

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE COMPLIANCE  
AUDIT OF DIAGNOSIS CODES THAT  
CIGNA HEALTHSPRING OF FLORIDA,  
INC. (CONTRACT H5410) SUBMITTED TO  
CMS**

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## Report in Brief

Date: August 2022

Report No. A-03-18-00002

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. Based on similar clinical characteristics and severity and cost implications, CMS then maps certain diagnosis codes into Hierarchical Condition Categories (HCCs). CMS makes higher payments for enrollees who receive diagnoses that map to HCCs. For this audit, we reviewed one CMS contract with Cigna HealthSpring of Florida, Inc.

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

### How OIG Did This Audit

We sampled 200 enrollees with at least 1 diagnosis code that mapped to an HCC for 2015. Cigna HealthSpring provided medical records as support for 1,470 HCCs associated with these enrollees.

## Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS

### What OIG Found

Cigna HealthSpring 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 Cigna HealthSpring submitted were supported in the medical records and therefore validated 1,401 of the 1,470 sampled enrollees' HCCs, the remaining 69 HCCs were not validated and resulted in overpayments. These 69 unvalidated HCCs included 7 HCCs for which we identified 7 other, replacement HCCs for more and less severe manifestations of the diseases. Second, there were an additional 18 HCCs for which the medical records supported diagnosis codes that Cigna HealthSpring should have submitted to CMS but did not.

Thus, the risk scores for the 200 sampled enrollees should not have been based on the 1,470 HCCs. Rather, the risk scores should have been based on 1,426 HCCs (1,401 validated HCCs + 7 other HCCs + 18 additional HCCs). As a result, Cigna HealthSpring received \$39,612 of net overpayments for 2015 for the sampled enrollees. As demonstrated by the errors found in our sample, Cigna HealthSpring's policies to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved.

### What OIG Recommends and Cigna HealthSpring Comments

We recommend that Cigna HealthSpring refund to the Federal Government the \$39,612 of net overpayments and improve its policies and procedures to prevent, detect, and correct noncompliance with Federal requirements for diagnosis codes that are used to calculate risk-adjusted payments.

In written comments on our draft report, Cigna HealthSpring disagreed with our findings and both of our recommendations. Cigna HealthSpring provided additional medical record documentation that it said substantiated specific HCCs. Cigna HealthSpring also questioned our audit and statistical sampling methodologies as well as our medical review process and stated that our report reflected misunderstandings of legal and regulatory requirements. After reviewing Cigna HealthSpring's comments and the additional documentation provided, we revised our findings and recommendations as appropriate. We maintain that our methodologies were reasonable and properly executed and that we correctly applied the Federal requirements.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations based in part on the characteristics of the enrollees being covered. Using a system of risk adjustment, CMS pays MA organizations the anticipated cost of providing Medicare benefits to a given enrollee, depending on such risk factors as the age, gender, and health status of that individual. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources relative to healthier enrollees, who would be expected to require fewer health care resources. To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes<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 6.78 percent of payments to MA organizations for calendar year 2018 were improper, mainly due to MA organizations submitting unsupported diagnosis codes to CMS.<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, Cigna HealthSpring of Florida, Inc., (Cigna HealthSpring) with respect to the diagnosis codes that Cigna HealthSpring submitted to CMS for contract number H5410.<sup>3</sup>

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

<sup>3</sup> All subsequent references to “Cigna HealthSpring” in this report refer solely to contract number H5410.

## OBJECTIVE

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

## 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 (FFS) 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 2019, CMS paid MA organizations \$274 billion, which represented 34 percent of all Medicare payments for that year.

### Risk Adjustment Program

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

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<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 §§ 1853(a)(1)(C) and (a)(3); 42 CFR § 422.308(c).

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



amount for each geographic area to determine the base rate that the MA organization is paid for each of its enrollees.<sup>7</sup>

- *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, which CMS calculates annually.

To determine an enrollee's health status for purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from acceptable data sources, including certain physicians and hospitals.<sup>8</sup> MA organizations collect the diagnosis codes from providers based on information documented in the medical records and submit these codes to CMS. CMS then maps certain diagnosis codes, on the basis of similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs). 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

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<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.

<sup>8</sup> CMS required face-to-face encounters during our audit period. However, in April 2020, CMS issued a memorandum to MA organizations stating that diagnoses resulting from telehealth services can meet the face-to-face requirement when the services are provided using an interactive audio and video telecommunications system that permits real-time interactive communication. This memorandum is available online at <https://www.cms.gov/files/document/applicability-diagnoses-telehealth-services-risk-adjustment-4102020.pdf> (accessed on Sept. 23, 2020).

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>9</sup>

The risk adjustment program is prospective; CMS uses the diagnosis codes that the enrollee received for 1 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 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 before applying the budget sequestration reduction.<sup>10</sup> 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 6.78 percent of payments to MA organizations for 2018. These CMS RADV audits verify that diagnoses submitted by MA organizations for risk-adjusted payment are supported by medical record documentation.

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

### **Cigna HealthSpring of Florida, Inc.**

Cigna HealthSpring, an MA organization with headquarters in Nashville, Tennessee, has several geographically based Medicare Part C contracts with CMS. As of December 31, 2015, Cigna HealthSpring provided coverage under contract number H5410 to approximately 57,000 enrollees, most of whom resided in counties in South Florida.<sup>11</sup> For our audit period (the 2015

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<sup>9</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) are in the same related-disease group.

<sup>10</sup> Budget sequestration refers to automatic spending cuts that occurred through the withdrawal of funding for certain Federal programs, including the MA program, as provided in the Budget Control Act of 2011 (BCA) (P.L. No. 112-25 (Aug. 2, 2011)). Under the BCA, the sequestration of mandatory spending began in April 2013.

<sup>11</sup> In August 2007, Cigna HealthSpring entered into a partnership with Leon Medical Health Plans, a Health Maintenance Organization that primarily serves the Medicare community of Miami-Dade County through an exclusive relationship with Leon Medical Centers.

payment year), CMS paid Cigna HealthSpring approximately \$845 million to provide this coverage.<sup>12</sup>

## **HOW WE CONDUCTED THIS AUDIT**

Our audit focused on enrollees on whose behalf Cigna HealthSpring 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 36,387 enrollees from which we selected a stratified random sample of 200 enrollees on whose behalf CMS made payments totaling \$4 million to Cigna HealthSpring. Cigna HealthSpring provided medical records as support for 1,470 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 from these medical records validated the 1,470 HCCs. The contractor also reviewed these same medical records to determine whether any additional HCCs were validated by diagnosis codes that Cigna HealthSpring 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, and Appendix C contains our statistical sampling methodology.

## **FINDINGS**

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

First, 1,401 of the 1,470 sampled enrollees' HCCs were validated; however, the medical records did not validate the remaining 69 HCCs, which resulted in overpayments. These 69 unvalidated HCCs included 7 HCCs for which we identified 7 other HCCs for more and less severe manifestations of the diseases. These 7 other HCCs should have been included in the enrollees'

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<sup>12</sup> All of the payment amounts that CMS made to Cigna HealthSpring as well as the adjustment amounts that we identified in this report reflect the budget sequestration reduction. The Medicare sequestration reduction is two percent.

risk scores (instead of the 7 unvalidated HCCs),<sup>13</sup> which would have reduced the overpayment associated with the 69 unvalidated HCCs in our sample.<sup>14</sup>

Second, in reviewing the medical record documentation for the diagnosis codes associated with the 1,470 sampled enrollee HCCs, we identified support for diagnosis codes that Cigna HealthSpring should have submitted to CMS but did not. If Cigna HealthSpring had submitted these diagnosis codes, an additional 18 HCCs would have been included in the enrollees' risk scores. These risk scores would have increased, and CMS's payments to Cigna HealthSpring would have been higher.

In summary, the risk scores for the 200 sampled enrollees should not have been based on the 1,470 HCCs. Rather, the risk scores should have been based on 1,426 HCCs (1,401 validated HCCs + 7 other HCCs associated with more and less severe manifestations of diseases + 18 additional validated HCCs that Cigna HealthSpring did not submit to CMS). As a result, Cigna HealthSpring received \$39,612 in net overpayments for 2015 for the enrollees in our sample.

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

## **FEDERAL REQUIREMENTS**

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

Federal regulations state that MA organizations must follow CMS's instructions and submit to CMS the data necessary to characterize the context and purposes of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner (42 CFR § 422.310(b)). MA organizations must obtain risk adjustment data required by CMS from the provider, supplier, physician, or other practitioner that furnished the item or service (42 CFR § 422.310(d)(3)).

Federal regulations also state that MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes and 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

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<sup>13</sup> There was one unvalidated HCC that was the most severe manifestation in the related-disease group. Although this HCC was not validated, Cigna HealthSpring submitted medical records showing that, for this sampled enrollee, one other HCC for a less severe manifestation was allowable in the enrollee's risk score calculation.

<sup>14</sup> The less severe manifestations of the diseases associated with six of the other HCCs led to net overpayments for those six HCCs. The more severe manifestation associated with the one remaining other HCC did not lead to any payment effect.

regarding the submission of data for risk scoring purposes (*Medicare Managed Care Manual* (the Manual) (last rev. Sept. 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 (CM), Official Guidelines for Coding and Reporting (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 B).

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

Cigna HealthSpring did not submit some diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. Specifically, Cigna HealthSpring 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 43 of the 200 sampled enrollees.<sup>15</sup>

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

The diagnosis codes that Cigna HealthSpring submitted to CMS were not supported in the medical records for 69 of the 1,470 sampled enrollees’ HCCs. The 69 HCCs were not validated and should not have been used in the enrollees’ risk scores. These errors, which also included more and less severe manifestations of the diseases, caused net overpayments from CMS to Cigna HealthSpring for 43 sampled enrollees.

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

For 62 of the 69 HCCs (30 sampled enrollees), the medical records did not support either the diagnosis code that Cigna HealthSpring submitted or any other diagnosis code that would have validated the HCC. These errors caused overpayments.

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<sup>15</sup> There was more than one type of error for some enrollees.

For example, for Enrollee A, Cigna HealthSpring submitted a diagnosis code for “malignant neoplasm of bladder, part unspecified” which maps to both the Version 12 model HCC for Breast, Prostate, Colorectal, and Other Cancers and Tumors 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 “[t]here is documentation of a history of bladder cancer (V10.51) that should have been assigned and does not result in an HCC. Record 03 was submitted by the urologist and documents the reason for the visit as a history of bladder cancer, no recurrence, an ultrasound was negative, and no hematuria or voiding issues were documented. The ICD-9-CM Official Guidelines for Coding and Reporting state that if the primary site has been eradicated, a history code should be assigned rather than an active cancer diagnosis.”<sup>16</sup>

As shown in Figure 1, the diagnosis codes that Cigna HealthSpring submitted to CMS on behalf of Enrollee A mapped to four HCCs, which CMS used to calculate a \$1,210 monthly payment that it made to Cigna HealthSpring. Because the HCC for Breast, Prostate, Colorectal, and Other Cancers and Tumors and the HCC for Colorectal, Bladder, and Other Cancers were not validated, the CMS payment should have been based on two HCCs, which would have resulted in a monthly payment of \$1,049. This error caused a \$1,932 overpayment for the year.

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

AS SUBMITTED BY CIGNA HEALTHSPRING		A
Number of HCCs	4	
Monthly CMS Payment	\$1,210	
AS AUDITED		
Number of HCCs	2	
Monthly CMS Payment	\$1,049	
OVERPAYMENT		
Monthly	\$161	
Annually	\$1,932	

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

For 7 of the 69 HCCs (4 sampled enrollees), the medical records did not support the diagnosis codes that Cigna HealthSpring submitted. However, we identified seven other HCCs (that were supported by other diagnosis codes) for more and less severe manifestations of the diseases.

<sup>16</sup> The ICD-9-CM Official Guidelines for Coding and Reporting are the ninth revision of the ICD Coding Guidelines. CMS transitioned to the tenth revision (ICD-10-CM) effective October 1, 2015.

These seven other HCCs should have been included in the enrollees' risk scores (instead of the seven unvalidated HCCs). Including the 7 other HCCs would have reduced the overpayments associated with the 69 unvalidated HCCs in our sample (footnotes 13 and 14).

For six of the seven submitted HCCs (three sampled enrollees), the diagnosis codes that Cigna HealthSpring submitted mapped to a more severe manifestation of the HCCs in the related-disease group but were not supported in the medical records. However, there were other diagnosis codes, which mapped to seven other HCCs for less severe manifestations, that should have been used in the enrollees' risk scores. These errors led to net overpayments for all seven HCCs.

For example, for Enrollee B, Cigna HealthSpring submitted a diagnosis for "Respiratory arrest." This diagnosis code maps to both the Version 12 model HCC for Respiratory Arrest and the Version 22 model HCC for Respiratory Arrest, 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 "Acute Respiratory Failure," which maps to HCCs that were both less severe manifestations of the HCCs in those related-disease groups (Cardio-Respiratory Failure and Shock 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, this error caused a \$4,596 overpayment for the year.

**Figure 2: Overpayment Calculation for Enrollee B, Who Had HCCs for Which a More Severe Manifestation of a Disease Was Replaced by a Less Severe Manifestation of That Disease**

AS SUBMITTED BY CIGNA HEALTHSPRING	
HCCs for Respiratory Arrest (More Severe Manifestation of That Disease)	
Monthly CMS Payment Attributed to HCCs	\$706
AS AUDITED	
HCCs for Cardio-Respiratory Failure and Shock (Less Severe Manifestation of That Disease)	
Monthly CMS Payment Attributed to HCCs	\$323
<b>OVERPAYMENT</b>	
<b>Monthly</b>	<b>\$383</b>
<b>Annually</b>	<b>\$4,596</b>

For one of the seven submitted HCCs (one sampled enrollee), Cigna HealthSpring did not submit a diagnosis code that mapped to the more severe manifestation of the HCC in the

related-disease group. Instead, Cigna HealthSpring submitted only the diagnosis code that mapped to the less severe manifestation. If Cigna HealthSpring had submitted the correct diagnosis code, the more severe HCC would have replaced the less severe HCC in the risk score. However, because the less severe HCCs and the more severe HCCs had the same factors, this error had no payment effect.<sup>17</sup>


### **There Were Some Diagnosis Codes That Cigna HealthSpring Should Have Submitted but Did Not Submit to CMS**

Cigna HealthSpring did not submit all of the correct diagnosis codes. Specifically, there were an additional 18 HCCs (11 sampled enrollees) for which the medical records supported diagnosis codes that Cigna HealthSpring 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 Cigna HealthSpring.

For example, for Enrollee C, Cigna HealthSpring did not submit a diagnosis code for "Severe sepsis." 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 diagnosis code, which Cigna HealthSpring should have submitted but did not submit to CMS, maps to and validates the Version 22 model HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.

As shown in Figure 3, this error caused a \$1,488 underpayment for the year.

**Figure 3: Underpayment Calculation for Enrollee C, Who Had an HCC That Was Validated From a Diagnosis Code That Cigna HealthSpring Should Have Submitted but Did Not Submit to CMS**

AS SUBMITTED BY CIGNA HEALTHSPRING		
Number of HCCs	4	
Monthly CMS Payment	\$1,398	
AS AUDITED		
Number of HCCs	5	
Monthly CMS Payment	\$1,522	
UNDERPAYMENT		
Monthly	\$124	
Annually	\$1,488	

<sup>17</sup> The less severe HCCs were Diabetes with Neurologic or Other Specified Manifestations (Version 12) and Diabetes with Chronic Complications (Version 22). The more severe HCCs were Diabetes with Renal or Peripheral Circulatory Manifestation (Version 12) and Diabetes with Chronic Complications (Version 22).



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

Because Cigna HealthSpring 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 1,470 HCCs. Rather, their risk scores should have been based on the 1,426 validated HCCs. Figure 4 summarizes these differences.

**Figure 4: 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**

BASED ON DIAGNOSIS CODES THAT CIGNA HEALTHSPRING SUBMITTED	
Total Number of HCCs	1,470
AS AUDITED	
HCCs That Were Validated	1,401
HCCs Validated by Other Diagnosis Codes	7
Additional HCCs That Were Validated	+ 18
<b>NUMBER OF HCCS THAT SHOULD HAVE BEEN USED</b>	<b>1,426</b>

## THE POLICIES AND PROCEDURES THAT CIGNA HEALTHSPRING USED TO PREVENT, DETECT, AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS COULD BE IMPROVED

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

Cigna HealthSpring had a compliance program to ensure that it submitted accurate diagnosis codes for use in CMS's risk adjustment program. To prevent the submission of incorrect diagnosis codes to CMS, Cigna HealthSpring educated its providers on medical record documentation practices and accurate reporting of diagnosis codes on claims. This education included provider-specific training related to the provider's medical record documentation practices. Cigna HealthSpring's compliance program also included procedures to detect and correct inaccurate coding.<sup>18</sup> In some cases, after Cigna HealthSpring received claims from its providers, it reviewed medical records to retrospectively assess the accuracy of the diagnosis reported. In addition, Cigna HealthSpring routinely educated its coders on best coding practices and acceptable medical documentation guidelines. Cigna HealthSpring required periodic

<sup>18</sup> Cigna HealthSpring contracted with Leon Medical Center, Inc. to perform medical coding services.

reviews of coded records to assess a coder's performance. Coders were expected to identify codes with at least 95-percent accuracy.<sup>19</sup> Coders who did not meet this standard received additional training and monitoring.

Cigna HealthSpring's policies and procedures were generally effective; however, because the risk scores for the 200 sampled enrollees should have been based on 1,426 HCCs instead of 1,470 HCCs, Cigna HealthSpring's policies and procedures could be improved, and this improvement could help reduce the occurrence of similar errors in subsequent periods.

## **CIGNA HEALTHSPRING RECEIVED NET OVERPAYMENTS**

Cigna HealthSpring received \$39,612 of net overpayments (consisting of \$77,812 of overpayments and \$38,200 of underpayments) for the 200 sampled enrollees.

## **RECOMMENDATIONS**

We recommend that Cigna HealthSpring of Florida, Inc.:

- refund to the Federal Government \$39,612 of net overpayments and
- improve its policies and procedures to prevent, detect, and correct noncompliance with Federal requirements for diagnosis codes that are used to calculate risk-adjusted payments.

## **CIGNA HEALTHSPRING COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, Cigna HealthSpring disagreed with our findings and both of our recommendations. Specifically, Cigna HealthSpring stated that our draft report understated Cigna HealthSpring's actual performance. In addition, Cigna HealthSpring stated that the audit was not adequately designed to identify underpayments. Cigna HealthSpring also had concerns regarding our medical review process and did not believe that the "few errors" identified by the independent medical review contractor were the result of Cigna HealthSpring's policies and procedures not always being effective.

We reviewed Cigna HealthSpring's comments and the additional information that it provided and revised our findings and our calculation of net overpayments as appropriate. In addition, because our draft report did not consider the effects of sequestration, we reduced the revised net overpayment amount by two percent. After considering Cigna HealthSpring's comments and the budget sequestration reduction, we revised the recovery amount for our first recommendation to only the net overpayments (\$39,612) for the items in our sample. We also revised the wording of our second recommendation.

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<sup>19</sup> Accuracy is measured as the percentage of diagnosis codes that the coder correctly identified as compared to a quality control reviewer.

A summary of Cigna HealthSpring's comments and our responses follows. Cigna HealthSpring's comments appear as Appendix D. We excluded attachments (which Cigna HealthSpring identified as Appendix A and Appendix B in its comments) because they contained personally identifiable information. We are separately providing Cigna HealthSpring's comments and attachments in their entirety to CMS.

## **CIGNA HEALTHSPRING DID NOT AGREE WITH CERTAIN HIERARCHICAL CONDITION CATEGORY DETERMINATIONS**

### **Cigna HealthSpring Comments**

Cigna HealthSpring, in the additional information that it provided, identified: (1) 60 HCCs that we did not validate, which Cigna HealthSpring believed were supported and should be reconsidered, and (2) 109 "new HCCs that accurately reflect the health status of its members in the audit sample."<sup>20</sup> Cigna HealthSpring stated that it performed a separate coding review that contained specific references to previously submitted medical records and, in some instances, references to newly submitted medical records that validated these 169 HCCs.

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

Not all of the information that Cigna HealthSpring provided as a result of its coding review complied with Chapter 7, section 40, of the Manual, which provides instructions to MA organizations regarding the submission of data for risk adjustment purposes. For example, Cigna HealthSpring gave us some medical records that were not from acceptable data sources and some medical records that were for services that occurred before or after service year 2014. Although we did not provide this noncompliant information to our independent medical review contractor for further review, we submitted the remaining information, which included 10 previously unsubmitted medical records.

Our independent medical review contractor validated 22 of the previously unvalidated 60 HCCs and found support for 15 of the 109 new HCCs. Consequently, we: (1) reduced the number of unvalidated HCCs from 91 in our draft report to 69 and (2) increased the number of additional HCCs that were validated from 3 to 18 for this final report. Accordingly, we revised our findings and monetary recommendation to \$39,612 (which also reflects the budget sequestration reduction).

To ensure that the reversals did not impact other determinations, our independent medical review contractor performed additional quality analyses and confirmed that there were no systemic issues in its medical review process for other sampled enrollees.

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<sup>20</sup> In its comments, Cigna HealthSpring indicated that it had submitted 65 additional HCCs. We subsequently confirmed with Cigna HealthSpring that it had submitted 109 additional HCCs.

## **CIGNA HEALTHSPRING STATED THAT THE OFFICE OF INSPECTOR GENERAL INCORRECTLY IMPOSED A REQUIREMENT THAT IT SUBMIT PERFECT RISK ADJUSTMENT DATA TO CMS**

### **Cigna HealthSpring Comments**

Cigna HealthSpring stated that our audit results showed that it “is performing at a high level that compares favorably to others in the MA program” in that more than 94 percent of the HCCs reviewed for the sampled enrollees were accurate.<sup>21</sup> Cigna HealthSpring stated that these results reflected “exemplary” performance and “underscore that [its] policies and procedures are effective.” Cigna HealthSpring also stated that our draft report took the preliminary position that the limited number of errors occurred because its policies and procedures were not always effective but that we did not identify how the policies and procedures caused the errors. According to Cigna HealthSpring, our report “reflects an incorrect assumption that MA plans are required to achieve perfection in [their] risk adjustment data and that any allegedly unsupported HCC indicates a policy or procedure failure.” To this point, Cigna HealthSpring asserted that we imposed “a perfection standard that is neither required nor attainable.”

Cigna HealthSpring stated that CMS does not impose a perfection standard and made the following points regarding what it considers to be inconsistencies between the Office of Inspector General (OIG) and CMS:

- Cigna HealthSpring stated that we misunderstood CMS’s regulation at 42 CFR section 422.504(l), “in taking the position that “MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS”.” With respect to this regulation, Cigna HealthSpring said that CMS has stated that there is no requirement that MA organizations need to verify every diagnosis submitted by providers.
- Cigna HealthSpring stated that we also misunderstood CMS’s regulation at 42 CFR section 422.503(b)(vi), which requires MA organizations to adopt an effective compliance program. Cigna HealthSpring asserted that perfection is not required for a compliance program to be effective. In contrast, Cigna HealthSpring stated that OIG (in previous comments made in the Federal Register) has recognized that: (1) the implementation of an effective compliance program may not entirely eliminate fraud and waste from the organization and (2) an MA organization’s attestation (that MA organizations must submit data that conform to CMS’s requirements for data equivalent

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<sup>21</sup> Cigna HealthSpring calculated its HCC accuracy rate by offsetting the number of unvalidated HCCs with the HCCs of more or less severe manifestations and additional HCCs. After reviewing the information that Cigna HealthSpring submitted, we calculated our 95.3 percent accuracy rate by dividing only the HCCs validated by the total HCCs reviewed. As such, we calculated Cigna HealthSpring’s final unvalidated HCC error rate to be 4.7 percent.

to Medicare FFS data, when appropriate, and to all relevant national standards) does not constitute an absolute guarantee of accuracy.

- Cigna HealthSpring stated that a “perfection standard would also be inconsistent with the Medicare Advantage statute, which requires CMS to pay MA organizations in a manner that achieves [a payment principle known as] ‘actuarial equivalence.’” In respect to this principle, Cigna HealthSpring said that “CMS also acknowledged in 2012 that holding MA organizations to a perfection standard in RADV audits would violate actuarial principles by treating similar data differently, and it agreed to apply a FFS adjuster to account for that issue.” Cigna HealthSpring also commented that the “perfection standard reflected in [our report] also is not consistent with the realities and limitations of attempting to perform a risk adjustment function.” To demonstrate its position, Cigna HealthSpring offered the following:
  - OIG did not take into account that “although [Cigna HealthSpring makes] coding and documentation training available to those providers, [Cigna HealthSpring] can not ultimately control their submissions.”
  - Coding disagreements “are inevitable” and “often arise from factors outside the control of any MA plan.” Cigna HealthSpring also said that “[m]edical practice is an inherently subjective process” and CMS generally “allows providers to use their best professional judgment.”
  - Coding is subjective, coders must use their best judgment, and both “OIG and CMS have acknowledged that the ICD-CM code set can contain errors that cause the wrong code to be submitted.”
  - The 7 years between the beginning of the audit, which covered dates of service in 2014, and the issuance of the draft report made it difficult to obtain the necessary records from providers.

In summary, Cigna HealthSpring asked that we amend our report “to recognize that perfection in risk adjustment data is not required or attainable” and that we “remove statements alleging that [its] policies and procedures were ‘not always effective,’ as well as all statements alleging that all ‘errors’ were attributable to [its] policies and procedures.”

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

Although we do not agree with Cigna HealthSpring’s assertion that we should amend our report to reflect that perfection in risk adjustment is not required or attainable, we agree with Cigna HealthSpring that we should not characterize its policies and procedures as “not always effective.” As discussed below, we changed our description of Cigna HealthSpring’s policies and

procedures for preventing, detecting, and correcting noncompliance with CMS's program requirements from "not always effective" to "could be improved."<sup>22</sup>

With respect to Cigna HealthSpring's policies and procedures, we disagree with Cigna HealthSpring's statement that the errors identified in this report were not attributable to its policies and procedures. We are required to report errors identified as a result of our audit and maintain that the errors identified in this report demonstrate that Cigna HealthSpring has compliance issues that need to be addressed. The requirements at 42 CFR section 422.503(b)(4)(vi)(G) require MA organizations to investigate "potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence." Thus, CMS has, through the issuance of these Federal regulations, assigned the responsibility for dealing with potential compliance issues to the MA organizations.

We also do not agree with Cigna HealthSpring's interpretation of the Federal requirements at 42 CFR sections 422.503(b)(4)(vi) and 422.04(l). We recognize that MA organizations have the latitude to design their own, federally mandated, compliance programs. We also recognize that CMS applies a "best knowledge, information and belief" standard when MA organizations certify the great volume of data that they submit to CMS for use in the risk adjustment program.<sup>23</sup>

However, Federal regulations at 42 CFR section 422.503(b)(4)(vi) also state that MA organizations must "implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS' program requirements." Further, these regulations specify that an MA organization's compliance plan "must, at a minimum, include [certain] core requirements," which include "an effective system for routine monitoring and identification of compliance risks. . . . [including] internal monitoring and audits and, as appropriate, external audits to evaluate . . . compliance with CMS requirements and the overall effectiveness of the compliance program."

The percentage of HCCs for the sampled enrollees in error (4.7 percent according to our revised findings (footnote 21)) and the number of sampled enrollees with at least 1 incorrect HCC included in their risk scores (43 of 200 or 21.5 percent) demonstrate that Cigna HealthSpring's compliance program could be improved.

With regard to Cigna HealthSpring's statement that a perfection standard violates actuarial principles such as actuarial equivalence and the application of an FFS adjuster, we note that our audit methodology correctly applied CMS requirements to properly identify the overpayment amount associated with unsubstantiated HCCs for each sampled enrollee. As discussed below, CMS is responsible for making operational and program payment determinations for the MA

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<sup>22</sup> See the "Cigna HealthSpring Did Not Agree That Its Policies And Procedures Were Not Always Effective and That Errors Were Attributable To Its Policies And Procedures" section.

<sup>23</sup> 79 Fed. Reg. 29844, 29926 (May 23, 2014).

program, including the application of any FFS adjuster requirements. CMS has not issued any requirements that compel us to reduce our net overpayment calculations.<sup>24</sup>

## **CIGNA HEALTHSPRING DID NOT AGREE WITH HOW THE OFFICE OF INSPECTOR GENERAL INCORPORATED UNDERPAYMENTS INTO ITS AUDIT METHODOLOGY**

### **Cigna HealthSpring Comments**

Cigna HealthSpring stated that our “audit methodology was not equally structured to find overpayments and underpayments.” With regard to this statement, Cigna HealthSpring made four related points:

- Cigna HealthSpring stated that “the audit frames were defined to exclude members with no reported HCCs,” and the “effect of this was to exclude the members for whom underpayments were most likely.”
- Cigna HealthSpring stated that we only asked it to collect records to validate HCCs that were already submitted. Specifically, Cigna HealthSpring stated that its “medical record submissions prior to the Draft Report consisted of far less than all available records for the 200 members in the audit sample.”
- Cigna HealthSpring stated that “although [it] identified 26 additional HCCs to be considered, only one was accepted by [our independent] medical record review contractor.”
- Cigna HealthSpring stated that the audit methodology that we shared with Cigna HealthSpring officials does not discuss how we and our independent medical review contractor identified or evaluated potential underpayments, including the additional HCCs Cigna HealthSpring identified.

Cigna HealthSpring stated that it “believe[s] these issues affected the audit results” and asked that we “comprehensively identify underpayments in the audit sample” for 109 additional HCCs for sampled members.

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

We disagree with Cigna HealthSpring that these issues affected our audit results.

Our objective was to determine whether Cigna HealthSpring submitted diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. In regard to this objective, the identification of: (1) enrollees for which Cigna HealthSpring did not submit any risk-adjusting diagnosis codes for our sampling frame, and (2) all possible diagnosis codes

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<sup>24</sup> See the “Cigna HealthSpring Did Not Agree With the Office Of Inspector General’s Application of CMS Requirements for the Calculation Of Overpayments” section.

that Cigna HealthSpring could have submitted on behalf of the sampled enrollees was beyond the scope of our audit.

In some cases, after Cigna HealthSpring received claims from its providers, it reviewed medical records to retrospectively assess the accuracy of the diagnoses that the providers reported. Cigna HealthSpring designed these procedures to detect and correct inaccurate coding. These procedures included analyses to determine whether Cigna HealthSpring should have submitted to CMS diagnosis codes that it did not previously submit to CMS. For our audit period, CMS allowed Cigna HealthSpring to delete unsupported diagnosis codes and submit supported diagnosis codes previously not submitted up until February 2016 for claims for services rendered during the 2014 service year.

A valid estimate of net overpayments does not need to cover all potential diagnosis codes or underpayments within the audit period. Our estimate of net overpayments does not extend to diagnosis codes beyond the scope of our audit. In accordance with our objective, we properly executed our statistical sampling methodology in that we defined our sampling frame (Cigna HealthSpring 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 Cigna HealthSpring.

During our fieldwork, we provided Cigna HealthSpring with an explanation of the independent medical review contractor's review process, including the methodology that the contractor used to identify or evaluate additional HCCs. Our contractor followed this methodology to perform a blind review of all physician and outpatient records that Cigna HealthSpring provided and abstracted all relevant diagnosis codes.<sup>25</sup> Our contractor did not perform a blind review of inpatient records; however, we instructed Cigna HealthSpring to identify all relevant diagnoses from these records, including any diagnoses that mapped to HCCs that were not initially included in the sampled enrollees' risk scores. We used the contractor's results 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 Medicare payment that CMS should have made for each enrollee. See Appendix A for more information about our audit methodology.

We discussed our review of the information that Cigna HealthSpring provided for the 109 "new" HCCs in the section "Cigna HealthSpring Did Not Agree With Certain Hierarchical Condition Category Determinations."

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<sup>25</sup> During the blind review, the diagnoses that mapped to HCCs and that were initially included in the sampled enrollees' risk score were not known to the contractor's coder performing the review.



## **CIGNA HEALTHSPRING DID NOT AGREE WITH OUR CHARACTERIZATION OF UNDERPAYMENTS AS IMPROPER PAYMENTS**

### **Cigna HealthSpring Comments**

Cigna HealthSpring stated that we incorrectly characterized underpayments as improper payments attributable to Cigna HealthSpring's policies and procedures. Cigna HealthSpring stated that we "[appear] to take the position that MA plans are required to identify every potential diagnosis . . . by any provider who may treat an enrolled beneficiary." In addition, Cigna HealthSpring stated that "underpayments do not harm the government in any way because the MA plan bears any financial loss associated with the underpayment" and "do not present any fraud, waste or abuse concerns."

Cigna HealthSpring stated that while it has a retrospective chart review program which is the "only way for a MA organization to know that a provider has omitted a code," neither CMS nor Congress has mandated chart review programs and that, furthermore, chart programs "cannot prevent all underpayments."

Lastly, Cigna HealthSpring stated that while the Payment Integrity Information Act and prior related statutes include both underpayments and overpayments in their definitions of improper payments, "nothing in those laws can be interpreted to classify CMS' underpayments as evidence of a compliance failure by MA plans."

For these reasons, Cigna HealthSpring requested that we amend our report to: (1) recognize that underpayments do not present fraud, waste, and abuse concerns, and (2) remove the language referring to underpayments as either being improper or being considered errors.

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

We do not agree with Cigna HealthSpring's assertion that we incorrectly characterized underpayments as improper payments. As Cigna HealthSpring correctly pointed out, the Payment Integrity Information Act and prior related statutes include both underpayments and overpayments in their definitions of improper payments. Incorrect diagnosis codes are errors that lead to improper payments, even if the payment is less than it should be.

## **CIGNA HEALTHSPRING DID NOT AGREE WITH HOW THE OFFICE OF INSPECTOR GENERAL INCORPORATED ITS INDEPENDENT MEDICAL REVIEW CONTRACTOR'S RESULT INTO THE REPORT**

### **Cigna HealthSpring Comments**

Cigna HealthSpring stated that it had a number of concerns regarding our independent medical review contractor and how we incorporated the contractor's results into our report. Specifically, Cigna HealthSpring stated that we have not "been sufficiently transparent regarding the standards that were applied during the medical record review" and that its concerns could affect its appeal rights under Federal regulations. Cigna HealthSpring also

stated that additional information about the contractor and the contractor's results "should be disclosed pursuant to the Data Quality Act and generally accepted audit practices." With regard to these concerns, Cigna HealthSpring made several related points:

- Cigna HealthSpring said that we should provide the name of the contractor so that Cigna HealthSpring can assess the contractor's credentials, training, and coding policies and procedures; determine whether there are any conflicts of interest; and "see if the positions taken are consistent with prior work undertaken by the contractor, or statements made by it." Cigna HealthSpring also stated it only received the last determination made by the contractor but that the draft report indicated multiple levels of review, and it would like to be able to review the interim determinations. Cigna HealthSpring stated it would like to know if the contractor was subject to inter-rater reliability reviews and what the results of those reviews were.<sup>26</sup>
- Cigna HealthSpring: (1) stated that our independent medical review contractor made inconsistent determinations and (2) provided examples of these inconsistencies. Cigna HealthSpring stated that our contractor "incorporated a review of the clinical validity of the provider's diagnosis" and that "CMS has not permitted the certified coders conducting its medical reviews to attempt to assess the clinical validity of diagnoses." Cigna HealthSpring said that it was "concerned that the physician [reviewer that we used] did not limit his or her analysis to issues of coding and documentation" and stated that the Enrollee A example (in our draft report) reflected "a clinical judgement." To this point, Cigna HealthSpring stated that this "was a recurring and significant issue in the audit" and referenced its concerns regarding 11 sampled enrollees for whom our independent medical review contractor did not find support for cancer-related diagnoses.
- Cigna HealthSpring also stated that our independent medical review contractor "did not identify the coding or documentation standards that drove its determinations." Cigna HealthSpring said that our draft report indicated that our contractor followed Chapter 7 of the Manual and the September 2017 version of CMS's RADV guidance. According to Cigna HealthSpring, CMS has identified additional guidance that MA organizations should rely on.<sup>27</sup> Cigna HealthSpring stated that our contractor "should identify the specific policies that were used to invalidate relevant diagnoses." Cigna HealthSpring provided an example and indicated that it could not identify what coding policies we relied upon. Further, Cigna HealthSpring stated that "[g]eneral principles of

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<sup>26</sup> Cigna HealthSpring described the inter-rater reliability reviews as reviews required by CMS to determine the accuracy rate of the coders involved in CMS's RADV audits.

<sup>27</sup> Cigna HealthSpring stated that CMS's *Risk Adjustment Data Training for Medicare Advantage Organizations Participant Guide*, 6-12, 7-18 (2007) identifies guidance from the American Health Information Management Association (AHIMA), the American Medical Association, the American Academy of Professional Coders, the *Fundamentals of Clinical Practice*, and the *Bates Guide to Physical Examination and History Tracking*.

administrative law require a clear statement of the reasons supporting the agency's determination."

### Office of Inspector General Response

We do not agree with Cigna HealthSpring's comments that we need to provide additional information about the contractor and the contractor's results, and we also do not agree that not providing the additional information will affect its appeal rights. Specifically:

- It is not our practice to name our independent medical review contractor. However, part of our audit process is to ensure that there are no conflicts of interest among the parties involved in the audit. The name of the contractor would not provide information about the contractor's qualifications beyond what we state in this audit report. Furthermore, during the course of our audit, we informed Cigna HealthSpring that our medical reviews were performed by professional coders credentialed by the American Health Information Management Association (AHIMA) and the American Association of Professional Coders (AAPC).<sup>28</sup> These coders are experienced in coding ICD-9-CM diagnosis codes for hospital inpatient, outpatient, and physician medical records. Furthermore, the contractor has a quality review process by which it periodically performs self-reviews on the accuracy of its previous decisions and makes corrections, if needed.
- With respect to the "inconsistent decisions" that Cigna HealthSpring stated our independent medical review contractor made, we provided our contractor with the explanations and medical records (that complied with CMS requirements) for all of the enrollees that Cigna HealthSpring provided in response to our draft report.
  - Cigna HealthSpring noted that, for two sampled enrollees, our contractor found support for a diagnosis of homocysteinemia<sup>29</sup> but did not find support on similar medical records associated with another sampled enrollee. However, upon further review, our contractor upheld its original decisions and stated that while the diagnosis was supported for two enrollees it "should not be assigned [for the other sampled enrollee] since the high homocysteine level for this patient is a manifestation of chronic kidney disease."

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<sup>28</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), CPC – Instructor, and Certified Risk Coder (CRC). RHITs have completed a 2-year degree program and have passed an AHIMA certification exam. AHIMA also credentials individuals with CCS and CCS-P certifications and the AAPC credentials both CPCs and CRCs.

<sup>29</sup> Homocysteinemia occurs when there are above normal levels of the amino acid homocysteine in the blood.

- With regard to a sampled enrollee for whom Cigna HealthSpring identified a diagnosis that was validated under one HCC model but not under the other HCC model, our contractor re-evaluated this sample and reversed its decision.

As previously stated, upon completion of all of its reviews (in response to Cigna HealthSpring's comments on our draft report), our contractor performed additional quality analyses and confirmed that there is no impact on decisions made for other sampled enrollees as a result of Cigna HealthSpring's arguments.

- 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 decision maker, was a reasonable method for determining whether the medical records adequately supported the reported diagnosis codes. With regard to the related statements that Cigna HealthSpring made:
  - Cigna HealthSpring's assertion that the decisions for two sampled enrollees are based explicitly on physician review is incorrect. The reviews of the HCCs for each sampled item were performed by senior coders with a physician acting as a final decision maker when there was not consensus between the first and second level coder. The use of a physician to make a coding determination in such an instance does not imply the use of clinical judgment, nor did the use of clinical judgment occur.
  - We disagree with Cigna HealthSpring's assertion that our independent medical review contractor's physician applied clinical judgment in the review of HCCs for Enrollee A in this report. Our contractor re-evaluated its decision and reviewed only the additional acceptable medical information that Cigna HealthSpring submitted for this enrollee<sup>30</sup> and did not find support for the HCC.
  - We also disagree with Cigna HealthSpring's statement regarding the 11 sampled enrollees associated with cancer-related HCCs that were not validated. Our contractor carefully evaluated each sampled item to determine whether the provider documented a history of malignancy; whether the organ or neoplasm was eradicated by surgery, radiation, or chemotherapy; and whether care provided was therapeutic or preventive. In many cases, the provider documented "history of" a malignant neoplasm, and the beneficiary received preventive care. Therefore, the contractor upheld its original decisions.
- Our independent medical review contractor used the following coding and documentation standards: (1) the CMS Contract-Level Risk Adjustment Data Validation

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<sup>30</sup> We did not submit to our independent medical contractor an attestation from the treating urologist and a medical record from a 2016 hospitalization because these records did not meet the eligibility requirements to be considered for risk adjustment for payment year 2015.

Medical Record Reviewer Guidance,<sup>31</sup> (2) 2011 ICD-9-CM Official Guidelines for Coding and Reporting,<sup>32</sup> (3) 2015 ICD-10-CM Official Guidelines for Coding and Reporting,<sup>33</sup> (4) the American Hospital Association (AHA) Coding Clinic for ICD-9-CM, and (5) the AHA Coding Clinic for ICD-10-CM and ICD-10-PCS.

**CIGNA HEALTHSPRING STATED THAT THE CODING AND DOCUMENTATION STANDARDS THAT WERE APPLIED DURING THE MEDICAL RECORD REVIEW WERE NOT ESTABLISHED IN ACCORDANCE WITH THE LAW**

**Cigna HealthSpring Comments**

Cigna HealthSpring stated that the coding and documentation standards that the independent medical review contractor used to differentiate between valid risk adjustment payments and overpayments were not established through notice and comment and that this is required by the Administrative Procedure Act (APA) (U.S.C. § 533) and more broadly by Medicare statute (42 U.S.C. § 1395hh(a)(2)) as acknowledged in *Azar v. Allina Health*. In addition, Cigna HealthSpring stated that ICD-CM coding guidelines, a “core RADV requirement,” are established jointly by CMS and private entities “through a largely closed process that does not involve notice and comment.” In regard to these guidelines, Cigna HealthSpring noted that the Medicare statute and the APA “do not allow CMS to delegate its responsibility to establish standards for risk adjustment to private, non-governmental entities.”

Cigna HealthSpring added that risk adjustment standards do not allow MA organizations to provide relevant evidence regarding an enrollee’s health status. Cigna HealthSpring provided seven examples of areas in which it believes CMS prohibits MA organizations from providing “important, credible evidence”:

- RADV requirements exclude portions of medical records that are otherwise from a valid provider type (e.g., the “problem list” in a medical record).
- RADV requirements limit documentation from certain physicians, such as radiologists, who could submit useful diagnoses for risk adjustment purposes.

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<sup>31</sup> CMS, *Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance As of 9/27/2017*. Available online at <https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-risk-adjustment-data-validation-program/other-content-types/radv-docs/coders-guidance.pdf>. Accessed on June 2, 2020.

<sup>32</sup> *ICD-9-CM Official Guidelines for Coding and Reporting Effective October 1, 2011*. Available online at [https://www.cdc.gov/nchs/data/icd/icd9cm\\_guidelines\\_2011.pdf](https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf). Accessed on September 2, 2021.

<sup>33</sup> *ICD-10-CM Official Guidelines for Coding and Reporting FY 2015*. Available online at <https://www.cdc.gov/nchs/data/icd/10cmguidelines-2015-updated-9-26-14.pdf>. Accessed on September 2, 2021.

- RADV requirements exclude other provider types such as durable medical equipment suppliers which Cigna HealthSpring maintained “[is] not consistent with the statutory focus on patients ‘health status’ or the purpose of risk adjustment.”
- CMS’s medical record signature and credential requirements are common technical issues that “impede accurate determinations of beneficiary ‘health status’.”
- RADV requirements exclude prescription data in beneficiary health status determinations “even though the relationship between some medications and health status is clear” and in contrast to the “the Affordable Care Act market [which utilizes] prescription data for risk adjustment.”
- RADV requirements exclude attestations for purposes other than “correcting signature issues” in a record when the attestation could provide information related to beneficiary health status, “clarify a record,” correct legibility issues, or otherwise explain shorthand and acronyms.
- Some coding guidelines are clinically incorrect. Specifically, Cigna HealthSpring noted that the guidelines for solid tumor cancers have not been recently updated, and the guidelines for pacemakers were clinically incorrect until they were updated in 2019. In addition, Cigna HealthSpring stated that the ICD guidelines vary regarding the treatment of acute conditions.

Cigna HealthSpring stated that it believed that these issues would have been rectified if the RADV rules went through notice and comment.

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

We disagree with Cigna HealthSpring’s assertion that our methodology for evaluating the validity of certain codes Cigna HealthSpring submitted was flawed because our methodology applied substantive standards that did not comply with notice-and-comment requirements set forth in *Azar v. Allina Health*. We designed our audit to comply with Federal requirements. Our independent medical review contractor reviewed medical records to determine whether the diagnosis codes that Cigna HealthSpring submitted to CMS for risk-adjustment purposes were supported.

In accordance with the Manual, the diagnoses must come from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities, and physicians. The Manual is legally binding on an MA organization, and this is based not only on regulation, but also on the organization’s contract with CMS. Federal regulations state that MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes and that such data must conform to all relevant national standards.<sup>34</sup> In addition, MA organizations that contract with CMS must agree to follow CMS’s instructions,

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<sup>34</sup> 42 CFR §§ 422.504(l) and 422.310(d)(1).

including the provisions of the Manual.<sup>35</sup> Cigna HealthSpring has agreed to operate in compliance with the Manual under the terms of its contract with CMS and is bound by the requirements of that contract, including any applicable provisions of the Manual.

## **CIGNA HEALTHSRING DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S APPLICATION OF CMS REQUIREMENTS FOR THE CALCULATION OF OVERPAYMENTS**

### **Cigna HealthSpring Comments**

Cigna HealthSpring stated that it does “not believe that extrapolation has been authorized by Congress in this situation. Part C of the Medicare statute does not authorize extrapolated recoveries and, in the absence of explicit Congressional authorization, we believe extrapolation is not available.” Cigna HealthSpring also said that “[e]ven if extrapolation were permitted, the methodology [that OIG] used would have to adhere to the final methodology established by CMS.” In this regard, Cigna HealthSpring stated that our extrapolation methodology does not adhere to the final methodology for RADV audits published by CMS in February 2012 and identified four areas in which it maintains that we incorrectly departed from this methodology.<sup>36</sup>

- Cigna HealthSpring stated that we used a stratification methodology that “is not permitted by regulation” and departs from CMS’s February 2012 methodology, which uses three strata based on the enrollee’s risk score. Cigna HealthSpring stated that OIG’s monthly-weighted-health risk score placed enrollees in different strata than they otherwise would have been placed in if the enrollee’s risk score was used. Cigna HealthSpring stated that this methodology “increases the risk that extrapolation involves apples-to-oranges comparisons of sick and healthy beneficiaries.”<sup>37</sup>
- Cigna HealthSpring also stated that by creating “three unequal strata of 50, 50, and 100 members [for our stratified random sample],” we did not follow CMS’s February 2012 methodology for strata size, which “calls for the creation of three equal strata of 67 members.”
- Cigna HealthSpring stated that CMS’s February 2012 methodology “mandates that the net overpayment amount be set at the lower bound of a 99 percent confidence interval,” and we “set the net overpayment amount at the lower bound of a 90 percent confidence interval.”

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<sup>35</sup> 42 CFR § 422.504(a).

<sup>36</sup> Cigna HealthSpring stated that it “was aware that CMS published a proposal to change the final methodology in November 2018.” However, according to Cigna HealthSpring, “the February 2012 methodology remains binding on OIG until a new approach is finalized and takes effect.”

<sup>37</sup> Appendix C explains the monthly-weighted-health risk score and the composition of the sampling frame.

- Cigna HealthSpring stated that we did not include a payment principle known as actuarial equivalence “to account for the errors in the FFS data used to create the HCC model.” With respect to this principle, Cigna HealthSpring said that “[i]t is well known that there are significant levels of error in the FFS diagnoses used to create the [CMS payment] model and those errors have a substantial impact on the model.” Thus, according to Cigna HealthSpring, to account for these coding errors, CMS adopted the use of an “FFS adjuster” to function as “an offset” in RADV audits. Cigna HealthSpring also said that the “lack of a reasonable FFS adjuster renders the use of extrapolation both legally and actuarially unsound” and that past OIG reports have “acknowledged that the actuarial equivalence requirement made it not appropriate to estimate an extrapolated audit liability in the absence of a FFS adjuster.”

For these reasons, Cigna HealthSpring stated that it believed that our first recommendation should be withdrawn.

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

We do not agree with Cigna HealthSpring that our first recommendation should be withdrawn. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.<sup>38</sup> However, for reasons unrelated to Cigna HealthSpring’s comment about our use of extrapolation, our recommendation is no longer based on a statistical estimate of overpayments. As previously stated, Cigna supplied additional information for several unvalidated and new HCCs, and some of these HCCs were then validated by our medical review contractor. We incorporated these changes into our estimate of overpayments, and the changes resulted in a revised lower limit that was less than the known overpayment amount for the sample. Therefore, we revised our recommended recovery amount to only the net overpayments for the items in our sample.

With regard to Cigna HealthSpring’s comment about our use of extrapolation, we did not establish a substantive legal standard that contradicted CMS’s RADV standards. The steps that we followed in our audit methodology complied with longstanding OIG Office of Audit Services policy and allowed us to obtain evidence that provided reasonable assurance with regard to the findings and recommendations, including our identified net overpayments in the sample.<sup>39</sup>

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<sup>38</sup> See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at \*26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at \*17 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

<sup>39</sup> OIG audit findings and recommendations do not represent final determinations by CMS. Action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures. In accordance with 42 CFR § 422.311, which addresses audits conducted by the Secretary (including those conducted by OIG), if a disallowance is taken, MA organizations have the right to appeal the determination that an overpayment occurred through the Secretary’s RADV appeals process.



In addition, in response to Cigna HealthSpring's comments about our extrapolation methodology:

- In accordance with the Inspector General Act of 1978, 5 U.S.C. App., our audits are intended to provide an independent assessment of Department of Health and Human Services (HHS) programs and operations. We conduct our audits in accordance with generally accepted government auditing standards, which require that audits be planned and performed so as to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions. Accordingly, we designed our audit to determine whether the diagnosis codes that Cigna HealthSpring submitted to CMS for use in the risk adjustment program were adequately supported in the medical records—and thus complied with Federal requirements. 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, nor did it have to. The method of stratification and strata sizes are design choices made by the audit team, and those made by OIG for this audit were statistically valid. These choices were then correctly incorporated into the computation of the estimate of net overpayments.
- Similarly, our estimation methodology does not need to mirror CMS's estimation methodology. Our policy recommends recovery at the lower limit of a two-sided 90-percent confidence interval. We maintain that the lower limit of a two-sided 90-percent confidence interval provides a reasonably conservative estimate of the total amount overpaid to Cigna HealthSpring for the enrollees and time period covered in our sampling frame and remedies any imprecision due to design choices. The two-sided 90-percent confidence interval, which HHS routinely uses for recovery calculations, results in a lower limit (the estimated overpayment amount to refund) that is designed to be less than the actual overpayment total 95 percent of the time.<sup>40</sup>
- Cigna HealthSpring commented that we did not consider actuarial equivalence in our overpayment calculations. To this point, and to Cigna HealthSpring's comment that previous OIG reports have withdrawn a recommendation that was similar to the monetary recommendation in this report, CMS has not issued any requirements that compel us to reduce our net overpayment calculations. If CMS deems it appropriate to apply an FFS adjuster, it will adjust our overpayment finding by whatever amount it determines is necessary.

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<sup>40</sup> For example, HHS has used the two-sided 90-percent confidence interval when calculating recoveries in both Administration for Child and Families and Medicaid programs. See, e.g., *New York State Department of Social Services*, DAB No. 1358 (1992); *Arizona Health Care Cost Containment System*, DAB No. 2981 (2019). In addition, HHS contractors rely on the one-sided 90-percent confidence interval, which is less conservative than the two-sided interval, for recoveries arising from Medicare FFS overpayments. See, e.g., *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 17-18 (E.D.N.Y. 2012).

## **CIGNA HEALTHSPRING DID NOT AGREE THAT ITS POLICIES AND PROCEDURES WERE NOT ALWAYS EFFECTIVE AND THAT ERRORS WERE ATTRIBUTABLE TO ITS POLICIES AND PROCEDURES**

### **Cigna HealthSpring Comments**

Cigna HealthSpring stated that given the results of this audit there is no “reasonable basis for OIG to ask us to revise our policies and procedures” and stated that our second recommendation to review those policies and procedures and identify areas of improvement should be withdrawn. Specifically, Cigna HealthSpring stated that based on the audit results, its contract “outperformed its peers, the MA program at large and even CMS’ own auditors.” In addition, Cigna HealthSpring 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. Lastly, Cigna HealthSpring stated that CMS has not asked it to change its policies and procedures and has not identified any areas that could be improved.

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

We do not agree with Cigna HealthSpring that our second recommendation should be withdrawn.

Federal regulations at 42 CFR section 422.503(b) require MA organizations like Cigna HealthSpring to establish and implement an effective system for routine monitoring and identification of compliance risks. This regulation further explains that a compliance system should consider both internal monitoring and external audits. We concluded that Cigna HealthSpring could make improvements. As previously discussed, the percentage of HCCs for the sampled enrollees in error (4.7 percent according to our revised findings (footnote 21)) and the number of sampled enrollees with at least 1 incorrect HCC included in their risk scores (43 of 200 or 21.5 percent) demonstrate that Cigna HealthSpring’s compliance program could be improved. Thus, Cigna HealthSpring should consider the results of this audit to reduce the occurrence of similar HCC errors in subsequent periods and to identify appropriate improvement opportunities consistent with CMS requirements and expectations.

With respect to Cigna HealthSpring’s statements about its policies and procedures and our audit findings, we changed our description of Cigna HealthSpring’s policies and procedures for preventing, detecting, and correcting noncompliance with CMS’s program requirements from “not always effective” to “could be improved.” Further, we have revised our second recommendation for Cigna HealthSpring to “improve its policies and procedures to prevent, detect, and correct noncompliance with Federal requirements for diagnosis codes that are used to calculate risk-adjusted payments.”

## **APPENDIX A: AUDIT SCOPE AND METHODOLOGY**

### **SCOPE**

CMS paid Cigna HealthSpring approximately \$845 million to provide coverage to approximately 57,000 enrollees, most of whom resided in counties in South Florida for the 2015 payment year. We identified a sampling frame of 36,387 enrollees who had at least 1 HCC in their risk scores; Cigna HealthSpring received \$635,281,826 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 \$3,998,157 to Cigna HealthSpring.

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

We performed audit work from December 2017 to March 2022.

### **METHODOLOGY**

To accomplish our objective, we performed the following steps:

- We reviewed applicable Federal laws, regulations, and guidance.
- We discussed with CMS program officials the Federal requirements that MA organizations should follow when submitting diagnosis codes to CMS.
- We interviewed Cigna HealthSpring officials to gain an understanding of: (1) the policies and procedures that Cigna HealthSpring followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Cigna HealthSpring's monitoring of those submissions to prevent, detect, and correct noncompliance with Federal requirements.
- We reviewed Cigna HealthSpring's policies and procedures to understand how Cigna HealthSpring submitted diagnosis codes to CMS.
- We developed our sampling frame using data from CMS systems. Our sampling frame consisted of enrollees who had at least one HCC in their risk scores. To create this frame, and as explained further in Appendix C, we used data from the 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 C).
- We obtained 792 medical records from Cigna HealthSpring as support for the 1,470 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 1,470 HCCs.
- The independent medical review contractor's coding review of the 792 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 Medicare payment, before applying the budget sequestration reduction, that CMS should have made for each enrollee.

We provided the results of our audit to Cigna HealthSpring officials on October 16, 2020, and provided updated results on March 2, 2022.

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

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

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

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

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

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

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

- (1) Articulate the organization's commitment to comply with all applicable Federal and State standards;
- (2) Describe compliance expectations as embodied in the standards of conduct;
- (3) Implement the operation of the compliance program;
- (4) Provide guidance to employees and others on dealing with potential compliance issues;
- (5) Identify how to communicate compliance issues to appropriate compliance personnel;
- (6) Describe how potential compliance issues are investigated and resolved by the organization; and
- (7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials . . . .

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

entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

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

- (1) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.
- (2) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.
- (3) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

## APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

### SAMPLING FRAME

Our sampling frame included only Cigna HealthSpring enrollees who: (1) were continuously enrolled under contract number H5410 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 Cigna HealthSpring 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 36,388. We presented this data to Cigna HealthSpring for verification, and Cigna HealthSpring removed one enrollee who did not meet the criteria of our sampling frame.<sup>41</sup> Our finalized sampling frame thus consisted of 36,387 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:

$$\frac{[\text{health-related portion of the enrollee's risk score}]}{[\text{number of monthly 2015 capitation payments affected by the enrollee's risk score}]}^{42}$$

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 36,387

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<sup>41</sup> This enrollee was retroactively disenrolled from contract number H5410.

<sup>42</sup> We excluded from this calculation months in 2015 for which beneficiaries were classified as having hospice or ESRD status.



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 below.

**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	12,355	0.09 – 7.02	\$131,302,593
2	50	12,028	7.028 – 14.305	190,297,284
3	100	12,004	14.311 – 144.408	313,681,949
<b>Total</b>	<b>200</b>	<b>36,387</b>		<b>\$635,281,826</b>

#### **SOURCE OF THE RANDOM NUMBERS**

We generated the random numbers using the OIG, 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 frame items for review.

#### **ESTIMATION METHODOLOGY**

For our draft report, we used the OAS statistical software to estimate the total amount of net overpayments to Cigna HealthSpring at the lower limit of a two-sided 90-percent confidence interval. However, after considering Cigna HealthSpring's comments and the budget sequestration reduction, we revised our recommended recovery amount to only the net overpayments (\$39,612) for the items in our sample.

## APPENDIX D: CIGNA HEALTHSPRING COMMENTS

Thomas A.  
Young Managing  
Director  
Medicare Compliance Officer  
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530 Great Circle Road  
Nashville, Tennessee 37228  
Email: Thomas.Young@healthspring.com



**July 30, 2021**

U.S. Department of Health & Human Services  
Office of Inspector General  
Office of Audit Services  
Attn: Naima King  
Senior Auditor  
Public Ledge Building, Suite 316  
150 South Independence Mall West  
Philadelphia, PA 19106-3499

**Re: Response to Draft Report A-03-18-00002**

Dear Ms. King:

Cigna HealthSpring of Florida, Inc. (Cigna) appreciates the opportunity to respond to the Draft Report provided by the U.S. Department of Health and Human Services Office of Inspector General (OIG) in connection with the risk adjustment data validation (RADV) audit of Medicare Advantage (MA) contract H5410.<sup>1</sup> Through contract H4510, Cigna provides healthcare and prescription drug benefits senior citizens and other qualified beneficiaries in North and South Florida. Our Florida plan is one of the highest performing MA contracts in the MA program and is routinely given the highest possible quality rating (5 out of 5 stars) by the Centers for Medicare & Medicaid Services (CMS).

We are a committed partner to OIG, CMS, and the MA program. We believe that the MA program serves Medicare beneficiaries so well because of the partnership between CMS and MA plans, like Cigna. In the spirit of that partnership, we previously shared concerns with you regarding a number of aspects of this audit. We also have shared details regarding our risk adjustment policies, procedures, and practices with CMS a number of times over the course of many years. CMS has not instructed us that we are required to make any changes to our risk adjustment systems.

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<sup>1</sup> OIG, *DRAFT – Medicare Advantage Compliance Audit of Diagnosis Codes that Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS, A-03-18-00002* (Feb. 2021) (“Draft Report”).

November 2, 2009

Page 2

We are quite proud of our performance in this audit, which reflects payment accuracy of at least 97 percent—a truly stellar achievement. We also were gratified to see the Draft Report conclude that our policies and procedures are “generally effective.”

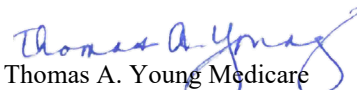
As discussed in the attached response, however, we have several concerns regarding the Draft Report and the two recommendations presented. The report and recommendations do not account for the realities of MA risk adjustment, including the facts that (i) coding is not a precise science in many instances; (ii) the passage of time makes it more challenging to locate and produce medical records; and (iii) a missing or incomplete record does not necessarily mean the beneficiary did not have the health status in question. We also are concerned that the medical record review results are not reliable. The medical record review contractor made a significant number of errors when purporting to identify overpayments. The audit also was not designed to identify underpayments and in fact missed a significant number of underpayments. Finally, we are concerned that the extrapolation methodology described in the Draft Report is inconsistent with statutory requirements, CMS policy, and generally accepted actuarial and statistical practices.

For these reasons, we respectfully disagree with the recommendations in the Draft Report. We do not believe that the “net overpayment” amount described is accurate, fair, or reasonable. In addition, given our performance in the audit, we do not believe there is a basis for OIG to recommend changes to our policies and procedures. We, therefore, urge OIG to revise the Draft Report by withdrawing both of its proposed recommendations.

We stand ready to work collaboratively with OIG, CMS, and other stakeholders to address the attached response together in an open, cooperative, and transparent way. We would appreciate the opportunity to meet prior to the finalization of the audit report to discuss our feedback and how it might be incorporated into a final report.

Thank you for your consideration.

Sincerely



Thomas A. Young Medicare

Compliance Officer

Cigna

Attachment

## Response to Draft Report A-03-18-00002 – Executive Summary

### EXECUTIVE SUMMARY

Cigna HealthSpring of Florida, Inc. (Cigna) appreciates the opportunity to respond to the Draft Report provided by the U.S. Department of Health and Human Services Office of Inspector General (OIG) in connection with the risk adjustment data validation (RADV) audit of Medicare Advantage (MA) contract H5410.<sup>1</sup> Through contract H5410, Cigna provides healthcare and prescription drug benefits to senior citizens and other qualified beneficiaries in North and South Florida. Our Florida plan is one of the highest performing MA contracts in the MA program and is routinely given the highest possible quality rating (5 out of 5 stars) by the Centers for Medicare & Medicaid Services (CMS). We are a committed partner to OIG, CMS, and the MA program. We believe that the Medicare Advantage program serves Medicare beneficiaries well because of the partnership between CMS and plans, like Cigna.

We are proud of our performance in this audit. As reflected in the Draft Report, OIG and its medical record review contractor (“Contractor”) validated 1,379 of the 1,470 hierarchical condition categories (HCCs) in the audit sample; partially validated another nine HCCs based on related health statuses; validated an additional HCC that Cigna identified; and validated two additional HCCs identified by the contractor. Overall, the Draft Report indicates payment accuracy of 97 percent. We believe these results show that we have effective policies and procedures in place and have taken reasonable steps to ensure reasonable accuracy in our data.

Although these are stellar results, we believe that the Draft Report understates our true performance. As discussed below, we believe that sixty of the ninety-one HCCs that the Contractor did not validate should have been validated under the applicable statutes, regulations, and CMS guidance. In addition, we do not believe that the audit methodology adequately addressed potential underpayments, which may arise due to the conservative nature of many of our policies, procedures, and practices. Our review indicates that there are approximately sixty-five new HCCs that should be considered in the audit because they accurately reflect the individual member’s “health status,” which is the standard articulated in the statute. With those corrections, we believe the audit sample reflects a significant net *underpayment*.

Even if the audit sample results are not corrected, this audit confirms our commitment to taking reasonable compliance efforts. OIG correctly observed that Cigna “ha[s] a compliance program to ensure that [it] submitted accurate diagnosis codes for use in CMS’ risk adjustment program” and that our “policies and procedures [are] generally effective.”<sup>2</sup> OIG highlighted the training we make available to healthcare providers regarding CMS’ guidance on coding and documentation. OIG also identified our retrospective chart review program, including the inter-rater reliability (IRR) requirements that we apply to the coders who conduct our chart reviews. We agree that these are all important aspects of our compliance efforts, which generally seek to reasonably assess the completeness and accuracy of the risk adjustment data that we receive from healthcare providers.

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<sup>1</sup> OIG, *DRAFT – Medicare Advantage Compliance Audit of Diagnosis Codes that Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS*, A-03-18-00002 (Feb. 2021) (“Draft Report”).

<sup>2</sup> Draft Report at 11.

## Response to Draft Report A-03-18-00002 – Executive Summary

We note, however, that our risk adjustment activities are broader and more comprehensive than indicated in the Draft Report, and we urge OIG to revise the report to accurately reflect that breadth and depth in the final version. We have implemented multiple controls to validate the claims and encounter data that we receive from healthcare providers, including filters that flag certain diagnosis codes for follow-up and verification prior to submission to CMS. Overall, we are confident that our policies and procedures constitute the “good faith efforts”<sup>3</sup> and “reasonable diligence”<sup>4</sup> that CMS seeks from MA plans.

Importantly, we believe that a fair evaluation of risk adjustment payments can occur only when the statutory standard directed by Congress is applied. Congress mandated that CMS make risk adjustment payments to account for the actuarial risk associated with each enrollee’s individual “health status.”<sup>5</sup> Congress also mandated that these payments ensure “actuarial equivalence” with the traditional, fee-for-service (FFS) Medicare program.<sup>6</sup> As CMS has recognized, these statutory requirements were intended to ensure that MA plans “are paid appropriately for their plan enrollees (that is, less for healthier enrollees and more for less healthy enrollees).”<sup>7</sup> Appropriate risk adjustment payments are critical to the viability and success of the MA program. Beneficiaries enrolled in Medicare Advantage plans typically receive more benefits at lower cost than those enrolled in traditional Medicare. Given the statutory medical loss ratio requirement and CMS’ margin tests,<sup>8</sup> MA plans must (and do) use risk adjustment payments to fund those supplemental benefits and to reduce cost share requirements. Reductions in risk adjustment payments could force plans to reduce benefits or increase cost share requirements, which would not be in the interest of either beneficiaries or the program.

With these observations in mind, we think that OIG should make several changes to the Draft Report.

[1] We do not agree that the few errors identified by the medical record review contractor “occurred because” our “policies and procedures were not always effective.”<sup>9</sup> The preliminary observation appears to assume that any coding or documentation discrepancy is inconsistent with an effective compliance program. An MA plan’s policies and procedures need not achieve perfection to be effective. CMS has made clear that perfect risk adjustment data are not expected and not required.<sup>10</sup> OIG, for its part, also has recognized previously that an effective compliance program cannot guarantee perfect risk adjustment data.<sup>11</sup> OIG also has recognized, in

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<sup>3</sup> 65 Fed. Reg. 40170, 40268 (June 29, 2000).

<sup>4</sup> 79 Fed. Reg. 29843, 29923 (May 23, 2014).

<sup>5</sup> 42 U.S.C. § 1395w-23(a)(1)(C)(i).

<sup>6</sup> *Id.*

<sup>7</sup> 70 Fed. Reg. 4588, 4657 (Jan. 28, 2005).

<sup>8</sup> 42 U.S.C. § 1395w-27(e)(4); 42 C.F.R. § 422.2410(b).

<sup>9</sup> Draft Report at 6, 11.

<sup>10</sup> See, e.g., 65 Fed. Reg. 40170, 40268 (June 29, 2000); 75 Fed. Reg. 19678, 19746, 19749 (April 15, 2010); 79 Fed. Reg. 29843, 29923, 29925 (May 23, 2014); see also CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* (Feb. 24, 2012) (“Final RADV Methodology”).

<sup>11</sup> See 64 Fed. Reg. 61893, 61895, 61900 (Nov. 15, 1999).

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both the MA program and in other contexts, that an effective compliance program does not eliminate all issues.<sup>12</sup> A perfection standard also would be inconsistent with the actuarial equivalence standard mandated by Congress, given the widespread recognition of the elevated coding and documentation error rates present in traditional Medicare.

Moreover, a number of practical considerations underscore why perfect risk adjustment data are not possible. Healthcare providers generate most of that data as part of their medical practices. The practice of medicine can be subjective, and CMS does not impose clinical criteria on providers participating in Medicare.<sup>13</sup> Rather, providers exercise their own judgement as to what criteria to apply. This necessarily means that there will be differences of opinion regarding how to diagnosis and document health conditions.

Coding also is inherently subjective. Coders must use their own judgment when reviewing medical records in order to decide what diagnosis codes to record and submit. The RADV standards compound that subjectivity. Those standards are found in a mix of CMS guidance and private, third-party publications, and they are often ambiguous and subject to multiple reasonable interpretations. As a result, providers and the medical record reviewers conducting an audit may (and frequently do) reasonably disagree about appropriate practices. We note that the results of this audit indicate that the Contractor's own reviewers disagreed in many cases.

In addition, the RADV standards can themselves be the source of potential errors. For instance, OIG and CMS have acknowledged that the ICD-CM code set previously contained erroneous guidance regarding malnutrition, which caused sophisticated providers around the country to inadvertently use the wrong code.<sup>14</sup> We believe that this audit revealed a similar error in the way that CMS mapped the ICD codes for sepsis to the corresponding HCC—we believe that CMS failed to update version 12 of its model to account for the 2003 changes to the ICD-CM code set, which likely caused underpayments throughout the industry.

Finally, RADV audits typically occur many years after the encounters that generated the relevant data. Conducting an audit so far in arrears significantly increases the difficulty of obtaining the relevant medical records, which leads to incorrect conclusions that diagnoses were not documented. For these and other reasons, we had understood that OIG would not attempt to impose a perfection standard in this audit. We are disappointed that OIG changed its scoring methodology midway through the audit.

**[2]** We are concerned that this audit was not adequately designed to identify underpayments, which affected the results in the Draft Report. As discussed below, our review of the medical records and other relevant information for the members in the audit sample revealed

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<sup>12</sup> See *id.*; see also, e.g., 68 Fed. Reg. 23731, 23732 (May 5, 2003) (“The OIG recognizes that the implementation of a compliance program may not entirely eliminate improper conduct from the operations of a pharmaceutical manufacturer.”); 70 Fed. Reg. 4858, 4859 (Jan. 31, 2005) (“The OIG recognizes that implementation of a compliance program may not entirely eliminate improper or unethical conduct from the operations of health care providers.”).

<sup>13</sup> See, e.g., 75 Fed. Reg. 73169, 73401 (Nov. 29, 2010) (“We believe that physicians can use their best clinical judgment in the detection and diagnosis of cognitive impairments ....”); 76 Fed. Reg. 73025, 73308 (Nov. 28, 2011) (similar quote).

<sup>14</sup> OIG, *CMS Did Not Adequately Address Discrepancies in the Coding Classification for Kwashiorkor*, A-03-14- 00010 (Nov. 2017)

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another approximately sixty-five new HCCs that should be included as underpayments that reduce the net overpayment amount for the audit sample. We ask that OIG reopen the audit to ensure that it meaningfully captures potential underpayments.

[3] In the few cases where OIG did identify an underpayment, the Draft Report asserts that Cigna “should have submitted but did not submit” the HCCs. We agree with OIG that unreported diagnoses identified during an audit (underpayments) must offset any discrepancy findings. The statute requires that Cigna be paid based on the health status of its enrolled members, and failing to credit Cigna for these underpayments would be inconsistent with the statutory mandate. We do not agree, however, with the implication that an underpayment represents a compliance issue or any sort of failure on Cigna’s part.

Underpayments occur when a healthcare provider documents a health status in the medical record, but does not include the corresponding code when submitting a claim or encounter data. MA plans do not have a way of knowing when a provider has omitted a diagnosis unless they collect the provider’s records and conduct retrospective chart reviews. As the Draft Report recognized, Cigna does conduct retrospective chart reviews in an effort to identify additional health statuses, and we appreciate the OIG’s recognition of our retrospective chart review program as a valid way to try to identify and add unreported diagnoses. CMS specifically authorized them through its 2014 rulemaking.<sup>15</sup> Neither CMS nor Congress has suggested, however, that MA plans must conduct retrospective reviews or that they are required to identify every underpayment by reviewing every chart for every encounter. To the contrary, CMS has recognized that there is no “duty to troll medical records in search of unknown vulnerabilities.”<sup>16</sup>

[4] We have a number of concerns regarding the medical record review performed by OIG and its contractor. Although we appreciate the dialogue that has occurred and look forward to additional communication, we do not believe that the agency has been sufficiently transparent regarding the standards that were applied during the medical record review. We also do not believe that the results of the medical record review are reliable. As noted above, sixty of the ninety-one alleged discrepancies should have been confirmed under the applicable statutory and regulatory requirements. More broadly, we believe that many of the coding and documentation standards applied in this audit were not established through notice and comment rulemaking and, in some cases, are not clinically appropriate.

[5] We ask that the OIG withdraw the first recommendation in the Draft Report regarding the “net overpayment” allegedly identified during the audit. We think that the asserted overpayment amount associated with the audit sample is significantly overstated. Indeed, we do not think the audit sample reflects an overpayment at all. In light of the discrepancies that were erroneously asserted by the Contractor, and the numerous underpayments that were not identified, we believe the audit sample actually reflects a significant net underpayment.

In addition, we are concerned that the audit’s sampling and extrapolation methodologies depart from CMS policy in several ways that make them less reliable. CMS policy, for instance, requires that extrapolation be based on the lower bound of a 99% confidence interval and include

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<sup>15</sup> See 79 Fed. Reg. at 29925-26.

<sup>16</sup> *Id.* at 29923.

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an actuarial adjustment to account for errors in the FFS data used to create the MA payment system. That policy is binding on OIG as a result of the 2014 rulemaking. We also note that the calculation of an extrapolated payment amount is a departure from OIG's established practice in prior contract-level audits. More fundamentally, we do not believe that extrapolation should be used in this audit, as we do not believe that the Medicare statute permits extrapolation.

[6] We also ask that the OIG withdraw the second recommendation in the Draft Report. Because OIG agrees our processes are generally effective, and does not identify any specific defect in those process, we do not see a need or way to revise them.

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We wish to reiterate our commitment to the MA program and to our partnership with both CMS and OIG. We would be happy to discuss any specific suggestions for enhancements to our risk adjustment program. More broadly, we stand ready to work collaboratively with OIG and CMS to discuss any concerns they may have about risk adjustment. Finally, we would appreciate the opportunity to meet prior to the finalization of the Draft Report to discuss our feedback and how it might be incorporated into a final report.



## Response to Draft Report A-03-18-00002

### RESPONSE TO DRAFT REPORT A-03-18-00002

#### **I. OIG SHOULD REVISE THE DRAFT REPORT TO RECOGNIZE THAT PERFECT RISK ADJUSTMENT DATA IS NOT REQUIRED OR OBTAINABLE.**

According to the Draft Report, OIG and its medical record review contractor fully validated 1,379 of the 1,470 hierarchical condition categories (HCCs) in the audit sample. The 91 HCCs that were not validated were partially offset by ten related HCCs and three new HCCs. The Draft Report indicates an HCC accuracy rate of more than 94 percent.

On a payment basis, the Draft Report is even more favorable. The Draft Report notes that Cigna originally received \$4,079,752 in risk adjustment payments in 2015 for the 200 members in the audit sample. The Draft Report further indicates the net overpayment amount for the audit sample was only \$120,971, which indicates that the risk adjustment payments that Cigna received from CMS were 97 percent accurate, even before the adjustments that we suggest below.

As positive as these results are, we believe that the Draft Report actually understates our performance. As discussed below, we believe that sixty of the HCCs that OIG and its contractor did not validate should have been validated under the applicable statutes, regulations, and CMS guidance. Similarly, our review indicates that OIG and its contractor did not capture approximately sixty-five new HCCs that accurately reflect the health status of the members in the audit sample. When those adjustments to the preliminary observations are made, the audit sample should reflect a significant net underpayment.

These audit results are exemplary, and they show that our Florida contract is performing at a high level that compares favorably to others in the MA program. For instance, the average HCC accuracy rate for all contracts included in the 2007 audits (the only round of contract-level audits for which CMS has disclosed results) was about 69%. We also substantially outperformed the program-wide error rates that CMS publishes based on the annual National Sample audit.<sup>17</sup>

In addition, it is important to note that our Florida contract outperformed the government's own coders. CMS requires its medical record review contractors to conduct inter-rater reliability (IRR) reviews of the individual coders involved in RADV audits, and it expects each coder to achieve and maintain a threshold of 95% coding accuracy. However, the IRR reviews of coders involved in the CON 2007 audits (the IRR reviews from other RADV audits have not been released to our knowledge) showed that some contractors averaged 92 to 93% coding accuracy, which suggests that at least some individual coders scored significantly below that level.

Our results demonstrate our commitment to compliance and underscore that our policies and procedures are effective. The Draft Report acknowledges that we had policies and procedures in place regarding our risk adjustment activities, and it further agrees that those policies and procedures were "generally effective."

The Draft Report takes the preliminary position that the limited number of "errors" observed in the audit "occurred because" our "policies and procedures were not always

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<sup>17</sup> Table 1 below summarizes the National Sample audit results, as reflected in HHS's financial reports.

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effective.”<sup>18</sup> The Draft Report does not identify, however, any shortcomings in our policies or procedures or enhancements that OIG deems necessary. The Draft Report also does not explain how our policies or procedures could have caused the discrepancies allegedly observed in the audit. Instead, it appears that the Draft Report reflects an incorrect assumption that MA plans are required to achieve perfection in their risk adjustment data and that any allegedly unsupported HCC indicates a policy or procedure failure. In short, the Draft Report is positing a perfection standard that is neither required nor obtainable.

### **A. CMS Does Not Impose A Perfection Standard.**

In our view, the perfection standard posited by the Draft Report reflects a misunderstanding regarding CMS regulations. For instance, the Draft Report cites 42 C.F.R. § 422.504(l) in taking the position that MA organizations “are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS.” Importantly, however, the attestation, referred to in the Draft Report and defined by subsection 422.504(l) is limited to the plan’s “best knowledge, information and belief.” CMS included this limitation to “allow for honest mistakes and unavoidable margins of error”<sup>19</sup> and “in recognition of the fact that [MA organizations] cannot reasonably be expected to know that every piece of data is correct.”<sup>20</sup> CMS also recognized at the time that “it would be unfair and unrealistic to hold [MA organizations] to a ‘100 percent accuracy’ certification standard.”<sup>21</sup> CMS has since reiterated that there is no requirement “to verify every diagnosis submitted by every provider.”<sup>22</sup>

The Draft Report also cites 42 C.F.R. § 422.503(b)(vi), which requires organizations to adopt an “effective” compliance program. Perfection is not required in order for a compliance program to be “effective.” OIG has “recognize[d that] the implementation of an effective compliance program may not entirely eliminate fraud, abuse and waste from an organization.”<sup>23</sup> OIG also has recognized that an MA organization’s attestation “does not constitute an absolute guarantee of accuracy.”<sup>24</sup>

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<sup>18</sup> Draft Report at 6, 11.

<sup>19</sup> 65 Fed. Reg. 40170, 40250 (June 29, 2000).

<sup>20</sup> *Id.* at 40268.

<sup>21</sup> *Id.*

<sup>22</sup> 79 Fed. Reg. 29843, 29925-26 (May 23, 2014).

<sup>23</sup> 64 Fed. Reg. 61893, 61895 (Nov. 15, 1999). *See also* United States Sentencing Manual 8B2.1(a) (“The failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct.”); Application Note 2(A)(i) (“effectiveness” must be assessed based on “applicable industry practice or the standards called for by any applicable governmental regulation”). We are not aware of OIG ever having indicated that an “effective” compliance program in any context needs to or is required to achieve perfection. *Cf.* Fed. Reg. 23731, 23732 (May 5, 2003) (“The OIG recognizes that the implementation of a compliance program may not entirely eliminate improper conduct from the operations of a pharmaceutical manufacturer.”); 70 Fed. Reg. 4858, 4859 (Jan. 31, 2005) (“The OIG recognizes that implementation of a compliance program may not entirely eliminate improper or unethical conduct from the operations of health care providers.”).

<sup>24</sup> 64 Fed. Reg. at 61900. The draft report also appears to suggest that perfection is required by 42 C.F.R. § 422.310(d)(l), which states that MA organizations “must submit data that conform to CMS’ requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards.” That regulation, however, does not relate to data validation. That rule refers to the “national standards” that define the *format* used by

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A perfection standard would also be inconsistent with the Medicare Advantage statute, which requires CMS to pay MA organizations in a manner that achieves “actuarial equivalence.”<sup>25</sup> The Draft Report treats any alleged discrepancy as an erroneous overpayment, and any newly identified diagnosis as an erroneous underpayment. Whether an MA organization is paid appropriately must be determined based on whether the payment to the MA plan is “actuarially equivalent” to what CMS would expect to pay for that same beneficiary population if they were enrolled in traditional Medicare.

For its part, CMS has recognized that MA organizations code “accurately” when their diagnosis coding is comparable to the diagnosis coding in the FFS program,<sup>26</sup> which is not audited and is known to contain significant levels of error. CMS also acknowledged in 2012 that holding MA organizations to a perfection standard in RADV audits would violate actuarial principles by treating similar data differently, and it agreed to apply an FFS adjuster to account for that issue.<sup>27</sup> As discussed in detail below, the potential errors identified in this audit are well below the amount of an appropriate FFS adjuster. As a result, the statutory mandate of actuarial equivalence forecloses payment recovery for any coding issues actually present in the data for H5410, a point which we believe should be reflected in the final report.

A perfection standard also would conflict with the “same methodology” requirement in 42 U.S.C. § 1395w-23(b)(4)(D). That provision mandates that CMS calculate risk adjustment payments in the MA program using the “same methodology” as when calculating the average risk factor for the FFS program. CMS does not audit the FFS data it uses to establish the average FFS risk score using the RADV documentation standards; it, therefore, accepts that those data contain significant errors. Finally, we note that the federal courts generally decline to require perfection as a standard of measure in the Medicare program.<sup>28</sup>

### **B. Perfection in Risk Adjustment Is Not Possible.**

The perfection standard reflected in the Draft Report also is not consistent with the realities and limitations of attempting to perform a risk adjustment function. As CMS has recognized, risk adjustment data “come into [MA organizations] in great volume and from a number of sources.”<sup>29</sup> In particular, an overwhelming majority of the 2014 risk adjustment data for our Florida contract were submitted by the healthcare providers who treated our enrolled beneficiaries. Although we

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providers to submit claims in the FFS program. *See* 63 Fed. Reg. 34968, 35006 (June 26, 1998) (“The format of the data we will require will be identical to the data we require of original Medicare providers. ”); *see also id.* at 35007 (directing the use of the HCFA 1500 paper form or the electronic UB-92).

<sup>25</sup> 42 U.S.C. § 1395w-23(a)(1)(C)(i).

<sup>26</sup> CMS, *Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies*, 20 (Apr. 6, 2009).

<sup>27</sup> *See* Final RADV Methodology at 4-5.

<sup>28</sup> *See, e.g., U.S. ex rel. Janssen v. Lawrence Mem. Hosp.*, 949 F.3d 533, 543-44 (10th Cir. 2020) (citing *U.S. ex rel. Conner v. Salina Reg. H. Ctr.*, 543 F.3d 1211, 1220-21 (10th Cir. 2008)); *U.S. ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 310 (3d Cir. 2011)).

<sup>29</sup> 65 Fed Reg. at 40628.

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do make coding and documentation training available to those providers, we ultimately cannot control their submissions.

In addition, coding and documentation disagreements are inevitable and often arise from factors outside the control of any MA plan. Medical practice is an inherently subjective process and there often are substantial differences in interpretation and opinion among health care practitioners about how conditions should be diagnosed and documented. CMS generally does not require providers to use any particular diagnostic or clinical criteria and allows providers to use their best professional judgment.<sup>30</sup>

Coding also is inherently subjective. Certified coders must use their best judgment when reviewing a record to determine which diagnosis codes to abstract, and they can reasonably disagree regarding a broad array of coding issues. For instance, “[o]ne study examining coding variation found that when 11 experienced, active medical coders reviewed 471 medical records and were told they would be reevaluated, all of the coders differed in one or more data fields for more than half of the records.”<sup>31</sup> In addition, the coding standards (which have never gone through notice and comment) are often vague and ambiguous and the source of variable coding throughout the healthcare industry. OIG and CMS have acknowledged that the ICD-CM code set can contain errors that cause the wrong code to be submitted.<sup>32</sup> Similarly, we believe that this audit has revealed that CMS failed to update version 12 of the HCC for sepsis to include the new sepsis codes adopted by the ICD Cooperating Parties in 2003.<sup>33</sup> We believe this problem resulted in significant underpayments for H5410, and may have affected all MA plans.

Finally, the timing of the audit also makes perfection unachievable as a practical matter. This audit, covering 2014 dates of service, did not commence until December 2017, it continued through December 2020, and we did not receive the Draft Report until February 2021. The seven- year gap between the encounters at issue and the audit is a significant issue. Providers may have moved, left our network, retired, or passed away. Paper records may have been lost. Electronic health record (EHR) systems may have been upgraded or replaced, making older electronic records harder or impossible to access. Facilities and other practices may not cooperate with requests seeking records from that far in the past (and they face no realistic sanction for deciding they cannot or do not wish to cooperate). These and similar practical realities make it impossible for an MA plan to achieve perfection in a RADV audit.

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<sup>30</sup> See, e.g., 75 Fed. Reg. at 73401 (“We believe that physicians can use their best clinical judgment in the detection and diagnosis of cognitive impairments ....”); 76 Fed. Reg. at 73308 (similar quote).

<sup>31</sup> Kimberly O'Malley, *Measuring Diagnoses: ICD Code Accuracy*, 40 Health Serv. Res. 1620 (2005).

<sup>32</sup> For instance, in a series of prior audits, OIG identified Kwashiorkor as a condition that had been frequently miscoded. OIG, *CMS Did Not Adequately Address Discrepancies in the Coding Classification for Kwashiorkor*, A- 03-14-00010 (Nov. 2017) (“We reviewed the medical records for 2,145 inpatient claims at 25 providers and found that all but 1 claim incorrectly included the diagnosis code for Kwashiorkor ....”). OIG determined that the root cause of this problem was an ambiguity in the ICD guidelines adopted by CMS. See *id.* (“The ICD-CM coding classification contained a discrepancy between the tabular list and the alpha index on the use of diagnosis code 260. In the alpha index, four other malnutrition diagnoses corresponded to diagnosis code 260, but in the tabular list, diagnosis code 260 was only for Kwashiorkor.”).

<sup>33</sup> Specifically, CMS failed to update version 12 to include the 995.9x code range from the ICD-9-CM code set. CMS corrected the oversight when it published version 22 of the HCC model.

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We do not think it is correct to conclude that an HCC is unsupported if the relevant medical record is missing. When a provider submits a diagnosis code, that submission is evidence that the provider in fact made the relevant diagnosis. We agree that MA plans should be required to make a good faith effort to locate the relevant records. However, when the record cannot be obtained from the provider through reasonable diligence, particularly after a significant period of time has elapsed, the absence of the record is not, in our view, a sufficient basis to reject a diagnosis code submitted by a provider.<sup>34</sup> We ask that the Draft Report be revised to acknowledge that a “missing” record cannot, by itself, invalidate a provider’s diagnosis code.

### **C.      OIG Appears to Have Changed Its Position During the Audit.**

As we explained in prior correspondence, we were originally informed that our Florida contract would pass this audit if the medical record review contractor validated at least 194 of the 200 audit samples. In other words, we understood that a 97% accuracy rate would not result in any adverse audit finding or demand for repayment. Because the perfection standard reflected in the Draft Report is inconsistent with that understanding, we are concerned that, as a practical matter, the methodology was revised during the course of the audit.

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We ask that OIG amend the Draft Report to recognize that perfection in risk adjustment data is not required or attainable. In addition, we request that OIG amend the Draft Report to remove statements alleging that our policies and procedures were “not always effective,” as well as all statements alleging that “errors” were attributable to our policies and procedures.

## **II.      OIG SHOULD ACKNOWLEDGE ADDITIONAL UNDERPAYMENTS IN THE AUDIT SAMPLE.**

For a number of reasons, we are concerned that the audit methodology was not equally structured to find overpayments and underpayments. First, the audit frames were defined to exclude members with no reported HCCs in the Risk Adjustment Processing System (RAPS). The effect of this was to exclude the members for whom underpayments were most likely. Second, we were asked by OIG only to collect and submit records to validate the HCCs already in RAPS.<sup>35</sup> Third, although we identified 26 additional HCCs to be considered, only one was accepted by the medical record review contractor. Fourth, the audit methodology shared with us does not discuss how OIG and its contractor identified or evaluated potential underpayments, including the additional HCCs that we had identified.

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<sup>34</sup> Because RADV audits are not defined by statute, the Administrative Procedure Act (APA) places the burden on OIG to advance an adequate basis to overturn CMS’s risk adjustment payments. *See* 5 U.S.C. § 556(d) (“Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof.”); *see also* *OWCP v. Greenwich Collieries*, 512 U.S. 267, 276 (1994) (“the drafters of the APA used the term ‘burden of proof’ to mean the burden of persuasion”); *Steadman v. SEC*, 450 U.S. 91, 95 (1981) (APA defines “the degree of proof which must be adduced by the proponent of a rule or order to carry its burden of persuasion in an administrative proceeding”).

<sup>35</sup> Based on OIG’s instructions, our medical record submissions prior to the Draft Report consisted of far less than all available records for the 200 members in the audit sample.

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We believe these issues affected the audit results. The Draft Report preliminarily asserted potential overpayments totaling \$124,332 versus only \$3,361 in underpayments—a ratio of approximately 37:1. That ratio does not appear reasonable to us.<sup>36</sup> In our view, it indicates that OIG’s audit methodology is not sufficiently designed to identify underpayments, and, as a consequence, does not appear to generate a statistically valid “net” overpayment figure for the audit sample. This reinforces our concern that the proposed net overpayment figure cannot be an adequate basis for a valid extrapolation.

In light of these concerns, we ask that OIG comprehensively identify underpayments in the audit sample. To assist with the process, we have identified approximately sixty-five additional HCCs (i.e., underpayments) for the members in the existing audit sample. Those HCCs are identified in Exhibit B.<sup>37</sup> Please note that this exhibit contains protected health information and is not eligible for public disclosure.

### **III. OIG SHOULD REVISE THE DRAFT REPORT TO RECOGNIZE THAT UNDERPAYMENTS ARE NOT “ERRORS.”**

The Draft Report incorrectly discusses underpayments as “improper payments” in the sense that they are “errors” attributable to the policies and procedures of the MA plan.<sup>38</sup> The Draft Report thus appears to take the position that MA plans are required to identify every potential diagnosis code that could be extracted from every medical record prepared by any provider who may treat an enrolled beneficiary. When discussing “Enrollee C,” the Draft Report suggests that an additional diagnosis identified during an audit constitutes a compliance failure even if the diagnosis had no payment impact.<sup>39</sup>

We are concerned that this position, if reflected in the Final Report, would be inconsistent with the realities of risk adjustment. Underpayments are not errors or compliance problems attributable to MA plans. Underpayments do not harm the government in any way because the MA plan bears any financial loss associated with underpayments. For that reason, underpayments do not present any fraud, waste, or abuse concerns.

In addition, underpayments are not factually attributable to MA plans. Underpayments typically occur when a healthcare provider documents a diagnosis in the medical record, but omits the corresponding code from the claim or encounter data. Such omissions may occur by accident or as a result of data limitations. Regardless, the only way for an MA organization to know that a provider has omitted a code is to collect medical records and conduct retrospective chart reviews. As the Draft Report acknowledges, Cigna does have a retrospective chart review program. Congress has acknowledged through the coding intensity adjuster that MA plans conduct retrospective chart reviews for the purpose of adding unreported diagnoses.<sup>40</sup> CMS has also

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<sup>36</sup> For instance, the ratio of overpayments to underpayments in the National Sample audits has historically been approximately 2.5:1. *See* Table 1, *infra*.

<sup>37</sup> The additional diagnoses identified in this Exhibit are supported by attached medical records and/or RAPS data.

<sup>38</sup> *See, e.g.*, Draft Report at 4, 10.

<sup>39</sup> Draft Report at 10.

<sup>40</sup> 42 U.S.C. 1395w-23(a)(1)

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acknowledged, and specifically authorized, so-called one-way chart reviews.<sup>41</sup> Indeed, given that the coding intensity reduces risk adjustment payments by 5.9% without regard to an MA plan's risk adjustment activities, Cigna would be systematically underpaid if it did not engage in retrospective chart review. We therefore agree that retrospective chart review plays an important function by promoting more complete coding.

Nevertheless, chart review programs are not mandatory, and they cannot prevent all underpayments. Neither Congress nor CMS has required MA organizations to conduct chart reviews or suggested that MA organizations are required to identify every possible diagnosis. To the contrary, CMS indicated in 2014 that there is no "duty to troll medical records in search of unknown vulnerabilities."<sup>42</sup> From a practical perspective, retrospective chart review programs are necessarily limited to only some encounters for only some beneficiaries. It is not possible for an MA organization to collect and review every chart for every encounter.

Finally, we note that the classification of underpayments as "improper payments" stems from the Payment Integrity Information Act and prior related statutes. Those laws define the term "improper payment" to include both overpayments and underpayments in order to ensure Congressional oversight of CMS and other agencies responsible for federal programs. Those statutes, however, do not define (and are not intended to define) the compliance obligations of regulated entities. Nothing in those laws can be interpreted to classify CMS' underpayments as evidence of a compliance failure by MA plans.<sup>43</sup>

For these reasons, we ask that OIG amend the Draft Report to (1) recognize that underpayments do not present fraud, waste, or abuse concerns, and (2) remove the language referring to underpayments as "improper" or "errors."

#### **IV. OIG SHOULD REVISE THE DRAFT REPORT TO ADDRESS SEVERAL CONCERNS REGARDING THE MEDICAL RECORD REVIEW.**

##### **A. OIG Should Provide Additional Information Regarding the Medical Record Review.**

We ask OIG to provide additional information regarding the review. For example, OIG has not identified the "independent medical record review contractor." Given the importance of this audit, we believe that we should know who is performing the review so that we can evaluate whether there is a conflict of interest, assess the contractor's credentials, coding policies.

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<sup>41</sup> See 79 Fed. Reg. at 29925-26.

<sup>42</sup> 79 Fed. Reg. at 29923.

<sup>43</sup> We also have concerns about how the draft report presents improper payment data. The draft report presents a total improper payment figure as the sum of underpayments and overpayments, which is one of the ways in which Congress assesses the payment accuracy of federal agencies. That figure, however, does not meaningfully measure the potential fraud, waste, or abuse in a federal program. That evaluation requires consideration of *net* overpayments (i.e., overpayments minus underpayments). As shown in Table 1 below, the MA program has relatively low levels of net overpayments. The draft report does not also include any improper payment information for the traditional Medicare program. As shown in Tables 2 and 3, the MA program significantly outperforms traditional Medicare on a net overpayment basis. We believe this is important context that should be included in the final report.

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procedures, and training, and see if the positions taken are consistent with prior work undertaken by the contractor, or statements made by it.

We also received only the “final” determination by the medical record review contractor. The Draft Report indicates, however, that there were two or three levels of review of each finding. We believe it is important for us to be able to evaluate the results at each level, as the subjective nature of coding determinations would be revealed by differing conclusions among contractor personnel. Similarly, it would be important to know whether the individuals conducting each level of review were subject to IRR (which we believe to be a standard practice in CMS audits) and to evaluate the results of such reviews. We believe that these issues affect our appeal rights under 42 C.F.R. § 422.311 and should be disclosed pursuant to the Data Quality Act and generally accepted audit practices.

The need for more information is highlighted by the inconsistencies in the determinations made by the Contractor that we can observe from the information provided. For instance, OIG’s contractor accepted language in a medical record as sufficient to validate an HCC for some beneficiaries, but found the same language insufficient to validate the same HCC for others.<sup>44</sup> OIG’s contractor also validated diagnoses under one HCC model but rejected the same diagnoses under the other HCC model for the same beneficiary, even though there was no relevant change in the models.<sup>45</sup> These internal inconsistencies affect the reliability of the audit and show that the government’s own auditors have not met a perfection standard.

### **B. OIG Should Revise the Medical Record Review Results and Net Overpayment Amount for the Audit Sample.**

We also note that the medical record review was not limited to coding and documentation issues; instead, it incorporated a review of the clinical validity of the provider’s diagnosis. CMS has stated that plans are only responsible for the accuracy of the coding of the diagnosis as provided by a practitioner.<sup>46</sup> The ICD Guidelines and American Hospital Association (AHA) Coding Clinic similarly state that coders do not have the ability or authority to question a provider’s diagnostic

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<sup>44</sup> For example, compare the medical records and determinations associated with homocysteinemia for Sample/Strata 3-166 on the one hand and Sample/Strata 3-182 and 3-200 on the other. Even though we see no material difference between the relevant medical records, the Contractor confirmed homocysteinemia for the latter two members, but invalidated homocysteinemia for 3-166.

<sup>45</sup> For example, see the contractor’s treatment of vascular disease for Sample/Strata 2-061.

<sup>46</sup> 65 Fed. Reg. 40170, 40251 (June 29, 2000) (“we have restricted the attestation requirement to confirmation of the completeness of the data and the accuracy of coding.”) CMS also has refused on a number of occasions to specific clinical criteria for particular diagnoses. *See supra* n.30.



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statement, as documented.<sup>47</sup> For that reason, CMS has not permitted the certified coders conducting its medical record reviews to attempt to assess the clinical validity of diagnoses.<sup>48</sup>

Unfortunately, we believe that OIG's contractor went beyond assessing coding and questioned the clinical validity of providers' diagnostic statements. For instance, the audit methodology indicates that a physician served as the tie-breaker when the first and second level coders disagreed. We are concerned that the physician did not limit his or her analysis to issues of coding and documentation.<sup>49</sup> In addition, the Draft Report's discussion of Enrollee A appears to reflect a clinical judgment. A trained urologist treating Enrollee A submitted ICD codes for that patient corresponding to malignant neoplasm of the bladder. The medical record submitted to support that diagnosis included the statement "Cancer of the Bladder" and a treatment plan. Nevertheless, OIG's contractor concluded that bladder cancer should be considered merely part of the member's "personal history."<sup>50</sup> We believe this conclusion necessarily involves a rejection of the provider's diagnostic statement, as documented.<sup>51</sup>

More broadly, we believe that sixty of the 91 HCCs that OIG's contractor did not validate should have been validated under the applicable statutory and regulatory standards. Discussions of those HCCs are attached as Exhibit A. Please note that these exhibits contain protected health information and are not eligible for public disclosure. Cigna reserves the right to supplement these HCC-specific appeals should additional information become available.

When the medical record review contractor's mistaken discrepancy findings are revisited, and the additional HCCs (underpayments) discussed above are included, the audit sample reflects a significant net underpayment.

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<sup>47</sup> *ICD-10-CM Official Guidelines for Coding and Reporting*, 13 (2019) ("[A]ssignment 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."); AHA Coding Clinic, *Ask the Editor* (2016) ("Coders should not be disregarding physician documentation and deciding on their own, based on clinical criteria, abnormal test results, etc., whether or not a condition should be coded.").

<sup>48</sup> CMS, *Statement of Work for the Recovery Audit Program*, 23 (2011) ("[C]ertified coders shall ensure they are not looking beyond what is documented by the physician. ... Clinical validation is beyond the scope of [a coding] validation, and the skills of certified coder.").

<sup>49</sup> Because the information has not been provided to date, we do not know how many HCCs were subject to physician review during this audit. However, a recent report regarding another MA organization indicated that the physician reviewed the medical records related to approximately 10% of the audit sample. See OIG, *Medicare Advantage Compliance Audit of Diagnosis Codes that Human, Inc. (Contract H1036) Submitted to CMS*, A-07-16-01165, 15 n.14 (Apr. 2021).

<sup>50</sup> Draft Report at 7-8.

<sup>51</sup> We view this as a recurring and significant issue in the audit. For example, with respect to cancer patients, for instance, we believe the medical record review contractor rejected providers' diagnoses of cancer for 11 beneficiaries, even though, in all of those cases, there was evidence in the record that the provider made the diagnosis and the patient was still undergoing observation, testing, or pharmacotherapy. As another example, we note that the discrepancy findings for Sample/Strata 3-149 and 3-194 are explicitly based on "physician review."

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### C. The Coding and Documentation Standards Applied During the Medical Record Review Were Not Adequately Identified.

The medical record review contractor did not identify the coding or documentation standards that drove its determinations. The Draft Report indicates that the audit followed the coding and documentation standards described in Chapter 7 of the Managed Care Manual.<sup>52</sup> We also were informed that the medical record review contractor was following the September 2017 version of CMS' RADV guidance. According to those sources, the requirements for a valid diagnosis code are:

- The diagnosis should be made by an acceptable provider type;
- Prior to 2020, the diagnosis should stem from a face-to-face encounter;
- The encounter should have occurred within the specific date of service year;
- The diagnosis should be documented in a medical record that includes the provider's signature and credentials; and
- The diagnosis should be coded according to the ICD-9-CM Official Guidelines and guidance from the AHA.<sup>53</sup>

CMS also has stated that providers and plans should rely on guidance from the American Health Information Management Association (AHIMA), the American Medical Association (AMA), and the American Academy of Professional Coders (AAPC), as well as the *Fundamentals of Clinical Practice* and the *Bates Guide to Physical Examination and History Taking*.<sup>54</sup>

Given the volume and breadth of these references and the fact that they are not consistent in many respects, we believe that OIG's contractor should identify the specific policies that were used to invalidate relevant diagnoses. Sample-Strata 3-122 provides an example that illustrates our concern. In that case, the medical record review contractor did not accept a provider's diagnosis of breast cancer, even though the patient was receiving adjuvant therapy. The contractor stated that it was "coding policy as guided by CMS." We do not understand what "coding policy" the contractor was referencing. General principles of administrative law require a clear statement of the reasons supporting an agency's determination.<sup>55</sup>

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<sup>52</sup> Draft Report at 6-7.

<sup>53</sup> CMS, *Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance*, 6 (Sept. 27, 2017) ("RADV Guidance"); see CMS, *Managed Care Manual, Chapter 7 – Risk Adjustment*, § 40 (Sept. 19, 2014).

<sup>54</sup> CMS, *Risk Adjustment Data Training for Medicare Advantage Organizations Participant Guide*, 6-12, 7-18 (2007).

<sup>55</sup> See, e.g., *Pearson v. Shalala*, 164 F.3d 650, 660 (D.C. Cir. 1999) ("It simply will not do for a government agency to declare—without explanation—that a proposed course of private action is not approved. ... To refuse to define the criteria it is applying is equivalent to simply saying no without explanation."); *Cactus Corner, LLC v. U.S. Dep't of Agric.*, 346 F. Supp. 2d 1075, 1110 (E.D. Cal. 2004) (an agency must provide an "explanation as to what criteria was considered in reaching [its] conclusion") (citation omitted). Regulations from the Department of Health and Human Services (HHS) also state that any guidance not posted to the Department's guidance portal by January 6, 2021 was rescinded as a matter of law. 45 C.F.R. § 1.4(a)(3). Because the medical record review contractor failed to identify the

**D. The Coding and Documentation Standards Applied During the Medical Record Review Were Not Validly Established.**

The Medicare statute provides that any “policy” that “establishes or changes a substantive legal standard governing ... payment” must be established through notice and comment rulemaking.<sup>56</sup> The Supreme Court has explained that this obligation is broad and is likely to invalidate many policies found only in the Medicare manuals.<sup>57</sup> The HHS Office of General Counsel has further advised that, when a Medicare manual “set[s] forth payment rules that are not closely tied to statutory or regulatory standards, the government generally cannot use violations of that guidance in enforcement actions, because ... it was not validly issued.”<sup>58</sup> Most recently, HHS promulgated regulations stating that a component of HHS may not “use any guidance” to compel regulated entities “to take any action, or refrain from taking any action, beyond what is required by the terms of an applicable statute or regulation.”<sup>59</sup>

As applied to this audit, the coding and documentation standards are offered as the difference between valid risk adjustment payments and alleged overpayments. The audit uses sub-regulatory standards to define the scope of Cigna’s entitlement to retain risk adjustment payments from CMS. CMS indicated in a recent proposed rule that the RADV coding and documentation guidance define “the payment standard” for MA risk adjustment payments.<sup>60</sup> To be valid, that standard must be established through notice and comment.

The notice and comment issue is made more significant by the fact that many aspects of the payment standard are defined by private entities. The ICD-CM coding guidelines are a core RADV requirement. Those guidelines are established jointly by CMS and two private entities (the AHA and AHIMA) through a largely closed process that does not involve notice and comment. As noted above, the RADV process also relies on publications from the AHA, AHIMA, the AAPC, and others, which do not involve public input. The Medicare statute and the APA do not allow CMS to delegate its responsibility to establish risk adjustment standards to private, non-governmental entities.<sup>61</sup>

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specific guidance on which it is purporting to rely, it is unclear whether the contractor may have relied on rescinded guidance.

<sup>56</sup> 42 U.S.C. § 1395hh(a)(2). The APA requires that all substantive rules be established through notice and comment. 5 U.S.C. § 553. However, because the notice and comment obligation imposed by the Medicare statute is broader than the equivalent APA requirement, *see generally* *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), we focus on the Medicare statute.

<sup>57</sup> *See Allina Health*, 139 S. Ct. at 1814.

<sup>58</sup> Memorandum from Kelly M. Cleary, *Impact of Allina on Medicare Payment Rules*, 2 (Oct. 31, 2019); *see also, e.g., Polansky v. Exec. Health Res., Inc.*, 422 F. Supp. 3d 916 (E.D. Pa. 2019).

<sup>59</sup> 45 C.F.R. § 1.3(a)(2). Although the regulations in 45 C.F.R., Part 1 may be reconsidered by the Department, it remains a binding regulation on all HHS components until it is withdrawn.

<sup>60</sup> *See* 83 Fed. Reg. 54928, 55041 (Nov. 1, 2018) (“If a payment has been made to an MA organization based on a diagnosis code that is not supported by medical record documentation, that entire payment is in error and should be recovered in full, because the payment standard has not been met.”).

<sup>61</sup> *See, e.g., U.S. Telecom Ass’n v. FCC*, 359 F.3d 554, 565-56 (D.C. Cir. 2004) (“subdelegations to outside parties are assumed to be improper absent an affirmative showing of congressional authorization”).

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### **E. Some of the Coding and Documentation Standards Applied During the Audit Are Inconsistent With the Statute and/or Medical Practice.**

As the Draft Report recognizes, the Medicare statute requires that risk adjustment payments be made based on the “health status” of each enrolled member.<sup>62</sup> The risk adjustment system relies on the ICD-CM diagnosis codes only as a proxy for such statuses.<sup>63</sup> Often, however, the coding and documentation standards published by CMS, the AHA, AHIMA, the AAPC, etc. turn on formalities or criteria that do not address the beneficiary’s health status. Those standards also have the effect of preventing Cigna and other plans from presenting important, credible evidence regarding their members’ health statuses.

Some examples include:

- *Definition of a “medical record”* – although the core RADV requirement is that each diagnosis must be supported by a “medical record”, various guidance documents have excluded portions of medical records from consideration, even if they are from a qualified provider type, are properly signed, and bear the requisite credentials. For instance, CMS issued a Q&A document in 2008 stating that it does not consider the “Problem List” to be “acceptable stand-alone documentation.”<sup>64</sup>
- *Limitation on physician types* – the RADV requirements included in the Managed Care Manual limits the types of physicians that may submit diagnoses. For instance, the manual excludes radiologists. We believe that exclusion is not consistent with the statutory focus on patients’ “health status” or the purpose of risk adjustment. The contractors that designed the HCC model noted that excluding diagnoses from radiologists would “lower[] predictive power” of the HCC model.<sup>65</sup> According to the contractor, the diagnoses made by radiologists and similar providers “contain information not duplicated in other hospital or physician diagnoses that is useful in predicting future expenditures.”<sup>66</sup>
- *Exclusion of other provider types* – the RADV standards also exclude diagnoses submitted on claims from home health agencies and durable medical equipment (DME) suppliers. Those exclusions are also not consistent with the statutory focus on patients’ “health status” or the purpose of risk adjustment. As CMS’ contractor observed, including home health diagnoses would “increase[] predictive power,”<sup>67</sup> while including DME diagnoses would “improve[] predictive power by a noticeable amount.”<sup>68</sup>

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<sup>62</sup> See Draft Report at 1, 2, 3, 6.

<sup>63</sup> See *id.* at 1 (“To determine the health status of enrollees, CMS relies on ... diagnosis codes ...”).

<sup>64</sup> CMS, *Risk Adjustment User Group 2007/2008 – February 2008 Questions & Answers* (Feb. 13, 2008).

<sup>65</sup> Gregory C. Pope, et al., *Diagnostic Cost Group Hierarchical Condition Category Models for Medicare Risk Adjustment – Final Report*, ES-13 (Dec. 21, 2000) (prepared for the Health Care Financing Administration pursuant to Contract No. 500-95-048) (“Final HCC Report”)

<sup>66</sup> *Id.* at 5-5.

<sup>67</sup> *Id.* at 5-6.

<sup>68</sup> *Id.* at 5-8.

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- *Signature Requirement* – according to CMS, the most common RADV discrepancy findings involve medical records that fail the agency’s strict signature and credential requirement.<sup>69</sup> For instance, our understanding is that, in the 2007 audits, a significant percentage of the HCCs found to be invalid were invalidated based on signature and credential issues. These issues are merely technical, and, in our view, impede accurate determinations of beneficiary “health status.”
- *Exclusion of prescription data* – the RADV guidance for the MA program currently precludes MA organizations from using prescription data to establish beneficiary health status, even though the relationship between some medications and health status is clear (e.g., insulin is prescribed for diabetes). This is particularly problematic, in our view, given that the RADV rules for the Affordable Care Act market do utilize prescription data for risk adjustment.<sup>70</sup>
- *Exclusion of attestations* – the RADV guidance excludes almost all attestations even when such information can directly address a patient’s health status. Provider attestations are largely limited to correcting signature issues. Providers are not allowed to correct legibility issues (and legibility is a frequent issue), to explain how to interpret acronyms or other shorthand used in the record (another frequent issue), or to otherwise clarify a record. Patients and their caregivers likewise are prohibited from providing relevant testimony.
- *Clinically inappropriate rules* – we are concerned that a number of the coding guidelines are incorrect as a clinical matter. For example, the ICD-CM coding guidelines for solid tumor cancers do not appear to have been updated since the mid-1990s. The AHA coding guidance for patients with pacemakers was clinically incorrect from 1993 until it was corrected in 2019.<sup>71</sup> Further, the ICD Guidelines appear to allow the codes for some acute conditions to be used for a period of time after the initial event or injury, while other codes for acute conditions cannot be so used.

We believe many of the above issues would have been addressed if the RADV rules for the MA program had been established through notice and comment. As the Supreme Court recently explained: “Notice and comment gives affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes—and it affords the agency a chance to avoid errors and make a more informed decision.”<sup>72</sup> The partnership between CMS and committed plans, like Cigna, works best when policy is the product of full and frank dialogue as occurs in notice and comment rulemaking.

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<sup>69</sup> See, e.g., 74 Fed. Reg. 54634, 54675 (Oct. 22, 2009)

<sup>70</sup> HHS, *Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Adult Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXC) Crosswalk* (Sept. 18, 2017).

<sup>71</sup> Compare AHA Coding Clinic 3Q 1993, with AHA Coding Clinic Q1 2019.

<sup>72</sup> *Allina Health*, 139 S. Ct. at 1816.

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### V. OIG SHOULD WITHDRAW ITS FIRST RECOMMENDATION.

The first recommendation in the Draft Report is that Cigna “refund to the Federal Government \$10,086,969 of net overpayments.”<sup>73</sup> The asserted net overpayment amount is based on an extrapolation from the \$120,971 of net overpayments allegedly observed in the audit sample (200 members) to the full audit population (36,387 members).<sup>74</sup>

We believe this recommendation is incorrect and should be withdrawn. When corrected as discussed above, the audit sample reflects a significant net underpayment. Given that the audit sample should reflect a net underpayment, there should not be any overpayment associated with this audit.

Even if the audit sample results are not corrected, extrapolation is not appropriate. We do not believe that extrapolation has been authorized by Congress in this situation. Part C of the Medicare statute does not authorize extrapolated recoveries and, in the absence of explicit Congressional authorization, we believe extrapolation is not available.<sup>75</sup> Significantly, Congress did address extrapolation in Part E of the Medicare statute. That provision states that an audit involving a contractor “may not use extrapolation ... unless the Secretary determines that—(A) there is a sustained or high level of payment error; or (B) documented educational intervention has failed to correct the payment error.”<sup>76</sup> Neither basis would apply here in this audit, given the high level of payment accuracy demonstrated and OIG’s conclusion that our policies and procedures were “generally effective.”

Even if extrapolation were permitted, the methodology used would have to adhere to the final methodology established by CMS. In 2010, CMS created regulations governing the conduct of RADV audits using the Secretary’s authority to establish MA program standards.<sup>77</sup> At the time, the regulations, by their terms, applied only to audits conducted by CMS.<sup>78</sup> Four years later, however, the regulations were amended to apply to all RADV audits conducted by any component of HHS, including OIG.<sup>79</sup> The preamble explained that the amendments were intended to clarify

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<sup>73</sup> Draft Report at 12.

<sup>74</sup> *Id.* at 19-20.

<sup>75</sup> We note that CMS previously told Congress that it lacked such authority and unsuccessfully requested a legislative change to authorize extrapolation in RADV audits. *See* Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations for 2011: Hearings Before the H.R. Comm. on Appropriations, 111th Cong. 7, 14 (2010) (written statement of William Corr, Deputy Sec’y, Dep’t of Health & Human Servs.); *see also* Ctrs. for Medicare & Medicaid Servs., Dep’t of Health & Human Servs., Fiscal Year 2011 Performance Budget 177 (2010) (describing proposal that would “[c]larify in statute that CMS can extrapolate the error rate found in the risk adjustment validation (RADV) audits to the entire MA plan payment for a given year when recouping overpayments”). We believe this reflects an acknowledgement that CMS does not have the authority. *See U.S. House of Representatives v. Burwell*, 185 F. Supp. 3d 165, 186 (D.D.C. 2016).

<sup>76</sup> 42 U.S.C. § 1395ddd(f)(3).

<sup>77</sup> *See* 74 Fed. Reg. 54634, 54674-75 (Oct. 22, 2009) (explaining that the RADV appeals process was created pursuant to section 1856(b)(1) of the Social Security Act); 75 Fed. Reg. 19678, 19742 (Apr. 15, 2010) (same).

<sup>78</sup> *See* 75 Fed. Reg. at 19804 (former 42 C.F.R. § 422.2: the term RADV audit meant “a CMS-administered payment audit”); *id.* at 19806 (former 42 C.F.R. § 422.311(a): “CMS annually conducts RADV audits ...”).

<sup>79</sup> *See* 42 C.F.R. § 422.2 (RADV audit means “a payment audit of a MA organization administered by the Secretary”); 42 C.F.R. § 422.311(a) (“the Secretary annually conducts RADV audits ...”).

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that the RADV regulations applied to RADV audits conducted by OIG pursuant to its authority under the Inspector General Act.<sup>80</sup> The preamble also addressed the statistical sampling and extrapolation methodologies to be used during such audits. It stated that audits would be conducted using the methodology published by CMS in February 2012, unless an updated methodology was published after opportunity for stakeholder comment.<sup>81</sup> To date, no update has been made to that methodology.<sup>82</sup> Even to the extent that extrapolation has been authorized by statute (which we believe is not the case) the 2014 rulemaking made the February 2012 methodology binding for all RADV audits.<sup>83</sup>

We believe that this audit departed from the February 2012 methodology in a number of ways.

- *Ranking and Stratification* – the February 2012 methodology calls for the creation of three strata within the audit population.<sup>84</sup> Strata are used to decrease heterogeneity in the audit population, increasing the representativeness of the sample that is subsequently drawn. CMS’ methodology achieves this by creating three strata based on the beneficiary’s risk score.<sup>85</sup> This ranking is designed to mitigate the risk that extrapolation might erroneously apply audit sample results for older, sicker beneficiaries to an audit frame that includes younger, healthier beneficiaries.<sup>86</sup>

OIG used a different ranking methodology, which is not permitted by regulation. It ranked the audit population by taking each member’s risk score and removing the demographic factors (including age) and then multiplying the residual score by the number of months that the member was enrolled in our contract during 2015. OIG called this the “monthly- weighted-health risk score.”<sup>87</sup> That ranking, however, increases risk of inappropriate comparisons. OIG’s approach ranks as equal a member with a health-related risk score of 1.0 who was enrolled through December 2015 and a member with a health-related risk score of 12.0 who passed away in January. OIG’s approach gives the incorrect appearance that every member who left our plan in 2015 was healthier than they actually were.

We believe that this had a significant effect on the audit. Our analysis indicates that OIG’s approach placed approximately 2,700 members in strata different from the strata in which they would have been placed using just the member’s risk score. This includes 13 members

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<sup>80</sup> See 79 Fed. Reg. 29843, 29934 (May 23, 2014).

<sup>81</sup> See *id.* at 29927-28 (discussing the Final RADV Methodology).

<sup>82</sup> We are, of course, aware that CMS published a proposal to change the final methodology in November 2018. As discussed below, however, the February 2012 methodology remains binding on OIG until a new approach is finalized and takes effect.

<sup>83</sup> We note that the decision by HHS to standardize all RADV audits is sound policy. It would be inconsistent with the APA for different components of HHS to conduct the same type of audits using different methodologies. This would raise the possibility of identically situated MA plans receiving different audit outcomes based on which HHS component conducted the audit.

<sup>84</sup> Final RADV Methodology at 2.

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> Draft Report at 18.

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in the audit sample, which significantly increases the risk that extrapolation involves apples-to-oranges comparisons of sick and healthy beneficiaries.

- *Strata size* – the February 2012 methodology calls for the creation of three equal strata of 67 members.<sup>88</sup> OIG prepared three unequal strata of 50, 50, and 100 members, with the larger strata containing the highest ranked (but for reasons just discussed, not necessarily the sickest) members.
- *Confidence interval* – the February 2012 policy mandates that the net overpayment amount be set at the lower bound of a 99 percent confidence interval.<sup>89</sup> The Draft Report, however, set the net overpayment payment amount at the lower bound of a 90 percent confidence interval.<sup>90</sup> The Draft Report describes this approach as “conservative.”<sup>91</sup> That is incorrect. The lower confidence interval is significantly less conservative; it increases the amount of, and reduces the reliability of, the net overpayment amount.<sup>92</sup> Actuarial and statistical experts have similarly stressed the ways in which extrapolation in RADV audits is unreliable.<sup>93</sup> This lack of reliability makes the use of a 99 percent confidence interval important. In any event, the use of a 99 percent confidence interval is required by regulation.
- *Actuarial adjustment* – OIG did not include an actuarial adjustment to account for the errors in the FFS data used to create the HCC model. This is perhaps the most significant departure from the February 2012 methodology. It is well known there are significant levels of error in the FFS diagnoses used to create the model and that those errors have a substantial impact on the model. For instance, CMS’ consultants wrote in their 2000 report that “the magnitude of claims diagnoses that are being incorrectly included while calculating risk scores” was likely much higher than 7 percent.<sup>94</sup> Ten years later, CMS recognized that it would have to “refine the error rate calculation” in RADV audits to account for the diagnosis coding errors that are “inherent in Medicare FFS.”<sup>95</sup> The February 2012 methodology similarly adopted the use of a “FFS adjuster” to function as “an offset” to “account[] for the fact that the documentation used in RADV audits ... is different from the documentation standard used” in the FFS program.<sup>96</sup> Around the same time, CMS

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<sup>88</sup> Final RADV Methodology at 3.

<sup>89</sup> *Id.* at 4.

<sup>90</sup> Draft Report at 20.

<sup>91</sup> *Id.* at 6 n.13.

<sup>92</sup> As explained in our prior correspondence, and holding all other things equal, using a 90 percent confidence interval incorrectly increased the extrapolated net overpayment amount by approximately \$3.4 million.

<sup>93</sup> Tim Murray et al., Wakely Consulting Group, [\*Medicare RADV: Review of CMS Sampling and Extrapolation Methodology\*](#) (July 2018).

<sup>94</sup> Final HCC Report at 5-11.

<sup>95</sup> 75 Fed. Reg. at 19746, 19749.

<sup>96</sup> Final RADV Methodology at 4-5.



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stated internally that adopting a FFS adjuster of 8.1 percent would be “the right thing to do.”<sup>97</sup>

These departures from the methodology mandated by regulation were not identified or explained in the Draft Report. We are not aware of any analysis establishing that OIG’s approach is superior to the final audit methodology that HHS adopted through the 2014 rulemaking.

We wish to emphasize that lack of a reasonable FFS Adjuster in this audit renders the use of extrapolation both legally and actuarially unsound. The MA statute requires that risk adjustment payments achieve actuarial equivalence with the FFS program.<sup>98</sup> Actuarial Standard of Practice 45, section 3.2 requires that the “type of input data that is used in the application of risk adjustment should be reasonably consistent with the type of data used to develop the model.”<sup>99</sup> In 2011, the American Academy of Actuaries wrote that the inconsistency between the unaudited data to create the HCC model and extrapolation in RADV audits “not only creates uncertainty, it also may create systematic underpayment, undermining the purpose of the risk-adjustment system and potentially resulting in payment inequities.”<sup>100</sup> More recently, every qualified statistician and actuary to publicly address the question concluded that a significant FFS adjuster was essential to meeting the statutory requirement of actuarial equivalence.<sup>101</sup>

The lack of an appropriate FFS adjuster also, in our view, violates important principles of administrative law. Because the February 2012 methodology remains in force, the failure to include an appropriate FFS adjuster would be unlawfully retroactive.<sup>102</sup> It also would mark a departure from OIG’s past audit practices. In several prior contract-level RADV audits, OIG

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<sup>97</sup> Exhibit C. In this audit, even if the draft findings are not corrected, a FFS adjuster of even three percent would be sufficient to eliminate all audit liability.

<sup>98</sup> 42 U.S.C. § 1395w-23(a)(1)(C)(i).

<sup>99</sup> CMS is required to follow actuarial standards. See 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 (Sept. 30, 2002).

<sup>100</sup> Letter from Thomas F. Wildsmith, American Academy of Actuaries, to Cheri Rice, Acting Director, Medicare Plan Payment Group, [Re: Comment on RADV Sampling and Error Calculation Methodology](#), 2 (Jan 21, 2011)

<sup>101</sup> See, e.g., Avalere Health, [Eliminating the FFS Adjuster from the RADV Methodology May Affect Plan Payment](#) (Mar. 2019); Avalere Health, [Impact of Eliminating the FFS Adjuster May Vary Based on Plan Enrollee Characteristics](#) (Aug. 21, 2019); Sean Creighton, [The FFS Adjuster matters for accurate Medicare Advantage payment: An examination of the methodology and evidence behind a regulatory proposal to eliminate the adjuster](#), RISE Health (Dec. 11, 2019); Rob Pipich, Milliman, [Medicare Advantage RADV FFS adjuster: White paper](#) (Aug. 23, 2019); Matthew G. Mercurio, [Response to CMS “Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits” Announcement](#) (Aug. 27, 2019); Bo Martin, Ankura Consulting Group, [Comment Regarding CMS’s Proposals Not to Implement a “Fee-for-Service Adjuster” For RADV Audits and To Implement a Sub-Cohort Audit Method](#) (Aug. 27, 2019); Ross Winkelman, Wakely Consulting Group, [Actuarial Report on CMS’ November 1, 2018 Proposed Rule](#) (Aug. 27, 2019); Julia Lambert, Wakely Consulting Group, [Actuarial Report on Medicare Advantage FFS Adjuster](#) (Aug 28, 2019); Stefan Boedeker, [Comment on The Centers for Medicare and Medicaid Services Proposed Rule](#) (Aug. 28, 2019).

<sup>102</sup> See e.g., *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 213-15 (1988); *Northeast Hospital Corp. v. Sebelius*, 657 F.3d 1 (D.C. Cir. 2011)

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acknowledged that the actuarial equivalence requirement made it not appropriate to estimate an extrapolated audit liability in the absence of a FFS adjuster:

Although an analysis to determine the potential impact of error rates inherent in FFS data on MA payments was beyond the scope of our audit, we acknowledge that CMS is studying this issue and its potential impact on audits of MA organizations. Therefore, because of the potential impact of these error rates on the CMS model that we used to recalculate MA payments for the beneficiaries in our sample, we (1) modified one recommendation to have [the MA plan] refund only the overpayments identified for the sampled beneficiaries rather than refund the estimated overpayments and (2) added a recommendation that [the MA plan] work with CMS to determine the correct contract-level adjustments for the estimated overpayments.<sup>103</sup>

OIG made similar statements in two prior audits involving Cigna affiliates.<sup>104</sup> The relevant circumstances have not changed since those prior audits. It follows that, under the APA, OIG cannot extrapolate liability in this audit.<sup>105</sup>

### VI. OIG SHOULD WITHDRAW ITS SECOND RECOMMENDATION.

The second recommendation in the Draft Report is that Cigna “review its existing compliance policies and procedures to identify areas where improvements can be made to ensure accurate diagnosis codes and take the necessary steps to enhance those policies and procedures.”<sup>106</sup> We ask that this recommendation also be withdrawn.

As discussed above, our Florida contract achieved exemplary results in this audit. We believe that, in terms of coding and documentation accuracy, our contract outperformed its peers, the MA program at large, and even CMS’ own auditors. Given these results, we do not see a reasonable basis for OIG to ask us to revise our policies and procedures.

We also note that OIG has not identified any specific areas of weakness in our policies and procedures. OIG has not identified specific enhancements that it thinks Cigna should make. We

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<sup>103</sup> OIG, *Risk Adjustment Data Validation of Payments Made to PacifiCare of California for Calendar Year 2007* (Contract Number H0543), A-09-09-00045, ii-iii (Nov. 2012); accord OIG, *Risk Adjustment Data Validation of Payments Made to Excellus Health Plan, Inc., for Calendar Year 2007* (Contract Number H3351), A-02-09-01014, 9 (Oct. 2012); OIG, *Risk Adjustment Data Validation of Payments Made to Paramount Care, Inc., for Calendar Year 2007* (Contract Number H3653), A-05-09-00044, ii-iii (Sept. 2012).

<sup>104</sup> OIG, *Bravo Health Pennsylvania, Inc. (Contract H3949), Submitted Many Diagnoses to the Centers for Medicare & Medicaid Services That Did Not Comply With Federal Requirements for Calendar Year 2007*, A-03-09-00003, 7 (Sept. 2013); OIG, *Cigna Healthcare of Arizona, Inc. (Contract H0354), Submitted Many Diagnoses to the Centers for Medicare & Medicaid Services That Did Not Comply With Federal Requirements for Calendar Year 2007*, A-07-10-01082, iii (May 2013).

<sup>105</sup> See, e.g., *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 31 (D.D.C. 1997).

<sup>106</sup> Draft Report at 12.

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would be happy to discuss any specific suggestions with OIG, to the extent it offers such suggestions, at OIG's convenience.

Finally, we observe again that we have shared details regarding our risk adjustment policies and procedures with CMS many times over the years. CMS has not asked us to change our policies or procedures or identified any specific areas that require additional enhancements. For this reason, too, we think that the second recommendation should be withdrawn.

### **CONCLUSION**

Cigna is a committed partner to OIG, CMS, and the MA program. In our view, the Medicare Advantage program serves Medicare beneficiaries well because of the partnership between CMS and plans, like Cigna. In the spirit of that partnership, and for the reasons discussed above and in the attached materials, we respectfully request that OIG revise the Draft Report and withdraw both draft recommendations.

**Table 1 – HHS Overpayment Estimates for Part C**

*(based on National Sample Audit results)*

Fiscal Year	Overpayments	Underpayments	Net Overpayments
2012	8.5%	2.8%	5.7%
2013	7.5%	2.0%	5.5%
2014	6.0%	3.0%	2.9%
2015	6.9%	2.6%	4.3%
2016	7.1%	2.9%	4.2%
2017	5.4%	2.9%	2.5%
2018	4.7%	3.4%	1.4%

**Table 2 – HHS Overpayment Estimates for FFS Medicare**

Fiscal Year	Overpayments	Underpayments	Net Overpayments
2012	8.2%	0.3%	7.8%
2013	9.7%	0.4%	9.3%
2014	12.3%	0.4%	11.8%
2015	12.1%	0.4%	11.7%
2016	10.7%	0.3%	10.3%
2017	9.2%	0.3%	8.9%
2018	7.9%	0.3%	7.6%

**Table 3 – Comparison of Part C and FFS Medicare Net Overpayments**

Fiscal Year	Part C	FFS Medicare
2012	5.7%	7.8%
2013	5.5%	9.3%
2014	2.9%	11.8%
2015	4.3%	11.7%
2016	4.2%	10.3%
2017	2.5%	8.9%
2018	1.4%	7.6%

**CMS0005897-5902**

## **Agenda**

### **Background**

- We released our latest payment error estimate for Medicare Advantage last November which was based on 2009 payments.
- We had an overall payment error rate of 11% -- which was driven almost entirely by errors in the diagnosis data that are submitted to CMS for risk adjustment purposes.
- Our primary corrective action to bring down this error rate is our RADV audit initiative in which we pick a subset of plans and audit the accuracy of the diagnosis data that they've submitted.
- We'll talk specifically about how later in the deck, but we think the RADV audit initiative can also be helpful as one tool to address the aggressive coding patterns of some Medicare Advantage organizations that Rick described at our last meeting.

### **Basic RADV Audit Methodology**

- Slide 4 describes the basic mechanics of each RADV audit.
- For each audited plan, we identify a sample of beneficiaries (stratified into groups by risk score).
- For each disease or condition, known as an HCC, we request that the plan provide medical record documentation to verify the accuracy of each reported condition.
- For example, if a particular beneficiary was reported to have diabetes and congestive heart failure, we would request medical record documentation to support the diabetes and medical record documentation to support the congestive heart failure.
- We then have coding experts reviewed the medical records to determine what conditions are documented in the medical record.
- Based on that review, we then calculate what the payment to the plan should have been for those beneficiaries.
- Then extrapolating those sample errors to the universe of beneficiaries enrolled in that plan contract, we calculate an aggregate contract-level payment error for the plan.

### **Current Status**

- In terms of the current status of the RADV audits, we have audited 37 contracts all for payment year 2007.
- We have preliminary medical record review findings for each of those audited contracts.
- The next step before finalizing these audits, or proceeding with audits for future payment years, is to finalize a few outstanding policy issues, including how we extrapolate the sample findings
- In December of 2010, we released for public comment our proposed methodology for extrapolating the sample findings to plans' aggregate payments.
- We got a lot of comments from the industry.
- There is intense interest given the dollars at stake.
- We're going to focus today on the four main outstanding questions/issues raised by plans that we need to finalize before moving forward.
- There are four main issues that we need to decide before publishing the final extrapolation methodology and proceeding with recoveries of overpayments.

- First, we need to decide whether we want to stay with 2007 as the first year for RADV or whether we should move to a later year.
- Second, we need to determine how many audits we will do for each payment year and how we select the plans to audit.
- Third, we need to finalize the methodology for calculating how much each plan owes and whether we include a FFS adjustor in that methodology.
- Finally, we need to decide what documentation we will allow plans to submit to prove whether a beneficiary truly has a particular condition.

#### **Timing of RADV Audits.**

- First, there is the issue of what year to begin with for RADV audits.
- The RADV audits are being done on our own initiative and not in response to a statutory or regulatory mandate.
- So we have complete discretion about when to start them.
- As I mentioned, the first and only year we have begun to audit is 2007.
- Plans have argued that the RADV audits are really a game changer and that they fundamentally change how much plans can expect to get paid in the years in which they are audited.
- Plans argue that they need to take potential RADV recoveries into account when they do their bids so they ensure they get the revenue they need.
- Plans argue that in 2006 when they did their bids for 2007 they didn't know about RADV and now we are retroactively changing the payment rules.
- We don't find that argument very persuasive and neither does OACT who reviews the bids.
- RADV is not changing our payment methodology it is just a mechanism to enforce the rules.
- In addition, if we take their argument to the logical extreme, we could only start auditing in a year when plans have perfect and complete advance knowledge of the RADV process and extrapolation methodology, which at this point would be 2013.
- We might want to pick a later year, however, to shorten the timeframe between when the audit is conducted and the payment year we are auditing.
- The 2007 audits have taken much longer than we ever dreamed possible.
- Our original goal when we started them in 2008 was to begin taking back money in 2008.
- The process has been drawn out because we needed to issue a reg on the appeals process before we could begin.
- Also the 2007 audits have been a learning process for us and the plans and as we've gone we've added steps and additional safeguards to the audit protocol to ensure that we have a process that will withstand challenge during appeals and litigation.
- If we move forward with 2008, we would be reviewing records from 4 to 5 years ago.
- Unfortunately, the longer the lag between the payment year and the audit, the more difficult it is for plans to track down medical records from providers that have moved or are no longer practicing.
- So to shorten the timeframe, we recommend starting with payment year 2011.
- This is the first year that we can implement the shortest lag possible – which is about 2 years.

- If we go that route, then we start the audits as soon as our final payment reconciliations are done for 2011 later this year and we would recoup overpayments in early 2014?
- For the 2007 audits, we propose to close them out by recouping overpayments for the individual beneficiaries in the sample rather than extrapolating the findings to each plan's entire payment.

**How many RADV Audits.**

- Going forward we also need to decide how many RADV audits to do each year.
- Given our current staffing and contractor resources, we can do up to 80 audits per year.
- As we discussed, we have done approximately 30 audits for 2007.
- We propose recommending 30 audits in anticipation that this is an item we can give on for OMB and go up to as high as 80 audits.

**Target High Coders.**

- In selecting which plans to audit, we recommend targeting those plans that are coding more intensively than other plans.
- There is significant variation in how aggressively plans identify and submit diagnosis codes.
- We have an across-the-board adjustment that we apply to all plans' payment to reflect coding patterns that differ from FFS Medicare.
- 25% of the audited plans would be selected at random, the rest would be the plans that are coding most aggressively.
- Doing so will also address concerns raised by ASPE about "high-flyers" that are taking advantage of the ability to submit diagnosis codes.

**Model Calibration Factor.**

- The next issue is the extrapolation methodology that we're going to use in RADV.
- The approach that we laid out in our December guidance was pretty straightforward and we don't recommend making any significant changes -- with one exception.
- Plans have argued that we should incorporate a FFS adjustor into the extrapolation methodology.
- The industry has argued that in the RADV audits we are holding them to a standard of perfection for diagnosis coding but that physician claims in FFS Medicare often include diagnoses that aren't supported in the medical record.
- And this wouldn't matter except that we use FFS claims data to develop our risk adjustors for Medicare Advantage.
- So when we estimate the relative cost of any given condition, we use diagnosis and cost data from FFS Medicare.
- So implicit in all of the adjustments we make to plans payments to account for the relative risk of their populations, are the factors that we developed using FFS data.
- So we've got one documentation standard for RADV, which is perfection.
- And we've got another documentation standard for risk adjustment, which reflects a certain level of codes that aren't documented in a medical record.
- For our payments to be as accurate as possible, we should be using the same standard for both.



- To answer this issue, we can incorporate a FFS adjustor that estimates how much higher the plan's payment would be if the model had been built using perfect data.
  - This factor would reduce the estimated RADV overpayments due from each plan.
  - We think this approach makes sense and from a technical point of view is the right thing to do.
  - It also will help bring the overpayments into a range that is more realistic for plans to be able to accommodate.
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- To estimate the FFS adjustor, we have done a RADV-like audit of 10,000 medical records from the CERT sample.
  - Based on this CERT RADV audit, we estimate the FFS adjustor to be 8.1%.
  - The approach we used to develop this estimate can be modified to dial the estimate down.
  - The FFS adjustor has a significant effect on RADV recoveries.
  - If we had no FFS adjustor, we would recoup about \$900 million for the 2007 audits. With a 8.1% FFS adjustor, we would recoup about \$500??
  - It is possible to modify the approach for calculating the FFS adjustor that results in a lower (or higher) adjustor.
  - If we use a 4.8% adjustor, recoveries total XX.
  - We think the 8.1% adjustor is the best approach – because is the most conservative estimate we think it puts us in the best position to withstand litigation challenges.
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- In risk adjustment, we are estimating the average cost of any given condition given the people who are reported to have it.
  - If we include diagnoses for beneficiaries who don't actually have the disease, or for whom the medical record documentation is not clear, this tends to reduce the estimated average cost of various conditions and therefore our risk adjustment factors.
  - So plans argue that we are paying them as if they are getting beneficiaries who look like FFS rather than the higher average cost of the beneficiaries we are allowing to be claimed in MA under the RADV audits.

#### **Documentation Standards.**

- The third issue is what documentation plans will be allowed to submit as evidence for the diagnoses they submitted.
- So under our current rules, plans must submit medical record documentation to confirm each diagnosis they have claimed.
- So, for example, if they told us that a beneficiary had diabetes and congestive heart failure, they would submit medical record documentation from one date of service to support the diabetes and medical record documentation from the same or another date of service to support the congestive heart failure.
- The documentation must be from the year prior to the payment year and must be from an acceptable provider type, i.e., hospital inpatient, hospital outpatient or physician.
- The plans have pushed back on these documentation requirements.
- They want to submit medical record documentation from time periods other than the prior year.

- They also want to use non-medical record documentation like prescriptions or claims to support diagnoses.
- They also want us to allow plans, when necessary, to combine evidence from these various sources.
- So under this approach, even though there is no single source that definitely shows that a beneficiary has a particular diagnosis, plans could combine multiple records that taken together would suggest that the beneficiary has the diagnosis.
- Our recommendation is to hold firm with the requirements that the only acceptable documentation are medical records from hospitals or physicians from the proper time period.
- First, it is important to make sure that the standards we use in RADV are consistent with the standards we use in calibrating our risk adjustment model.
- If we allow data from time periods other than the prior year or from sources other than hospitals or physicians, then our RADV audits will be out of sync with our risk adjustment model and we will be paying plans more than we should.
- Second, if we deviate from medical records as the source of documentation, we will have no consistent standard.
- And then we are in very dangerous territory with being able to ensure that we are applying uniform set of rules to determine when the documentation is sufficient and when it isn't.
- What we do recommend, however, to address the industry's concerns is to allow plans to submit as many medical records as they like.
- So rather than limiting plans to one medical record, we would be accept multiple records.
- Our coders would code each record until they find a record that supports the condition in question.
- As we do with the one best medical record, we would also gives plans credit for any additional diagnoses we find in that record that we not initially claimed.
- One of the underlying problems here is that outside of the hospital setting, physicians are not consistent in following coding guidelines and there are issues with the quality of medical record documentation that are not unique to MA providers.

#### **Anticipated Reactions to CMS' Recommendations**

- For the model calibration factor, the MA industry will be very supportive.
- We have discussed this concept with the OIG; they appear at least at a staff level to understand the technical reasons for making such an adjustment.
- So if we decide to move forward with such an adjustment, we don't expect criticism from the OIG.
- On the documentation standards, the plans will oppose our proposed position and will use this as one of the legal challenges they make to RADV.
- The OIG, on the other hand, supports our proposed approach.
- On using 2011 as the first year for RADV audits, the plans will be supportive that we will not extrapolate for 2007, 2008 or 2009. However, they will continue to argue that we should skip 2010 and 2011 as well.
- It is unclear where the OIG will come out on this issue.
- They too have done 2007 audits, but have not completed them.

- They are likely to skip 2008 for the same reason we are considering to shorten up the timeframe between the audit and the data collection period.

### **Background**

- As you know, we have a large payment error rate in Part C.
- It is approximately 11% and it is driven almost exclusively by error in diagnosis codes submitted to CMS by Medicare Advantage organizations.
- As you know, under our risk adjustment methodology we are largely reliant on plans to report diagnosis information.
- The more diagnoses plans submit, generally the higher their payment.
- Back in 2008, we launched our Risk Adjustment Data Validation initiative as our primary corrective action to reduce this payment error.

### **RADV Contract-Level Audits Basic RADV Methodology**

- Under our RADV audits, we confirm whether or not the diagnoses submitted by the audited plan are documented in the patient's medical record.
- Under these audits, we select a statistically valid sample of diagnoses for each audited plan.
- We then ask the plan to submit medical record documentation that prove that the beneficiary truly has the reported condition.
- We have teams of medical coding experts that review the documentation.
- Based on their review, we calculate an error rate for the sample, and extrapolate the error rate to the total payment made by the CMS to the plan for the year.
- This extrapolation approach means that significant dollars are at risk for audited plans.
- We first announced our plan to extrapolate back in 2008 and, at that time, began RADV audits of 5 pilot plans and 32 additional plans for calendar year 2007 payments.