral infarction, reversed its original decision, and validated the HCC for Acute Stroke. However, our contractor also confirmed that the HCC for Acute Heart Attack was not validated.

[28] HumanaChoice provided a medical record, for an enrollee in the Acute Heart Attack high-risk group, it believed supported a diagnosis of acute myocardial infarction of other anterior wall episode of care unspecified, which translates to the assignment of an HCC for Unstable Angina and Other Acute Ischemic Heart Disease, a less severe HCC in the same hierarchy as the audited HCC for Acute Myocardial Infarction.

Although we adjusted our calculation of net overpayments for the validated HCC, we did not reduce the number of errors because this enrollee-year had an unvalidated HCC.

Our independent medical review contractor confirmed that HumanaChoice's written comments and additional explanations had no impact on the decisions that the contractor made for other sampled enrollee-years and stated that there were no "systemic issues identified" in its reviews.

HumanaChoice's request that we review a diagnosis that mapped to an HCC for a less severe manifestation of disease in a related-disease group (footnote 28) was beyond the scope of our audit. Specifically, HumanaChoice provided a new medical record for which the associated claim, when originally submitted to CMS, did not have a diagnosis code that mapped to the HCC under review. Accordingly, it was not possible for the less severe diagnosis to have been included on the medical record instead of a diagnosis that mapped to the audited HCC. We did, however, review this medical record for the HCC under review and did not identify support for any of the diagnoses that map to this HCC.

As a result, we reduced the number of enrollee-years in error from 159 (as reported in our draft report) to 157. We also revised our findings and reduced the associated monetary recommendation.

**HumanaChoice Did Not Agree With How OIG Incorporated Underpayments Into Its Estimates**

*HumanaChoice Comments*

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

- For OIG's sampled enrollee-years, HumanaChoice 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).

- HumanaChoice also stated that "OIG excluded from its sampling frame all non 'high-risk' diagnosis codes associated with payment years 2015 and 2016 for [HumanaChoice] enrollees as well as those for which Humana[Choice] did not submit any risk-adjusting diagnosis codes." According to HumanaChoice, this exclusion systematically reduced the probability of identifying underpayments.

Accordingly, HumanaChoice 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, HumanaChoice noted that "OIG should consider such underpayment credits in its overpayment estimates." HumanaChoice also asked that "OIG modify its recommended estimated repayment amount" and requested that we justify our approach under applicable government auditing standards.

*Office of Inspector General Response*

As stated above, our recommendation to refund overpayments is no longer based on an estimation and is now limited to the net overpayments associated with the sampled enrollee-years. However, we believe that our sample results continue to provide a reasonable basis for our findings and conclusions.

We disagree with HumanaChoice's statements regarding underpayments. In accordance with the Inspector General Act of 1978, 5 U.S.C. App., our audits are intended to provide an independent assessment of Department of Health and Human Services (HHS) programs and operations. We conduct our audits in accordance with generally accepted government auditing standards, which require that audits be planned and performed so as to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions. Our objective was to determine whether selected high-risk diagnosis codes that HumanaChoice submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements. In this regard, the identification of: (1) all possible diagnosis codes that 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.

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

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 in 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 HumanaChoice as "underpayment credits") in our calculation of overpayments and the resulting estimate. Thus, we did not change our first recommendation based upon HumanaChoice's comments; rather, we made the change based upon the Federal regulations that CMS updated.

**HumanaChoice Stated That OIG's Extrapolation Methodology Did Not Apply Certain CMS Requirements**

*HumanaChoice Comments*

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

HumanaChoice cited the provision of the Act that mandates that risk-adjusted payments be made in a manner that ensures actuarial equivalence between CMS payments for health care coverage under MA and CMS payments under Medicare's traditional fee-for-service (FFS) program. According to HumanaChoice, 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." HumanaChoice stated, "[i]n its recent reports, OIG does not seem to seriously contest these principles, instead deferring to CMS on the issue. Because the issue is subject to pending rulemaking at CMS, however, Humana[Choice] reiterates its positions here."

HumanaChoice asserted that identifying diagnosis codes that were incorrect under MA would create a data inconsistency issue because these diagnosis codes would be subjected to different documentation standards than those that exist under the Medicare FFS program.[29] HumanaChoice 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."

HumanaChoice stated that, to address the data inconsistency issue, CMS announced in CY 2012 "that it would determine a contract-level payment error in RADV audits only after applying a Fee-for-Service Adjuster ('FFSA') to account for the rate of unsubstantiated diagnosis codes in the Medicare FFS claims data from which CMS's HCC [factors] were initially derived." HumanaChoice additionally stated that "[t]he Medicare Advantage program requirements, which apply to CMS's audits and overpayment determinations, are equally applicable to OIG's audits and calculation of estimated repayment amounts for the same program."

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

HumanaChoice stated that, in its bid to CMS for payment years 2015 and 2016, it notified CMS that it was "relying on CMS's plan to develop and apply an FFSA as part of any RADV process." Further, HumanaChoice stated, "CMS did not respond to this bid certification or otherwise suggest to Humana[Choice] that Humana[Choice]'s bid should be modified." HumanaChoice also cited a November 2018 proposed rule by CMS to eliminate the FFSA. HumanaChoice stated that this was only a proposal; therefore, the RADV methodology (using the FFSA) that CMS introduced in CY 2012 remains operative.

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

HumanaChoice also referenced a related report 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, including the application of any FFSA…[i]f CMS deems it appropriate to apply an FFSA, it will adjust our overpayment finding by whatever amount it determines is necessary." HumanaChoice 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."

*Office of Inspector General Response*

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

Regarding HumanaChoice's statement that we did not consider "actuarial equivalence" in our overpayment calculations, we note that CMS stated, after we issued our draft report, that it "will not apply an adjustment factor (known as a Fee-For-Service (FFS) Adjuster) in RADV audits."[30] Further, we do not agree with HumanaChoice's assertion that it is "misleading, arbitrary and capricious" for us to issue an audit report that identifies estimated overpayments and recognizes that CMS will make certain determinations while we were aware that CMS needed to address statutory requirements. On the contrary, HumanaChoice's statement expresses exactly what we were supposed to do. Our audits are intended to provide an

[30] 88 Fed. Reg. 6643 (Feb. 1, 2023).

independent assessment of HHS programs and operations in accordance with the Inspector General Act of 1978, 5 U.S.C. App. Thus, we believe that our audit methodology provides a reasonable basis for our findings and recommendations, including our estimation of overpayments.[31] Any OIG audit findings and recommendations do not represent final determinations by CMS. We continue to recognize that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program. In this respect and as discussed above, we reiterate that we updated our monetary recommendation for this report in response to the CMS's updated guidance. CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures.

**HumanaChoice Noted That Similar OIG Audits Used Different Overpayment Calculations**

*HumanaChoice Comments*

HumanaChoice stated that we should reconsider our monetary recommendation because our "use of different repayment calculation methodologies" for other audits of MA organizations is "arbitrary and capricious." HumanaChoice noted that, as of September 2022, we issued 10 similar audits of "so-called 'high-risk' diagnosis codes" submitted by MA organizations to CMS. HumanaChoice stated that these audits focused on different high-risk diagnosis codes, defined the scope of the audited high-risk diagnosis codes differently, and applied different methodologies (judgmental samples without extrapolation for two audits and statistical sampling with extrapolation for eight audits) for calculating overpayments. Further, HumanaChoice stated that OIG has not defined what it means for a diagnosis code to be "high-risk." To these points, HumanaChoice stated that we have "never acknowledged that [our] audit methodology is in constant flux" and must "explain why [we are] justified in adopting such dissimilar practices in audits that all purport to cover so-called 'high-risk' diagnosis code submissions by [MA organizations]."

*Office of Inspector General Response*

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

[31] Action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures. In accordance with 42 CFR § 422.311, which addresses audits conducted by the Secretary (including those conducted by OIG), if a disallowance is taken, MA organizations have the right to appeal the determination that an overpayment occurred through the Secretary's RADV appeals process.

Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.[32] Although our initial audits of high-risk diagnosis codes only included non-statistical sampling, we determined that the best use of our resources was to transition to statistical sampling and estimation for subsequent audits in this area. As a result, the methodology used in this audit did not mirror the methodology used in the initial audits, nor did it have to.

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

Thus, we did not change our first recommendation based upon HumanaChoice's comments; rather, we made the change based upon the regulations that CMS updated.

**HumanaChoice Noted That OIG Did Not Follow CMS's Established Risk Adjustment Data Validation Methodology**

*HumanaChoice Comments*

HumanaChoice "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." HumanaChoice noted that our audit methodology "departs from CMS's established RADV methodology in several important respects." Specifically:

- HumanaChoice took exception to our use of a physician (as described in Appendix A) as a "tiebreaker" in instances when two coding reviewers disagree. HumanaChoice 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. HumanaChoice stated that "CMS's approach reflects a true coding analysis" and believes the number of HCCs that we determined unsubstantiated would be reduced if we followed CMS's coding methodology.

- HumanaChoice stated that "it is unclear what specific diagnosis coding guidance" our independent medical review contractor followed and "it does not appear to have complied with the notice-and-comment requirements of *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019)." As an example, HumanaChoice questioned whether we followed CMS's "2017 RADV Medical Record Reviewer Guidance," which, according to

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

HumanaChoice, "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, HumanaChoice stated that "[t]o the extent the contractor's review underlying OIG's audit findings did not conform to CMS diagnosis coding guidance, the contractor's approach would have biased OIG's results and recommendations."

In addition, HumanaChoice 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. HumanaChoice 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)."[33]

*Office of Inspector General Response*

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

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

- Regarding HumanaChoice's statement about the guidance our independent medical review contractor followed, we note that, prior to the issuance of the draft report, we informed HumanaChoice that our contractor performed its review to determine whether diagnoses were coded according to the ICD Coding Guidelines and CMS's 2017 RADV Medical Record Reviewer Guidance. We did not apply any new regulatory requirements that would be subject to notice-and-comment rulemaking. In addition, as previously stated, our contractor reviewed all medical records that HumanaChoice

[33] 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.

submitted to determine whether the reviewed HCCs were supported in the medical records. With respect to the "chronic condition" example that HumanaChoice cited, our contractor's methodology complied with applicable CMS guidance, and we provided this guidance to HumanaChoice prior to the issuance of the draft report.

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

*HumanaChoice Comments*

HumanaChoice disagreed with how we calculated our estimated overpayments. Specifically, HumanaChoice stated that our use of the two-sided 90-percent confidence interval in estimating overpayments is inconsistent with CMS's practice for RADV audits. HumanaChoice stated that "[a]bsent a prospective process involving appropriate and necessary notice-and-comment rulemaking, OIG must be consistent with CMS practice for RADV audits by using the lower bound of a 99[-percent] confidence interval." HumanaChoice requested that we recalculate the extrapolated overpayment amount using the lower limit of a 99-percent confidence interval to be consistent with CMS's practice for RADV audits.

*Office of Inspector General Response*

OIG is an independent oversight agency; therefore, we are not required to mirror CMS's estimation methodology. Although we have limited the recommended recovery in this final report to the overpayments associated with the sampled enrollee-years, 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 provided a reasonably conservative estimate of the total amount overpaid to HumanaChoice for the enrollee-years and time period covered in our sampling frame. Further, we note that this approach, which is routinely used by HHS for recovery calculations,[34] results in a lower limit (the estimated overpayment amount to refund) that is designed to be less than the actual overpayment amount 95 percent of the time.

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

Additionally, the legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.[35] As detailed in Appendix C, we properly executed a statistically valid sampling methodology in that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

**HumanaChoice Stated That OIG's Recommended Recovery Is Duplicative of Recoveries Identified by HumanaChoice's Self-Audits**

*HumanaChoice Comments*

HumanaChoice stated that one aspect of its MA compliance program is "regular internal RADV-like [self-audits]" to confirm the accuracy of CMS risk adjusted payments.[36] According to HumanaChoice, the self-audits consist of reviews of all HCCs submitted to CMS for a sample of enrollees. HumanaChoice stated that a data correction is submitted for every HCC that HumanaChoice determines is not supported and HumanaChoice calculates a corresponding payment recovery amount. HumanaChoice then applies an "estimated FFSA" to the calculated payment recovery amount to determine the final estimated recovery amount. HumanaChoice asserted that it is duplicative of OIG to recommend refunds of payment amounts other than those found by the self-audits.[37]

*Office of Inspector General Response*

Regarding HumanaChoice's argument that our recommended recovery amount is duplicative of the recovery amounts identified by the self-audits, HumanaChoice did not provide the information that would be needed to determine whether there is duplication. Specifically, HumanaChoice did not indicate whether a self-audit was performed for our audit period; nor did HumanaChoice indicate whether it paid CMS estimated recovery amounts calculated using the self-audit results for our audit period.

[35] S*ee 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).

[36] The self-audits are conducted by Humana, Inc.

[37] HumanaChoice made these statements in footnote 77 of its comments.

**HUMANACHOICE DID NOT AGREE WITH OIG'S RECOMMENDATION TO PERFORM ADDITIONAL REVIEWS BEFORE AND AFTER THE AUDIT PERIOD**

*HumanaChoice Comments*

HumanaChoice disagreed with our second recommendation—that it perform additional reviews to determine whether similar instances of high-risk diagnoses occurred before or after the audit period and to refund any overpayments—because, according to HumanaChoice, "[MA] regulations do not require the sort of audits that OIG recommends." Moreover, HumanaChoice stated that, "OIG has not provided Humana[Choice] with sufficient information to replicate its process for identifying 'potentially miskeyed diagnoses.'"

HumanaChoice 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, HumanaChoice stated that CMS recognizes that MA organizations receive risk adjustment data from many different sources, which presents "significant verification challenges" and that OIG guidance recognizes that MA organizations' certification of these data does not constitute an absolute guarantee of accuracy.

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

HumanaChoice also stated that it does not have the necessary information, such as OIG's underlying algorithm, to replicate our process for identifying "'potentially miskeyed diagnosis codes'" and requests that we reconsider our second recommendation.

*Office of Inspector General Response*

We do not agree with HumanaChoice's interpretation of Federal requirements. We recognize that MA organizations have the latitude to design their own federally mandated compliance programs. We also recognize that the requirement that MA organizations certify the data they submit to CMS is based on "best knowledge, information, and belief." However, contrary to HumanaChoice's assertions, we believe that our second recommendation conforms to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (see Appendix E)).

These Federal regulations state that MA organizations must "implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS's program requirements." Further, the regulations specify that HumanaChoice's compliance plan "must, at a minimum, include [certain] core requirements," such as "an effective system for routine monitoring and identification of compliance risks . . . [including] internal monitoring and audits and, as appropriate, external audits to evaluate . . . compliance with CMS requirements and the overall effectiveness of the compliance program." These regulations also require MA organizations to implement procedures and a system for investigating "potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence." Thus, CMS has, through the issuance of these Federal regulations, assigned the responsibility for dealing with potential compliance issues to the MA organizations themselves.

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

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

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

Regarding HumanaChoice's statement about not being provided sufficient information to replicate our process for identifying potentially miskeyed diagnosis codes, we provided HumanaChoice, subsequent to the issuance of our draft report, with our list of 832 scenarios representing potentially miskeyed diagnosis codes (each of which mapped to a potentially unvalidated HCC) and multiple instances of diagnosis codes that were likely keyed correctly.[38]

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

[38] Our draft report showed 811 scenarios of potentially miskeyed diagnosis codes. We verified that there were actually 832 scenarios and have made clarifications for this final report.

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

*HumanaChoice Comments*

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

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

HumanaChoice stated that it is unclear "from OIG's recommendations to date what policies and procedures would be acceptable, as OIG arbitrarily and capriciously provides this recommendation to a variety of circumstances: in one report stating that it did not review the full compliance program, but still issuing this same overarching recommendation; in the report for a prior Humana[Choice] 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."

*Office of Inspector General Response*

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

completeness and truthfulness" of the risk adjustment data that it submits in the future. Accordingly, we maintain that our third recommendation is valid.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

CMS paid HumanaChoice $13,956,617,930 to provide coverage to its enrollees for 2015 and 2016. We identified a sampling frame of 18,483 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2014 and 2015 service years; HumanaChoice received $308,223,406 in payments from CMS for these enrollee-years for 2015 and 2016. We selected for audit 210 enrollee-years with payments totaling $3,645,990.

The 210 enrollee-years included 30 acute stroke diagnoses, 30 acute heart attack diagnoses, 30 acute stroke diagnosis and acute heart attack diagnosis combinations, 30 embolism diagnoses, 30 vascular claudication diagnoses, 30 major depressive disorder diagnoses, and 30 potentially miskeyed diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $694,939 for our sample.

We reviewed HumanaChoice's internal controls for ensuring that diagnosis codes it submitted to CMS were coded in accordance with Federal requirements.

We performed audit work from January 2019 through July 2022.

### 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:

    - 6 diagnosis codes for acute stroke,
    - 35 diagnosis codes for acute heart attack,
    - 58 diagnosis codes for embolism,
    - 4 diagnosis codes for vascular claudication, and
    - 27 diagnosis codes for major depressive disorder.

- We developed an analytical tool that identified 832 scenarios in which either ICD-9 or ICD-10 diagnosis codes, when miskeyed 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 832 occurrences, the tool identified a potentially miskeyed diagnosis code and the likely correct diagnosis code. Accordingly, we considered the potentially miskeyed 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)[39] to identify enrollees who received high-risk diagnosis codes from a physician during the service years;

    - Risk Adjustment System (RAS)[40] to identify enrollees who received an HCC for the high-risk diagnosis codes;

    - Medicare Advantage Prescription Drug System (MARx)[41] 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 C);

    - Encounter Data System (EDS)[42] to identify enrollees who received specific procedures; and

    - Prescription Drug Event (PDE) file[43] 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 identify and correct noncompliance with Federal requirements.

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

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

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

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

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

- We selected for audit a sample of 210 enrollee-years, which comprised: (1) a stratified random sample of 180 (out of 18,453) enrollee-years for the first 6 high-risk groups and (2) a nonstatistical sample of 30 enrollee-years for the remaining high-risk group.

- We used an independent medical review contractor to perform a coding review for the 210 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, the HCC was considered validated.

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

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

        - If the second senior coder found support, then a physician independently reviewed the medical record to make the final determination.

    - If either the first or second senior coder asked a physician for assistance, the physician's decision became the final determination.

- We used the results of the independent medical review contractor to calculate overpayments or underpayments (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 net overpayment made to HumanaChoice during the audit period.

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

- We limited the total net overpayment that we recommended for recovery to the sampled enrollee-years.[45]

- We discussed the results of our audit with HumanaChoice officials.

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

[45] Federal regulations (42 CFR § 422.311(a)) state: ". . . the Secretary annually conducts RADV audits to ensure risk-adjusted payment integrity and accuracy." Recovery of improper payments from MA organizations will be conducted in accordance with the Secretary's payment error extrapolation and recovery methodologies. CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years. 88 Fed. Reg. 6643, 6655 (Feb. 1, 2023)

## APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

| Report Title | Report Number | Date Issued |
|---|---|---|
| *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health Network (Contract H1961) Submitted to CMS* | A-06-18-05002 | 5/22/2022 |
| *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS* | A-01-19-00500 | 2/14/2022 |
| *Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS* | A-07-17-01169 | 2/3/2022 |
| *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc. (Contract H3359) Submitted to CMS* | A-02-18-01029 | 1/5/2022 |
| *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS* | A-07-19-01188 | 11/5/2021 |
| *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS* | A-07-17-01173 | 10/28/2021 |
| *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS* | A-07-19-01187 | 5/21/2021 |
| *Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc. (Contract H1036) Submitted to CMS* | A-07-16-01165 | 4/19/2021 |
| *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS* | A-02-18-01028 | 2/24/2021 |
| *Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements* | A-07-17-01170 | 4/30/2019 |

## APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

### SAMPLING FRAME

We identified HumanaChoice enrollees who: (1) were continuously enrolled under contract H6609 throughout all of the 2014 or 2015 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 2014 or 2015 or in January of the following year, and (3) received a high-risk diagnosis during 2014 or 2015 that caused an increased payment to HumanaChoice for 2015 or 2016, 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 18,483 enrollee-years.

### SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2015 or 2016.

### SAMPLE DESIGN

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

- an acute stroke diagnosis (that mapped to the HCCs for Ischemic or Unspecified Stroke) on only one physician claim during the service year but did not have that diagnosis on a corresponding inpatient or outpatient hospital claim (5,763 enrollee-years);

- a diagnosis (that mapped to an Acute Heart Attack HCC) on only one physician or outpatient claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician or outpatient claim (4,147 enrollee-years);

- an acute stroke diagnosis and a diagnosis that mapped to an Acute Heart Attack HCC in the same year and that met the criteria mentioned in the previous two bullets (70 enrollee-years);

- a diagnosis (that mapped to an Embolism HCC) on only one claim during the service year but did not have an anticoagulant medication dispensed on his or her behalf (1,948 enrollee-years);

- a vascular claudication diagnosis (that mapped to the HCCs for Vascular Disease) on only one claim during the service year (and had not been documented during the 2 years

that preceded the service year), but had medication dispensed on his or her behalf for neurogenic claudication (2,721 enrollee-years); or

- a major depressive disorder diagnosis (that mapped to the HCCs for Major Depressive, Bipolar, and Paranoid Disorders) on only one claim during the service year but did not have an antidepressant medication dispensed on his or her behalf (3,804 enrollee-years).

The specific strata are shown in Table 2.

**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 | 5,763 | $15,197,317 | 30 |
| 2 – Acute heart attack | 4,147 | 9,284,489 | 30 |
| 3 – Acute stroke/acute heart attack combination | 70 | 325,496 | 30 |
| 4 – Embolism | 1,948 | 5,448,418 | 30 |
| 5 – Vascular claudication | 2,721 | 6,619,003 | 30 |
| 6 – Major depressive disorder | 3,804 | 10,892,073 | 30 |
| **Total – First Six Strata** | **18,453** | **$47,766,796** | **180** |

*Rounded to the nearest whole dollar amount.

After we selected the 180 enrollee-years, we identified an additional group of 30 enrollee-years that represented individuals who received 1 of the 832 potentially miskeyed diagnosis codes (each of which mapped to a potentially unvalidated HCC) and multiple instances of diagnosis codes that were likely keyed correctly. Thus, we selected for audit a total of 210 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 beneficiary identification number and then consecutively numbered the items in each stratum in the stratified sampling frame. After generating 180 random numbers according to our sample design, we selected the corresponding frame items for review. We also selected all 30 nonstatistical sample items from the potentially miskeyed group.

**ESTIMATION METHODOLOGY**

We used the OIG, OAS, statistical software to estimate the total amount of net overpayments to HumanaChoice at the lower limit of the two-sided 90-percent confidence interval (Appendix D). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time. We also identified the overpayments from the nonstatistical sample of 30 items for the potentially miskeyed diagnosis codes and added that amount to the estimate for the statistical sample to obtain the total net overpayments.

## APPENDIX D: SAMPLE RESULTS AND ESTIMATES

### Table 4: Sample Results

| Audited High-Risk Groups | Frame Size | CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame) | Sample Size | CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years) | Number of Sampled Enrollee-Years With Unvalidated HCCs | Net Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years) |
|---|---|---|---|---|---|---|
| 1 – Acute stroke | 5,763 | $15,197,317 | 30 | $75,350 | 30 | $70,174 |
| 2 – Acute heart attack | 4,147 | 9,284,489 | 30 | 67,159 | 29 | 51,251 |
| 3 – Acute stroke/acute heart attack combination | 70 | 325,496 | 30 | 135,234 | 30 | 113,962 |
| 4 – Embolism | 1,948 | 5,448,418 | 30 | 100,270 | 25 | 76,777 |
| 5 – Vascular claudication | 2,721 | 6,619,003 | 30 | 71,518 | 6 | 15,125 |
| 6 – Major depressive disorder | 3,804 | 10,892,073 | 30 | 84,176 | 10 | 25,180 |
| **Totals for Statistical Sample** | **18,453** | **$47,766,796** | **180** | **$533,707** | **130** | **$352,469** |
| | | | | | | |
| 7 – Potentially miskeyed diagnoses | 30 | 161,232 | 30 | 161,232 | 27 | 127,826 |
| **Totals – All** | **18,483** | **$47,928,028** | **210** | **$694,939** | **157** | **$480,295** |

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

| | Estimated Net Overpayment for Statistically Sampled High-Risk Groups | Overpayment for High-Risk Group With Potentially Miskeyed Diagnosis Codes | Total Estimated Net Overpayments |
|---|---|---|---|
| Point estimate | $30,380,815 | $127,826 | $30,508,641 |
| Lower limit | 27,260,354 | 127,826 | 27,388,180 |
| Upper limit | 33,501,275 | 127,826 | 33,629,101 |

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

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

> Any entity seeking to contract as an MA organization must . . . .
>
> (4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following . . . .
>
> (vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:
>
> (A) Written policies, procedures, and standards of conduct that—
>
> (1) Articulate the organization's commitment to comply with all applicable Federal and State standards;
>
> (2) Describe compliance expectations as embodied in the standards of conduct;
>
> (3) Implement the operation of the compliance program;
>
> (4) Provide guidance to employees and others on dealing with potential compliance issues;
>
> (5) Identify how to communicate compliance issues to appropriate compliance personnel;
>
> (6) Describe how potential compliance issues are investigated and resolved by the organization; and
>
> (7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials. . . .

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

(G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

(1) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

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

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

## APPENDIX F: DETAILS OF POTENTIALLY MISKEYED DIAGNOSIS CODES

### Table 6: Potentially Miskeyed 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) | | Overpayment |
|---|---|---|---|---|---|---|
| | Diagnosis Code | Diagnosis Code Description | Hierarchical Condition Category That Was Not Validated | Diagnosis Code | Diagnosis Code Description | |
| 4 | 482.0 | Pneumonia due to *Klebsiella pneumoniae* | Aspiration and Specified Bacterial Pneumonias | 428.0 | Congestive heart failure, unspecified | $14,213 |
| 2 | 714.9 | Unspecified inflammatory polyarthropathy | Rheumatoid Arthritis and Inflammatory Connective Tissue Disease | 174.9 | Malignant neoplasm of breast (female), unspecified | 6,312 |
| 2 | 205.00 | Acute myeloid leukemia, without mention of having achieved remission | Metastatic Cancer and Acute Leukemia | 250.00 | Diabetes mellitus without mention of complications, type II or unspecified type, not stated as uncontrolled | 33,758 |
| 2 | 441.00 | Dissection of aorta, unspecified site | Vascular Disease With Complications | 414.00 | Coronary atherosclerosis of unspecified type of vessel, native or graft | 6,500 |
| 2 | 441.01 | Dissection of aorta, thoracic | Vascular Disease With Complications | 414.01 | Coronary atherosclerosis of native coronary artery | 3,916 |
| 2 | E32.9 | Disease of thymus, unspecified | Other Significant Endocrine and Metabolic Disorders | F32.9 | Major depressive disorder, single episode, unspecified | 2,749 |
| 1 | 249.20 | Secondary diabetes mellitus with hyperosmolarity, not stated as uncontrolled, or unspecified | Diabetes With Acute Complications | 294.20 | Dementia, unspecified, without behavioral disturbance | 0 |
| 1 | I24.9 | Acute ischemic heart disease, unspecified | Unstable Angina and Other Acute Ischemic Heart Disease | I42.9 | Cardiomyopathy, unspecified | 942 |

| Number of Sampled Enrollee-Years | One Diagnosis for a Condition (Determined To Be Incorrect) | | | Multiple Diagnoses for a Condition (Not Reviewed) | | Overpayment |
|---|---|---|---|---|---|---|
| | Diagnosis Code | Diagnosis Code Description | Hierarchical Condition Category That Was Not Validated | Diagnosis Code | Diagnosis Code Description | |
| 1 | 493.20 | Chronic obstructive asthma, unspecified | Chronic Obstructive Pulmonary Disease | 493.02 | Extrinsic asthma with (acute) exacerbation | $3,029 |
| 1 | 200.00 | Reticulosarcoma, unspecified site, extranodal and solid organ sites | Lymphatic, Head and Neck, Brain, and Other Major Cancers (Version 12 model) and Lymphoma and Other Cancers (Version 22 model) | 250.00 | Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled | 6,238 |
| 1 | 205.02 | Acute myeloid leukemia, in relapse | Metastatic Cancer and Acute Leukemia | 250.02 | Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled | 20,175 |
| 1 | 205.80 | Other myeloid leukemia, without mention of having achieved remission | Lung, Upper Digestive Tract, and Other Severe Cancers (Version 12 Model) and Lung and Other Severe Cancers (Version 22 Model) | 250.80 | Diabetes with other specified manifestations, type II or unspecified type, not stated as uncontrolled | 8,371 |
| 1 | 402.01 | Malignant hypertensive heart disease with heart failure | Congestive Heart Failure | 402.10 | Benign hypertensive heart disease without heart failure | 5,463 |
| 1 | 433.01 | Occlusion and stenosis of basilar artery with cerebral infarction | Ischemic or Unspecified Stroke | 433.10 | Occlusion and stenosis of carotid artery without mention of cerebral infarction | 2,460 |
| 1 | 707.01 | Pressure ulcer, elbow | Decubitus Ulcer of Skin | 707.10 | Ulcer of lower limb, unspecified | 6,470 |
| 1 | 707.21 | Pressure ulcer, stage I | Decubitus Ulcer of Skin | 707.12 | Ulcer of calf | $4,107 |

| Number of Sampled Enrollee-Years | One Diagnosis for a Condition (Determined To Be Incorrect) | | | Multiple Diagnoses for a Condition (Not Reviewed) | | Overpayment |
|---|---|---|---|---|---|---|
| | Diagnosis Code | Diagnosis Code Description | Hierarchical Condition Category That Was Not Validated | Diagnosis Code | Diagnosis Code Description | |
| 1 | 174.9 | Malignant neoplasm of breast (female), unspecified | Breast, Prostate, Colorectal and Other Cancers and Tumors (Version 12 Model) and Breast, Prostate, and Other Cancers and Tumors (Version 22 Model) | 714.9 | Unspecified inflammatory polyarthritis | 1,558 |
| 1 | 802.5 | Open fracture of malar and maxillary bones | Major Head Injury | 805.2 | Closed fracture of dorsal [thoracic] vertebra without mention of spinal cord injury | 1,375 |
| 1 | I24.8 | Other forms of acute ischemic heart disease | Unstable Angina and Other Acute Ischemic Heart Disease | I42.8 | Other cardio-myopathies | 190 |
| **27** | | | | | | **$127,826** |

**Table 7: Hierarchical Condition Categories (HCCs) That Were Not Validated, but We Found Support for an HCC for a Less Severe Manifestation of the Related-Disease Group**

| Count of Sampled Enrollee-Years | More Severe Hierarchical Condition Category That Was Not Validated | Less Severe Hierarchical Condition Category That Was Supported |
|---|---|---|
| 3 | Vascular Disease With Complications | Vascular Disease |
| 2 | Decubitus Ulcer of Skin | Chronic Ulcer of Skin, Except Decubitus |
| 1 | Metastatic Cancer and Acute Leukemia | Lymphoma and Other Cancers |
| 1 | Diabetes With Acute Complications | Diabetes With Chronic Complications |
| 1 | Aspiration and Specified Bacterial Pneumonias | Pneumococcal Pneumonia, Emphysema, Lung Abscess |

## APPENDIX G: HUMANACHOICE COMMENTS

Humana.

September 9, 2022

Sheri L. Fulcher
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Audit Services, Region V
233 North Michigan, Suite 1360
Chicago, IL 60601

**VIA EMAIL**

RE: Humana's Response to Draft Audit Report No. A-05-19-00013

Dear Ms. Fulcher:

Humana Inc. ("Humana" or "Company") appreciates the opportunity you have provided to respond to the U.S. Department of Health and Human Services, Office of Inspector General's ("OIG's") Draft Audit Report No. A-05-19-00013, entitled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice, (Contract H6609) Submitted to CMS* (the "Draft Report"). As detailed below, Humana respectfully submits that OIG should not finalize the Draft Report's three recommendations because (1) medical record documentation substantiates certain of the conditions in question, (2) OIG's audit methodology reflects important departures from governing statistical and actuarial principles, the statutory requirements of the Medicare Advantage ("MA") program, and CMS's Risk Adjustment Data Validation ("RADV") processes, (3) Medicare Advantage Organizations ("MAOs") are not required to conduct audits to the standard that OIG suggests, and (4) Humana's risk adjustment compliance program satisfies all legal and regulatory requirements. These issues should not come as a surprise to OIG as they are the same issues that Humana recently explained to OIG in connection with its report entitled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS*[1] and with its report entitled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that HumanaChoice (Contract R5826) Submitted to CMS*.

Humana takes great pride in what the Company believes to be its industry-leading approach to Medicare risk adjustment ("MRA") compliance. Indeed, Humana has described its MRA compliance program to CMS over the course of many years, and has never received feedback from CMS that its program is deficient in any respect. As OIG and CMS are now well aware, Humana's policies and procedures not only extend to the so-called "high-risk diagnosis

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

codes" on which the Draft Report focuses, but to *all* diagnosis codes. Humana continues to believe its processes and reviews satisfy all legal requirements, for the reasons explained previously to OIG and CMS and reiterated again below.

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

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

Humana's internal risk adjustment compliance efforts and performance on CMS's RADV audits demonstrate that the vast majority of the risk adjustment data submitted by Humana to CMS meet CMS RADV standards. Considering that risk adjustment data is principally generated by Humana's vast network of medical providers based on the providers' clinical judgment and their implementation of a complex diagnosis coding system, it is not feasible for MAOs to eliminate all risk adjustment data discrepancies, nor is there any legal requirement for them to do so.[2] Humana has several programs in place to enhance the accuracy of risk adjustment data, consistent with MA program requirements and OIG's guidance.[3] Neither MA program requirements nor OIG guidance, however, offer specific direction related to the so-called "high-risk" diagnosis codes that are the subject of OIG's Draft Report.[4] MAOs are instead afforded broad discretion in designing compliance and education programs.[5]

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

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[2] *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.").

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

[4] 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").

[5] *See* 65 Fed. Reg. at 40,265.

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.[6] Indeed, setting aside for the moment all other concerns raised in this letter, addressing *only* the HCCs referenced in Appendix A would change the outcome of OIG's review 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.[7]

## 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 HumanaChoice received $490,453 in net overpayments for the 210 sampled enrollee-years.[8] OIG then applied an extrapolation methodology to all 2015 and 2016 payments for H6609 based on OIG's sample results and estimated that HumanaChoice "received at least $28,056,088 of net overpayments" for 2015 and 2016 which OIG recommends HumanaChoice return.[9] For the reasons below, Humana respectfully requests that OIG reconsider its recommendation.

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

Humana disagrees with some of OIG's determinations that HCCs for sampled enrollee-years are not substantiated by documentation in the relevant medical records. Specifically,

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[6] *See* Draft Report at 4–6.

[7] During Humana's Exit Conference with the OIG auditors for H6609, Humana inquired about the process to submit rebuttals to OIG's medical coding determinations, and Humana was informed that the Company should submit any rebuttals along with Humana's written response to the Draft Report. Failing to incorporate results from OIG's review of additional records would be an arbitrary and capricious departure from the approach OIG took in prior RADV audits. *See* HHS OIG, Audit Report No. A-07-19-01188, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS* (Nov. 2021) at 22, *available at* https://oig.hhs.gov/oas/reports/region7/71901188.pdf ("UPMC Report"); HHS OIG, Audit Report No. A-07-17-01173, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS* (Oct. 2021) at 18, *available at* https://oig.hhs.gov/oas/reports/region7/71701173.pdf ("Coventry Report"); HHS OIG, Audit Report No. A-07-16-01165, *Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted To CMS* (Apr. 2021) at 13–14, *available at* https://oig.hhs.gov/oas/reports/region7/71601165.pdf ("Humana Report"); HHS OIG, Audit Report No. A-02-09-01014, *Risk Adjustment Data Validation Of Payments Made To Excellus Health Plan, Inc., For Calendar Year 2007 (Contract H3351)* (Oct. 2012) at 8, *available at* https://www.oig.hhs.gov/oas/reports/region2/20901014.pdf ("Excellus Report"); HHS OIG, Audit Report No. A-05-09-00044, *Risk Adjustment Data Validation Of Payments Made To Paramount Care, Inc., For Calendar Year 2007 (Contract H3653)* (Sept. 2012) at 10–11, *available at* https://oig.hhs.gov/oas/reports/region5/50900044.pdf ("Paramount Report").

[8] Draft Report at 27 (Appendix D).

[9] OIG's estimated net overpayment amount of $28,056,088 is comprised of $27,928,262 of estimated net overpayments for the statistically sampled groups plus $127,826 for the group of potentially miskeyed diagnosis codes. *Id.* at 8, 17. OIG's recommended recovery used the lower limit of a two-sided 90-percent confidence interval. *Id.* at 8, 28 (Appendix D).

Humana has provided OIG with 12 appeals[10] reflecting instances where, contrary to OIG's determination, the following conditions are substantiated by medical record documentation: Major Depressive Disorder (HCC v22 58), Acute Myocardial Infarction (HCC v22 86), Unstable Angina and Other Acute Ischemic Heart Disease (HCC v12 82 / v22 87), Ischemic or Unspecified Stroke (HCC v12 96 / v22 100), and Vascular Disease with Complications (HCC v12 104 / v22 107).[11]

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

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

Based on Humana's understanding of OIG's audit procedures and methodology, Humana believes OIG's findings are systematically skewed towards identifying overpayments rather than underpayments, rendering its results inherently unreliable.[12] 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.[13] 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 to calculate overpayments or underpayments (if any) for each enrollee-year."[14] Following this approach, OIG determined that "HumanaChoice received at least $28,056,088 of

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[10] The 12 appeals correspond to 17 total v12 and v22 HCCs.

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

[12] 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 $28 million. This is important because, as leading industry experts have previously described in detail, flaws in a RADV extrapolation methodology can cause substantial bias in the final estimates produced by the methodology. *See* Wakely Consulting Group, LLC, *Medicare RADV: Review of CMS Sampling and Extrapolation Methodology* (July 2018). Moreover, such full detail is necessary to confirm OIG's audit methodology conforms to government auditing and actuarial standards. *See* U.S. Government Accountability Office, Government Auditing Standards, 2011 Revision (Dec. 2011) ("Government Auditing Standards"), *available at* https://www.gao.gov/assets/590/587281.pdf; U.S. Dep't of Health & Human Servs., *HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public*, Part II: HHS Agency Responsibilities and Guidelines, E. Centers for Medicare & Medicaid Services, V. Agency Quality Assurance Policies, Standards and Processes (Oct. l, 2002) ("Information Quality Guidelines"), *available at* https://aspe.hhs.gov/reports/hhs-guidelines-ensuring-maximizing-quality-objectivity-utility-integrity-information-disseminated.

[13] HHS OIG, Audit Report No. A-07-19-01187, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS* (May 2021), *available at* https://www.oig.hhs.gov/oas/reports/region7/71901187.pdf ("Anthem Report"); HHS OIG, Audit Report No. A-01-19-00500, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Tufts Health Plan (Contract H2256) Submitted to CMS* (Feb. 2022), *available at* https://oig.hhs.gov/oas/reports/region1/11900500.pdf ("Tufts Report"); Coventry Report at 27; UPMC Report at 25; *see also* Humana Report at 16.

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

net overpayments" in 2015 and 2016.[15] But Humana was tasked only with supplying medical records to substantiate specific HCCs actually submitted to CMS, not to collect and submit medical records to substantiate all HCCs that *could have been* submitted to CMS (*i.e.*, potential underpayments).[16]

Based on OIG's instructions, Humana's medical record submissions consisted of far less than all records available for the sampled enrollee-years. Thus, OIG's review could not and does not account for all HCCs that are substantiated but not submitted for the sampled enrollee-years—just as OIG found certain "underpayments" in the records actually subject to review,[17] other records that were never submitted to or reviewed by OIG could contain unsubmitted HCCs that would have been found upon review. Moreover, OIG excluded from its sampling frame all non-"high-risk" diagnosis codes associated with payment years 2015 and 2016 for H6609 enrollees as well as those for which Humana did not submit any risk-adjusting diagnosis codes.[18] This aspect of OIG's methodology also systematically reduced the probability of identifying underpayments.[19] 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.[20] OIG should consider such underpayment credits in its overpayment estimates. Accordingly, Humana also asks OIG to modify its recommended estimated repayment amount.

And because OIG's auditing methodology and recommendations are skewed towards identifying overpayments rather than underpayments, we respectfully request that OIG justify its approach under applicable government auditing standards, which Humana believes have been implicated by OIG's recommendations in other recent reports and would be implicated again if OIG were to finalize the Draft Report in its current form.[21]

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.[22] Thus, "actuarial equivalence" requires risk-adjusted

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[15] *Id.* at 17.
[16] OIG acknowledged in the Draft Report that "if medical records support diagnosis codes that MA organizations do 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.
[17] *See id.* at 10 (concluding for 1 enrollee-year, HumanaChoice submitted an acute stroke diagnosis code where OIG determined an HCC for hemiparesis should have been assigned and that "[t]his error caused an underpayment").
[18] *See id.* at 19 (Appendix A).
[19] *See* Matthew G. Mercurio, *Statistical Analysis of Draft Report Number A-07-16-01165* (Dec. 3, 2019).
[20] *See id.*
[21] *See* Government Auditing Standards; Information Quality Guidelines.
[22] *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i). Humana acknowledges the recent decision in *UnitedHealthcare Ins. Co. v. Becerra*. 16 F.4th 867 (D.C. Cir. 2021). However, the court expressly acknowledged that its decision did not

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.[23] The Actuarial Standards of Practice ("ASOPs"), especially ASOP No. 45, necessarily govern these actuarial calculations.[24] In its recent reports, OIG does not seem to seriously contest these principles, instead deferring to CMS on the issue.[25] Because the issue is subject to pending rulemaking at CMS,[26] however, Humana reiterates its positions here.

Industry experts have explained to CMS over the course of many years that it would violate "an underlying principle of risk adjustment systems" to determine MAO payments by applying (1) coefficients calculated using Medicare FFS diagnosis codes that are *partially unsubstantiated* by medical records, to (2) MAO diagnosis codes that are *fully substantiated* by medical records.[27] 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.[28] Industry experts refer to this error mode as the "Data Inconsistency Issue."[29]

CMS acknowledged the need to address the differing documentation standards that are the cause of the Data Inconsistency Issue in 2012. In CMS's 2012 RADV extrapolation methodology, it announced that it would determine a contract-level payment error in RADV audits only after applying a Fee-for-Service Adjuster ("FFSA") to account for the rate of unsubstantiated diagnosis codes in the Medicare FFS claims data from which CMS's HCC risk

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address the applicability of actuarial equivalence to RADV audits such as this. *Id.* at 893, n. 1 ("As mentioned above, CMS has since proposed not to use an FFS Adjuster in the context of contract-level RADV audits. *See* CMS Study at 5, J.A. 731. We express no opinion on whether the actuarial-equivalence requirement in section 1395w-23(a)(1)(C)(i) of the Medicare statute requires such an adjuster in that context. For current purposes, it suffices that the contexts of contract-level RADV audits and overpayment refunds are plainly distinguishable, such that CMS did not need to further explain, when it issued the Overpayment Rule in 2014, why it then intended to use an adjuster in the former context but not the latter.").

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

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

[25] HHS OIG, Audit Report No. A-02-18-01029, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS* (Jan. 2022), *available at* https://oig.hhs.gov/oas/reports/region2/21801029.pdf ("Healthfirst Report"); *See also* Tufts Report at 21; Coventry Report at 22; UPMC Report at 28; Anthem Report at 21.

[26] Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program for All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54982 (proposed Nov. 1, 2018) (to be codified at 42 C.F.R. §§ 422, 423, 438, 498).

[27] *See* Letter from American Academy of Actuaries to Cheri Rice, Acting Director, Medicare Plan Payment Group (Jan. 21, 2011) (on file with author); *see also* Wakely Consulting Group, LLC, *Actuarial Report on CMS' November 1, 2018 Proposed Rule* (Aug. 27, 2019) ("Wakely Report"), Section IV; Avalere Health, *Eliminating the FFS Adjuster from the RADV Methodology May Affect Plan Payment* (March 2019), *available at* https://avalere.com/wp-content/uploads/2019/03/20190318-FFS-Adjuster-Analysis-Final-.pdf; Milliman, *Medicare Advantage RADV FFS Adjuster: White Paper* (Aug. 23, 2019), *available at* https://assets.milliman.com/ektron/Medicare_Advantage_RADV_FFS_adjuster_8-23-2019.pdf.

[28] *See* Wakely Consulting Group, LLC, *Actuarial Analysis of OIG's September 24, 2019 Draft Report Regarding Humana Contract H1036* (Dec. 3, 2019) ("Wakely Analysis"); *see also* Wakely Report Section IV.

[29] *See* Wakely Report Section IV.

coefficients were initially derived.[30] CMS acknowledged that the FFSA was a function of the actuarial requirements of risk-adjusted compensation: "The FFS Adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model ([Medicare] FFS Claims)."[31] Because CMS is the agency designated by Congress to oversee and administer the Medicare Advantage program,[32] OIG cannot depart from CMS's methodology in place for the years that are the subject of OIG's Draft Report. The Medicare Advantage program requirements, which apply to CMS's audit determinations, are equally applicable to OIG's audits and calculation of estimated repayment amounts for the same program.

Humana notified CMS of the importance of the FFSA and the Data Inconsistency Issue to Humana's bids under H6609 for the years that are the subject of OIG's Draft Report. Specifically, Humana's Calendar Year 2015 and 2016 Actuarial Certifications for each filed Plan Benefit Package under H6609 stated explicitly that the Company was relying on CMS's plan to develop and apply an FFSA as part of any RADV process:

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

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[30] See CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audit* (Feb. 24, 2012) ("2012 RADV Audit Notice.").
[31] *Id.* at 4–5. On November 1, 2018, CMS published in proposed rule related to the methodology for Medicare RADV audits in the Federal Register. *See* Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54982 (Nov. 1, 2018) ("Proposed Rule"). This Proposed Rule is only a proposal; therefore, the RADV methodology that CMS announced in 2012 is still operative for RADV audits of MAO risk adjustment data. *See* 2012 RADV Audit Notice. In accordance with the notice-and-comment process, Humana has been joined by numerous industry participants and subject-matter experts, including independent actuaries and statisticians, in challenging various aspects of the Proposed Rule, including the proposal to eliminate a FFSA. On October 20, 2021, CMS announced that it extended the deadline for the Final RADV Rule to November 1, 2022. *See* Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021; Extension of Timeline To Finalize a Rulemaking, 86 Fed. Reg. 58245 (Oct. 21, 2021).
[32] 42 U.S.C. § 1395b-9.

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."[33] 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.[34]

If finalized, the Draft Report's treatment of individual unsubstantiated HCC submissions as overpayments would violate the actuarial equivalence requirement by failing to remedy the Data Inconsistency Issue. To reiterate: the Draft Report implicates the Data Inconsistency Issue because one documentation standard (unaudited data) was used to calibrate the CMS-HCC model while another documentation standard (audited data) was used to measure payment accuracy in an audit context.[35] Recognized industry experts have stated that "[t]his principle applies with equal force irrespective of the type of RADV audit."[36]

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, including the application of any FFSA . . . [i]f CMS deems it appropriate to apply an FFSA, it will adjust our overpayment finding by whatever amount it determines necessary." It is misleading, arbitrary and capricious for OIG to issue a report that suggests a certain level of overpayment when OIG is already aware that there are statutory requirements that will need to be addressed by CMS before any actual overpayment can be measured. This is particularly true where, as is the case here, an MAO expressly conditioned its bid on an understanding that an FFSA would be applied before the government measured any overpayments in a risk adjustment data validation audit. CMS approved Humana's bids for H6609 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.

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[33] Acute Stroke Audit Report at 6.
[34] *See id.* at 8.
[35] *See* Wakely Analysis.
[36] *See* Wakely Report at 33; *see also* Wakely Analysis.

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

As of the date of this letter, OIG has released ten similar audits of so-called "high-risk" diagnosis codes.[37] In these reports, OIG has focused on different diagnosis codes, defined the scope of the audited codes differently, and taken differing approaches to calculating the payment error.

Neither OIG nor CMS have ever even defined what it means for a diagnosis code to be "high-risk."[38] OIG has indeed changed the conditions that it considers to be "high-risk" throughout its ongoing audits.[39] With respect to OIG's audits of Humana contracts specifically, this is the third draft report that Humana has received from OIG related to "high-risk" diagnoses[40], but the first such audit to include a "potentially miskeyed" diagnosis code category.

Additionally, OIG has also been inconsistent in its methodology for characterizing of diagnosis codes within the "high risk" condition categories. For example, in OIG's Cariten Report, OIG analyzed 74 "high-risk" diagnosis codes for acute stroke, 38 diagnoses codes for acute heart attack, and 85 diagnosis codes for embolism. However, in its Draft Report here, OIG analyzed 6 "high-risk" diagnosis codes for acute stroke, 35 diagnosis codes for acute heart attack, and 58 diagnosis codes for embolism.[41] OIG's changing approach to the conditions under review evidences a deviation from prior audit methodologies.

Finally, in calculating payment errors associated with these supposedly "high-risk" codes, OIG has applied two completely distinct methodologies, with no rationale supplied to explain these arbitrarily differing approaches. In the first approach, used by OIG in two reports, OIG recommended that the audited MAOs refund to the Federal Government the "net overpayments"

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[37] *See* Cariten Report; HHS OIG, Audit Report No. A-07-17-01170, *Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements* (Apr. 2019), *available at* https://oig.hhs.gov/oas/reports/region7/71701170.pdf ("Essence Report"); HHS OIG, Audit Report No. A-02-18-01028, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS* (Feb. 2021), *available at* https://oig.hhs.gov/oas/reports/region2/21801028.pdf ("BCBSM Report"); HHS OIG, Audit Report No. A-06-18-05002, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Peoples Health Network (Contract H1961) Submitted to CMS* (May 2022), *available at* https://oig.hhs.gov/oas/reports/region6/61805002.pdf ("Peoples Health Report"); HHS OIG, Audit Report No. A-04-19-07084, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc., (Contract H1032) Submitted to CMS* (Aug. 2022), *available at* https://oig.hhs.gov/oas/reports/region4/41907084.pdf ("WellCare Report"); Anthem Report; Coventry Report; UPMC Report; Healthfirst Report; Tufts Report.

[38] In HHS OIG's recent audit report regarding Cariten Health Plan, Inc., OIG claimed that it defined what OIG considers to be a "high-risk" code. *See* Cariten Report at 22. Humana acknowledges that OIG has provided information on which codes it deems to be "high-risk" codes for purposes of that audit, but OIG has not indicated why the industry more broadly should have an aligned definition of "high-risk" codes, particularly where OIG has changed the conditions and codes under review in its own audits and has noted that it used its own undetailed "data mining techniques" to isolate such codes. *See* Draft Report at 1, 12, 19 (Appendix A).

[39] For example, *compare* UPMC Report at 22–23 (including lung cancer, breast cancer, and colon cancer) *with* Tufts Report at 4–5 (not including lung cancer, breast cancer, or colon cancer); Peoples Health Report at 4–5 (same).

[40] *See* Draft Report; Cariten Report; *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that HumanaChoice (Contract R5826) Submitted to CMS.*

[41] *Compare* Cariten Report at 29 (Appendix A) *with* Draft Report at 19.

based on OIG's "judgmentally selected" subset of "unique enrollee-years."[42] In the second approach, used by OIG in its other eight reports, OIG calculated "net overpayments" for statistically sampled enrollee-years and then applied an extrapolation methodology to estimate a total net overpayment amount for the sampling frame and recommended audited MAOs refund to the Federal Government the total extrapolated amount.[43] OIG has never acknowledged that its audit methodology is in constant flux, or explained why it needs two different methodologies.

Here, OIG used the second approach, and so it must, at the very least, acknowledge its departure from prior policy, provide a rationale as to why OIG has selected this approach for this report, and explain why it is justified in adopting such dissimilar practices in audits that all purport to cover so-called "high-risk" diagnosis code submissions by MAOs.[44] *See* 5 U.S.C. § 706(2)(A).

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

Humana understands that OIG generally intended the audit described in its Draft Report to follow CMS's procedures.[45] Humana agrees that OIG should not apply an audit methodology that enforces different standards than CMS, particularly one that has not been subject to required notice-and-comment rulemaking. Nevertheless, OIG's Draft Report appears to do so in several significant respects:

- First, OIG's audit methodology relies on a physician to act as a "tiebreaker" in situations where two coders disagree regarding whether a medical record substantiates an HCC.[46] 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."[47] If the second coder determines that the medical record in question substantiates a diagnosis code that maps to the HCC, then CMS treats the HCC as substantiated without further analysis. CMS's approach reflects a true coding analysis. If OIG were to implement CMS's coding methodology, Humana believes the number of HCCs that OIG determined to be unsubstantiated would be reduced.

- Second, it is unclear what specific diagnosis coding guidance the OIG's contracted reviewer provided to its staff to interpret, add to, or inform the use of ICD Coding Guidelines that we understand were used to guide the medical record review.[48] The standards used by the contractor could have a substantial impact on OIG's findings, and

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[42] *See* Coventry Report at 6, 14; Essence Report at 3–4, 8.
[43] *See* Anthem Report at 14, 31–32; BCBSM Report at 16, 24–25; Healthfirst Report at 16, 30–31; Peoples Health Report at 29; Tufts Report at 31; UPMC Report at 19, 40–41; Cariten Report at 36–37; WellCare Report at 33.
[44] *See* Draft Report at 26.
[45] *See* Draft Report at 19 (Appendix A).
[46] *See id.* at 21 (Appendix A).
[47] *See* CMS, Risk Adjustment Data Validation (RADV) Medical Record Intake Process And Guidance To Coders CY2011 ver. 4.0, at 18–19 (May 8, 2014) ("RADV Guidance").
[48] 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).

could also explain a number of the issues described further in the Draft Report.[49] 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."[50] To the extent the contractor's review underlying OIG's audit findings did not conform to CMS diagnosis coding guidance, the contractor's approach would have biased OIG's results and recommendations.

As we explained in connection with OIG's recent report related to contract H4461 and R5826, Humana does not understand the legal basis for OIG's apparent recommendation that Humana repay funds based on audit methodologies inconsistent with CMS's approach in RADV audits. Surely, OIG does not mean to suggest that the Department of Health and Human Services ("HHS") seeks to hold MAOs to different risk-adjustment data standards based solely on whether CMS or OIG happens to conduct the audit. Such a policy would be, at best, arbitrary and capricious under the Administrative Procedure Act. And it would force MAOs to decide between calibrating their compliance programs to satisfy OIG or CMS.

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

The Draft Report states that OIG used the lower limit of a two-sided 90% confidence interval when estimating the total amount of net overpayments,[51] rather than the lower bound of a 95% or 99% confidence interval.[52] While OIG has defended the use of the 90% confidence interval in other reports,[53] CMS announced that it uses the lower bound of a 99% confidence interval when calculating extrapolated repayment amounts for its RADV audits[54] and Humana relied on that announcement in submitting its bids. Absent a prospective process involving appropriate and necessary notice-and-comment rulemaking, OIG must be consistent with CMS

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[49] *See* Draft Report at 9.
[50] *See* CMS, Contract-Level Risk Adjustment Data Validation: Medical Record Reviewer Guidance (Sept. 27, 2017), *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/Coders-Guidance.pdf; *see also* RADV Guidance at 5 ("Though official coding rules do not change based on the type of audit, the coder should be aware of the background and prospective nature of the RA payment process including its basis on chronic conditions, and dependence on validating chronic conditions for an annual payment on just the review of one record. It is imperative therefore to code all chronic conditions documented by an acceptable provider type during a face to face encounter with the patient, whether or not there was specific treatment mentioned in the one record submitted. 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.").
[51] Draft Report at 26.
[52] Federal Judicial Center, National Academies Press, Reference Manual on Scientific Evidence 245 (3d ed. 2011) ("The 95% confidence level is the most popular, but some authors use 99%, and 90% is seen on occasion.").
[53] *E.g.,* Healthfirst Report at 24–25; Cariten Report at 24–25.
[54] CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* (Feb. 24, 2012) at **4**.

practice for RADV audits by using the lower bound of a 99% confidence interval. This is especially true given Humana's reliance interests. Humana thus respectfully requests that OIG recalculate the extrapolated "overpayment" amount using the lower bound of a 99% confidence interval. OIG's inconsistent approach in the Draft Report would further disrupt actuarial equivalence if finalized.

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

OIG recommends that Humana "identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government[.]"[55] Once again, this recommendation presents issues that Humana and other audited MAOs have addressed with OIG in connection with other recent audits. For the reasons described by Humana and other industry participants, reiterated below, Humana respectfully requests that OIG reconsider this recommendation because (1) Medicare Advantage regulations do not require the sort of audits that OIG recommends and (2) OIG has not provided Humana with sufficient information to replicate its process for identifying "potentially miskeyed diagnoses."

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

Humana, like all MAOs, relies on medical providers to generate large volumes of risk adjustment data based on the providers' clinical judgment and their implementation of a complex diagnosis coding system. CMS regulations state that MAOs should take reasonable steps to ensure the "accuracy, completeness, and truthfulness" of the risk adjustment data they submit based on "best knowledge, information, and belief," but do not impose a requirement of 100 percent accuracy.[56] CMS implemented the current regulatory regime after acknowledging industry concerns about widespread healthcare provider "mistakes" and "incomplete or inaccurate" provider-generated data.[57] Commenters at the time explained that "it would be unfair and unrealistic to hold [MA] organizations to a '100 percent accuracy' certification standard."[58] 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."[59] 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."[60]

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

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[55] Draft Report at 18.
[56] 42 C.F.R. § 422.504(l).
[57] Medicare Program: Medicare+Choice Program, 65 Fed. Reg. 40,169, 40,250, 40,268 (June 29, 2000).
[58] *See id.* at 40,268.
[59] *Id.*
[60] *Id.*

knowledge, information and belief, does not constitute an absolute guarantee of accuracy."[61] In addition, OIG has suggested that MAOs should conduct "sample audits and spot checks" to confirm that their information collection and reporting system is working correctly, but OIG has offered no other specific guidance to the industry in this regard.[62]

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."[63] 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. 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."[64] 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[65] 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."[66] OIG's recommendation does not align with the requirements of a MA compliance program because the MA program does not compel Humana or other MAOs to conduct audits of specific "high-risk diagnoses." Despite CMS's awareness of "several diagnosis codes that are at high-risk for inaccurate payments" throughout the MA industry, CMS has not implemented any regulations or guidance to address such issues or require additional compliance measures.[67] Nor does OIG identify any statutory or regulatory authority that would allow it to unilaterally impose new substantive requirements on Humana, rather than merely identifying non-compliance with duly-promulgated regulations. And, as explained, to the extent OIG's recommendation conflicts with CMS's regulations and guidance, it would arbitrarily and capriciously subject Humana to two contradictory regulatory regimes from the same agency. To the extent HHS intends to impose new regulatory requirements on Humana, it must do so through notice-and-comment, under both the Administrative Procedure Act and the SSA.[68]

Accordingly, Humana respectfully requests that OIG reconsider this recommendation.

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[61] *See* Publication of the OIG's Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans, 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999).
[62] 64 Fed. Reg. 61,900 (Nov. 15, 1999).
[63] Draft Report at 9.
[64] *Id.* at 8.
[65] *See* Cariten Report at 27.
[66] *Id.* at 18.
[67] *See* Acute Stroke Audit Report at 1.
[68] *See* 5 U.S.C. § 553; 42 U.S.C. § 1395hh(a)(2).

2. OIG should reconsider its recommendation because OIG has not supplied sufficient information for Humana to replicate OIG's process for identifying "potentially miskeyed diagnosis codes."

With respect to the "potentially miskeyed diagnosis codes" identified in OIG's Draft Report, Humana does not have the necessary information to replicate OIG's process. Although OIG provided some information about the process OIG used to identify such codes, OIG did not provide sufficient information, such as the underlying algorithm OIG used to identify such codes. To the extent that OIG recommends Humana identify similar instances of "potentially miskeyed diagnosis codes" that occurred before or after the audit period, Humana respectfully requests that OIG reconsider this recommendation.

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

Despite acknowledging that HumanaChoice had compliance procedures in place designed to promote accuracy in diagnoses coding, including guidance relevant to the so-called "high-risk diagnoses" under review, OIG recommends that Humana "examine its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high-risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures."[69] This exact recommendation came up in connection with OIG's other recent "high-risk" code reports, and again it appears that OIG and the MA industry are at an impasse. For the reasons described below, explained previously to OIG by Humana and other industry participants, Humana respectfully requests that OIG reconsider this recommendation.

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

As explained in Section IV.2, Humana has several programs in place to enhance the accuracy of risk adjustment data, consistent with MA program requirements and OIG's guidance,[70] 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.

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[69] Draft Report at 18.

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

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."[71] This effectively imposes the perfection standard that CMS and OIG have previously recognized is not reasonable to enforce, as discussed above.[72] 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.[73] 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;[74] 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.[75] Thus, Humana requests that OIG reconsider its position that Humana's policies and procedures "could be improved" and its recommendation that Humana "enhance" its current policies and procedures.

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

As noted above, since 2013 Humana has regularly described to CMS the Company's risk adjustment data policies and procedures and the particulars of Humana's MRA compliance program.[76] 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.[77] Further, Humana described its risk adjustment data

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[71] Draft Report at 17.
[72] *See* Medicare Program: Medicare+Choice Program, 65 Fed. Reg. 40,268 (June 29, 2000).
[73] *See* Draft Report at 8–9.
[74] *See* Anthem Report at 24.
[75] *See* Humana Report at 13; Healthfirst Report at 29; UPMC Report at 31.
[76] *See, e.g.*, Letter from Sean J. O'Reilly, Chief Compliance Officer, Humana to Cheri Rice, Acting Deputy Center Director, Centers for Medicare and Medicaid Services (Mar. 4, 2019).
[77] Humana acknowledges that, in the Cariten Report, OIG cites to 42 CFR § 422.503(b)(4)(vi)(G) to argue that a MAOs must take action to enhance their programs. Humana maintains that is has an effective compliance program for the reasons outlined in this letter. To the extent that OIG is requiring an additional audit procedure not required by existing regulations, those are subject to notice and comment rulemaking. Additionally, one element of Humana's extensive MRA compliance activities that was in place during the service years at issue in this audit involved regular internal RADV-like audits that Humana conducted to confirm the accuracy of the risk-adjusted premiums that Humana received from CMS (called Humana Self Audits), the results of which Humana reported to CMS. Humana believes that these Self Audits satisfied the Company's legal obligations (contractual, regulatory, or otherwise) with respect to risk adjustment payment accuracy and, therefore, it is duplicative for OIG to recommend that Humana refund premium amounts other than those found by the Company's Self Audits. As discussed with OIG, to administer Self Audits, Humana reviewed, in a manner generally consistent with the standards that CMS has applied in its past RADV audits of Humana's contracts, all HCCs submitted to CMS for a sample of members. This included requesting additional documentation for further review if the initial documentation received from providers

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.[78] As those communications demonstrate, Humana has for years incurred tremendous expense in implementing numerous MRA audits and compliance measures in reliance on the government methodologies and compliance standards articulated in the regulations and sub-regulatory guidance described herein.

Consistent with the discretion afforded to Humana under MA program requirements, Humana has several programs in place to enhance the accuracy of risk adjustment data, which include but are not limited to, Provider Data Validation reviews, Humana's Risk Adjustment Integrity Unit, Humana-conducted Risk Adjustment Data Validation audits, and Administrative Quality Audits. With regard to the so-called "high-risk diagnoses" OIG has identified, OIG acknowledges that "HumanaChoice had compliance procedures for determining whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct" and these procedures included a "provider education program that was designed to promote accurate diagnosis codes, which provided instructions to its providers on the proper coding of several risk adjustment diagnoses, including those in the seven high-risk groups reviewed in our audit."[79] OIG also acknowledges that "HumanaChoice's compliance procedures included routine internal medical reviews to compare diagnosis codes from a random sample of claims to the diagnoses that were documented on the associated medical records."[80] Humana believes these programs satisfy Humana's obligations under applicable MA program requirements.

Despite these findings, OIG's Draft Report concludes that HumanaChoice's compliance procedures "could be improved" because HumanaChoice'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."[81] All of Humana's risk adjustment compliance processes and reviews, by their nature, include such diagnosis codes. Humana disagrees with the notion that existing CMS guidance requires a particular approach to OIG's unilaterally selected "higher-risk" areas. As explained in Section I, CMS has acknowledged that it does not have policies and procedures in place that would have guaranteed so-called "high-risk" diagnosis codes, like acute stroke,

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did not support an HCC. Consistent with CMS's regulatory guidance and the aforementioned actuarial equivalence requirement, the Self Audit process involved the calculation and comparison of the contract level Self Audit results against an estimated FFSA. Specifically, if Humana determined that an unsubstantiated HCC has been submitted for a sampled member, Humana recalculated the member's risk score and risk adjustment premium to determine any projected payment imprecision related to that member. Humana then calculated each Self Audit contract group's preliminary payment recovery amount and applied an estimated FFSA to determine the final estimated recovery amount from the Self Audit. For any Self Audit contract group that ultimately had a final estimated recovery amount, Humana sought to return the resulting overpayment to CMS. Humana also submitted a corresponding data correction for every HCC that had been selected for Self Audit that was not supported by at least one available medical record.

[78] *See* Draft Report at 20 ("[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 identify and detect noncompliance with Federal requirements.").

[79] *Id.* at 17.

[80] *Id.*

[81] *Id.*

were always supported by underlying medical record documentation.[82] In the absence of specific CMS-implemented MA program requirements, Humana and other MAOs are afforded broad discretion in designing compliance and education programs.[83]

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

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

Sincerely,

/Sean O'Reilly/

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

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[82] *See* Acute Stroke Audit Report at 8.
[83] *See* 65 Fed. Reg. at 40,265.