

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE COMPLIANCE  
AUDIT OF DIAGNOSIS CODES THAT  
HUMANA, INC., (CONTRACT H1036)  
SUBMITTED TO CMS**

*Inquiries about this report may be addressed to the Office of Public Affairs at  
[Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov).*



Christi A. Grimm  
Principal Deputy Inspector General

April 2021  
A-07-16-01165

# *Office of Inspector General*

<https://oig.hhs.gov/>

---

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

## *Office of Audit Services*

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

## *Office of Evaluation and Inspections*

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

## *Office of Investigations*

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

## *Office of Counsel to the Inspector General*

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

# *Notices*

---

**THIS REPORT IS AVAILABLE TO THE PUBLIC**  
at <https://oig.hhs.gov>

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website.

## **OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS**

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

## Report in Brief

Date: April 2021

Report No. A-07-16-01165

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



### Why OIG Did This Audit

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

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

For this audit, we reviewed one of the contracts that Humana, Inc., has with CMS with respect to the diagnosis codes that Humana submitted to CMS. Our objective was to determine whether Humana 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. Humana provided medical records as support for 1,525 HCCs associated with the 200 enrollees. We used an independent medical review contractor to determine whether the diagnosis codes complied with Federal requirements.

## Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS

### What OIG Found

Humana 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 Humana submitted were supported in the medical records and therefore validated 1,322 of the 1,525 sampled enrollees' HCCs, the remaining 203 HCCs were not validated and resulted in overpayments. These 203 unvalidated HCCs included 20 HCCs for which we identified 22 other, replacement HCCs for more and less severe manifestations of the diseases. Second, there were an additional 15 HCCs for which the medical records supported diagnosis codes that Humana should have submitted to CMS but did not.

Thus, the risk scores for the 200 sampled enrollees should not have been based on the 1,525 HCCs. Rather, the risk scores should have been based on 1,359 HCCs (1,322 validated HCCs + 22 other HCCs + 15 additional HCCs). As a result, we estimated that Humana received at least \$197.7 million in net overpayments for 2015. These errors occurred because Humana's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, were not always effective.

### What OIG Recommends and Humana's Comments

We recommend that Humana refund to the Federal Government the \$197.7 million of net overpayments and enhance its policies and procedures to prevent, detect, and correct noncompliance with Federal requirements for diagnosis codes that are used to calculate risk-adjusted payments.

Humana disagreed with our findings and with both of our recommendations. Humana provided additional medical record documentation which, Humana said, substantiated specific HCCs. Humana also questioned our audit and statistical sampling methodologies and said that our report reflected misunderstandings of legal and regulatory requirements underlying the MA program. After reviewing Humana's comments and the additional information that it provided, we revised the number of unvalidated HCCs for this final report. We followed a reasonable audit methodology, properly executed our sampling methodology, and correctly applied applicable Federal requirements underlying the MA program. We revised the amount in our first recommendation from \$263.1 million (in our draft report) to \$197.7 million but made no change to our second recommendation.

## TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objective.....	1
Background.....	2
Medicare Advantage Program.....	2
Risk Adjustment Program.....	2
Humana, Inc.....	4
How We Conducted This Audit.....	4
FINDINGS.....	5
Federal Requirements.....	5
Humana Did Not Submit Some Diagnosis Codes in Accordance With Federal Requirements.....	6
Some of the Diagnosis Codes That Humana Submitted to CMS Were Not Supported in the Medical Records.....	6
Diagnosis Codes That Humana Should Have Submitted but Did Not Submit to CMS.....	10
Summary of Diagnosis Codes Not Submitted in Accordance With Federal Requirements.....	11
The Policies and Procedures That Humana Used To Prevent, Detect, and Correct Noncompliance With Federal Requirements Were Not Always Effective.....	12
Humana Received Net Overpayments.....	12
RECOMMENDATIONS.....	13
HUMANA COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE.....	13
Humana Did Not Agree With All Hierarchical Condition Category Determinations.....	13
Humana Comments.....	13
Office of Inspector General Response.....	13

Humana Noted That Office of Inspector General Did Not Follow CMS’s Established Risk Adjustment Data Validation Methodology .....	14
Humana Comments .....	14
Office of Inspector General Response .....	14
Humana Did Not Agree With How Office of Inspector General Incorporated Underpayments Into Its Estimates.....	15
Humana Comments .....	15
Office of Inspector General Response .....	16
Humana Did Not Agree With Office of Inspector General’s Application of CMS Requirements for Calculations of Overpayments .....	17
Humana Comments .....	17
Office of Inspector General Response .....	18
Humana Did Not Agree With Office of Inspector General Recommendation To Enhance Policies and Procedures.....	18
Humana Comments .....	18
Office of Inspector General Response .....	19

APPENDICES

A: Audit Scope and Methodology .....	20
B: Statistical Sampling Methodology .....	23
C: Sample Results and Estimates .....	25
D: Federal Regulations Regarding Compliance Programs That Medicare Advantage Organizations Must Follow .....	26
E: Humana Comments .....	28

## 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<sup>1</sup> from their providers and submit these codes to CMS.

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 8.1 percent of payments to MA organizations for calendar year 2016 were improper, mainly due to MA organizations submitting unsupported diagnosis codes to CMS.<sup>2</sup> Our previous audits have shown that MA organizations submitted diagnosis codes that did not comply with Federal requirements.

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, Humana, Inc., with respect to the diagnosis codes that Humana submitted to CMS for contract number H1036.<sup>3</sup>

### OBJECTIVE

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

---

<sup>1</sup> 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.

<sup>2</sup> The U.S. [Department of Health and Human Services \[HHS\] FY \[Federal fiscal year\] 2018 Agency Financial Report](#) estimated that 8.1 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 Improper Payments Elimination and Recovery Improvement Act of 2012, P.L. No. 112-248 (Jan. 10, 2013), which 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.

<sup>3</sup> All subsequent references to “Humana” in this report refer solely to contract number H1036.

## BACKGROUND

### Medicare Advantage Program

The MA program<sup>4</sup> offers beneficiaries managed care options by allowing them to enroll in private health care plans rather than having their care covered through Medicare's traditional fee-for-service program. Beneficiaries who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

Under the MA program, CMS makes advance payments each month to MA organizations for the expected costs of providing health care coverage to enrollees. These payments are not adjusted to reflect the actual costs that the organizations incurred for providing benefits and services. Thus, MA organizations will generally 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 2017, CMS paid MA organizations \$209 billion, which represented 35 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.<sup>5</sup>

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

- *Base rate*: Before the start of each year, each MA organization submits bids to CMS that reflect the MA organization's estimate of the monthly revenue required to cover an enrollee with an average risk profile.<sup>6</sup> 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.<sup>7</sup>

---

<sup>4</sup> 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.

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

<sup>6</sup> The Act § 1854(a)(6); 42 CFR § 422.254.

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



- *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 face-to-face encounters with a physician (in an office, or in an inpatient or outpatient setting). MA organizations collect the diagnosis codes that physicians document on the medical records and submit these codes to CMS. CMS then maps certain diagnosis codes, on the basis of similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs). 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 model HCC, a 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 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.<sup>8</sup>

The risk adjustment program is prospective; 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 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

---

<sup>8</sup> 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 model) are in the same related-disease group.

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 payment that an MA organization receives for each enrollee. Miscoded diagnoses submitted to CMS may result in HCCs that are not validated and incorrect enrollee risk scores, which may lead to improper payments (overpayments) from CMS to MA organizations. Conversely, correctly coded diagnoses that MA organizations do not submit to CMS may lead to improper payments (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 8.1 percent of payments to MA organizations for 2016. These CMS RADV audits verify that diagnoses submitted by MA organizations for risk-adjusted payment are supported by medical record documentation.

### **Humana, Inc.**

Humana, an MA organization with headquarters in Louisville, Kentucky, has several geographically based Medicare Part C contracts with CMS. As of December 31, 2015, Humana provided coverage under contract number H1036 to approximately 485,000 enrollees, most of whom resided in counties in South Florida. For our audit period (the 2015 payment year), CMS paid Humana approximately \$5.6 billion to provide this coverage.

### **HOW WE CONDUCTED THIS AUDIT**

Our audit focused on enrollees on whose behalf Humana 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 255,518 enrollees from which we selected a stratified random sample of 200 enrollees on whose behalf CMS made payments totaling \$3,522,179 to Humana. Humana provided medical records as support for 1,525 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 1,525 HCCs. The contractor reviewed these same records to determine whether any additional HCCs were validated by diagnosis codes that Humana 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 B contains our statistical sampling methodology, and Appendix C contains our sample results and estimates.

## FINDINGS

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

First, 1,322 of the 1,525 sampled enrollees' HCCs were validated; however, the medical records did not validate the remaining 203 HCCs, which resulted in overpayments. These 203 unvalidated HCCs included 20 HCCs for which we identified 22 other HCCs for more and less severe manifestations of the diseases. These 22 other HCCs should have been included in the enrollees' risk scores (instead of the 20 unvalidated HCCs),<sup>9</sup> which would have reduced the overpayments associated with the 203 unvalidated HCCs in our sample.<sup>10</sup>

Second, in reviewing the medical record documentation for the diagnosis codes associated with the 1,525 sampled enrollee HCCs, we identified support for diagnosis codes that Humana should have submitted but did not submit to CMS. If Humana had submitted these diagnosis codes, an additional 15 HCCs would have been included in the enrollees' risk scores. These risk scores would have increased, and CMS's payments to Humana would have been higher.

In summary, the risk scores for the 200 sampled enrollees should not have been based on the 1,525 HCCs. Rather, the risk scores should have been based on 1,359 HCCs (1,322 validated HCCs + 22 other HCCs associated with more and less severe manifestations of diseases + 15 additional validated HCCs that Humana did not submit to CMS). On the basis of our sample results, we estimated that Humana received at least \$197,720,651 in net overpayments for 2015.

These errors occurred because Humana's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, were not always effective.

## 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)).

---

<sup>9</sup> There were two unvalidated HCCs that were the most severe manifestations in a related-disease group. Although these two HCCs were not validated, Humana submitted medical records showing that, for each sampled enrollee, two other HCCs for less severe manifestations were allowable in the enrollees' risk score calculations.

<sup>10</sup> The less severe manifestations of the diseases associated with 20 other HCCs led to net overpayments for 19 HCCs and no payment effect for 1 HCC. The more severe manifestations associated with two other HCCs led to net underpayments.

MA organizations must obtain risk adjustment data required by CMS from the provider, supplier, physician, or other practitioner that furnished the item or service (42 CFR § 422.310(d)(3)).

Federal regulations also state that MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes and add that if any related entity, subcontractor, or contractor generates such data, that entity is similarly responsible (42 CFR § 422.504(l)). CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (*Medicare Managed Care Manual* (the Manual) (last rev. Sep. 19, 2014), chap. 7).

CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7, § 40). The diagnosis must be coded according to the International Classification of Diseases (ICD), Clinical Modification, *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), Appendix D).

## **HUMANA DID NOT SUBMIT SOME DIAGNOSIS CODES IN ACCORDANCE WITH FEDERAL REQUIREMENTS**

Humana did not submit some diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. Specifically, Humana 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 73 of the 200 sampled enrollees.<sup>11</sup>

### **Some of the Diagnosis Codes That Humana Submitted to CMS Were Not Supported in the Medical Records**

The diagnosis codes that Humana submitted to CMS were not supported in the medical records for 203 of the 1,525 sampled enrollees’ HCCs. The 203 HCCs were not validated and should not have been used in the enrollees’ risk scores. These errors, which also included more and less

---

<sup>11</sup> There was more than one type of error for some enrollees.

severe manifestations of the diseases, caused net overpayments from CMS to Humana for 68 sampled enrollees.


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

For 166 of the 203 HCCs (63 sampled enrollees), the medical records did not support either the diagnosis code that Humana submitted or any other diagnosis code that would have validated the HCC. These errors caused overpayments.

For example, for Enrollee A, Humana submitted a diagnosis code for “malignant neoplasm of the larynx,” which maps to both the Version 12 model HCC for Lymphatic, Head and Neck, Brain, and Other Major Cancers and the Version 22 model HCC for Colorectal, Bladder, and Other Cancers. However, that diagnosis was not supported in the submitted medical records. Our independent medical review contractor stated that “[a]lthough these diagnoses were listed, there is no documentation that indicates that they were monitored, evaluated, or treated. The documentation clearly indicates that the diagnosis had been [previously] treated and was noted as resolved. Additionally, there are no other diagnoses in the medical records submitted that would result in this HCC.”

As shown in Figure 1, the diagnosis codes that Humana submitted to CMS on behalf of Enrollee A mapped to 15 HCCs, which CMS used to calculate a \$3,371 monthly payment that it made to Humana. Because the HCC for Lymphatic, Head and Neck, Brain, and Other Major Cancers and the HCC for Colorectal, Bladder, and Other Cancers were not validated, the CMS payment should have been based on 13 HCCs, which would have resulted in a monthly payment of \$3,006. This error caused a \$4,380 overpayment for the year.

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

<b>AS SUBMITTED BY HUMANA</b>		
Number of HCCs	15	
Monthly CMS Payment	\$3,371	
<b>AS AUDITED</b>		
Number of HCCs	13	
Monthly CMS Payment	\$3,006	
<b>OVERPAYMENT</b>		
Monthly	\$365	
Annually	\$4,380	

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

For 20 of the 203 HCCs (12 sampled enrollees), the medical records did not support the diagnosis codes that Humana submitted. However, we identified 22 other HCCs (that were supported by other diagnosis codes) for more and less severe manifestations of the diseases. These 22 other HCCs should have been included in the enrollees' risk scores (instead of the 20 unvalidated HCCs). Including the 22 other HCCs would have reduced the overpayments associated with the 203 unvalidated HCCs in our sample (footnotes 9 and 10).

For 18 of the 20 submitted HCCs (11 sampled enrollees), the diagnosis codes that Humana submitted mapped to a more severe manifestation of the HCCs in the related-disease group but were not supported in the medical records.<sup>12</sup> However, there were other diagnosis codes, which mapped to 20 other HCCs for less severe manifestations, that should have been used in the enrollees' risk scores. These errors led to net overpayments for 19 of the 20 other HCCs and no payment effect for 1 of the 20 other HCCs.


For example, for Enrollee B, Humana submitted a diagnosis for "Diabetes with peripheral circulatory disorders, type II or unspecified type, not stated as uncontrolled." This diagnosis code maps to both the Version 12 model HCC for Diabetes With Renal or Peripheral Circulatory Manifestation and the Version 22 model HCC for Diabetes With Chronic Complications, both of which are more severe manifestations of the HCCs in those related-disease groups. That diagnosis was not supported in the submitted medical records. 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 model HCCs). 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 on the following page, this error caused a \$1,956 overpayment for the year.

---

<sup>12</sup> Two of the 20 submitted HCCs were not supported because the medical records did not meet Medicare signature requirements.

**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**


<b>AS SUBMITTED BY HUMANA</b>		
HCC for Diabetes With Renal or Peripheral Circulatory Manifestation and HCC for Diabetes With Chronic Complications ( <b>More</b> Severe Manifestation of That Disease)		
Monthly CMS Payment		
Attributed to HCCs	\$244	
<b>AS AUDITED</b>		
HCCs for Diabetes Without Complication ( <b>Less</b> Severe Manifestation of That Disease)		
Monthly CMS Payment		
Attributed to HCCs	\$81	
<b>OVERPAYMENT</b>		
<b>Monthly</b>	<b>\$163</b>	
<b>Annually</b>	<b>\$1,956</b>	

For 2 of the 20 submitted HCCs (1 sampled enrollee), Humana did not submit diagnosis codes that mapped to the most severe manifestation of the HCCs in the related-disease groups. Instead, Humana submitted only the diagnosis codes that mapped to the less severe manifestations. If Humana 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 net underpayments.

For this sampled enrollee (Enrollee C), Humana submitted a diagnosis for “Multiple myeloma, without mention of having achieved remission.” This diagnosis code maps to both the Version 12 model HCC for Lymphatic, Head and Neck, Brain, and Other Major Cancers and the Version 22 model HCC for Lung and Other Severe Cancers, both of which are less severe manifestations of the HCCs in those related-disease groups. However, our independent medical review contractor found support in the submitted medical records for the diagnosis “Secondary malignant neoplasm of bone and bone marrow,” which maps to HCCs that were both more severe manifestations of the HCCs in those related-disease groups (Metastatic Cancer and Acute Leukemia for both the Version 12 and 22 model HCCs). 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 on the following page, this error caused a \$13,212 underpayment for the year.

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

<b>AS SUBMITTED BY HUMANA</b>		
HCC for Lymphatic, Head and Neck, Brain and Other Major Cancers and HCC for Lung and Other Severe Cancers ( <i>Less Severe</i> Manifestation of That Disease)		
Monthly CMS Payment	Attributed to HCCs	\$588
<b>AS AUDITED</b>		
HCCs for Metastatic Cancer and Acute Leukemia ( <i>More Severe</i> Manifestation of That Disease)		
Monthly CMS Payment	Attributed to HCCs	\$1,689
<b>UNDERPAYMENT</b>		
<b>Monthly</b>		<b>\$1,101</b>
<b>Annually</b>		<b>\$13,212</b>

*Medical Records With Other Issues That Caused Unsupported Diagnosis Codes*

Seventeen of the HCCs (three sampled enrollees) were not validated either because the medical records did not meet Medicare signature requirements (two sampled enrollees)<sup>13</sup> or because Humana could not locate the records (one sampled enrollee). These errors caused overpayments.

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

Humana did not submit all of the correct diagnosis codes. Specifically, there were an additional 15 HCCs (9 sampled enrollees) for which the medical records supported diagnosis codes that Humana 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 Humana.

For example, for Enrollee D, Humana did not submit a diagnosis code for “chronic obstructive pulmonary disease.” However, our independent medical review contractor, as part of its review of a different HCC, found support for this diagnosis documented in a medical record. This


<sup>13</sup> For purposes of medical review, services provided or ordered must be authenticated by a signature in accordance with Medicare’s policies (*Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance*). MA organizations may submit attestations for eligible medical records with missing or illegible signatures or credentials (42 CFR § 422.2). Humana was not able to obtain attestations from the associated providers.



diagnosis code, which Humana should have submitted but did not submit to CMS, maps to and validates two HCCs: the Version 12 model HCC for Chronic Obstructive Pulmonary Disease and the Version 22 model HCC that is also for Chronic Obstructive Pulmonary Disease.

As shown in Figure 4, this error caused a \$2,232 underpayment.

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

<b>AS SUBMITTED BY HUMANA</b>		
Number of HCCs	10	
Monthly CMS Payment	\$1,060	
<b>AS AUDITED</b>		
Number of HCCs	12	
Monthly CMS Payment	\$1,246	
<b>UNDERPAYMENT</b>		
<b>Monthly</b>	<b>\$186</b>	
<b>Annually</b>	<b>\$2,232</b>	

### Summary of Diagnosis Codes Not Submitted in Accordance With Federal Requirements

Because Humana 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 1,525 HCCs. Rather, their risk scores should have been based on the 1,359 validated HCCs. Figure 5 on the following page 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**

<b>BASED ON DIAGNOSIS CODES THAT HUMANA SUBMITTED</b>	
Total Number of HCCs	1,525
<b>AS AUDITED</b>	
HCCs That Were Validated	1,322
HCCs Validated by Other Diagnosis Codes	22
Additional HCCs That Were Validated	+ 15
<b>NUMBER OF HCCS THAT SHOULD HAVE BEEN USED</b>	<b>1,359</b>

**THE POLICIES AND PROCEDURES THAT HUMANA USED TO PREVENT, DETECT, AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS WERE NOT ALWAYS EFFECTIVE**

As demonstrated by the errors found in our sample, the policies and procedures that Humana had to prevent, detect, and correct noncompliance with CMS’s program requirements, as mandated by Federal regulations at 42 CFR § 422.503(b)(4)(vi), were not always effective.

Humana designed its compliance system to submit accurate diagnosis codes for use in CMS’s risk adjustment program. To prevent the submission of incorrect diagnosis codes to CMS, Humana educated its providers, through training sessions, on how to document and report accurate diagnosis codes on its claims. In some cases, after Humana received claims from its providers, it requested medical records from providers and reviewed the accuracy of the diagnoses that the providers reported on the claims. Humana designed these procedures to detect and correct inaccurate coding. However, because the risk scores for the 200 sampled enrollees should have been based on 1,359 HCCs instead of 1,525 HCCs, we do not believe that Humana’s policies and procedures associated with its compliance system were always effective.

**HUMANA RECEIVED NET OVERPAYMENTS**

Humana received \$249,279 of net overpayments (consisting of \$266,134 of overpayments and \$16,855 of underpayments) for the 200 sampled enrollees (Appendix C). On the basis of our sample results, we estimated that Humana received at least \$197,720,651 of net overpayments for 2015.

## RECOMMENDATIONS

We recommend that Humana, Inc.:

- refund to the Federal Government the \$197,720,651 of net overpayments and
- enhance its policies and procedures to prevent, detect, and correct noncompliance with Federal requirements for diagnosis codes that are used to calculate risk-adjusted payments.

### HUMANA COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Humana disagreed with our findings and with both of our recommendations. Specifically, Humana stated that it disagreed because: “(1) medical record documentation substantiates certain . . . diagnosis codes in question, and (2) OIG’s [Office of Inspector General] Draft Report reflects misunderstandings related to certain statistical and actuarial principles, and legal and regulatory requirements, underlying the Medicare Advantage . . . program.” After reviewing Humana’s comments and the additional information that it provided, we revised our findings (including the examples depicted in Figures 2 and 3) and the associated monetary recommendation (from \$263,133,686 to \$197,720,651) for this final report. We made no change to our second recommendation.

A summary of Humana’s comments and our responses follows. Humana’s comments appear as Appendix E. We excluded an attachment (which Humana identified as Appendix A in its comments) that contained personally identifiable information. We also excluded two attachments that Humana referred to as “expert reports”—one submitted to Humana by an actuary, the other by a statistical expert—and cited in its comments. We are separately providing Humana’s comments and attachments in their entirety to CMS.

### HUMANA DID NOT AGREE WITH ALL HIERARCHICAL CONDITION CATEGORY DETERMINATIONS

#### Humana Comments

Humana, in the additional information that it provided, identified 60 HCCs that it believed we should reconsider for 34 sampled enrollees. Specifically, Humana performed a separate coding review and gave us the results of that review, which contained specific references to previously submitted medical records and which, Humana believed, validated 58 HCCs. In addition, Humana gave us two previously unsubmitted medical records that it believed validated 3 HCCs (1 of which was included in the 58 HCCs).

#### Office of Inspector General Response

Our independent medical review contractor reviewed all of the additional information that Humana provided and, as a result, validated 41 of the 60 HCCs. Consequently, the number of

unvalidated HCCs in our draft report decreased from 244 to 203 for this final report. Accordingly, we revised our findings and reduced the associated monetary recommendation from \$263,133,686 to \$197,720,651.

## **HUMANA NOTED THAT OFFICE OF INSPECTOR GENERAL DID NOT FOLLOW CMS'S ESTABLISHED RISK ADJUSTMENT DATA VALIDATION METHODOLOGY**

### **Humana Comments**

Humana noted that our audit methodology “departs from CMS’s established RADV methodology in several important respects” and requested that we explain and justify our audit methodology:

- Humana questioned our use of a physician as a “tiebreaker” in instances when two coding reviewers disagree and said that our audit methodology did not constitute a true coding analysis. Humana stated that “[i]nstead of relying on the clinical judgment of a physician to resolve a disagreement between two coders, OIG should use the same method that CMS uses during a RADV audit” in that as long as one of the two coders substantiates a diagnosis code for the HCC under review, then the HCC is considered to be validated.
- In addition, Humana stated that the “specific coding guidance” that our independent medical review contractor followed was unclear. As an example, Humana 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.”
- Humana 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).

Humana stated that departures in our audit methodology from the coding methodology that CMS uses in its RADV audits would have biased our results and recommendations.

### **Office of Inspector General Response**

In accordance with the Inspector General Act of 1978, 5 U.S.C. App., our audits are intended to provide an independent assessment of HHS programs and operations. We conduct our audits in accordance with generally accepted government auditing standards, which require that audits be planned and performed so as to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions. Accordingly, we designed our audit to determine whether the diagnosis codes that Humana submitted to CMS for use in the risk adjustment program were adequately supported—and thus complied with Federal requirements—in the medical records. Although our approach was generally consistent with the methodology used by CMS in its RADV audits, it did not mirror CMS’s approach in all aspects. Specifically:

- We believe that the independent medical review contractor’s use of senior coders to perform coding reviews, as well as its use of a physician—who was board certified and who did not apply clinical judgment when serving as the final decisionmaker—reflected a reasonable method to determine whether the medical record adequately supported the reported diagnosis codes.<sup>14</sup> To clarify that our contractor did not rely on the application of clinical judgment, during our audit work we provided Humana with the following description of our coding reviews: “The coders/reviewers examined all of the medical records and documentation that the MA organization submitted in conjunction with applicable ICD guidelines and [applicable CMS guidance]. The coders/reviewers based all HCC assignments upon their coding determinations and the applicable CMS guidance to map diagnoses to HCCs.”
- With respect to Humana’s description of our “specific 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 Humana cited, our independent medical review contractor’s methodology complied with applicable CMS guidance.
- With respect to Humana’s statement questioning whether our senior coders were certified, we informed Humana during our audit work that the coding reviews had been performed by professional coders credentialed by the American Health Information Management Association (AHIMA) and the AAPC.<sup>15</sup> These coders were duly experienced in coding ICD-9-CM and ICD-10-CM diagnosis codes for hospital inpatient, outpatient, and physician medical records.

## **HUMANA DID NOT AGREE WITH HOW OFFICE OF INSPECTOR GENERAL INCORPORATED UNDERPAYMENTS INTO ITS ESTIMATES**

### **Humana Comments**

Humana stated that our estimate of underpayments is “significantly understated and statistically unsupported.” Specifically, Humana stated that, based on its “understanding of OIG’s audit procedures and methodology, Humana believes OIG’s findings are systematically skewed

---

<sup>14</sup> Our independent medical review contractor used a physician as the final decisionmaker when two senior coders disagreed on whether the medical record supported the diagnosis code for only 19 of the 200 sampled enrollees.

<sup>15</sup> 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 (CPC-I), 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.

towards identifying overpayments rather than underpayments.” In this regard, Humana made two related points:

- Humana stated that “OIG excluded from its sampling frame all . . . enrollees for which Humana did not submit any risk-adjusting diagnosis codes.” According to Humana, this exclusion substantially reduced the possibility of identifying underpayments.
- Humana added that for the sampled enrollees 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).”

Accordingly, Humana 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.”

### **Office of Inspector General Response**

Our objective was to determine whether Humana 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 Humana did not submit any risk-adjusting diagnosis codes for our sampling frame and (2) all possible diagnosis codes that Humana could have submitted on behalf of the sampled enrollees was beyond the scope of our review.

In some cases, after Humana received claims from its providers, it requested medical records from providers and reviewed the accuracy of the diagnoses that the providers reported on the claims. Humana designed these procedures to detect and correct inaccurate coding. Accordingly, Humana’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 Humana to make and submit adjustments up until February 2016 for claims for services rendered during the 2014 service year.

Contrary to Humana’s assertion, 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 review. In accordance with our objective, we properly executed our statistical sampling methodology in that we defined our sampling frame (Humana 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 made to Humana.

## HUMANA DID NOT AGREE WITH OFFICE OF INSPECTOR GENERAL'S APPLICATION OF CMS REQUIREMENTS FOR CALCULATIONS OF OVERPAYMENTS

### Humana Comments

Humana said that our audit methodology did not apply certain CMS requirements and thus “improperly equates individual unsubstantiated HCC submissions with overpayments.” Moreover, Humana stated that our audit methodology violated a payment principle known as “actuarial equivalence.”

Humana cited the provision of the Act that mandates that risk-adjusted payments be made in a manner that ensures “actuarial equivalence” between CMS payments for health care coverage under MA and CMS payments under Medicare’s traditional fee-for-service (FFS) program. “Thus, ‘actuarial equivalence’ requires risk-adjusted payments to MAOs [MA organizations] based on actuarially supportable calculations of the expected cost to CMS if the MAOs’ enrollees received their health benefits through the Medicare FFS program.” In this regard, Humana 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.<sup>16</sup>

Humana stated that to address the Data Inconsistency Issue, CMS announced in CY 2012 “that it would determine a contract-level payment error in RADV audits only after applying a Fee-for-Service Adjuster (‘FFSA’) to account for the rate of unsubstantiated diagnosis codes in the Medicare FFS claims data from which CMS’s HCC [factors] were initially derived.” Humana stated that in the bid it submitted to CMS for the 2015 payment year, it notified CMS that Humana was relying “on CMS’s plan to develop and apply an FFSA as part of any RADV process.” Further, “CMS did not respond to this bid certification or otherwise suggest to Humana that Humana’s bid should be modified.” Humana also cited a Proposed Rule regarding the FFSA that CMS introduced in November 2018 to eliminate the FFSA; Humana stated that this was only a proposal and that therefore, the RADV methodology (using the FFSA) that CMS introduced in CY 2012 remains operative.

In this regard, Humana stated that our draft report “does not appear to reference in any way the Act’s actuarial equivalence requirement [of applying an FFSA]. 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.”

---

<sup>16</sup> The different documentation standard to which Humana 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.

## Office of Inspector General Response

Our audit methodology correctly applied CMS requirements to properly equate individual unsubstantiated HCC submissions with 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.

Humana commented that we did not consider actuarial equivalence in our overpayment calculations. To this point, we recognize that CMS is responsible for making operational and program payment determinations for the Medicare Advantage program, including the application of any FFSA requirements. Moreover, CMS has not issued any requirements that compel us to reduce our net overpayment calculations.<sup>17</sup> Thus, we believe that the steps that we followed for this report provided reasonable assurance with regard to the findings and recommendations, including our estimation of net overpayments.<sup>18</sup>

### **HUMANA DID NOT AGREE WITH OFFICE OF INSPECTOR GENERAL RECOMMENDATION TO ENHANCE POLICIES AND PROCEDURES**

#### **Humana Comments**

Humana stated that our draft report did not identify any specific deficiencies in its policies and procedures and did not provide any concrete suggestions as to how to improve those policies and procedures. Humana added that we should revise our recommendation to enhance policies and procedures because CMS regulations require that MA organizations should take "reasonable steps to ensure the 'accuracy, completeness, and truthfulness' of the risk adjustment data they submit" but do not impose a requirement of 100 percent accuracy for those data. Humana also referred to the challenges associated with verifying data submitted by providers and added that our identification of some unsupported HCCs "does not, on its own, indicate a failure of Humana's policies and procedures." In addition, Humana stated that our description of its policies and procedures as not always effective "effectively imposes the perfection standard that CMS and OIG have previously recognized is not reasonable to enforce."

---

<sup>17</sup> In 2018, CMS proposed "not to include an FFS adjuster in any final RADV payment error methodology." (Proposed Rule at 83 Fed. Reg. 54982, 55041.) To Humana's point about CMS's 2012 statement, we reiterate that CMS has not issued any guidance that compels us to reduce our overpayment calculations.

<sup>18</sup> OIG audit findings and recommendations do not represent final determinations by CMS. Action officials at CMS will determine whether a potential overpayment exists and will recoup any overpayments consistent with its policies and procedures. If a disallowance is taken, MA organizations have the right to appeal the determination that an overpayment occurred through the CMS RADV appeals process.



## **Office of Inspector General Response**

Our description of Humana’s policies and procedures as “not always effective” in ensuring compliance with CMS’s program requirements serves to point directly to our second recommendation to enhance these policies and procedures. In this context, Humana’s comments referred to an 84 percent accuracy rate within our sample for the HCCs that it submitted to CMS (now 87 percent after our revisions to our findings). The continued improvement of those policies and procedures, based on the results of this audit as well as the results of Humana’s RADV-like self-audits, will assist Humana in attaining better assurance with regard to the “accuracy, completeness, and truthfulness” of the risk adjustment data that it submits in the future.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

CMS paid Humana approximately \$5.6 billion to provide coverage to approximately 485,000 enrollees, most of whom resided in counties in South Florida for the 2015 payment year. We identified a sampling frame of 255,518 enrollees who had at least 1 HCC in their risk scores; Humana received \$3,855,240,657 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 \$3,522,179 to Humana.

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

We performed audit work from February 2017 to August 2020.

### 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 Humana officials to gain an understanding of: (1) the policies and procedures that Humana followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Humana's monitoring of those submissions to prevent, detect, and correct noncompliance with Federal requirements.
- We reviewed Humana's policies and procedures to understand how Humana 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 1 HCC in their risk scores. To create this frame, and as explained further in Appendix B, we used data from the CMS:
  - Risk Adjustment Processing System, which MA organizations use to submit diagnosis codes to CMS;
  - Risk Adjustment System, which identifies the HCCs that CMS factors into each enrollee's risk score calculation; and

- Medicare Advantage Prescription Drug system, which identifies the payments made to MA organizations.
- We selected a stratified random sample of 200 enrollees from the sampling frame (see Appendix B).
- We obtained 461 medical records from Humana (including 2 medical records that we received in response to our draft report) as support for the 1,525 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 1,525 HCCs.
- The independent medical review contractor’s coding review of the 461 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 plus a physician did so.
- 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:
  - a revised risk score in accordance with CMS’s risk adjustment program and

- the payment that CMS should have made for each enrollee.
- We used the overpayments and underpayments identified for each enrollee to estimate net overpayments.
- We provided the results of our audit to Humana officials on September 30, 2020.

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

## APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

### SAMPLING FRAME

Our sampling frame included only Humana enrollees who: (1) were continuously enrolled under contract number H1036 throughout all of the 2014 service year and January 2015 and (2) had at least one HCC in their 2015 payment year risk scores. Because CMS adjusts its risk-adjusted payments in the calendar year subsequent to when a beneficiary is diagnosed, we restricted our population to individuals who were enrolled—and thus diagnosed—at Humana during the 2014 service year.

Our sampling frame did not include enrollees who were:

- classified as having hospice or end-stage renal disease (ESRD) status at any time during the 2014 service year through January 2015 or
- not continuously enrolled in Medicare Part B coverage during the 2014 service year.

The number of enrollees who remained after we performed these steps was 255,718. We presented this data to Humana for verification, and Humana removed 200 enrollees who did not meet the criteria of our sampling frame. Our finalized sampling frame thus consisted of 255,518 enrollees.

### 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:

$$\frac{[\text{health-related portion of the enrollee's risk score}]}{x} \times [\text{number of monthly 2015 capitation payments affected by the enrollee's risk score}]^{19}$$

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 255,518

---

<sup>19</sup> We excluded from this calculation months in 2015 for which beneficiaries were classified as having hospice or ESRD status for this calculation.

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.

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

<b>Stratum</b>	<b>Sample Size</b>	<b>Number of Enrollees</b>	<b>Monthly-Weighted-Health Risk Score Range</b>	<b>Sampling Frame Dollar Total</b>
1	50	85,165	0.103 – 7.304	\$663,327,595
2	50	85,208	7.308 – 15.708	1,116,849,316
3	100	85,145	15.714 – 144.624	2,075,063,746
<b>Total</b>	<b>200</b>	<b>255,518</b>		<b>\$3,855,240,657</b>

**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 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 Humana at the lower limit of the two-sided 90-percent confidence interval (see Appendix C). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

**APPENDIX C: SAMPLE RESULTS AND ESTIMATES**

**Table 2: Sample Results**

<b>Stratum</b>	<b>Frame Size</b>	<b>Value of Frame</b>	<b>Sample Size</b>	<b>Dollar Value of Sample</b>	<b>Number of Sampled Enrollees With Incorrect Diagnosis Codes</b>	<b>Dollar Value of Net Overpayments for Sampled Enrollees</b>
1	85,165	\$663,327,595	50	\$352,006	12	\$12,096
2	85,208	1,116,849,316	50	685,609	18	54,461
3	85,145	2,075,063,746	100	2,484,564	43	182,722
<b>Total</b>	<b>255,518</b>	<b>\$3,855,240,657</b>	<b>200</b>	<b>\$3,522,179</b>	<b>73</b>	<b>\$249,279</b>

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

Point estimate	\$268,992,933
Lower limit	\$197,720,651
Upper limit	\$340,265,214

**APPENDIX D: FEDERAL REGULATIONS REGARDING COMPLIANCE PROGRAMS  
THAT MEDICARE ADVANTAGE ORGANIZATIONS MUST FOLLOW**

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

Any entity seeking to contract as an MA organization must . . . .

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following . . . .

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

(1) Articulate the organization's commitment to comply with all applicable Federal and State standards;

(2) Describe compliance expectations as embodied in the standards of conduct;

(3) Implement the operation of the compliance program;

(4) Provide guidance to employees and others on dealing with potential compliance issues;

(5) Identify how to communicate compliance issues to appropriate compliance personnel;

(6) Describe how potential compliance issues are investigated and resolved by the organization; and

(7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials . . . .

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The



system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the MA organization, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

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

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

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

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



500 W. Main Street  
Louisville, KY 40202

December 6, 2019

Mr. Patrick J. Cogley  
Regional Inspector General for Audit Services  
Office of Audit Services, Region VII  
601 East 12<sup>th</sup> Street, Room 0429  
Kansas City, Missouri 64106  
**VIA UPS NEXT DAY AIR AND EMAIL**

RE: Humana's Response to Draft Audit Report No. A-07-16-01165

Dear Mr. Cogley:

Humana Inc. ("Humana" or "Company") appreciates the opportunity you have provided to respond to the U.S. Department of Health and Human Services, Office of Inspector General's ("OIG's") Draft Audit Report No. A-07-16-01165, entitled *Medicare Advantage Compliance Review of Diagnosis Codes That Humana, Inc. (Contract H1036), 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, and (2) OIG's Draft Report reflects misunderstandings related to certain statistical and actuarial principles, and legal and regulatory requirements, underlying the Medicare Advantage ("MA") program.

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. We believe OIG's findings are reflective of Humana's efforts to improve the quality of MRA data submissions to CMS, consistent with our Company policies and dedication to MRA compliance. 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.

**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 vast majority of Hierarchical Condition Categories ("HCCs") subject to OIG's review (84%). 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



The information transmitted is intended only for the person or entity to which it is addressed and may contain CONFIDENTIAL material. If you receive this material/information in error, please contact the sender and delete or destroy the material/information.

is particularly true given that the HCC substantiation rate increases to 90% after accounting for (1) certain “replacement HCCs” that OIG identified during the course of its review, and (2) certain HCCs that Humana believes should be reconsidered by OIG, described more fully in Appendix A.

Given OIG’s reliance on a Risk Adjustment Data Validation (“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. We would therefore appreciate the opportunity to discuss with OIG the HCCs referenced in Appendix A in greater detail. 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.

Humana separately requests that OIG provide Humana with the opportunity to locate and submit additional records associated with the relatively small number of HCCs that OIG’s Contractor deemed to be unsubstantiated. We request that OIG then review these additional records and incorporate the results into its calculations.<sup>1</sup> Given the critical impact that each unsubstantiated HCC has on OIG’s extrapolation calculation, we believe it is appropriate to provide Humana with an additional eight weeks to work with our network providers to locate supporting documentation. Our expectation is that this supplemental record collection will reduce the likelihood that OIG’s ultimate findings primarily reflect the extent of provider compliance with OIG’s record collection deadline, as opposed to the actual substantiation rate of HCCs in medical records, which we understand to be OIG’s objective in conducting this audit.

**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 \$325,428 of net overpayments (consisting of \$343,204 of overpayments and \$17,776 of underpayment) for the 200 sampled enrollees.”<sup>2</sup> OIG then applies an extrapolation methodology to all 2015 payments for H1036 and recommends that Humana “refund to the Federal Government the \$263,133,686 of net overpayments” found by that analysis.<sup>3</sup> For the reasons discussed below, Humana respectfully requests that OIG reconsider its recommendation.

---

<sup>1</sup> Incorporating results from OIG’s review of additional records would be consistent with the approach OIG took in prior RADV audits. See HHS OIG, *RISK ADJUSTMENT DATA VALIDATION OF PAYMENTS MADE TO EXCELLUS HEALTH PLAN, INC., FOR CALENDAR YEAR 2007 (CONTRACT NUMBER H3351)* (October 2012), pp. 11; HHS OIG, *RISK ADJUSTMENT DATA VALIDATION OF PAYMENTS MADE TO PARAMOUNT CARE, INC., FOR CALENDAR YEAR 2007 (CONTRACT NUMBER H3653)* (September 2012), pp. 10-11.

<sup>2</sup> Draft Report at 12.

<sup>3</sup> *Id.*

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 intended its RADV sample to 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.<sup>4</sup> Instead of relying on the clinical judgment of a physician 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."<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup> To the

---

<sup>4</sup> 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.").

<sup>5</sup> 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").

<sup>6</sup> 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.

<sup>7</sup> 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 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.").

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.

2. 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.<sup>8</sup> 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 \$325,428 of net overpayments (consisting of \$343,204 of overpayments and \$17,776 of underpayments) for the 200 sampled enrollees." But there is an important reason why OIG's underpayment findings are nearly 20 times less than its overpayment findings: 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 PY 2015 H1036 enrollees for which Humana did not submit any risk-adjusting diagnosis codes.<sup>9</sup> This aspect of OIG's methodology also systematically reduced the probability of identifying underpayments.<sup>10</sup>

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.<sup>11</sup> 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

---

<sup>8</sup> 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 \$260 million. This is important because, as leading industry experts have previously described in detail, flaws in a RADV extrapolation methodology can cause substantial bias in the final estimates produced by the methodology. See Wakely Consulting Group, LLC, *Medicare RADV: Review of CMS Sampling and Extrapolation Methodology* (July 2018). Moreover, such full detail is necessary to confirm OIG's audit methodology conforms to government auditing and actuarial standards. See U.S. Government Accountability Office, *Government Auditing Standards, 2011 Revision* (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>.

<sup>9</sup> See Draft Report at 16-17.

<sup>10</sup> See Matthew G. Mercurio, *Statistical Analysis of Draft Report Number A-07-16-01165* (Dec. 3, 2019).

<sup>11</sup> See *id.*

applicable government auditing standards, which Humana believes would be implicated if OIG were to finalize the Draft Report in its current form.<sup>12</sup>

3. OIG should reconsider its recommendation because the audit and extrapolation methodology described in the Draft Report improperly equates individual unsubstantiated HCC submissions with overpayments.

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 ensures “‘actuarial equivalence’ between CMS payments for healthcare coverage under Medicare Advantage plans and CMS payments under traditional Medicare [FFS].”<sup>13</sup> 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.<sup>14</sup> The Actuarial Standards of Practice (“ASOPs”), especially ASOP No. 45, necessarily govern these actuarial calculations.<sup>15</sup>

As explained by recognized industry experts, it would violate “an underlying principle of risk-adjustment systems” to determine MAO payments by applying (1) coefficients calculated using Medicare FFS diagnosis codes that are *partially unsubstantiated* by medical records, to (2) MAO diagnosis codes that are *fully substantiated* by medical records.<sup>16</sup> 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.<sup>17</sup> Industry experts refer to this error mode as the “Data Inconsistency Issue.”<sup>18</sup>

For at least six 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 rate of unsubstantiated diagnosis codes in the Medicare FFS claims data from which CMS’s HCC risk coefficients were initially derived.<sup>19</sup> 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

---

<sup>12</sup> See Government Auditing Standards; Information Quality Guidelines.

<sup>13</sup> *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 176 (D.D.C. 2018) (“*Azar II*”); see 42 U.S.C. § 1395w-23(a)(1)(C)(i).

<sup>14</sup> See 42 U.S.C. §§ 1395w-24(a)(5)(A), (6)(A)(i)-(iii).

<sup>15</sup> Actuarial Standards Board, *Actuarial Standard of Practice No. 45: The Use of Health Status Based Risk Adjustment Methodologies* (Jan. 2012).

<sup>16</sup> 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](http://assets.milliman.com/ektron/Medicare_Advantage_RADV_FFS_adjuster_8-23-2019.pdf).

<sup>17</sup> 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.

<sup>18</sup> See Wakely Report Section IV.

<sup>19</sup> 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”).

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)."<sup>20</sup>

Humana notified CMS of the importance of the FFSA and the Data Inconsistency Issue to Humana's bid for H1036 for the year that is the subject of OIG's Draft Report. Specifically, Humana's Calendar Year 2015 Actuarial Certification for H1036 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.

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.<sup>21</sup> 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."<sup>22</sup>

---

<sup>20</sup> *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. The study underlying the Proposed Rule has also been entered into the administrative record for consideration by the Court in the aforementioned *Azar II* litigation.

<sup>21</sup> *See* Wakely Analysis.

<sup>22</sup> *See* Wakely Report at 33; *see also* Wakely Analysis.



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 H1036. 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 . . . were not always effective" and recommended that Humana "enhance [these] policies and procedures."<sup>23</sup> For the reasons described below, 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.<sup>24</sup> CMS implemented the current regulatory regime after acknowledging industry concerns about widespread healthcare provider "mistakes" and "incomplete or inaccurate" provider-generated data.<sup>25</sup> Commenters at the time explained that "it would be unfair and unrealistic to hold [MA] organizations to a '100 percent accuracy' certification standard."<sup>26</sup> 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."<sup>27</sup> 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."<sup>28</sup>

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."<sup>29</sup> In addition, OIG has suggested that MAOs should conduct "sample audits and spot checks" to confirm that their information collection and

---

<sup>23</sup> Draft Report at 12.

<sup>24</sup> 42 C.F.R. § 422.504(l).

<sup>25</sup> Medicare Program: Medicare+Choice Program, 65 Fed. Reg. 40,169, 40,250, 40,268 (June 29, 2000).

<sup>26</sup> *See id.* at 40,268.

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *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).



reporting system is working correctly, but OIG has offered no other specific guidance to the industry in this regard.<sup>30</sup>

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 "were not always effective."<sup>31</sup> This effectively imposes the perfection standard that CMS and OIG have previously recognized is not reasonable to enforce.<sup>32</sup> Indeed, none of the authorities cited in the Draft Report support OIG's apparent position that the presence of inaccurate risk adjustment data in an MAO's risk adjustment submissions constitutes *per se* noncompliance with federal requirements.<sup>33</sup> 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. Thus, Humana requests that OIG reconsider its position that Humana's policies and procedures "were not always effective" and its recommendation that Humana "enhance" its current policies and procedures.

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.<sup>34</sup> 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.<sup>35</sup> Further, Humana described its risk adjustment data policies and procedures to OIG in connection with the review OIG conducted in support of the Draft Report.<sup>36</sup> As those communications

---

<sup>30</sup> 64 Fed. Reg. 61,900 (Nov. 15, 1999).

<sup>31</sup> Draft Report at 12.

<sup>32</sup> See Medicare Program: Medicare+Choice Program, 65 Fed. Reg. 40,268 (June 29, 2000).

<sup>33</sup> See Draft Report at 5-6.

<sup>34</sup> 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).

<sup>35</sup> One element of Humana's extensive MRA compliance program involves regular internal RADV-like audits that Humana conducts to confirm the accuracy of the risk-adjusted premiums that Humana receives from CMS (called Humana Self Audits). Humana believes that these Self Audits satisfy 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 reviews, 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 includes requesting additional documentation for further review if the initial documentation received from providers does not support an HCC. Consistent with CMS's regulatory guidance and the aforementioned actuarial equivalence requirement, the Self Audit process involves the calculation and comparison of the contract-level Self Audit results against an estimated FFSA. Specifically, if Humana determines that an unsupported HCC has been submitted for a sampled member, Humana recalculates the member's risk score and risk adjustment premium to determine any projected payment imprecision related to that member. Humana then calculates each Self Audit contract group's preliminary payment recovery amount and applies an estimated FFSA to determine the final estimated recovery amount from the Self Audit. Humana also submits a corresponding data correction for every HCC that has been selected for Self Audit that is not supported by at least one available medical record.

<sup>36</sup> See Draft Report at 13 ("[OIG] interviewed Humana officials to gain an understanding of (1) the policies and procedures that Humana followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Humana's monitoring of those submissions to prevent, detect, and correct noncompliance with Federal

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. 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.<sup>37</sup> 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 have been based on 1,325 HCCs instead of 1,525 HCCs."<sup>38</sup> But, as discussed above, Humana's inability to detect and correct every single unsubstantiated HCC in its submissions to CMS for H1036 does not constitute *per se* noncompliance with federal requirements. To the contrary, 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 that OIG reconsider its recommendation that the Company "enhance" its risk adjustment policies and procedures.

\* \* \*

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, JD  
Vice President and Chief Compliance Officer  
Enterprise Risk & Compliance Group

cc: Jane Susott, Assistant General Counsel & Associate VP of Humana Inc.

---

requirements. . . . [OIG] reviewed Humana's policies and procedures to understand how Humana submitted diagnosis codes to CMS.").

<sup>37</sup> See Draft Report at 12.

<sup>38</sup> *Id.*

The information transmitted is intended only for the person or entity to which it is addressed and may contain CONFIDENTIAL material. If you receive this material/information in error, please contact the sender and delete or destroy the material/information.