Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE ADVANTAGE COMPLIANCE AUDIT OF DIAGNOSIS CODES THAT CAREPLUS HEALTH PLANS, INC. (CONTRACT H1019) SUBMITTED TO CMS

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Report in Brief
Date: October 2023
Report No. A-04-19-07082

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

Medicare Advantage Compliance Audit of Diagnosis Codes That CarePlus Health Plans, Inc. (Contract H1019) 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 each enrollee's health status. MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources than to healthier enrollees, who would be expected to require fewer health care resources.

To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS. CMS then maps certain diagnosis codes into Hierarchical Condition Categories (HCCs), based on similar clinical characteristics and severity and cost implications. CMS makes higher payments for enrollees who receive diagnoses that map to HCCs.

For this audit, we reviewed one of the contracts that CarePlus Health Plans, Inc., has with CMS with respect to the diagnosis codes that CarePlus submitted. Our objective was to determine whether CarePlus submitted diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements.

How OIG Did This Audit

We selected a sample of 200 enrollees with at least 1 diagnosis code that mapped to an HCC for 2015. CarePlus provided medical records as support for 1,656 HCCs associated with these enrollees. We used an independent medical review contractor to determine whether the diagnosis codes complied with Federal requirements.

What OIG Found

CarePlus did not submit some diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. First, although most of the diagnosis codes that CarePlus submitted were supported in the medical records and therefore validated 1,210 of the 1,656 sampled enrollees' HCCs, the remaining 446 HCCs were not validated and resulted in overpayments. These 446 unvalidated HCCs included 64 HCCs for which we identified 64 other HCCs for more and less severe manifestations of the diseases. Second, there were an additional 52 HCCs for which the medical records supported diagnosis codes that CarePlus should have submitted to CMS but did not.

Thus, the risk scores for the 200 sampled enrollees should not have been based on the 1,656 HCCs. Rather, the risk scores should have been based on 1,326 HCCs (1,210 validated HCCs plus 64 other HCCs plus 52 additional HCCs) and resulted in $641,467 in net overpayments. On the basis of our sample results, we estimated that CarePlus received at least $117.3 million in net overpayments for 2015. As demonstrated by the errors found in our sample, CarePlus's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved.

What OIG Recommends and CarePlus Comments

We recommend that CarePlus refund to the Federal Government $641,467 of net overpayments and ensure that its policies and procedures have been adequately designed and implemented to prevent, detect, and correct noncompliance with Federal requirements for diagnosis codes that are used to calculate risk-adjusted payments. CarePlus disagreed with our findings and recommendations and provided additional information to validate specific HCCs. CarePlus also questioned our audit and statistical sampling methodologies and said that we misunderstood certain legal and regulatory requirements underlying the MA program.

After reviewing CarePlus's comments and the additional information provided, we revised our findings and the associated net overpayment amount in our first recommendation. 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. We changed the amount of the recommended refund to include only the net overpayments of $641,467. We made no changes to our second recommendation.

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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]

Incorrect diagnosis codes can lead to improper payments. An improper payment is any payment that should not have been made or that was made in an incorrect amount (either an overpayment or an underpayment). An estimated 6.78 percent of payments to MA organizations for calendar year 2018 were improper, mainly due to MA organizations submitting unsupported diagnosis codes to CMS.[2] Our previous audits have shown that MA organizations submitted diagnosis codes that did not comply with Federal requirements.[3]

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. We reviewed one MA organization, CarePlus Health Plans, Inc., with respect to the diagnosis codes that CarePlus submitted to CMS for contract number H1019.[4]

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

[2] The Department of Health and Human Services Agency Financial Report, Fiscal Year 2020, estimated that 6.78 percent of the payments for the MA program were improper. This figure includes errors for both overpayments and underpayments. The error rate is determined in accordance with the Payment Integrity Information Act of 2019, P.L. No. 116-117 (Mar. 2, 2020) which repealed and replaced the Improper Payments Information Act of 2002, P.L. No. 107-300 (Nov. 26, 2002); the Improper Payments Elimination and Recovery Act of 2010, P.L. No. 111-204 (July 22, 2010); the Improper Payments Elimination and Recovery Improvement Act of 2012, P.L. No. 112-248 (Jan. 10, 2013); and the Fraud Reduction and Data Analytics Act of 2015, P.L. No. 114-186 (June 30, 2016). Similar to the Improper Payments Elimination and Recovery Improvement Act of 2012, the Payment Integrity Information Act of 2019 requires Federal agencies to: (1) review their programs and activities to identify programs that may be susceptible to significant improper payments, (2) test for improper payments in high-risk programs, and (3) develop and implement corrective action plans for high-risk programs.

[3] See Appendix B for a list of related Office of Inspector General reports.

[4] All subsequent references to "CarePlus" in this report refer solely to contract number H1019.

OBJECTIVE

Our objective was to determine whether CarePlus submitted diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements.

BACKGROUND

Medicare Advantage Program

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

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

For 2021, CMS paid MA organizations $349.9 billion, which represented 42 percent of all Medicare payments for that year.

Risk Adjustment Program

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

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

- Base rate: Before the start of each year, each MA organization submits bids to CMS that reflect the MA organization's estimate of the monthly revenue required to cover an

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

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

enrollee with an average risk profile.[7] CMS compares each bid to a specific benchmark amount for each geographic area to determine the base rate that the MA organization is paid for each of its enrollees.[8]

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

To determine an enrollee's health status for purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from acceptable data sources, including certain physicians and hospitals.[9] 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, severity, and cost implications, into Hierarchical Condition Categories (HCCs). Each HCC has a factor (which is a numerical value) assigned to it for use in each enrollee's risk score.

CMS transitioned from one HCC payment model to another during our audit period. As part of this transition, for 2015, CMS calculated risk scores based on both payment models. CMS refers to these models as the Version 12 model and the Version 22 model, each of which has unique HCCs. Accordingly, a diagnosis code can map to either a Version 12 or Version 22 model HCC, or to both models. For example, the diagnosis code for Acute Kidney Failure, Unspecified maps to the Version 12 model HCC for Renal Failure and the Version 22 model HCC for Acute Renal Failure.

CMS blended the risk scores from both models into a single risk score for each enrollee. Thus, the total number of HCCs associated with an enrollee's risk score is based on the HCCs from both payment models.

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

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

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

[9] CMS required face-to-face encounters during our audit period. However, in April 2020, CMS issued a memorandum to MA organizations stating that diagnoses resulting from telehealth services can meet the face-to-face requirement when the services are provided using an interactive audio and video telecommunications system that permits real-time interactive communication. This memorandum is available online at https://www.cms.gov/files/document/applicability-diagnoses-telehealth-services-risk-adjustment-4102020.pdf (accessed on September 29, 2023).

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.[10]

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

CMS multiplies the risk scores by the base rates to calculate the total monthly Medicare payment that an MA organization receives for each enrollee before applying the budget sequestration reduction.[11] 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.[12] Conversely, if medical records support the diagnosis codes that an MA organization did not submit to CMS, validated HCCs may not have been included in enrollees' risk scores, which may cause those risk scores to be understated and may result in underpayments.

CMS designed its contract-level Risk Adjustment Data Validation (RADV) audits to be its primary corrective action on improper payments, which were estimated at 6.78 percent of payments to MA organizations for 2018. These CMS RADV audits verify that diagnoses submitted by MA organizations for risk-adjusted payment are supported by medical record documentation.

[10] In some instances, CMS has assigned the same factors for certain HCCs in a related-disease group. For example, the factor for the HCC for Drug/Alcohol Psychosis is the same as the factor for the HCC for Drug/Alcohol Dependence. These two HCCs (Version 12) are in the same related-disease group.

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

[12] 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 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.

CarePlus Health Plans, Inc.

CarePlus is an MA organization with headquarters in Miami, Florida, that provides coverage in several counties statewide. As of December 31, 2015, CarePlus provided coverage under contract number H1019 to approximately 131,000 enrollees in Florida. For our audit period (the 2015 payment year), CMS paid CarePlus approximately $1.7 billion to provide this coverage.[13]

HOW WE CONDUCTED THIS AUDIT

Our audit focused on enrollees on whose behalf CarePlus submitted to CMS, for the 2014 service year, at least one diagnosis code that mapped to an HCC used in the enrollees' risk scores for the 2015 payment year. We identified a sampling frame of 55,891 enrollees from which we selected a stratified random sample of 200 enrollees on whose behalf CMS made payments totaling $3,967,569 to CarePlus. CarePlus provided medical records as support for 1,656 HCCs (total of both HCC payment models) associated with the 200 enrollees.

We used an independent medical review contractor to review the medical records to determine whether the diagnosis codes validated the 1,656 HCCs. The contractor also reviewed these same records to determine whether any additional HCCs were validated by diagnosis codes that CarePlus did not submit but should have submitted.

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

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

FINDINGS

CarePlus did not submit some diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements.

First, 1,210 of the 1,656 sampled enrollees' HCCs were validated; however, the medical records did not validate the remaining 446 HCCs and resulted in overpayments. These 446 unvalidated HCCs included 64 HCCs for which we identified 64 other HCCs for more and less severe manifestations of the diseases. These 64 other HCCs should have been included in the

[13] All payment amounts that CMS made to CarePlus, and the adjustment amounts that we identified in this report reflect the budget sequestration reduction.

enrollees' risk scores (instead of the 64 unvalidated HCCs), which would have reduced the overpayments associated with the 446 unvalidated HCCs in our sample.[14]

Second, in reviewing the medical record documentation for the diagnosis codes associated with the 1,656 sampled enrollee HCCs, we identified support for diagnosis codes that CarePlus should have submitted to CMS but did not. If CarePlus had submitted these diagnosis codes, an additional 52 HCCs would have been included in the enrollees' risk scores. These risk scores would have increased, and CMS's payments to CarePlus would have been higher.

In summary, the risk scores for the 200 sampled enrollees should not have been based on the 1,656 HCCs. Rather, the risk scores should have been based on 1,326 HCCs (1,210 validated HCCs plus 64 other HCCs associated with more and less severe manifestations of diseases plus 52 additional validated HCCs that CarePlus did not submit to CMS). As a result, CarePlus received $641,467 in net overpayments. On the basis of our sample results, we estimated that CarePlus received at least $117,334,526 in net overpayments for 2015.[15] Because of Federal regulations that limit the use of extrapolation in RADV audits for recovery purposes to payment years 2018 and forward, we are reporting the overall estimated net overpayment amount but are recommending a refund of $641,467 in net overpayments.[16]

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

FEDERAL REQUIREMENTS

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

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

[14] The less severe manifestations of the diseases for 61 HCCs led to overpayments for 51 HCCs and no payment effect for 10 HCCs. The more severe manifestations for three HCCs led to an underpayment for two HCCs and no payment effect for one HCC.

[15] To be conservative, we estimated 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.

[16] After we had reviewed the sampled enrollees, 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)).

provider, supplier, physician, or other practitioner that furnished the item or service (42 CFR § 422.310(d)(3)).

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

CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap. 7 (last rev. Sep. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented on the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7 § 40). The diagnosis must be coded according to the *International Classification of Diseases (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, the MA organizations must implement procedures to ensure that diagnoses come only from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities, and physicians (the Manual, chap. 7 § 40).

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

See Appendix E for Federal regulations regarding compliance programs that MA organizations must follow.

CAREPLUS DID NOT SUBMIT SOME DIAGNOSIS CODES IN ACCORDANCE WITH FEDERAL REQUIREMENTS

CarePlus did not submit some diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. Specifically, CarePlus either submitted some diagnosis codes that were not supported in the medical records or did not submit all of the correct diagnosis codes. Both types of errors caused CMS to calculate incorrect risk scores for 116 of the 200 sampled enrollees.[17]

[17] There was more than one type of error for some enrollees.

Some of the Diagnosis Codes That CarePlus Submitted to CMS Were Not Supported in the Medical Records

The diagnosis codes that CarePlus submitted to CMS were not supported in the medical records for 446 of the 1,656 sampled enrollees' HCCs. The 446 HCCs were not validated and should not have been used in the enrollees' risk scores. These errors, which also included more and less severe manifestations of the diseases, caused net overpayments from CMS to CarePlus for the 116 sampled enrollees.

Medical Records Did Not Support Submitted Diagnosis Codes or Any Other Diagnosis Codes

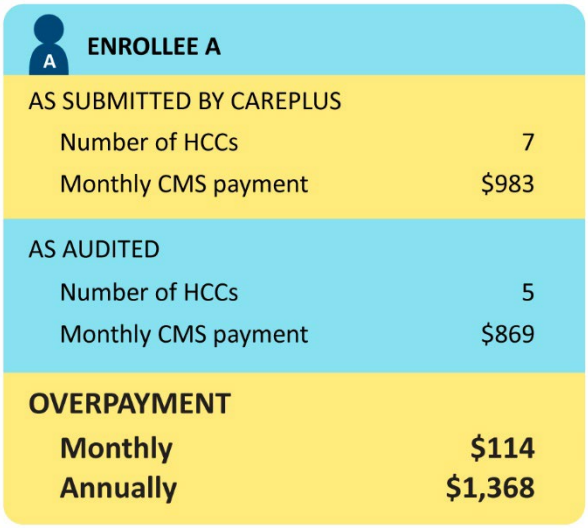
For 382 of the 446 unvalidated HCCs (109 sampled enrollees), the medical records did not support either the diagnosis code that CarePlus submitted or any other diagnosis code that would have validated the HCC.[18] These errors caused overpayments.

For example, for Enrollee A, CarePlus submitted a diagnosis code for Angina Pectoris, which maps to the Version 12 model HCC for Angina Pectoris/Old Myocardial Infarction and to the Version 22 model HCC for Angina Pectoris. However, that diagnosis was not supported in the medical records that CarePlus provided to us. Our independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the HCC for Angina Pectoris]. There is documentation of chest pain . . . that does not result in an HCC."

As shown in Figure 1 on the following page, the diagnosis codes that CarePlus submitted to CMS on behalf of Enrollee A mapped to seven HCCs, which CMS used to calculate a $983 monthly payment that it made to CarePlus. Because the Angina Pectoris/Old Myocardial Infarction and Angina Pectoris HCCs were not validated, the CMS payment should have been based on five HCCs, which would have resulted in a monthly payment of $869. This error caused an overpayment of $1,368 for the year.

[18] For one sampled enrollee, CarePlus did not provide any medical records to support four HCCs; therefore, the HCCs were not validated.

Figure 1: Overpayment Calculation for Enrollee A, Who Had HCCs That Were Not Validated



Medical Records Did Not Support Submitted Diagnosis Codes, but We Identified Other Hierarchical Condition Categories That Were Supported by Other Diagnosis Codes

For 64 of the 446 unvalidated HCCs (30 sampled enrollees), the medical records did not support the diagnosis codes that CarePlus submitted. However, we identified 64 other HCCs (that were supported by other diagnosis codes) for more and less severe manifestations of the diseases. These 64 other HCCs should have been included in the enrollees' risk scores (instead of the 64 unvalidated HCCs).

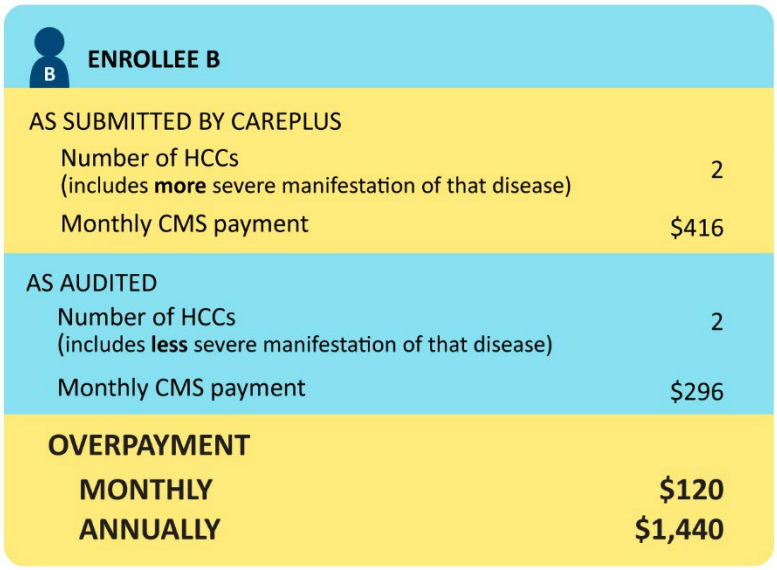
For 61 of the 64 unvalidated HCCs (28 sampled enrollees), the diagnosis codes that CarePlus submitted mapped to a more severe manifestation of the HCCs in the related-disease group but were not supported in the medical records. However, there were other diagnosis codes mapped to 61 other HCCs for less severe manifestations that should have been used in the enrollees' risk scores. These errors led to overpayments for 51 HCCs and no payment effect for 10 HCCs.

For example, for Enrollee B, the medical records did not support the diagnosis Diabetes With Other Specified Manifestations, Type II or Unspecified Type, Not Stated as Uncontrolled. This diagnosis maps to HCCs that are both more severe manifestations of the HCCs in those related-disease groups (Diabetes With Neurologic or Other Specified Manifestation for the Version 12 model and Diabetes With Chronic Complications for the Version 22 model). However, there was support for the diagnosis Diabetes Mellitus Without Mention of Complication, Type II or Unspecified Type, Not Stated as Uncontrolled, which maps to HCCs that were both less severe manifestations of the HCCs in those related-disease groups (Diabetes Without Complication for both the Version 12 and 22 models). Accordingly, Enrollee B's risk score should have been

based on the HCCs with the less severe manifestation instead of the HCCs with the more severe manifestation.

As shown in Figure 2, this error caused an overpayment of $1,440 for the year.

Figure 2: Overpayment Calculation for Enrollee B, Who Had HCCs for a Less Severe Manifestation of a Disease That Should Have Been Used Instead of HCCs for a More Severe Manifestation of That Disease

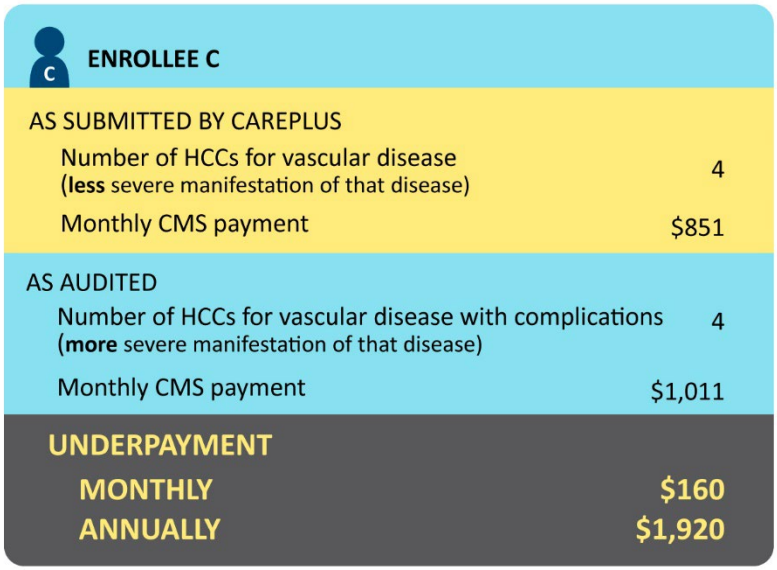


For 3 of the 64 unvalidated HCCs (2 sampled enrollees), CarePlus did not submit diagnosis codes to CMS that mapped to a more severe manifestation of the HCCs in the related-disease groups. Instead, CarePlus submitted only the diagnosis codes that mapped to the less severe manifestations. If CarePlus had submitted the correct diagnosis codes, the more severe HCCs would have been used instead of the less severe HCCs in the risk scores. These errors led to underpayments for two HCCs and no payment effect for one HCC.

For example, for Enrollee C, CarePlus submitted to CMS a diagnosis for Aortic Aneurysm of Unspecified Site Without Mention of Rupture. This diagnosis code maps to both the Version 12 model HCC and the Version 22 model HCC for Vascular Disease, both of which are less severe manifestations of the HCCs in those related-disease groups. That diagnosis was not supported in the medical records that CarePlus provided to us. However, our independent medical review contractor found support for the diagnosis Dissection of Aorta, Thoracic, which maps to HCCs that were both more severe manifestations of the HCCs in those related-disease groups (Vascular Disease With Complications, for both the Version 12 and 22 models). Accordingly, Enrollee C's risk score should have been based on the HCCs with the more severe manifestation instead of the HCCs with the less severe manifestation.

As shown in Figure 3, this error caused an underpayment of $1,920 for the year.

Figure 3: Underpayment Calculation for Enrollee C, Who Had HCCs for a More Severe Manifestation of a Disease That Should Have Been Used Instead of HCCs for a Less Severe Manifestation of That Disease

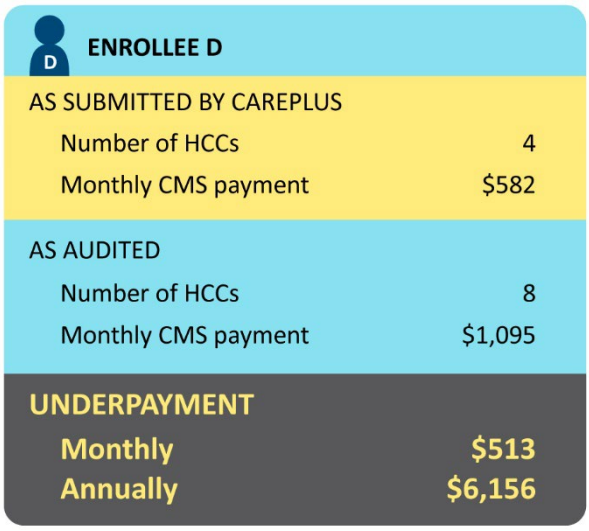


Diagnosis Codes That CarePlus Should Have Submitted but Did Not Submit to CMS

CarePlus did not submit all of the correct diagnosis codes. Specifically, there were an additional 52 HCCs (26 sampled enrollees) for which the medical records supported diagnosis codes that CarePlus should have submitted but did not submit to CMS and that should have been used in the enrollees' risk scores. These errors caused underpayments from CMS to CarePlus.
For example, for Enrollee D, CarePlus did not submit diagnosis codes for Rheumatoid Arthritis and Congestive Heart Failure Unspecified. However, our independent medical review contractor, as part of its review of a different HCC, found support for these diagnoses documented in a medical record. These diagnosis codes—which CarePlus should have submitted but did not submit to CMS—map to and validate the Version 12 model HCCs and the Version 22 model HCCs for Rheumatoid Arthritis and Inflammatory Connective Tissue Disease and for Congestive Heart Failure.

As shown in Figure 4 on the following page, this error caused an underpayment of $6,156.

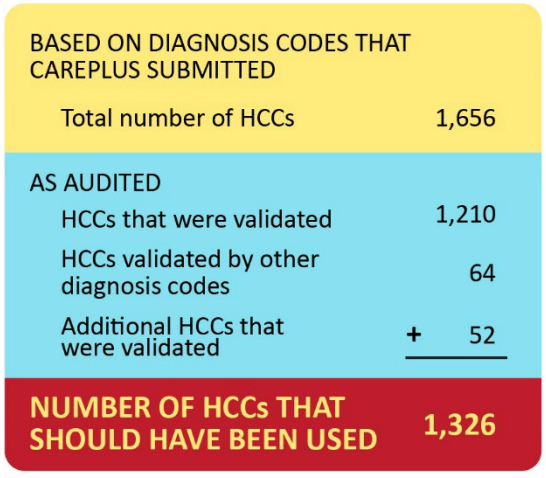
Figure 4: Underpayment Calculation for Enrollee D, Who Had HCCs That Were Validated From a Diagnosis Code That CarePlus Should Have Submitted but Did Not Submit to CMS



Summary of Diagnosis Codes Not Submitted in Accordance With Federal Requirements

Because CarePlus did not submit some diagnosis codes in accordance with Federal requirements for the 200 sampled enrollees, their risk scores should not have been based on the 1,656 HCCs. Rather, their risk scores should have been based on the 1,326 validated HCCs. Figure 5 summarizes these differences.

Figure 5: Number of HCCs Used in Risk Scores Contrasted With Number of HCCs That Should Have Been Used in Risk Scores for the 200 Sampled Enrollees



Moreover, CarePlus received $641,467 in net overpayments (consisting of $682,274 of overpayments and $40,807 of underpayments) for the 200 sampled enrollee-years (Appendix D).

THE POLICIES AND PROCEDURES THAT CAREPLUS HAD TO PREVENT, DETECT, AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS COULD BE IMPROVED

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

CarePlus officials told us that its compliance program had several procedures to ensure that it submitted accurate diagnosis codes for use in CMS's risk adjustment program. For example, one of these procedures was designed to prevent the submission of incorrect diagnosis codes to CMS, which included provider education on how to document and report accurate diagnosis codes on CarePlus's claims. CarePlus also conducted retrospective coding reviews of medical records (as discussed further in the next paragraph) and that it followed up with providers that did not improve their coding accuracy or refused coding education.

CarePlus's compliance program also had procedures to detect and correct noncompliance that included, but were not limited to, provider data validation and fraud detection. Specifically, CarePlus had a provider data validation process to assess and improve the diagnosis coding accuracy of its contracted health care providers through medical record reviews with its own internal certified coders. Furthermore, CarePlus's risk adjustment integrity unit was a fraud detection and compliance unit that investigated and remediated improper risk adjustment data submissions to CMS.

However, because our audit found that 446 of the 1,656 HCCs should not have been included in the sampled enrollees' risk scores, we concluded that CarePlus's compliance policies and procedures could be improved.

CAREPLUS RECEIVED NET OVERPAYMENTS

On the basis of our sample results, we estimated that CarePlus received at least $117,334,526 of net overpayments for 2015.

Because of Federal regulations that limit the use of extrapolation in RADV audits for recovery purposes, we are reporting the estimated net overpayment amount but are recommending a refund of only the $641,467 in net overpayments that CarePlus received for the 200 sampled enrollee-years.[19]

[19] 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)).

RECOMMENDATIONS

We recommend that CarePlus Health Plans, Inc.:

- refund to the Federal Government the $641,467 of net overpayments; and

- ensure that its policies and procedures have been adequately designed and implemented to prevent, detect, and correct noncompliance with Federal requirements for diagnosis codes that are used to calculate risk-adjusted payments.

CAREPLUS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CarePlus did not agree with our findings and recommendations.[20] CarePlus stated the following: (1) medical record documentation substantiated some of the diagnosis codes in question; (2) we misunderstood certain statistical and actuarial principles, the legal and regulatory requirements underlying the MA program, and CMS's RADV processes; and (3) CarePlus's risk adjustment compliance program satisfies all legal and regulatory requirements. CarePlus requested that we reconsider both of our recommendations.

We reviewed CarePlus's comments and the additional information that it provided and, accordingly, reduced the number of HCCs in error from 465 to 446. We then adjusted our calculation of overpayments for this final report. 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 year 2015, we changed our first recommendation to reflect only the net overpayments for the 200 sampled enrollees. We made no changes to our second recommendation.

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

[20] Written comments to the draft report were received directly from Humana, Inc. CarePlus is a subsidiary of Humana, Inc. We will refer to the comments as CarePlus's comments.

CAREPLUS DID NOT AGREE THAT MEDICAL RECORDS DO NOT SUBSTANTIATE CERTAIN AUDITED HIERARCHICAL CONDITION CATEGORIES

CarePlus Comments

CarePlus did not agree with our findings for 34 of the HCCs (15 sampled enrollees) and provided explanations in its comments as to why it believed these HCCs were validated.[21] It also supplied one new medical record supporting its position that the HCCs in that case were validated. Specifically, CarePlus made the following points and referenced specific examples in its comments and the attachment:

- For 26 HCCs (11 sampled enrollees), CarePlus either (1) disagreed with the decisions of the independent medical review contractor (25 HCCs) or (2) identified support for an HCC that CarePlus should have submitted to CMS but did not (1 HCC).

- For 2 HCCs (1 sampled enrollee), CarePlus asserted that the independent medical review contractor did not validate a chronic diagnosis (systemic lupus erythematosus) consistent with "the Chronic Condition[s] List" that we used in an audit of another MA organization. To this point, CarePlus noted that we should validate the HCCs associated with systemic lupus erythematosus because that diagnosis is documented under the patient's medical history and because we validated other chronic conditions associated with our sampled enrollees that were similarly documented.

- For 6 HCCs (3 sampled enrollees), CarePlus stated that we did not apply the same standard that we have applied to validate conditions in connection with other risk adjustment audits of MA organizations.

Office of Inspector General Response

We disagree with CarePlus's comments that our independent medical review contractor (1) invalidated HCCs in a manner that was inconsistent with a Chronic Conditions List used in an audit of another MA organization and (2) applied a standard for its reviews for this audit that was inconsistent with other OIG audits. For this audit and other OIG audits, our contractor reviewed the medical records that the MA organizations provided to us to determine whether support existed for diagnosis codes that were or should have been used in CMS's risk adjustment system. To this extent, MA organizations can and have commented on our draft reports as to whether our contractor made the correct decisions. These comments have addressed specific diagnosis codes and the methodologies that our contractor followed to

[21] CarePlus indicated in its comments that there were 19 instances for which it believed the conditions were substantiated by medical record documentation. However, CarePlus separately submitted a medical record, along with their comments, and confirmed that it did not agree with our findings for 34 HCCs on behalf of 15 sampled enrollees.

reach its conclusions. We have reviewed each of these comments with careful consideration and are confident that our contractor performed its reviews in accordance with CMS's requirements and reached accurate conclusions as to whether the diagnoses were supported in the medical records.

Our independent medical review contractor reviewed the additional information that CarePlus provided for the 34 HCCs (15 sampled enrollees). [22] As a result of the consideration of CarePlus's comments and additional information that it submitted, our contractor (1) found support and validated the 19 HCCs and reversed its original decisions; (2) reaffirmed that 14 HCCs were not validated and upheld its original decision; and (3) found support for a diagnosis code that CarePlus should have submitted but did not submit to CMS, thus validating 1 additional HCC.

- For 19 HCCs (9 sampled enrollees), our independent medical review contractor found support for the audited HCCs and reversed its original decisions and validated the HCCs.

  For example, for sampled enrollee number 2-66, for which CarePlus indicated coding inconsistencies existed between OIG audits, the contractor stated, "There is documentation of angina pectoris that results in [HCCs for Angina Pectoris]. This condition was assessed, and the patient continues to receive treatment." Accordingly, the HCCs were validated.

  In another example, for sampled enrollee number 3-136, for which CarePlus disagreed with the application of the Chronic Conditions List, the contractor agreed with CarePlus and stated, "There is documentation of a past medical history of lupus that results in [HCCs for Rheumatoid Arthritis and Inflammatory Connective Tissue Disease]." Accordingly, the HCCs were validated.

- For 14 HCCs (8 sampled enrollees), however, the independent medical review contractor did not find support for the audited HCCs and thereby reaffirmed that the HCCs were not validated.

  For example, for sampled enrollee number 3-187, for which CarePlus indicated that there were coding inconsistencies between OIG audits, the contractor disagreed with CarePlus and stated, "[t]here is no documentation to support this condition is active, with a normal physical exam, no monitoring by a cardiologist or [electrocardiogram] ordered, and no medication or treatment plan with a pacemaker…There [are] no current medications list attached with the medical record submitted."

  In another example, for sampled enrollee number 3-192, for which CarePlus also indicated that there were coding inconsistencies between OIG audits, the contractor

[22] The number of sampled enrollees in the bullets below adds up to more than 15 because some sampled enrollees had more than 1 reviewed HCC.

disagreed with CarePlus and stated, "[p]er coding protocol, sick sinus syndrome should not be coded with the presence of a pacemaker. The Coding Clinic guidance referenced is not applicable for the date of service under review."

- For 1 HCC (1 sampled enrollee) the independent medical review contractor confirmed that the medical record supported a diagnosis code that CarePlus should have submitted but did not submit to CMS; thus, the additional HCC should have been used in the enrollee's risk score.

Consequently, the number of unvalidated HCCs in our draft report decreased from 465 to 446 for this final report and the number of additional validated HCCs in our draft report increased from 51 to 52. Our independent medical review contractor performed a multifaceted quality review process during its initial medical record review and re-evaluation processes. In addition, the contractor performed a quality review on the determinations for which it either reversed its original decisions or identified an additional HCC and did not identify any systemic issues.

CAREPLUS DID NOT AGREE WITH OIG'S FIRST RECOMMENDATION TO REFUND NET OVERPAYMENTS

CarePlus Stated That OIG Did Not Follow CMS's Established Risk Adjustment Data Validation Methodology

CarePlus Comments

CarePlus stated that we "should not apply an audit methodology that enforces different standards than CMS, particularly one that has not [been subjected] to required notice-and-comment rulemaking." CarePlus also noted variations between this report and other reports that we issued to MA organizations for which we "focused on different diagnosis codes, defined the scope of the audited codes differently, and taken differing approaches to calculating the payment error." CarePlus also noted that our audit methodology "departs from CMS's established RADV methodology in several important respects" and requested that we explain and justify these aspects of our audit methodology:

- CarePlus questioned our use of a physician as a "tiebreaker" in instances when two coding reviewers disagreed and said that our audit methodology did not constitute a true coding analysis. CarePlus stated that "[i]nstead of relying on the judgment of a physician that did not create the medical record to resolve a disagreement between two coders, OIG should use the same method that CMS uses during a RADV audit" and that if one of the two coders substantiates a diagnosis code for the HCC under review, then the HCC is considered to be validated.

- In addition, CarePlus stated that the "specific diagnosis coding guidance" that the independent medical review contractor followed was unclear. As an example, CarePlus questioned whether we followed "CMS RADV standards . . . [that] expressly state that

documentation of a treatment or management plan is not required to validate a chronic condition as long as the condition is 'mentioned' in writing by an acceptable provider in connection with a [face-to-face] patient encounter." Moreover, CarePlus stated that "[t]o the extent the [c]ontractor's review underlying OIG's audit findings did not conform to CMS diagnosis coding standards applicable to diagnosis code submissions in the MA program, the [c]ontractor's approach would have biased OIG's results and recommendations."

- CarePlus also stated that it was unclear whether the independent medical review contractor's senior coders were certified by any professional organization, such as the American Association of Professional Coders (AAPC).

Office of Inspector General Response

We do not agree with CarePlus's comments regarding the need for notice-and-comment rulemaking to establish the methodology we used in this audit. Our application of the regulatory requirements through a review of the medical records that CarePlus provided does not constitute the creation of a new payment rule. Rather, we designed our audits to determine whether CarePlus adhered to those regulatory requirements and when we identified errors, we recommended that those errors be corrected. No new regulatory requirements were imposed and, thus, there was no need for notice-and-comment rulemaking. Our audits, including the prior audits of other MA organizations that CarePlus refers to, are intended to provide an independent assessment of Department of Health and Human Services (HHS) programs and operations in accordance with the Inspector General Act of 1978, 5 U.S.C. Ch. 4. Although our approach was generally consistent with the methodology used by CMS in its RADV audits, we were not required to mirror CMS's approach to its RADV audits. Further, we have explained our audit methodologies in each of the reports that we issued to the MA organizations. Regarding CarePlus's related points about our methodology, we note the following:

- We believe that the independent medical review contractor's use of senior coders to perform coding reviews, and its use of a board-certified physician reflected a reasonable method to determine whether the medical record adequately supported the reported diagnosis codes. During our audit, we explained to CarePlus that the reviewers examined the entirety of the medical records and documentation that the MA organization submitted in conjunction with applicable ICD guidelines and CMS guidance and that the reviewers based the HCC assignments on their coding determinations and applicable CMS guidance to map diagnoses to HCCs.

- With respect to CarePlus's description of our "specific diagnosis coding guidance" as "unclear," our independent medical review contractor performed its review to determine whether the diagnoses on the sampled enrollee's medical records were coded according to the ICD Coding Guidelines as required by the Manual, chapter 7, section 40. With respect to the "chronic condition" example that CarePlus cited, our

independent medical review contractor's methodology complied with applicable CMS guidance.

- With respect to CarePlus's statement about whether our senior coders were certified, we explained to CarePlus during our audit that the coding reviews had been performed by professional coders credentialed by the American Health Information Management Association (AHIMA) and the AAPC.[23] These coders were experienced in coding for hospital inpatient, outpatient, and physician medical records.

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

CarePlus Comments

CarePlus disagreed with our use of the two-sided 90-percent confidence interval to estimate overpayments because our methodology is inconsistent with CMS's practice for RADV audits. CarePlus 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."

Office of Inspector General Response

OIG is an independent oversight agency; therefore, we are not required to mirror CMS's estimation methodology. Our policy is to recommend recovery at the lower limit of a two-sided 90-percent confidence interval. 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 CarePlus for the enrollees and the time period covered in our sampling frame. Further, we note that this approach, which is routinely used by HHS for recovery calculations, 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.[24] In addition, the legal standard for use of

[23] 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), Certified Professional Coder—Instructor, and Certified Risk Coder (CRC). RHITs have completed a 2-year degree program and have passed an AHIMA certification exam. The AHIMA also credentials individuals with CCS and CCS-P certifications and the AAPC credentials both CPCs and CRCs.

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

sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.[25] 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 to apply the correct formulas for the extrapolation.

However, because of Federal regulations that limit the use of extrapolation in RADV audits for recovery purposes to payment years 2018 and forward, we are reporting the overall estimated overpayment amount but are recommending a refund only for the overpayment amount for the sampled enrollees.

CarePlus Did Not Agree With How OIG Incorporated Underpayments Into the Estimates

CarePlus Comments

CarePlus stated that our estimate of underpayments is "significantly understated and statistically unsupported." Specifically, CarePlus stated that, based on its "understanding of OIG's audit procedures and methodology, [CarePlus] believes OIG's findings are systematically skewed toward identifying overpayments rather than underpayments." In this regard, CarePlus made two related points:

- CarePlus 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)."

- CarePlus also said that "OIG excluded from its sampling frame all . . . enrollees for which [CarePlus] did not submit any risk-adjusting diagnosis codes." According to CarePlus, this exclusion substantially reduced the possibility of identifying underpayments.

CarePlus stated that "[b]ecause OIG's RADV methodology did not conduct a systematic or statistically valid search for substantiated but unsubmitted HCCs, OIG's extrapolation methodology is statistically unsupported."

[25] 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).

Office of Inspector General Response

Our objective was to determine whether CarePlus submitted diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. In this regard, the identification of (1) enrollees for which CarePlus did not submit any risk-adjusting diagnosis codes for our sampling frame and (2) all possible diagnosis codes that CarePlus could have submitted on behalf of the sampled enrollees were beyond the scope of our audit.

We requested that CarePlus provide us with the medical records for the audited HCCs. For outpatient and physician records, we performed a blind review to capture all HCCs.[26] For inpatient records, we requested that CarePlus provide us with an indication of where the support for the reviewed and possibly additional HCCs were in the medical record. If the independent medical review contractor was able to locate the corresponding support, then the HCCs were considered validated.

CMS requires MA organizations like CarePlus to establish compliance programs and processes to ensure that it submits accurate diagnosis codes to CMS.[27] In this respect, when CMS updated the Federal regulations for RADV audits, CMS stated that "[t]hese processes should enable MAOs to identify not only instances where diagnoses submitted for risk adjustment payment are not supported by the medical record, but also diagnoses that may not have been submitted to CMS."[28] CarePlus had a process to request, in some instances, medical records from providers and review the accuracy of the diagnoses that the providers reported on the corresponding claims. CarePlus designed these procedures to detect and correct inaccurate coding. Accordingly, CarePlus's medical record review process included steps to identify diagnosis codes that had not been submitted but should have been submitted to CMS.

For our audit period, CMS allowed CarePlus to make and submit adjustments up until February 2016, for claims for services rendered during the 2014 service year. To this point, CMS also stated in its update of the Federal regulations, "the purpose of RADV audits is not to reopen submission deadlines and for CMS to make additional payments. RADV audits identify overpayments after the final risk adjustment data submission deadline."

[26] A blind review refers to identifying all diagnoses, including any diagnoses that led to an additional HCC, from these records.

[27] 42 CFR §§ 422.503 and 504

[28] 88 Fed. Reg. 6652, (Feb. 1, 2023)

Further and contrary to CarePlus's assertion, our extrapolation methodology is statistically supported. A valid estimate of net overpayments does not need to cover all potential diagnosis codes or underpayments within the audit period. Accordingly, our estimate of net overpayments does not extend to the diagnosis codes that were beyond the scope of our audit. In accordance with our objective, we properly executed our statistical sampling methodology in that we defined our sampling frame (CarePlus enrollees with at least one HCC) and sample unit, randomly selected our sample, applied relevant criteria to evaluate the sample, and used statistical sampling software to apply the correct formulas to estimate the net overpayments in the sampling frame made to CarePlus.

CarePlus Did Not Agree With OIG's Application of CMS Requirements for Calculations of Overpayments

CarePlus Comments

CarePlus said that our audit methodology did not apply certain CMS requirements and therefore improperly identified HCC submissions as overpayments. Moreover, CarePlus stated that our audit methodology violated a payment principle known as "actuarial equivalence."

CarePlus cited the provision of the Act that mandates risk-adjusted payments be made in a manner that ensures "actuarial equivalence" between CMS payments for health care coverage under MA and CMS payments under Medicare's traditional FFS program. CarePlus stated, "[t]hus, '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." CarePlus asserted that identifying diagnosis codes that were incorrect in 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]

CarePlus stated that to address the data inconsistency issue, CMS announced in 2012 that it would determine a contract-level payment error in RADV audits 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. CarePlus stated that in the bid it submitted to CMS for the 2015 payment year, it notified CMS that CarePlus was relying on CMS's plan to develop and apply an FFSA as part of any RADV process, but that CMS did not respond to this bid certification or otherwise suggest that CarePlus's bid should be modified. CarePlus also cited a CMS proposal introduced in November 2018 that would eliminate the FFSA. CarePlus officials stated that because it was a proposed rule, the RADV methodology using the FFSA remains operative.

[29] The different documentation standard to which CarePlus referred involves the fact that although different diagnosis codes affect payment methodologies in MA, they do not have the same effect in the Medicare FFS program.

CarePlus also stated that our draft report does not reference the Act's actuarial equivalence requirement of applying an FFSA and that we did not resolve the data inconsistency issue in our overpayment calculation.

Office of Inspector General Response

Our audit methodology correctly applied CMS requirements to properly identify unsupported HCC submissions as overpayments. We used the results of the independent medical 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 sampled enrollees' risk score calculations. We followed the requirements of CMS's risk adjustment program to determine the payment that CMS should have made for each enrollee. We used the overpayments and underpayments identified for each enrollee to estimate net overpayments.

With regard to CarePlus's comment that we did not consider actuarial equivalence in our overpayment calculations, we note that after we issued our draft report, CMS stated that it "will not apply an adjustment factor (known as a Fee-For-Service (FFS) Adjuster) in RADV audits." To this point, we recognize that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program. [30]

CAREPLUS DID NOT AGREE WITH OIG'S SECOND RECOMMENDATION TO ENSURE POLICIES AND PROCEDURES HAVE BEEN ADEQUATELY DESIGNED AND IMPLEMENTED

CarePlus Comments

CarePlus stated that we should reconsider our recommendation to ensure policies and procedures have been adequately designed and implemented because CMS regulations require that MA organizations 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. CarePlus also "disagrees with OIG's contention that its recommendation is in line with the requirements of the Federal regulations." In that respect, CarePlus stated that it has an effective compliance program, which includes self-audits. In addition, CarePlus stated that our description that its policies and procedures "could be improved" imposes the perfection standard that CMS and OIG have previously recognized as not being reasonable. CarePlus also stated that we "[fail] to identify any specific deficiency in the policies and procedures" and that we do not "provide any concrete suggestions as to how [CarePlus's] policies and procedures can be improved."

[30] OIG audit findings and recommendations do not represent final determinations by CMS. Action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures. In accordance with 42 CFR § 422.311, which addresses audits conducted by the Secretary (including those conducted by 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.

Office of Inspector General Response

We acknowledge that CarePlus had compliance procedures in place to promote the accuracy of diagnosis codes submitted to CMS to calculate risk-adjusted payments. However, based on the materiality of our findings—estimated net overpayments of approximately $117 million—we do not agree with CarePlus that our second recommendation should be reconsidered.

Federal regulations (42 CFR § 422.503(b)) require MA organizations like CarePlus to establish and implement an effective system for routine monitoring and identification of compliance risks. This regulation further explains that a compliance system should consider both internal monitoring and external audits. In this regard, we note that CarePlus identified steps that it took to ensure the accuracy of its risk adjustment submissions to CMS. We also concluded that CarePlus should continue to make improvements. In this context, we note that CarePlus's comments referred to a 72 percent accuracy rate within our sample for the HCCs that it submitted to CMS. We also do not agree with CarePlus's statement that our recommendation imposes a requirement of 100 percent accuracy on CarePlus. Our description of CarePlus's policies and procedures as "could be improved" to ensure compliance with CMS's program requirements serves to point directly to our second recommendation to ensure that its policies and procedures have been adequately designed and implemented to prevent, detect, and correct noncompliance with Federal requirements.

Accordingly, we believe that addressing this recommendation will assist CarePlus in attaining better assurance with regard to the accuracy and completeness of the risk adjustment data that it submits in the future. Thus, we maintain that our second recommendation is valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid CarePlus approximately $1.7 billion to provide coverage to approximately 131,000 enrollees in Florida for the 2015 payment year.[31] We identified a sampling frame of 55,891 enrollees who had at least 1 HCC in their risk scores. CarePlus received $978,653,429 in payments from CMS for these enrollees for 2015. We selected for audit a stratified random sample of 200 enrollees on whose behalf CMS made payments totaling $3,967,569 to CarePlus.

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

We performed audit work from January 2019 through November 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 interviewed CarePlus officials to gain an understanding of: (1) the policies and procedures that CarePlus followed to submit diagnosis codes to CMS for use in the risk adjustment program; and (2) CarePlus's monitoring of those submissions to prevent, detect, and correct noncompliance with Federal requirements.

- We reviewed CarePlus's policies and procedures to understand how CarePlus submitted diagnosis codes to CMS.

- We developed our sampling frame using data from CMS systems. Our sampling frame consisted of enrollees who had at least one HCC in their risk scores. To create this frame, and as explained further in Appendix C, we used data from the following CMS systems:

    - the Risk Adjustment Processing System, which MA organizations use to submit diagnosis codes to CMS;

[31] Payment year 2015 data were the most current data available when we started our audit.

- the Risk Adjustment System, which identifies the HCCs that CMS factors into each enrollee's risk score calculation; and

- the Medicare Advantage Prescription Drug System, which identifies the Medicare payments, before applying the budget sequestration reduction, made to MA organizations.

- We selected a stratified random sample of 200 enrollees from the sampling frame (Appendix C).

- We obtained 430 medical records from CarePlus as support for the 1,656 HCCs associated with the 200 sampled enrollees.

- We used an independent medical review contractor to determine whether the diagnosis codes in the medical records validated the 1,656 HCCs.

- The independent medical review contractor's coding review of the 430 medical records followed a specific process to determine whether there was support for a diagnosis code and associated HCC. Under the process:

  - 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 and then:

    - 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.

  - For any diagnosis code that had not been previously submitted, the HCC was considered validated as an additional HCC if either (1) both senior coders found support in the medical record or (2) one senior coder and a physician found support.

- We reviewed available data from CMS's systems for the sampled enrollees to determine whether CMS's payments had been canceled or adjusted.

- We used the results of the independent medical review to calculate overpayments or underpayments (if any) for each enrollee. Specifically, we calculated the following:

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

    - the Medicare payment, before applying the budget sequestration reduction, that CMS should have made for each enrollee.

- We used the overpayments and underpayments identified for each enrollee to estimate net overpayments.

- We limited the total net overpayment that we recommended for recovery to the sampled enrollee-years.[32]

- We provided the results of our audit to CarePlus officials on May 16, 2022.

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.

[32] 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 Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS	A-07-20-01197	8/4/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS	A-07-20-01202	7/10/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. (H3952) Submitted to CMS	A-02-20-00001	5/31/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring Life & Health Insurance Company, Inc. (Contract H4513) Submitted to CMS	A-07-19-01192	3/28/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS	A-02-20-01008	3/24/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS	A-09-21-03011	3/16/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Cigna-HealthSpring of Tennessee, Inc. (Contract H4454) Submitted to CMS	A-07-19-01193	12/22/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BCBS of Rhode Island (Contract H4152) Submitted to CMS	A-01-20-00500	11/16/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That California Physician's Service, Inc. (Contract H0504) Submitted to CMS	A-09-19-03001	11/10/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract R5826) Submitted to CMS	A-05-19-00039	9/30/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (H3916) Submitted to CMS	A-03-19-00001	9/29/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS	A-07-19-01195	9/29/2022
Medicare Advantage Compliance Audit of Diagnosis Codes that Inter Valley Health Plan, Inc. (Contract H0545) Submitted to CMS	A-05-18-00020	9/26/2022

Report Title	Report Number	Date Issued
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS	A-09-20-03009	9/13/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc. (Contract H1032) Submitted to CMS	A-04-19-07084	8/29/2022
Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS	A-03-18-00002	8/19/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc. (Contract H4461) Submitted to CMS	A-02-20-01009	7/18/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health Network (Contract H1961) Submitted to CMS	A-06-18-05002	5/25/2022
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	11/05/2021
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

Our sampling frame consisted of 55,891 CarePlus enrollees who: (1) were continuously enrolled under contract number H1019 throughout all of the 2014 service year and January 2015 and (2) had at least 1 HCC in their 2015 payment year risk scores. Because CMS adjusts its risk-adjusted payments in the calendar year subsequent to when an individual is diagnosed, we restricted our population to individuals who were enrolled—and thus diagnosed—at CarePlus during the 2014 service year.

Our sampling frame included enrollees who were:

- not classified as having hospice or end-stage renal disease (ESRD) status at any time during the 2014 service year through January 2015; and

- continuously enrolled in Medicare Part B coverage during the 2014 service year.

SAMPLE UNIT

The sample unit was one enrollee.

SAMPLE DESIGN

We used a stratified random sample. To identify the strata, we used a two-step process in which we first calculated a value we refer to as the monthly-weighted-health risk score. We computed the monthly-weighted-health risk score using the following formula:

[health-related portion of the enrollee's risk score]
x
[number of monthly 2015 capitation payments affected by the enrollee's risk score][33]

We classified the enrollees according to the magnitude of the risk-adjusted payments made on their behalf. A higher monthly-weighted-health risk score signified a higher amount of risk-adjusted payments on behalf of that enrollee for the year. We then ranked the 55,891 enrollees according to their monthly-weighted-health risk score from lowest to highest and separated them into 3 strata. The specific strata are shown in Table 1 on the following page.

[33] We excluded from this calculation months in 2015 for which enrollees were classified as having hospice or ESRD status.

Table 1: Strata Based on Monthly-Weighted-Health Risk Scores

Stratum	Sample Size	Number of Enrollees	Monthly-Weighted-Health Risk Score Range	Sampling Frame Dollar Total
1	50	18,666	0.081 to 7.944	$171,042,953
2	50	18,628	7.954 to 16.824	285,360,633
3	100	18,597	16.836 to 132.096	522,249,843
Total	**200**	**55,891**		**$978,653,429**

SOURCE OF THE RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We sorted the sample units in each stratum by the health-related portion of the risk score, the number of payment months, and a unique enrollee identifier number. We then consecutively numbered the sample units within each stratum. After generating the random numbers, we selected the corresponding sample units in each stratum.

ESTIMATION METHODOLOGY

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

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 2: Sample Results

Stratum	Frame Size	Sampling Frame Dollar Total	Sample Size	Dollar Value of Sample	Number of Sampled Enrollees With Incorrect Diagnosis Codes	Dollar Value of Net Overpayments for Unvalidated HCCs for Sampled Enrollees
1	18,666	$171,042,953	50	$428,428	17	$24,211
2	18,628	285,360,633	50	751,307	31	118,258
3	18,597	522,249,843	100	2,787,834	68	498,998
Total	**55,891**	**$978,653,429**	**200**	**$3,967,569**	**116**	**$641,467**

Table 3: Estimated Value of Net Medicare Overpayments in the Sampling Frame
(Limits Calculated for a 90 percent Confidence Interval)

Point estimate	$145,895,470
Lower limit	117,334,526
Upper limit	174,456,414

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.

Humana.

January 18, 2023

Lori S. Pilcher
Regional Inspector General for Audit Services
Office of Audit Services, Region IV
61 Forsyth Street, SW, Suite 3T41
Atlanta, GA 30303

VIA EMAIL

RE: Humana's Response to Draft Audit Report No. A-04-19-07082

Dear Ms. Pilcher:

Humana Inc. ("Humana" or "Company")[1] 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-04-19-07082, entitled *Medicare Advantage Compliance Audit of Diagnosis Codes That CarePlus Health Plans, Inc. (Contract H1019), Submitted to CMS* (the "Draft Report"). As detailed below, Humana respectfully submits that OIG should not finalize the Draft Report's two recommendations because (1) medical record documentation substantiates certain of the diagnosis codes in question, (2) OIG's Draft Report reflects misunderstandings related to certain statistical and actuarial principles, the legal and regulatory requirements underlying the Medicare Advantage ("MA") program, and CMS's Risk Adjustment Data Validation ("RADV") processes, and (3) 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 explained to OIG in connection with its report entitled *Medicare Advantage Compliance Audit of Diagnosis Codes that Humana, Inc., (Contract H1036) Submitted to CMS*.[2]

Humana takes great pride in what the Company believes to be its industry-leading approach to Medicare risk adjustment ("MRA") compliance. Indeed, Humana has described its MRA compliance program to CMS over the course of many years, and has never received feedback from CMS that its program is deficient in any respect. Humana continues to believe its

[1] CarePlus Health Plans, Inc. Contract H1019 (CarePlus) is a subsidiary of Humana Inc. (Humana). The controls and programs described herein are implemented by Humana and apply to the diagnosis codes that CarePlus submits to CMS.

[2] Humana also explained these issues to OIG in connection with its report related to contract H4461 and contract R5826. *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"); HHS OIG, Audit Report No. A-05-19-00039, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that HumanaChoice (Contract R5826) Submitted to CMS* (Sep. 2022), available at https://oig.hhs.gov/oas/reports/region5/51900039.pdf ("HumanaChoice Report")

processes and reviews satisfy all legal requirements, for the reasons previously explained 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 ready to assist OIG in this regard, as we have conveyed previously to both agencies.

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

Humana finds it encouraging that OIG's audit contractor (the "Contractor") determined that medical records substantiate the majority of Hierarchical Condition Categories ("HCCs") subject to OIG's review (71.92%). Considering that risk adjustment data is principally generated by Humana's vast network of medical providers, we believe this substantiation rate reinforces the fact that our MRA compliance program is working, consistent with CMS expectations and MA program requirements. This is particularly true given that the HCC substantiation rate increases to at least 81.04% after accounting for:

(1) other HCCs that OIG identified that should have been included in the enrollees' risk scores during the course of its review, which OIG identified during the course of its review as "Hierarchy Adds," "Hierarchy Add HCCs," "Additional HCCs" and "Addback HCCs" and when added to the HCCs that OIG substantiated increase the validation percentage to 78.86%;

(2) certain HCCs that Humana believes should be reconsidered by OIG, as described more fully in Appendix A, which would increase the validation percentage to at least 81.04%;

(3) the application of the chronic condition list that OIG provided to Humana in connection with its audit of the H4461 contract, as discussed more fully in section I.1; and

(4) the application of the same standard that OIG has applied to validate conditions in connection with other risk adjustment audits, as discussed more fully in section I.2.

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 Humana (or other Medicare Advantage Organizations ("MAOs") for that matter) to eliminate all risk adjustment data discrepancies, nor is there any legal requirement for them to do so.[3] Humana has several programs in place to enhance the accuracy of risk adjustment data,

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

consistent with MA program requirements and OIG's guidance.[4] MAOs are afforded broad discretion in designing compliance and education programs.[5]

Given OIG's reliance on a RADV extrapolation methodology as part of its "overpayment" calculation (discussed in more detail below), it goes without saying that every single HCC subject to review is of critical importance and could greatly affect the outcome of this audit. Indeed, setting aside for the moment all other concerns raised in this letter, addressing only the HCCs referenced in Appendix A would substantially change the outcome of OIG's review as those HCCs account for a considerable portion of OIG's overpayment calculation for the sampled enrollees, and would therefore presumably have a significant impact on OIG's extrapolation estimate.

We request that OIG review the additional records that Humana has provided and incorporate the results into its calculations.[6] Specifically, Humana has provided OIG with 19 appeals in Appendix A reflecting instances where, contrary to OIG's determination, the following conditions are substantiated by medical record documentation: Septicemia/Shock and Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock (HCC v12 2 / v22 2), Cardio-Respiratory Failure and Shock (HCC v12 79 / v22 84), Major Head Injury (HCC v12 155/ v12 167), Lung, Upper Digestive Tract, and Other Severe Cancers and Lung and Other Severe Cancers (HCC v12 8 / v22 9), Angina Pectoris/Old Myocardial Infarction and Angina Pectoris (HCC v12 83 / v22 88), Ischemic or Unspecified Stroke (HCC v12 96 / v22 100), Rheumatoid Arthritis and Inflammatory Connective Tissue Disease (HCC v12 38 / v22 40), Coagulation Defects and Other Specified Hematological Disorders (HCC v22 48), Chronic Ulcer of Skin, Except Decubitus and Chronic Ulcer of Skin, Except Pressure (HCC v12 149 / v22 161), Renal Failure (HCC v12 131), Spinal Cord Disorders/Injuries (HCC v12 69 / v22 72), Specified

[4] *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.").

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

[6] During Humana's Exit Conference with the OIG auditors for this audit of contract H1019, 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-07-16-01165, *Medicare Advantage Compliance Audit of Diagnosis Codes that Humana, Inc., (Contract H1036) Submitted to CMS* (April 2021), at 13–14, *available at* https://oig.hhs.gov/oas/reports/region7/71601165.pdf ("Humana H1036 Report"); HHS OIG, Audit Report No. A-07-17-01169, *Medicare Advantage Compliance Audit of Diagnosis Codes that SCAN Health Plan (Contract H5425) Submitted to CMS* (February 2022), at 13–14, *available at* https://oig.hhs.gov/oas/reports/region7/71701169.pdf ("SCAN Report"); HHS OIG, Audit Report No. A-03-18-00002, *Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS*, at 13, *available at* https://oig.hhs.gov/oas/reports/region3/31800002.pdf ("Cigna Report"); HHS OIG, Audit Report No. A-05-18-00020, *Medicare Advantage Compliance Audit of Diagnosis Codes That Inter Valley Health Plan, Inc. (Contract H0545), Submitted to CMS*, at 13-14, *available at* https://oig.hhs.gov/oas/reports/region5/51800020.pdf ("Inter Valley Report").

Heart Arrhythmias (HCC v12 92 / v22 96), Drug/Alcohol Psychosis (HCC v12 51 / v22 54), Unstable Angina and Other Acute Ischemic Heart Disease (HCC v12 82 / v22 87).[7]

1. The HCC substantiation rate increases after accounting for the application of OIG's Chronic Condition List.

In addition to the reasons addressed in Appendix A regarding systemic lupus erythematosus for sample ID 3-136, OIG should validate this condition because OIG's invalidation is inconsistent with the Chronic Conditions list that OIG provided in connection with the H4461 audit and represented was prepared by CMS, which states:

> These are some common chronic conditions that should always be picked up, but is not an exhaustive list. These conditions should not be picked up for a single episode that is resolved and no longer requires treatment. Additionally, any condition qualified by the term 'chronic' may also be considered for coding as a chronic condition.

This list includes "SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)." Under these guidelines, systemic lupus erythematosus should be coded because (i) it is documented under the patient's Medical History ("Lupus: Skin"), and (ii) Hydroxychloroquine Sulfate, which is used to treat Lupus, is listed in the Current Medications. There is no documentation to indicate that the condition was for a single episode that no longer existed or had resolved.

Consistent with this approach to chronic conditions, the OIG validated or identified as additional HCC's for at least 26 other member-HCCs in this audit by using a Decision Rationale that included, "This diagnosis is defined as a CMS chronic condition and in this case is listed in the medical record" or "This diagnosis appears on the CMS chronic condition list and in this case is noted on the diagnosis list." Please see Appendix A for Sample Stratum 3-136 for additional information.

2. The HCC substantiation rate increases after accounting for the application of the same standard that OIG has applied to validate conditions in connection with other risk adjustment audits.

Humana also believes that for this audit, the OIG did not apply the same standard that OIG has applied to validate conditions in connection with other risk adjustment audits. For example, for sample strata 2-66 in this audit, OIG did not validate v12 HCC 83 (Angina Pectoris/Old Myocardial Infarction) or v22 HCC 88 (Angina Pectoris) on the basis that, "there is no documentation of any condition that will result in the assignment of HCC [83/88]." Within the medical record submitted to OIG dated 9/17/2014, the provider documented "Angina pectoris" under the Assessment as diagnosis #1 and documented treatment #1 as "Angina pectoris, Continue Plavix Tablet, 75 MG, 1 tablet, Orally, Once a day." However, in OIG's audit report for Humana's contract H1036, OIG validated angina pectoris for sample strata 3-021

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

using medical record 05, in which "ANGINA PECTORIS NEC/NOS – 413.9" was documented in the Assessment but without a corresponding treatment plan.

As another example, for sample strata 3-187 in this audit, OIG did not validate v12 HCC 92 (Specified Heart Arrhythmias) or v22 HCC 96 (Specified Heart Arrhythmias) on the basis that, "There is documentation of sinoatrial node dysfunction (427.81) in the assessment with no active/current treatment. The documentation provided does not sufficiently address sick sinus syndrome to determine this." However, within the medical record submitted to OIG dated 1/13/2014, the provider documented, "Sick sinus syndrome" (also known as sinoatrial node dysfunction) and "LBBB" (left bundle branch block) under the Assessment. The provider also documented a cardiac evaluation as part of the physical examination and the Medications list included several medications used to treat cardiac conditions, including arrhythmias. In OIG's audit report for Humana's contract H1036, the OIG validated sinoatrial node dysfunction for sample strata 3-042 using medical record 01 in which, "Chronic Sinus Bradycardia/Sinoatrial node dysfunction – 427.81" was documented in the Assessment and a cardiac physical exam was performed but there was no corresponding treatment plan or medications used to treat arrhythmias documented.

As a final example, for sample strata 3-192 in this audit, OIG did not validate v12 HCC 92 or v22 HCC 96 on the basis that, "there is no documentation of a diagnosis that results in HCC [92/96]. There is documentation of a pacemaker (V45.01) which does not result in an HCC." However, within the medical record submitted to OIG dated 4/8/2014, the provider documented, "Hypertension/SSS [sick sinus syndrome]" under the Chief complaint, that the patient, "has not had palpitations, syncope or near syncope" under the History of present illness, "Arrhythmia: SSS [PPM, DDD Medtronic [dual chamber pacemaker]] – 4/24/2009" under the Cardiac History, and "13. Sick Sinus Syndrome" and "14. S/P Pacemaker" under the Assessment. In OIG's audit report for Humana's contract H1036, OIG validated sinoatrial node dysfunction for sample strata 2-025 using medical record 01 in which the provider documented, "Sinoatrial node dysfunction – 427.81, Has pacemaker" under diagnosis #2 in the Assessments and "Cardiac pacemaker in situ – V45.01, Regular pacer checks are done at home and office" as diagnosis #11.

Please see Appendix A for Sample Strata 2-66, 3-187 and 3-192 for additional information.

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

Based on the Contractor's medical record review, OIG concludes that Humana "received $665,418 of net overpayments for…the 200 sampled enrollees."[8] OIG then applies an extrapolation methodology to all 2015 payments for H1019 and recommends that Humana "refund to the Federal Government the $123,694,207 of net overpayments" found by that

[8] Draft Report at 13.

analysis.[9] For the reasons discussed below, Humana respectfully requests that OIG reconsider its recommendation.

1. OIG should reconsider its recommendation because OIG's RADV 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. Humana agrees that OIG should not apply an audit methodology that enforces different standards than CMS, particularly one that has not be subject to required notice-and-comment rulemaking.[10] Humana understands that OIG intended its RADV sample to

[9] *Id*.

[10] OIG's recent "high-risk" audits also exemplify the variations in the audit methodology applied by OIG. As of the date of this letter, OIG has released seventeen audits of so-called "high-risk" diagnosis codes. 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." And in calculating payment errors associated with these supposedly "high-risk" codes, OIG has applied two completely distinct methodologies, with no rationale supplied to explain these arbitrarily differing approaches. *See* HHS OIG, Audit Report No. A-07-17-01170, *Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements* (Apr. 2019), *available at* https://oig.hhs.gov/oas/reports/region7/71701170.pdf ("Essence Report"); HHS OIG, Audit Report 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-07-19-01187, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS* (May 2021), *available at* https://www.oig.hhs.gov/oas/reports/region7/71901187.pdf ("Anthem Report"); HHS OIG, Audit Report No. A-07-17-01173, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS* (Oct. 2021) at 18, *available at* https://oig.hhs.gov/oas/reports/region7/71701173.pdf ("Coventry Report"); HHS OIG, Audit Report No. A-07-19-01188, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS* (Nov. 2021) at 22, *available at* https://oig.hhs.gov/oas/reports/region7/71901188.pdf ("UPMC Report"); 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"); 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"); Cariten 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"); HHS OIG, Audit Report No. A-09-20-03009, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS* (Aug. 2022), *available at* https://oig.hhs.gov/oas/reports/region9/92003009.pdf ("Regence Report"); HumanaChoice Report; HHS OIG, Audit Report No. A-07-19-01195, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS* (Sep. 2022), *available at* https://oig.hhs.gov/oas/reports/region7/71901195.pdf ("BCBS Tennessee Report"); HHS OIG, Audit Report No. A-03-19-00001, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (Contact H3916) Submitted to CMS* (Sep. 2022), *available at* https://oig.hhs.gov/oas/reports/region3/31900001.pdf ("Highmark Report"); HHS OIG, Audit Report No. A-09-19-03001, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That California Physicians' Service, Inc. (Contract H0504) Submitted to CMS* (Nov. 2022), *available at* https://oig.hhs.gov/oas/reports/region9/91903001.pdf ("Physicians' Service Report"); HHS OIG, Audit Report No.

generate results that could be extrapolated at the contract-level, similar to CMS-conducted RADV audits. While there may be multiple ways to conduct a RADV review to allow for extrapolation of this type, Humana requests that OIG explain and justify several aspects of its RADV methodology:

- 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. Per CMS guidance, once a provider has rendered a diagnosis, clinical judgment plays no role in the process of determining or reviewing the appropriateness of any diagnosis code assigned based on that diagnosis.[11] Instead of relying on the judgment of a physician that did not create the medical record to resolve a disagreement between two coders, OIG should use the same method that CMS uses during a RADV audit. Specifically, during a RADV audit, if an HCC appears to be unsubstantiated after the first round of coding, the HCC is escalated to a second coder for "Discrepant Confirmation."[12] If the second coder determines that the medical record in question substantiates a diagnosis code that maps to the HCC, then CMS treats the HCC as substantiated without further analysis. CMS's approach reflects a true coding analysis, rather than an assessment of the clinical support for a particular condition, which need not exist in every record to substantiate coding the condition. If OIG were to implement CMS's coding methodology, Humana believes the number of HCCs that OIG determined to be unsubstantiated would be reduced.

- Second, it is unclear what specific diagnosis coding guidance the Contractor provided to its staff to guide the medical record review.[13] The standards used by the Contractor could have a substantial impact on OIG's findings, and could also explain a number of the issues described further in Appendix A. For instance, CMS RADV standards that Humana received in 2014 (*e.g.*, during the course of the service year now subject to OIG's audit) expressly state that documentation of a treatment or management plan is not required to validate a chronic condition as long as the condition is "mentioned" in writing by an acceptable provider in connection with a face to face patient encounter.[14] To the

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A-01-20-00500, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BCBS of Rhode Island (Contract H4152) Submitted to CMS* (Nov. 2022), *available at* https://oig.hhs.gov/oas/reports/region1/12000500.pdf ("BCBS Rhode Island Report"); HHS OIG, Audit Report No. A-07-19-01193, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring of Tennessee, Inc. (Contract H4454) Submitted to CMS* (Dec. 2022), *available at* https://oig.hhs.gov/oas/reports/region7/71901193.pdf ("Cigna-HealthSpring Report").

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

[12] *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").

[13] It is also unclear whether the Contractor's "senior coders" used in the review were certified by any professional organization, such as the American Association of Professional Coders ("AAPC"). Humana requests clarification from OIG as to the qualifications of the Contractor's staff involved in the review.

[14] *See* 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

extent the Contractor's review underlying OIG's audit findings did not conform to CMS diagnosis coding standards applicable to diagnosis code submissions in the MA program, 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 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.[15] 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.

2. 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, rather than the lower bound of a 95% or 99% confidence interval. While OIG has defended the use of the 90% confidence interval in other reports,[16] CMS announced that it uses the lower bound of a 99% confidence interval when calculating extrapolated repayment amounts for its RADV audits 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 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.

3. OIG should reconsider its recommendation because OIG's estimate of "underpayments" to Humana is significantly understated and statistically unsupported.

Based on Humana's understanding of OIG's audit procedures and methodology, Humana believes OIG's findings are systematically skewed towards identifying overpayments rather than underpayments, rendering its results inherently unreliable.[17] OIG has indeed been clear in the

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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.").

[15] HumanaChoice Report at 24.

[16] *See* SCAN Report at 16; Tufts Report at 22; Healthfirst Report at 18.

[17] While Humana appreciates the information OIG has shared regarding its audit methodology, OIG has not provided full detail on the extrapolation approach it applied to arrive at its estimate that Humana was overpaid by more than $123 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

response to comments submitted for related audits that such an analysis of potential underpayments is beyond the scope of OIG's review.[18] OIG and the MA industry therefore appear to be at an impasse on this critical issue.

OIG explains in its Draft Report that it "used the results of the independent medical review contractor to calculate overpayments or underpayments (if any) for each enrollee." Following this approach, OIG determined that Humana "received $665,418 of net overpayments…for the 200 sampled enrollees." 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).

Based on OIG's instructions, Humana's medical record submissions consisted of far less than all records available for the sampled enrollees. Thus, OIG's review could not and does not account for all HCCs that are substantiated but not submitted for the sampled enrollees—just as OIG found certain "underpayments" in the records actually subject to review, other records that were never submitted to or reviewed by OIG contain unsubmitted HCCs that would have been found upon review. Moreover, OIG excluded from its sampling frame all payment year 2015 H1019 enrollees for which Humana did not submit any risk-adjusting diagnosis codes.[19] This aspect of OIG's methodology also systematically reduced the probability of identifying underpayments.[20]

Because OIG's RADV methodology did not conduct a systematic or statistically valid search for substantiated but unsubmitted HCCs, OIG's extrapolation methodology is statistically unsupported.[21] In addition, 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 if OIG were to finalize the Draft Report in its current form.[22]

4. <u>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.</u>

The Social Security Act ("Act") requires risk adjustment payments to Medicare Advantage organizations ("MAOs") and mandates that those payments be made in a manner that

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Standards, 2011 Revision (December 2011) ("Government Auditing Standards"), *available at* https://www.gao.gov/assets/590/587281.pdf; U.S. Department of Health & Human Services, HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, Part II: HHS Agency Responsibilities and Guidelines, E. Centers for Medicare & Medicaid Services, V. Agency Quality Assurance Policies, Standards and Processes (Oct. 1, 2002) ("Information Quality Guidelines"), *available at* https://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public/v-agency-quality-assurance-policies-standards-and-processes-0.

[18] Humana H1036 Report at 16; SCAN Report at 15.

[19] *See* Draft Report at 14-16.

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

[21] *See id*.

[22] *See* Government Auditing Standards; Information Quality Guidelines.

ensures "'actuarial equivalence' between CMS payments for healthcare coverage under Medicare Advantage plans and CMS payments under traditional Medicare [FFS]."[23] Thus, "actuarial equivalence" requires risk-adjusted payments to MAOs based on actuarially supportable calculations of the expected cost to CMS if the MAOs' enrollees received their health benefits through the Medicare FFS program.[24] The Actuarial Standards of Practice ("ASOPs"), especially ASOP No. 45, necessarily govern these actuarial calculations.[25] In its recent reports, OIG does not seem to seriously contest these principles, instead deferring to CMS on the issue.[26] Because the issue is subject to pending rulemaking at CMS,[27] however, Humana reiterates its positions here.

As explained by recognized industry experts, it would violate "an underlying principle of risk-adjustment systems" to determine MAO payments in risk adjustment data validation audits by applying (1) coefficients calculated using Medicare FFS diagnosis codes that are *partially unsubstantiated* by medical records to (2) MAO diagnosis codes that are *fully substantiated* by medical records.[28] Subjecting diagnosis codes from the Medicare FFS and MA programs to different documentation standards contravenes ASOP No. 45 and disrupts actuarial equivalence in violation of the Act.[29] Industry experts refer to this error mode as the "Data Inconsistency Issue."[30]

For at least ten years, CMS has acknowledged the need to address the differing documentation standards that are the cause of the Data Inconsistency Issue. In its 2012 RADV extrapolation methodology, CMS announced that it would determine a contract-level payment error in RADV audits only after applying a Fee-for-Service Adjuster ("FFSA") to account for the

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[23] 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 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.").

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

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

[26] *See* Tufts Report at 21; Coventry Report at 2; UPMC Report at 28; Anthem Report at 21.

[27] 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).

[28] *See* Letter from American Academy of Actuaries to Cheri Rice, Acting Director, Medicare Plan Payment Group (Jan. 21, 2011) (on file with author); *see also* Wakely Consulting Group, LLC, *Actuarial Report on CMS' November 1, 2018 Proposed Rule* (Aug. 27, 2019) ("Wakely Report"), 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* http://assets.milliman.com/ektron/Medicare_Advantage_RADV_FFS_adjuster_8-23-2019.pdf.

[29] *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.

[30] *See* Wakely Report Section IV.

rate of unsubstantiated diagnosis codes in the Medicare FFS claims data from which CMS's HCC risk coefficients were initially derived.[31] 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)."[32] Because CMS is the agency designated by Congress to oversee and administer the Medicare Advantage program,[33] 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 risk adjustment data validation 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 bid for H1019 for the year that is the subject of OIG's Draft Report. Specifically, Humana's Calendar Year 2015 Actuarial Certification for H1019 stated explicitly that the Company was relying on CMS's plan to develop and apply an FFSA as part of any RADV process:

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

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[31] *See* CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audit* (February 24, 2012) ("2012 RADV Audit Notice.").
[32] *Id*. at 4-5. On November 1, 2018, CMS published a 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.
[33] 42 U.S.C. § 1395b-9.

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

If finalized, the Draft Report's treatment of individual unsubstantiated HCC submissions as overpayments would violate the actuarial equivalence requirement by failing to remedy the Data Inconsistency Issue. The Draft Report implicates the Data Inconsistency Issue because one documentation standard (unaudited data) was used to calibrate the CMS-HCC model while another documentation standard (audited data) was used to measure payment accuracy.[34] Recognized industry experts have stated that "[t]his principle applies with equal force irrespective of the type of RADV audit or other documentation-based 'overpayment' analysis."[35]

In short, the Draft Report does not appear to reference in any way the Act's actuarial equivalence requirement. As a result, it appears that OIG did not take the necessary steps to resolve the Data Inconsistency Issue in its "overpayment" calculation underlying the Draft Report's recommendations. If true, this outcome would be in direct conflict with the assumption upon which Humana explicitly conditioned its Calendar Year 2015 bid for H1019. Thus, Humana respectfully requests that OIG reconsider its recommendation that Humana refund the amounts identified in the Draft Report.

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

Despite finding that medical records substantiate the vast majority of audited HCCs, OIG stated that Humana's "policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved."[36] For the reasons described below, Humana respectfully requests that OIG reconsider this recommendation. This similar recommendation came up in connection with OIG's other recent contract audits,[37] 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 CMS regulations do not impose a requirement of 100 percent accuracy for risk adjustment data.

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.[38] CMS implemented the current regulatory regime after acknowledging industry concerns about widespread healthcare provider "mistakes" and "incomplete or inaccurate" provider-generated

[34] *See* Wakely Analysis.
[35] *See* Wakely Report at 33; *see also* Wakely Analysis.
[36] Draft Report at 6.
[37] Humana H1036 Report at 13; SCAN Report at 12.
[38] 42 C.F.R. § 422.504(l).

data.[39] Commenters at the time explained that "it would be unfair and unrealistic to hold [MA] organizations to a '100 percent accuracy' certification standard."[40] 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."[41] 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."[42]

OIG guidance similarly recognizes that "[t]he requirement that the CEO or CFO certify as to the accuracy, completeness and truthfulness of [risk adjustment] data, based on best knowledge, information and belief, does not constitute an absolute guarantee of accuracy."[43] 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.[44]

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."[45] 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."[46] 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[47] that its recommendation is in line with the requirements of the Federal regulations.

The fact that OIG determined that some unsubstantiated HCCs existed as part of this audit is not surprising and does not, on its own, indicate a failure of Humana's policies and procedures. Nonetheless, in the Draft Report, OIG states that the unsubstantiated HCCs 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."[48] This effectively imposes the perfection standard that CMS and OIG have previously recognized is not reasonable to enforce.[49] Indeed, none of the authorities cited in the Draft Report support OIG's

[39] Medicare Program: Medicare+Choice Program, 65 Fed. Reg. 40,169, 40,250, 40,268 (June 29, 2000).
[40] *See id.* at 40,268.
[41] *Id.*
[42] *Id.*
[43] *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).
[44] 64 Fed. Reg. 61,900 (Nov. 15, 1999).
[45] Draft Report at 7.
[46] Draft Report at 6.
[47] *See* Cariten Report at 27.
[48] Draft Report at 13.
[49] *See* Medicare Program: Medicare+Choice Program, 65 Fed. Reg, 40,268 (June 29, 2000).

apparent position that the presence of inaccurate risk adjustment data in an MAO's risk adjustment submissions constitutes *per se* noncompliance with federal requirements.[50] 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;[51] in the response to a prior Humana audit, providing this recommendation even with a high 87% accuracy rate; and giving this recommendation in two other reports after acknowledging that the plans had already made improvements.[52] Thus, Humana requests that OIG reconsider its position that Humana's policies and procedures "could be improved" and its recommendation that Humana "ensure that is policies and procedures have been adequately designed and implemented."

2. OIG should reconsider its recommendation because Humana's industry-leading MRA compliance program satisfies 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.[53] 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.[54] Further, Humana described its risk adjustment data policies and procedures to OIG in connection with the review OIG conducted in support of the

[50] See Draft Report at 6-7.
[51] *See* Anthem Report at 24.
[52] *See* Humana H1036 Report at 19; Healthfirst Report at 29; UPMC Report at 31.
[53] *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).
[54] Humana acknowledges that in the Cariten Report, OIG cites to 42 CFR § 422.503(b)(4)(vi)(G) to argue that MAOs must take action to enhance its 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). 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 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 unsupported 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. Humana also submitted a corresponding data correction for every HCC that had been selected for Self Audit that is not supported by at least one available medical record.

Draft Report.[55] 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 and activities in place to enhance the accuracy of risk adjustment data, which include but are not limited to, Provider Data Validation reviews, Humana's Risk Adjustment Integrity Unit, and Administrative Quality Audits. During the years subject to this audit, Humana also conducted Risk Adjustment Data Validation Audits. OIG also acknowledges that Humana's "compliance program also had procedures to detect and correct noncompliance that included, but were not limited to, provider data validation and fraud detection."[56] Humana believes these programs satisfy Humana's obligations under applicable MA program requirements.

Nonetheless, the Draft Report fails to identify any specific deficiency in the policies and procedures that Humana described, nor does OIG provide any concrete suggestions as to how Humana's policies and procedures can be improved.[57] Instead, according to the Draft Report, the only evidence of any shortcoming in Humana's policies and procedures is that "the risk scores for the 200 sampled enrollees should not have been based on the 1,656 HCCs. Rather, the risk scores should have been based on the 1,306 validated HCCs (1,191 validated HCCs plus 64 other HCCs associated with more and less severe manifestations of diseases plus 51 additional validated HCCs that CarePlus did not submit to CMS)."[58] But, as discussed above, Humana's inability to detect and correct every single unsubstantiated HCC in its submissions to CMS for H1019 does not constitute *per se* noncompliance with federal requirements. Humana disagrees with the notion that existing CMS guidance requires a particular approach. In the absence of specific CMS-implemented MA program requirements, Humana and other MAOs are afforded broad discretion in designing compliance and education programs.

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. Humana believes its industry-leading compliance program demonstrates full compliance. 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 year subject to OIG's audit. Humana therefore requests

[55] *See* Draft Report at 14 ("[OIG] interviewed CarePlus officials to gain an understanding of (1) the policies and procedures that CarePlus followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) CarePlus's monitoring of those submissions to prevent, detect, and correct noncompliance with Federal requirements . . . . [OIG] reviewed CarePlus's policies and procedures to understand how CarePlus submitted diagnosis codes to CMS.").
[56] *See* Draft Report at 13.
[57] *See* Draft Report at 13.
[58] *Id* at 6.

that OIG reconsider its recommendation that the Company's risk adjustment policies and procedures "could be improved.".

* * *

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

Sincerely,

/Sean O'Reilly/

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

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

Appendix A

[Submitted via Secure Submission to Guard Beneficiary Protected Health Information]