

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE COMPLIANCE
AUDIT OF SPECIFIC DIAGNOSIS CODES
THAT CIGNA-HEALTHSPRING
LIFE & HEALTH INSURANCE
COMPANY, INC. (CONTRACT H4513)
SUBMITTED TO CMS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



Amy J. Frontz
Deputy Inspector General
for Audit Services

March 2023
A-07-19-01192

Office of Inspector General

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Report in Brief

Date: March 2023

Report No. A-07-19-01192

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. Some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.

For this audit, we reviewed one MA organization, Cigna-HealthSpring Life & Health Insurance Company, Inc. (Cigna), and focused on nine groups of high-risk diagnosis codes. Our objective was to determine whether selected diagnosis codes that Cigna submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

How OIG Did This Audit

We sampled 300 unique enrollee-years with the high-risk diagnosis codes for which Cigna received higher payments for 2016 through 2017. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$720,395.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring Life & Health Insurance Company, Inc. (Contract H4513) Submitted to CMS

What OIG Found

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Cigna submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, for 200 of the 300 sampled enrollee-years, the medical records that Cigna provided did not support the diagnosis codes and resulted in \$468,372 in overpayments. As demonstrated by the errors found in our sample, Cigna's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements could be improved. On the basis of our sample results, we estimated that Cigna received at least \$6.24 million in overpayments for 2016 and 2017.

What OIG Recommends and Cigna Comments

We recommend that Cigna: (1) refund to the Federal Government the \$468,372 of overpayments; (2) identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and (3) continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements and take the necessary steps to enhance those procedures.

Cigna did not concur with our recommendations and did not concur with our findings for 6 sampled enrollee-years which, according to Cigna, were supported by the medical records. Cigna did not directly agree or disagree with our findings for the remaining enrollee-years. Cigna did not agree with our audit methodology, use of extrapolation, and standards for data accuracy, coding, and documentation requirements.

After reviewing Cigna's comments and the additional information that Cigna provided, we revised the number of enrollee-years in error from 201 to 200 for this final report. After we had issued our draft report, CMS updated regulations for audits in its risk adjustment program to specify that extrapolated overpayments could only be recouped beginning with payment year 2018. Because our audit period covered payment years 2016 and 2017, we revised our first recommendation to specify a refund of only the overpayments for the sampled enrollee-years. We made no changes to our other recommendations. We followed a reasonable audit methodology and correctly applied applicable Federal requirements underlying the MA program.

TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objective.....	1
Background.....	2
Medicare Advantage Program.....	2
Risk Adjustment Program.....	2
High-Risk Groups of Diagnoses.....	4
Cigna-HealthSpring Life & Health Insurance Company, Inc.....	6
How We Conducted This Audit.....	6
FINDINGS.....	7
Federal Requirements.....	8
Most of the Selected High-Risk Diagnosis Codes That Cigna-HealthSpring Life & Health Insurance Company Submitted to CMS Did Not Comply With Federal Requirements ...	9
Incorrectly Submitted Diagnosis Codes for Acute Stroke.....	10
Incorrectly Submitted Diagnosis Codes for Acute Heart Attack.....	10
Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder.....	12
Incorrectly Submitted Diagnosis Codes for Embolism.....	12
Incorrectly Submitted Diagnosis Codes for Vascular Claudication.....	13
Incorrectly Submitted Diagnosis Codes for Lung Cancer.....	13
Incorrectly Submitted Diagnosis Codes for Breast Cancer.....	14
Incorrectly Submitted Diagnosis Codes for Colon Cancer.....	15
Incorrectly Submitted Diagnosis Codes for Prostate Cancer.....	16
Summary of Incorrectly Submitted Diagnosis Codes.....	16
The Policies and Procedures That Cigna-HealthSpring Life & Health Insurance Company Had To Prevent, Detect, and Correct Noncompliance With Federal Requirements Could Be Improved.....	17
Cigna-HealthSpring Life & Health Insurance Company Received Overpayments.....	17
RECOMMENDATIONS.....	18
CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE.....	18

Cigna-HealthSpring Life & Health Insurance Company Did Not Concur With the Office of Inspector General’s Recommendation That It Refund Overpayments	19
Cigna-HealthSpring Life & Health Insurance Company Did Not Agree With the Office of Inspector General’s Findings for 6 Sampled Enrollee-Years.....	19
Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General’s Audits Were Focused Only on Identifying Overpayments	20
Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General Did Not Follow CMS’s Established Risk Adjustment Data Validation Methodology	21
Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General’s Audits Were Inconsistent With CMS Standards for Data Accuracy	22
Cigna-HealthSpring Life & Health Insurance Company Did Not Agree With the Office of Inspector General’s Use of Extrapolation	24
Cigna-HealthSpring Life & Health Insurance Company Did Not Agree With the Office of Inspector General’s Medical Record Coding Review Process	26
Cigna-HealthSpring Life & Health Insurance Company Did Not Agree With the Office of Inspector General’s Use of Medicare Administrative Contractors	26
Cigna-HealthSpring Life & Health Insurance Company Stated That Coding and Documentation Standards Used During the Audit Were Not Validly Established	27
Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General Did Not Provide Any Information Regarding the Independent Medical Review Contractor and the Coding Standards Used for This Audit	28
Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General Used an Arbitrary Date Range That Prohibited Cigna From Submitting Documentation That Would Substantiate a Diagnosis	30
Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General Used Problematic Standards To Determine the Validity of Diagnoses	31
Cigna-HealthSpring Life & Health Insurance Company Did Not Concur With the Office of Inspector General’s Recommendation To Perform Additional Reviews Before or After the Audit Period	33
Cigna-HealthSpring Life & Health Insurance Company Comments.....	33
Office of Inspector General Response	33
Cigna-HealthSpring Life & Health Insurance Company Did Not Concur With the Office of Inspector General’s Recommendation That It Enhance Its Existing Compliance Procedures	34
Cigna-HealthSpring Life & Health Insurance Company Comments.....	34

Office of Inspector General Response 34

APPENDICES

A: Audit Scope and Methodology 36
B: Related Office of Inspector General Reports..... 40
C: Statistical Sampling Methodology 42
D: Sample Results and Estimates 45
E: Federal Regulations Regarding Compliance Programs That Medicare Advantage Organizations Must Follow 46
F: Cigna-HealthSpring Life & Health Insurance Company Comments 48

INTRODUCTION

WHY WE DID THIS AUDIT

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations based in part on the characteristics of the enrollees being covered. Using a system of risk adjustment, CMS pays MA organizations the anticipated cost of providing Medicare benefits to a given enrollee, depending on such risk factors as the age, gender, and health status of that individual. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources relative to healthier enrollees, who would be expected to require fewer health care resources. To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS.¹ We are auditing MA organizations because some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS.² Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 29 major depressive disorder diagnoses into 1 group.) This audit covered Cigna-HealthSpring Life & Health Insurance Company, Inc. (Cigna), for contract number H4513 and focused on nine groups of high-risk diagnosis codes for payment years 2016 and 2017.³

OBJECTIVE

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

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

² See Appendix B for a list of related Office of Inspector General reports.

³ All subsequent references to "Cigna" in this report refer solely to contract number H4513.

BACKGROUND

Medicare Advantage Program

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

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

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

Risk Adjustment Program

Federal requirements mandate that payments to MA organizations be based on the anticipated cost of providing Medicare benefits to a given enrollee and, in doing so, also account for variations in the demographic characteristics and health status of each enrollee.⁵

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.⁶ CMS compares each bid to a specific benchmark amount for each geographic area to determine the base rate that an MA organization is paid for each of its enrollees.⁷

⁴ 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.

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

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

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

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

To determine an enrollee's health status for purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from acceptable data sources, including certain physicians and hospitals. MA organizations collect the diagnosis codes from providers based on information documented in the medical records and submit these codes to CMS. CMS then maps certain diagnosis codes, on the basis of similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs).⁸ Each HCC has a factor (which is a numerical value) assigned to it for use in each enrollee's risk score.

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

For enrollees who have certain combinations of HCCs, CMS assigns a separate factor that further increases the risk score. CMS refers to these combinations as disease interactions. For example, if MA organizations submit diagnosis codes for an enrollee that map to the HCCs for lung cancer and immune disorders, CMS assigns a separate factor for this disease interaction. By doing so, CMS increases the enrollee's risk score for each of the two HCC factors and by an additional factor for the disease interaction.

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

CMS multiplies the risk scores by the base rates to calculate the total monthly Medicare payment that an MA organization receives for each enrollee before applying the budget

⁸ During our audit period CMS calculated risk scores based on the Version 22 CMS-HCC model.

sequestration reduction.⁹ Thus, if the factors used to determine an enrollee's risk score are incorrect, CMS will make an improper payment to an MA organization. Specifically, if medical records do not support the diagnosis codes that an MA organization submitted to CMS, the HCCs are unvalidated, which causes overstated enrollee risk scores and overpayments from CMS.¹⁰ Conversely, if medical records support the diagnosis codes that an MA organization did not submit to CMS, validated HCCs may not have been included in enrollees' risk scores, which may cause those risk scores to be understated and may result in underpayments.

High-Risk Groups of Diagnoses

Using data mining techniques and discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. For this audit, we focused on nine high-risk groups:

- *Acute stroke*: An enrollee received one acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient or outpatient hospital claim. In these instances, a diagnosis of history of stroke (which does not map to an HCC) typically should have been used.
- *Acute heart attack*: An enrollee received one diagnosis that mapped to either the HCC for Acute Myocardial Infarction or to the HCC for Unstable Angina and Other Acute Ischemic Heart Disease (Acute Heart Attack HCCs) on only one physician or outpatient claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician or outpatient claim). In these instances, a diagnosis for a less severe manifestation of a disease in the related-disease group typically should have been used.
- *Major depressive disorder*: An enrollee received one major depressive disorder diagnosis (that mapped to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) during the service year but did not have an antidepressant medication dispensed on his or her behalf. In these instances, a major depressive disorder diagnosis may not be supported in the medical records.

⁹ 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.

¹⁰ 42 CFR § 422.310(e) requires MA organizations (when undergoing an audit conducted by the Secretary) to submit "medical records for the validation of risk adjustment data." For purposes of this report, we use the terms "supported" or "unsupported" to denote whether or not the reviewed diagnoses were evidenced in the medical records. If our audit determines that the diagnoses are supported or unsupported, we accordingly use the terms "validated" or "unvalidated" with respect to the associated HCC.

- *Embolism*: An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease With Complications (Embolism HCCs) during the service year but did not have an anticoagulant medication dispensed on his or her behalf. An anticoagulant medication is typically used to treat an embolism. In these instances, a diagnosis of history of embolism (an indication that the provider is evaluating a prior acute embolism diagnosis, which does not map to an HCC) typically should have been used.
- *Vascular claudication*: An enrollee received one diagnosis related to vascular claudication (that mapped to the HCC for Vascular Disease) during the service year, but had not received one of these diagnoses during the 2 preceding years and had medication dispensed on his or her behalf that is frequently dispensed for a diagnosis of neurogenic claudication.¹¹ In these instances, the diagnosis related to vascular claudication may not be supported in the medical records.
- *Lung cancer*: An enrollee received one lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period either before or after the diagnosis. In these instances, a diagnosis of history of lung cancer (which does not map to an HCC) typically should have been used.
- *Breast cancer*: An enrollee received one breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of breast cancer (which does not map to an HCC) typically should have been used.
- *Colon cancer*: An enrollee received one colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of colon cancer (which does not map to an HCC) typically should have been used.
- *Prostate cancer*: An enrollee 74 years old or younger received one prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after

¹¹ Vascular claudication and neurogenic claudication are different diagnoses. Vascular claudication is a condition that can result in leg pain while walking and is caused by insufficient blood flow. Neurogenic claudication is a condition that can also result in leg pain but is caused by damage to the neurological system, namely the spinal cord and nerves.

the diagnosis. In these instances, a diagnosis of history of prostate cancer (which does not map to an HCC) typically should have been used.

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

Cigna-HealthSpring Life & Health Insurance Company, Inc.

Cigna is an MA organization based in Nashville, Tennessee. As of December 2017, Cigna provided coverage under contract number H4513 to 82,539 enrollees. For the 2016 and 2017 payment years (audit period), CMS paid Cigna approximately \$2.1 billion to provide coverage to its enrollees.^{12, 13}

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of the nine high-risk groups during the 2015 and 2016 service years, for which Cigna received increased risk-adjusted payments for payment years 2016 and 2017, respectively. Because enrollees could be classified into more than one high-risk group or could have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment year, which we refer to as “enrollee-years.”

We identified 8,667 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$19,537,407). We selected for audit a stratified sample of 300 enrollee-years as shown in Table 1 on the following page.

¹² The 2016 and 2017 payment year data were the most recent data available at the start of the audit.

¹³ All of the payment amounts that CMS made to Cigna and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

Table 1: Sampled Enrollee-Years

High-Risk Group	Number of Sampled Enrollee-Years
1. Acute stroke	30
2. Acute heart attack	30
3. Major depressive disorder	60
4. Embolism	30
5. Vascular claudication	30
6. Lung cancer	30
7. Breast cancer	30
8. Colon cancer	30
9. Prostate cancer	30
Total for All High-Risk Groups	300

Cigna provided medical records as support for the selected diagnosis codes associated with 288 of the 300 sampled enrollee-years.¹⁴ We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. If the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

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

FINDINGS

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Cigna submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 100 of the 300 sampled enrollee-years, the medical records

¹⁴ Cigna could not locate medical records for the remaining 12 sampled enrollee-years.

validated the reviewed HCCs.¹⁵ For the remaining 200 enrollee-years, however, either the medical records that Cigna provided did not support the diagnosis codes or Cigna could not locate the medical records to support the diagnosis codes and the associated HCCs were therefore not validated. As a result, Cigna received \$468,372 in overpayments.

As demonstrated by the errors found in our sample, Cigna's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that Cigna received at least \$6.24 million in overpayments for 2016 and 2017.¹⁶

FEDERAL REQUIREMENTS

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

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

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

CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap. 7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7, § 40). The diagnosis must be coded

¹⁵ For 1 of the 100 enrollee-years, Cigna informed us that it could not locate the associated medical record because the record had been destroyed in a natural disaster. CMS provides guidance for medical records that are unavailable because of "extraordinary circumstances" (*Contract-Level Risk Adjustment Data Validation CMS Submission Instructions*). Based on our assessment of the information provided by Cigna, we determined that an extraordinary circumstance prevented Cigna from locating the medical record for this enrollee-year, and we treated the sample item as a non-error.

¹⁶ Specifically, we estimated that Cigna received at least \$6,247,399 of overpayments. To be conservative, we estimate overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

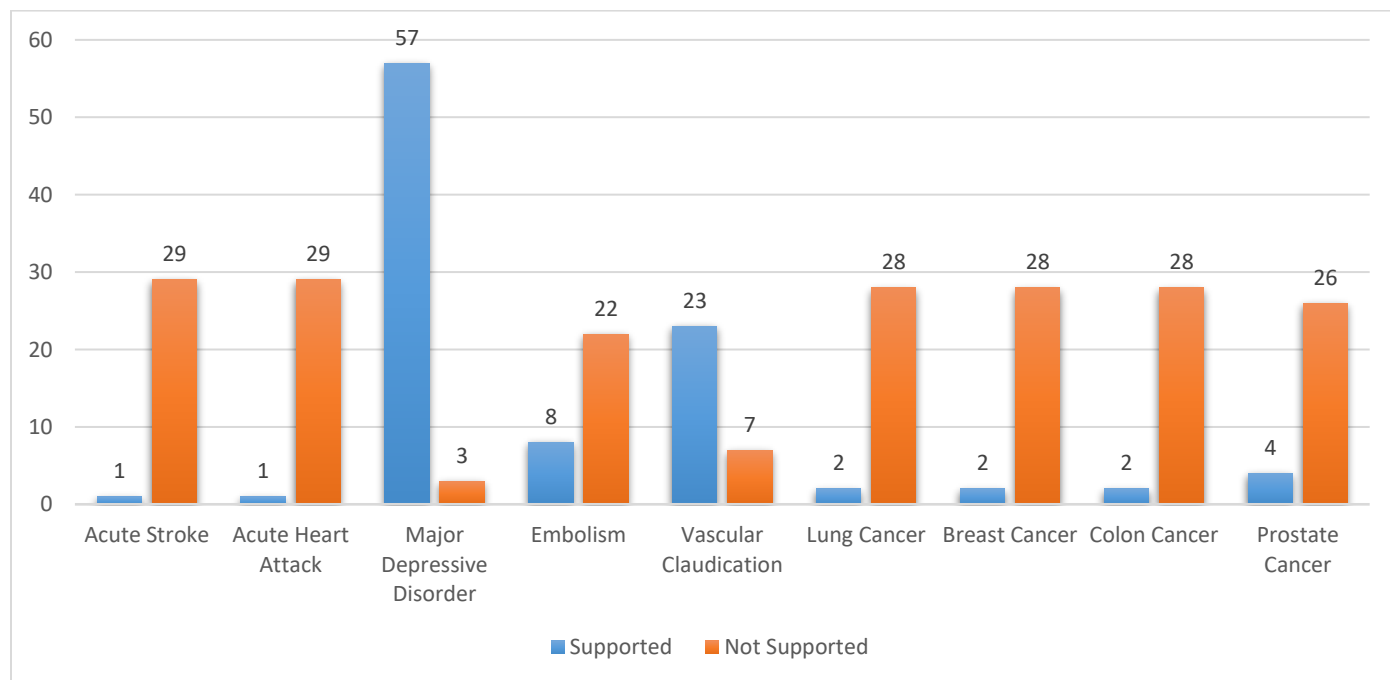
according to the International Classification of Diseases (ICD), Clinical Modification, *Official Guidelines for Coding and Reporting* (42 CFR § 422.310(d)(1) and 45 CFR §§ 162.1002(b)(1) and (c)(2)-(3)). Further, MA organizations must implement procedures to ensure that diagnoses come only from acceptable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

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

MOST OF THE SELECTED HIGH-RISK DIAGNOSIS CODES THAT CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Most of the selected high-risk diagnosis codes that Cigna submitted to CMS for use in CMS’s risk adjustment program did not comply with Federal requirements. Specifically, as shown in the figure below, the medical records for 200 of the 300 sampled enrollee-years did not support the diagnosis codes. In these instances, Cigna should not have submitted the diagnosis codes to CMS and received the resulting overpayments.

Figure: Analysis of High-Risk Groups



Incorrectly Submitted Diagnosis Codes for Acute Stroke

Cigna incorrectly submitted diagnosis codes for acute stroke for 29 of 30 sampled enrollee-years. Specifically:

- For 23 enrollee-years, the medical records indicated in each case that the individual had previously had a stroke, but the records did not justify an acute stroke diagnosis at the time of the physician's service.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC or a related HCC. There is mention of a history of a stroke [diagnosis] but no description of residuals or sequelae that should be coded."¹⁷ The history of stroke diagnosis code does not map to an HCC.

- For the remaining 6 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.¹⁸

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC [for Ischemic or Unspecified Stroke] or a related HCC. Although [there] is mention of a cerebral infarction [diagnosis] in the current assessment there is no indication that this condition is active."¹⁹

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and Cigna received \$62,466 in overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Heart Attack

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

- For 13 enrollee-years, the medical records indicated in each case that the individual had an old myocardial infarction diagnosis, but the records did not justify one of the

¹⁷ Residuals or sequelae are the late effects of an injury that can occur only after the acute phase of the injury or illness has passed.

¹⁸ For 1 of these enrollee-years, the medical record that Cigna provided to support the reviewed HCC was a magnetic resonance imaging (MRI) report. This record was not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3)); the Manual, chap. 7, §§ 40 and 120.1).

¹⁹ A cerebral infarction, or stroke, is defined as a brain lesion in which a cluster of brain cells dies due to lack of blood.

diagnoses that mapped to an Acute Heart Attack HCC at the time of the physician's service.²⁰

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

- For 9 enrollee-years, the medical records in each case did not support the submitted diagnosis that mapped to an Acute Heart Attack HCC. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to the HCC for Angina Pectoris, which is a less severe manifestation of the related-disease group.²¹

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Unstable Angina and Other Acute Ischemic Heart Disease]. There is documentation of [an] angina pectoris [diagnosis] that results in [the] HCC [for Angina Pectoris]"

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

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Acute Myocardial Infarction]. The discharge final diagnosis stated that the patient was ruled out for an acute myocardial infarction."

- For the remaining 1 enrollee-year, Cigna could not locate any medical records to support a diagnosis that mapped to an Acute Heart Attack HCC; therefore, an Acute Heart Attack HCC was not validated.

As a result of these errors, the Acute Heart Attack HCCs were not validated, and Cigna received \$41,309 in overpayments for these 29 sampled enrollee-years.

²⁰ An "old myocardial infarction" is a distinct diagnosis that represents a myocardial infarction that occurred more than 4 weeks previously, has no current symptoms directly associated with that myocardial infarction, and requires no current care.

²¹ Angina pectoris is defined as a disease marked by brief sudden attacks of chest pain or discomfort caused by deficient oxygenation of the heart muscles, usually due to impaired blood flow to the heart.

Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder

Cigna incorrectly submitted diagnosis codes for major depressive disorder for 3 of 60 sampled enrollee-years. Specifically:

- For 2 enrollee-years, the medical records in each case did not support a major depressive disorder diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Major Depressive, Bipolar, and Paranoid Disorders].”

- For the remaining 1 enrollee-year, Cigna could not locate any medical records to support the major depressive disorder diagnosis; therefore, the HCC for Major Depressive, Bipolar, and Paranoid Disorders was not validated.

As a result of these errors, the HCC for Major Depressive, Bipolar, and Paranoid Disorders was not validated, and Cigna received \$7,247 in overpayments for these 3 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

Cigna incorrectly submitted diagnosis codes for embolism for 22 of 30 sampled enrollee-years. Specifically:

- For 13 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Embolism HCC.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Vascular Disease]. Per . . . ultrasound test results, there was no evidence of deep vein thrombosis.”²²

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

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Vascular Disease]. There is documentation of a past medical history of deep vein thrombosis [diagnosis] that does not result in an HCC.”

²² Deep vein thrombosis is defined as a blood clot that forms in one or more of the deep veins in the body, usually in the legs.

- For the remaining 1 enrollee-year, Cigna could not locate any medical records to support a diagnosis that mapped to an Embolism HCC; therefore, an Embolism HCC was not validated.

As a result of these errors, the Embolism HCCs were not validated, and Cigna received \$51,125 in overpayments for these 22 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Vascular Claudication

Cigna incorrectly submitted diagnosis codes for vascular claudication for 7 of 30 sampled enrollee-years. Specifically:

- For 6 enrollee-years, the medical records in each case did not support a vascular claudication diagnosis.

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

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

As a result of these errors, the HCC for Vascular Disease was not validated, and Cigna received \$12,872 in overpayments for these 7 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

Cigna incorrectly submitted diagnosis codes for lung cancer for 28 of 30 sampled enrollee-years. Specifically:

- For 14 enrollee-years, the medical records indicated in each case that the individual had previously had lung cancer, but the records did not justify a lung cancer diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC for [Lung and Other Severe Cancers]. There is documentation of a past medical history of lung cancer [diagnosis] that does not result in an HCC.”

- For 10 enrollee-years, the medical records in each case did not support a lung cancer diagnosis.²³

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Lung and Other Severe Cancers]. There was not enough documentation to support that the lung cancer was an active condition on this date of service.”

- For 2 enrollee-years, the medical records in each case did not support a lung cancer diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Cigna should not have received an increased payment for the submitted lung cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.
- For each of the remaining 2 enrollee-years, Cigna could not locate any medical records to support the lung cancer diagnosis; therefore, the HCC for Lung and Other Severe Cancers was not validated.

As a result of these errors, the HCC for Lung and Other Severe Cancers was not validated, and Cigna received \$169,930 in overpayments for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

Cigna incorrectly submitted diagnosis codes for breast cancer for 28 of 30 sampled enrollee-years. Specifically:

- For 20 enrollee-years, the medical records indicated in each case that the individual had previously had breast cancer, but the records did not justify a breast cancer diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors]. There is documentation of a past medical history of breast cancer [diagnosis] that does not result in an HCC.”

²³ For 1 of these enrollee-years, the medical record that Cigna provided to support the reviewed HCC contained only laboratory test results. This record was not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3)); the Manual, chap. 7, §§ 40 and 120.1).

- For 7 enrollee years, the medical records in each case did not support a breast cancer diagnosis.²⁴

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors] There was not enough documentation to support that the breast cancer was an active condition on this date of service.”

- For the remaining 1 enrollee-year, Cigna could not locate any medical records to support the breast cancer diagnosis; therefore, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated.

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Cigna received \$31,104 in overpayments for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

Cigna incorrectly submitted diagnosis codes for colon cancer for 28 of 30 sampled enrollee-years. Specifically:

- For 18 enrollee-years, the medical records indicated in each case that the individual had previously had colon cancer, but the records did not justify a colon cancer diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of a diagnosis that results in [the] HCC [for Colorectal, Bladder, and Other Cancers]. There is documentation of a past medical history of colon cancer [diagnosis] that does not result in an HCC.”

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

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Colorectal, Bladder, and Other Cancers]. The medical documentation does not indicate an active diagnosis of colon cancer.”

- For 3 enrollee-years, the medical records in each case did not support a colon cancer diagnosis. However, for each of these enrollee-years, we identified support for another

²⁴ For 1 of these enrollee-years, the medical record that Cigna provided to support the reviewed HCC was a radiology order requisition. This record was not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3)); the Manual, chap. 7, §§ 40 and 120.1).

diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, in each case Cigna should not have received an increased payment for the submitted colon cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

- For each of the remaining 2 enrollee-years, Cigna could not locate any medical records to support the colon cancer diagnosis; therefore, the HCC for Colorectal, Bladder, and Other Cancers was not validated.

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and Cigna received \$56,923 in overpayments for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

Cigna incorrectly submitted diagnosis codes for prostate cancer for 26 of 30 sampled enrollee-years. Specifically:

- For 23 enrollee-years, the medical records indicated in each case that the individual had previously had prostate cancer, but the records did not justify a prostate cancer diagnosis at the time of the physician's service.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors] . . . History of prostate cancer [diagnosis] should have been assigned . . . and does not result in an HCC."

- For each of 2 enrollee-years, Cigna could not locate any medical records to support the prostate cancer diagnosis; therefore, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated.
- For the remaining 1 enrollee-year, the medical records did not support a prostate cancer diagnosis. Specifically, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors]. There was not enough documentation to support that the prostate cancer was an active condition on this date of service."

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Cigna received \$35,396 in overpayments for these 26 sampled enrollee-years.

Summary of Incorrectly Submitted Diagnosis Codes

In summary and with respect to the nine high-risk groups covered by our audit, Cigna received \$468,372 in overpayments for the 200 sampled enrollee-years.

THE POLICIES AND PROCEDURES THAT CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY HAD TO PREVENT, DETECT, AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS COULD BE IMPROVED

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

During our audit period, Cigna had compliance procedures in place that were designed to prevent providers from submitting incorrect diagnosis codes. These procedures included a variety of provider-specific outreach efforts to help educate its providers on medical record documentation, including accurately differentiating between: (1) conditions that were manifesting as acute and (2) conditions that were not currently active but had been historically present, such as stroke, myocardial infarction, and cancer. In addition, Cigna routinely educated its coders on best coding practices and acceptable medical documentation guidelines, and coders were expected to identify codes with at least 95-percent accuracy.

Cigna also had compliance procedures in place that were designed to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. These procedures included the use of internal data quality reviews that selected diagnosis codes from specific claims and compared them to the diagnoses that were documented on the associated medical records. Cigna had several criteria governing its selection of these diagnosis codes, including: (1) the frequency of usage by specific physicians and (2) the presence of diagnosis codes that met certain conditions (such as diagnosis codes for acute conditions that could be inaccurate when coded in an outpatient setting). Cigna's procedures also included guidance on how its reviewers should address the coding of certain conditions, including acute stroke, myocardial infarction, cancer, and the use of "history of" diagnosis codes. If the reviewers detected a compliance problem, Cigna's policies and procedures provided guidance on how to communicate the correction of the problem to CMS.

Although Cigna had policies and procedures that addressed some incorrect high-risk diagnosis codes, Cigna did not identify these diagnosis codes as problematic unless they appeared on a specific claim that was selected for review. For this reason, we concluded that Cigna's policies and procedures to prevent, detect, and correct miscoded high-risk diagnoses during our audit period could be improved.

CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY RECEIVED OVERPAYMENTS

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Cigna received at least \$6,247,399 in overpayments for 2016 and 2017. (See Appendix D for sample results and estimates).

Because of Federal regulations that limit the use of extrapolation in Risk Adjustment Data Validation (RADV) audits for recovery purposes, we are reporting the estimated overpayment amount but are recommending a refund of only the \$468,372 in overpayments that Cigna received for the 200 sampled enrollee-years.²⁵

RECOMMENDATIONS

We recommend that Cigna-HealthSpring Life & Health Insurance Company, Inc.:

- refund to the Federal Government the \$468,372 of overpayments;
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
- continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Cigna did not concur with some of our findings and did not concur with any of our recommendations. More specifically, Cigna did not concur with our findings for 6 of the 201 enrollee-years in error identified in our draft report. For these 6 enrollee-years, Cigna provided explanations as to why it believed that the medical records that it previously gave us validated the reviewed HCCs. Cigna did not directly agree or disagree with our findings for the HCCs under audit for each of the remaining 195 enrollee-years.²⁶ With respect to the estimated overpayments, Cigna stated that our audit was “skewed toward identifying ‘overpayments’” and that the basic premise of our audit was inconsistent with Federal requirements.

We reviewed the entirety of Cigna's comments and the additional information that it provided and, accordingly, reduced the number of enrollee-years in error from 201 to 200 and adjusted our calculation of overpayments for this final report. After we issued our draft report, CMS updated its regulations for RADV audits to specify that extrapolated overpayments could only

²⁵ After we had issued our draft report, CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643 (Feb. 1, 2023)). RADV audits are conducted to verify that diagnoses submitted by MA organizations for risk-adjusted payment are supported by medical record documentation.

²⁶ For 19 of the 195 enrollee-years, Cigna provided additional information that was outside the scope of our audit; accordingly, this information did not impact our audit results.

be recouped beginning with payment year 2018 (footnote 25). Because our audit period covered payment years 2016 and 2017, we revised the amount in our first recommendation to reflect only the overpayments for the 200 sampled enrollee-years. We maintain that our second and third recommendations remain valid.

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

CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY DID NOT CONCUR WITH THE OFFICE OF INSPECTOR GENERAL’S RECOMMENDATION THAT IT REFUND OVERPAYMENTS

Cigna-HealthSpring Life & Health Insurance Company Did Not Agree With the Office of Inspector General’s Findings for 6 Sampled Enrollee-Years

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna did not concur with our findings for 6 of the sampled enrollee-years (as shown in Table 2) and provided explanations as to why it believed that the medical records that it previously gave us validated the reviewed HCCs.

Table 2: Summary of Enrollee-Years for Which Cigna-HealthSpring Life & Health Insurance Company Disagreed With Our Findings

High-Risk Group	Number of Sampled Enrollee-Years
Prostate cancer	4
Vascular claudication	1
Lung cancer	1
Total	6

Office of Inspector General Response

For 1 of the 6 enrollee-years that Cigna specifically disputed, our independent medical review contractor reversed its original decision after reviewing the explanation that Cigna submitted, and determined that the HCC was validated.

Specifically, for the 1 enrollee-year from the vascular claudication high-risk group, Cigna cited the medical record’s reference to a physical exam that noted “dorsalis pedis pulses . . . a follow up lower extremity arterial doppler was performed 3 weeks later . . . confirming a diagnosis of

[peripheral vascular disease] PVD.”²⁷ After reviewing Cigna’s explanation for this enrollee-year, our independent medical review contractor reversed its original decision. In so doing, the contractor stated: “[t]here is documentation of [a] lower extremity claudication [diagnosis] that results in [the] HCC [for Vascular Disease].”

Accordingly, we reduced the number of enrollee-years in error from 201 (in our draft report) to 200 for this final report. We also revised our findings and reduced the associated monetary recommendation. Our independent medical review contractor confirmed that Cigna’s written comments and additional explanations had no impact on the decisions that the contractor made for other sampled enrollee-years and stated that there were no “systemic issues identified” in its reviews.

For the remaining 5 enrollee-years for which Cigna disagreed with the results of our independent medical review contractor’s coding review, our contractor reaffirmed that the HCCs were not validated and thus upheld its original decision. For example, for 1 enrollee-year from the prostate cancer high-risk group, the contractor stated that “[t]he medical record for the date of service . . . indicates a past history of prostate cancer that was under surveillance.” Further, the contractor stated that “[t]here is no medical record evidence to support the diagnosis of prostate cancer, including no documentation of PSA [prostate-specific antigen] [test], monitoring or treatment.”²⁸

Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General’s Audits Were Focused Only on Identifying Overpayments

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna stated that our “audit methodology was so targeted that it could not equally identify overpayments and underpayments.” Furthermore, Cigna stated that our audit targeted “specific diagnosis categories that OIG [Office of Inspector General] hypothesized . . . [are] likely to have resulted in an ‘overpayment.’” Cigna also stated that we did not allow it “to demonstrate support for and receive credit for diagnosis codes that had not previously been submitted to CMS for the audited [enrollees] that were unrelated to the target diagnosis codes.” Furthermore, according to Cigna, “OIG only focused on samples that it viewed to be high-risk diagnoses so that it could only identify a potential overpayment.” Cigna added that this “biased targeting resulted in findings that do not ensure accuracy because the audit was

²⁷ The dorsalis pedis artery is the main source of blood supply to the foot. A lower extremity arterial doppler is an ultrasound test used to check the blood flow of the arteries and veins in the lower extremities (leg, ankle and foot). PVD is a systemic disorder that involves the narrowing of peripheral blood vessels (i.e., vessels situated away from the heart or the brain). Both PVD and vascular claudication map to the HCC for Vascular Disease.

²⁸ The PSA blood test measures the amount of PSA in the blood and is used primarily to screen for prostate cancer.

not designed to look at payment accuracy, which would include both overpayments and underpayments.”

For these reasons, Cigna stated that it was concerned “that the proposed overpayment figure used by OIG cannot be an adequate basis” for the audit results in this report.

Office of Inspector General Response

Our objective was to determine whether selected high-risk diagnosis codes that Cigna submitted to CMS for use in CMS’s risk adjustment program complied with Federal requirements. We identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into nine specific high-risk groups. This process involved a carefully designed audit methodology (see Appendix A) rather than “hypothesized” categories of diagnoses. Our objective did not extend to diagnosis codes not previously submitted by Cigna or to HCCs that were beyond the scope of our audit. A valid calculation of overpayments, given the objective of our audit, does not need to take into consideration all potential HCCs or underpayments within the audit period. Although for this final report we reduced the amount in our first recommendation (as discussed above), we based our calculation of overpayments on the results of the independent medical review contractor’s review; this calculation addressed only the accuracy of the portion of payments related to the reviewed HCCs and does not extend to HCCs that were beyond the scope of this audit.

Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General Did Not Follow CMS’s Established Risk Adjustment Data Validation Methodology

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna stated that our audit methodology did not account for a payment principal known as “actuarial equivalence,” because we did not apply an adjustment called a Fee-for-Service (FFS) Adjuster. The FFS Adjuster, according to Cigna, “incorporate[s] the FFS error rate into [CMS’s] methodology for calculating recovery amounts for unsupported HCCs identified during its RADV audits.” Cigna noted that, to address the FFS error rate, CMS published a notice in 2012 that notified MA organizations that it planned to calculate and apply an FFS Adjuster to payment recoveries in RADV audits to adjust for diagnosis coding errors in claims data from traditional Medicare.²⁹ Cigna also cited recent Federal court cases that have dealt with the principle of actuarial equivalence and mentioned that a CMS final rule on this issue (that CMS proposed in 2018) is still pending. In addition, Cigna stated that because we did not apply an FFS Adjuster, we “violate[d]” requirements for notice-and-comment Federal rulemaking and departed from how we addressed the FFS adjuster in a previous report.³⁰

²⁹ Cigna’s comment in this respect cited to CMS’s *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation for Contract-Level Audits* (Feb. 24, 2012), pages 3-4.

³⁰ The previous report to which Cigna referred was *Risk Adjustment Data Validation of Payments Made to PacifiCare of California for Calendar Year 2007 (Contract Number H0543)* (A-09-09-00045; Nov. 2012).

Cigna added that “[the] actuarial equivalence requirement extends to OIG’s estimation and extrapolation of a potential ‘overpayment’ amount in this audit,” and that because we did not apply an FFS Adjuster, “it is not possible for OIG to determine whether Cigna received an overpayment.”

Office of Inspector General Response

Our audit methodology correctly applied CMS requirements to properly identify the overpayment amount associated with the unvalidated HCCs for each sample item. Specifically, we used the results of the independent medical review contractor’s review to determine which HCCs were not validated and, in some instances, to identify HCCs that should have been used but were not used in the associated enrollees’ risk score calculations. We followed CMS’s risk adjustment program requirements to determine the payment that CMS should have made for each enrollee and to estimate overpayments. With respect to Cigna’s comment regarding actuarial equivalence in our overpayment calculations, we note that after we issued our draft report, CMS stated that it “will not apply an adjustment factor (known as an FFS Adjuster) in RADV audits.”³¹ In the context of CMS’s requirements and updated guidance, we recognize that CMS—not OIG—was responsible in 2012 and is responsible now for making operational and program payment determinations for the MA program.

Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General’s Audits Were Inconsistent With CMS Standards for Data Accuracy

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna stated that we “designed and conducted an audit that was inconsistent with RADV regulations and CMS standards for data accuracy.” According to Cigna, “[t]he perfection standard posited by [our report] reflects either a misunderstanding of CMS regulations or a rejection of the data standards set by CMS.” Specifically:

- Cigna stated that we misunderstood Federal regulations at 42 CFR § 422.504(l), “in taking the position that MA organizations ‘are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS.’” Cigna added that this regulation also states that when submitting data to CMS, an MA organization attests to the accuracy of those data according to its “best knowledge, information and belief.” In this context, Cigna said that CMS has stated that there is no requirement that MA organizations need to verify every diagnosis submitted by providers. Cigna also referred to a CMS comment that MA organizations “cannot reasonably be expected to know that every piece of data is correct.”³²

³¹ 88 Fed. Reg. 6643 (Feb. 1, 2023).

³² For this comment, Cigna cited 65 Fed. Reg. 40170, 40268 (Jun. 29, 2000).

- Additionally, Cigna commented that the “perfection standard reflected in [our report] also is inconsistent with the realities and limitations of attempting to perform a risk adjustment function.” Cigna elaborated on this position in several ways:
 - Cigna referred to the “inherently subjective” nature of diagnosis coding and stated that we did not take into account that “[a]lthough [Cigna] make[s] coding and documentation training available to . . . providers, [Cigna] ultimately cannot control their submissions.” Cigna also said that CMS generally “allows providers to use their best professional judgment.”
 - Cigna also alluded to various difficulties in obtaining medical records from providers. Cigna said that the 5 to 6 years between the encounters at issue and the audit, as well as the onset of COVID-19 during the audit and resulting staff shortages, made it difficult to obtain the necessary records from providers. Moreover, according to Cigna, this 5-to-6-year “gap creates a significant data validation issue for Cigna,” because of providers that are no longer in its network and various recordkeeping challenges.
 - Furthermore, Cigna stated that the “consolidation of hospital systems and large provider groups and the increasing number of providers who are publicly traded or private investor-backed has led to some large groups and health systems refusing to respond to records requests [from MA organizations] in a timely fashion, if at all.”

Office of Inspector General Response

We disagree with Cigna’s statement that we misunderstood regulations or rejected the data standards set by CMS. Specifically, we do not agree with Cigna’s interpretation of the Federal requirements at 42 CFR § 422.504(l). We 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.³³ We recognize as well that, as Cigna said, there is no CMS requirement that MA organizations verify every diagnosis submitted by providers. We also acknowledge that Cigna cannot “reasonably be expected to know that every piece of data is correct.”

However, our audit revealed a significant error rate (200 of 300 enrollee-years) with unsupported diagnosis codes (see Appendix D)) for the high-risk areas we audited. Federal regulations require MA organizations to implement procedures for “promptly responding to compliance issues as they are raised” and to “[correct] such problems promptly and thoroughly to reduce the potential for recurrence” (42 CFR § 422.503(b)(4)(vi)(G) (see Appendix E)). Accordingly, we believe that Cigna is responsible for addressing the issues that resulted in that significant error rate. Correcting these issues will also assist Cigna in attaining better assurance

³³ 79 Fed. Reg. 29844, 29926 (May 23, 2014).

with regard to the “accuracy, completeness and truthfulness” of the risk adjustment data that it submits in the future.

With respect to Cigna’s comment about the “inherently subjective” coding process, we designed our audit methodology (see Appendix A) to be as objective as possible—that is, to minimize the effects of any potential coding subjectivities on our overpayment calculations. Our independent medical review contractor followed a specific process when reviewing the medical records that Cigna gave to us, to determine whether the diagnosis codes that Cigna submitted to CMS for risk-adjustment purposes were supported. If the first reviewer (a senior coder) found that a diagnosis was not supported on the medical records, then a second senior coder (and sometimes a third reviewer, a physician) performed a separate review of the same medical records. Two reviewers needed to agree that the diagnosis was unsupported for it to be counted as an error and be included in our overpayment calculations.

Moreover, CMS’s RADV Submission Instructions, issued to MA organizations, recognizes that “there may be extraordinary circumstances that prevent an MA Organization . . . from submitting medical records for the audited enrollee(s) and CMS-HCC(s) in accordance with . . . audit requirements.”³⁴ However, CMS also notes in these instructions that “extraordinary circumstances do not typically include ordinary issues encountered during the process of requesting medical records and attestations from providers.” These ordinary issues include, but are not limited to, (1) difficulty in communicating with the provider, (2) provider difficulty in locating the record, and (3) delay caused by health information management system issues, including issues with third-party companies or vendors.

During our audit work, we worked with Cigna officials to extend (by several months) the medical record collection timeframe to account for the collection difficulties associated with the COVID-19 pandemic. Furthermore, Cigna did not convey to us during the audit that it was confronting any other extraordinary circumstances that prevented it from obtaining and providing to us medical records that would have supported the diagnosis codes submitted to CMS and validated the HCCs under review.

Cigna-HealthSpring Life & Health Insurance Company Did Not Agree With the Office of Inspector General’s Use of Extrapolation

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna disagreed with our use of extrapolation to calculate overpayments for the following reasons:

- Cigna did not agree with the fact that we used the lower limit of a two-sided 90-percent confidence interval to calculate the extrapolated repayment amount. Cigna noted that

³⁴ *Contract-Level Risk Adjustment Data Validation CMS Submission Instructions*, Sep. 7, 2016.

CMS follows the “statistically valid and more robust practice” of using the lower limit of a 95-percent or 99-percent confidence interval for its RADV audits.

- Cigna also stated that it “do[es] not believe that extrapolation has been authorized by Congress. . . . 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.” In addition, Cigna stated that “[e]ven if extrapolation were permitted, the methodology used would have to adhere to the final methodology established by CMS.”

Office of Inspector General Response

As stated above, for this final report our recommendation to refund overpayments is limited to the overpayments associated with the 200 sampled enrollee-years, rather than to an estimate (footnote 25). However, we believe that the results of our sampling, as well as our estimate of overpayments (Appendix D), provide a reasonable basis for our findings and conclusions—and support our recommendation that Cigna continue to examine its existing compliance procedures to identify areas where improvements can be made.

OIG is an independent oversight agency; therefore, 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 believe that the lower limit of a two-sided 90-percent confidence interval provides a reasonably conservative estimate of the total amount overpaid to Cigna for the enrollee-years and time period covered in our sampling frame. This approach, which is routinely used by HHS for recovery calculations,³⁵ results in a lower limit (the estimated overpayment amount) that is designed to be less than the actual overpayment total 95 percent of the time.

With respect to Cigna’s comments that we are not authorized to extrapolate, we note that neither Federal statute nor any other authority limits our ability to recommend a recovery to CMS based on extrapolation. Extrapolation has long been recognized as a permissible method of calculating overpayments in Medicare. Further, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in

³⁵ For example, HHS has used the two-sided 90-percent confidence interval when calculating recoveries in both the Administration for Child and Families and Medicaid programs. See e.g., *New York State Department of Social Services*, HHS Departmental Appeals Board (DAB) No. 1358, 13 (1992); *Arizona Health Care Cost Containment System*, DAB No. 2981, 4-5 (2019). In addition, HHS contractors rely on the one-sided 90-percent confidence interval, which is less conservative than the two-sided interval, for recoveries arising from 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).

Medicare and Medicaid.³⁶ The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.³⁷ We properly executed our statistical sampling methodology in that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. Thus, we did not revise the amount in our first recommendation based on Cigna’s comments; rather, we revised the amount in response to the updated regulations that CMS published after we issued our draft report.

CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL’S MEDICAL RECORD CODING REVIEW PROCESS

Cigna-HealthSpring Life & Health Insurance Company Did Not Agree With the Office of Inspector General’s Use of Medicare Administrative Contractors

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna disagreed with our use of a Medicare Administrative Contractor (MAC) to identify HCCs that were at a high risk for noncompliance. Cigna stated that our “sampling methodology was arbitrary and relied on a source [a MAC] that lacks sufficient MA experience,” and added that furthermore, “[n]o MAC is assigned to evaluate the MA risk adjustment system.” Cigna stated that we did not: explain why a MAC was consulted, disclose the MAC that was consulted, or indicate the qualifications and level of expertise of the MAC medical professionals whom we consulted. Cigna described these considerations as indicative of a “lack of transparency” that prevented it from being able to evaluate the standards to which it and its contracted providers were being held.

Office of Inspector General Response

Cigna’s assertions regarding our use of a MAC are not accurate. In order to accomplish our objective, we used a reasonable approach to identify diagnoses that were at higher risk for being miscoded. The MAC medical professionals whom we consulted advised us only on information that we had previously gathered from other sources, including information on some of the high-risk groups identified in this report. We did not ask the MAC professionals to

³⁶ 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).

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

provide opinions related to the MA risk adjustment process or to perform a coding review for the sampled enrollee-years; rather we relied only on our independent medical review contractor to perform the coding reviews. Thus, we do not believe that identifying the MAC would provide additional information that is relevant to our findings and recommendations.

Cigna-HealthSpring Life & Health Insurance Company Stated That Coding and Documentation Standards Used During the Audit Were Not Validly Established

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna stated that the “coding and documentation standards” applied during our audit were not validly established through the notice-and-comment rulemaking process that is required by the Administrative Procedure Act³⁸ and more broadly by Medicare statute.³⁹ Cigna argued that “[t]he Supreme Court has explained that this [notice and comment] obligation is broad and is likely to invalidate many policies found only in the Medicare manuals.” In addition, Cigna stated that “[a]s 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” (i.e., policies found only in Medicare manuals) to determine whether any overpayments occurred. For these reasons, Cigna stated that our “potential reliance on these standards is improper.”

Office of Inspector General Response

We disagree with Cigna’s assertion that our reliance on the Manual to differentiate between a valid risk adjustment payment and an overpayment was improper. We designed our audit to comply with Federal requirements. Specifically, our audit methodology required that our independent medical review contractor review medical records to determine whether the diagnosis codes that Cigna submitted to CMS for risk-adjustment purposes were supported. With regard to Cigna’s comment about *Azar v. Allina Health Services*, our reliance on the Manual does not constitute the creation of new payment rules. Rather, we have designed our audit to determine whether Cigna complied with Federal requirements.

Moreover, the Manual is legally binding on an MA organization, a fact that 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.⁴⁰ In addition, MA organizations that contract with CMS must agree to

³⁸ 5 U.S.C. § 553.

³⁹ 42 U.S.C. § 1395hh(a)(2) as acknowledged in *Azar v. Allina Health Services*, 139 S.Ct. 1804 (2019).

⁴⁰ 42 CFR §§ 422.504(l) and 422.310(d)(1).

follow CMS’s instructions, including the provisions of the Manual.⁴¹ Cigna 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-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General Did Not Provide Any Information Regarding the Independent Medical Review Contractor and the Coding Standards Used for This Audit

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna stated that it had concerns regarding our independent medical review contractor’s review and that the review methodology was “[n]eedlessly [o]paque.” With regard to these concerns, Cigna made several related points:

- Cigna stated that we should identify our independent medical review contractor so that Cigna can assess: (1) whether there is a conflict of interest, (2) the contractor’s credentials, coding policies, procedures, and training, (3) consistency between this audit and prior work, and (4) the results of each level of medical review as well as any inter-rater reliability (IRR) reviews.⁴²
- Cigna stated that we did not provide the coding or documentation standards used by the independent medical review contractor. In this context, Cigna referred to “inconsistencies and variations” in the ICD-9-CM and ICD-10-CM coding guidelines (footnote 1) and added that we should identify the specific coding and documentation standards used to evaluate the high-risk groups of diagnoses.
- Cigna cited our report’s discussion of multiple levels of reviews performed by our independent medical review contractor, and stated that Cigna received only the final medical review determinations. Cigna added that “the subjective nature of coding determinations” made it important for Cigna to be able to evaluate the results of each level of review.
- In addition, Cigna stated that it believed “that OIG’s contractor went beyond assessing coding and questioned the clinical validity of providers’ diagnostic statements . . . [because] the audit methodology indicate[d] that a physician was required to serve as a tie-breaker when at least one coder already determined a code to be supported.”

⁴¹ 42 CFR § 422.504(a).

⁴² IRR reviews verify the accuracy of medical record decisions and identify the consistency of decisions between two reviewers.

Office of Inspector General Response

We do not agree with Cigna's comments that we should provide additional information about the independent medical review contractor and results of each level of the contractor's reviews. Specifically:

- It is not our practice to name our independent medical review contractor. However, our audit process includes measures to ensure that there are no conflicts of interest among the parties involved in the audit. The name of the independent medical review 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 that our medical reviews were performed by professional coders credentialed by the American Health Information Management Association (AHIMA) and the American Academy of Professional Coders (AAPC).⁴³ These coders were experienced in coding ICD-9-CM and ICD-10-CM diagnosis codes for hospital inpatient, outpatient, and physician medical records.

The independent medical review contractor's quality review process included IRR reviews along with additional supervisory review of case determinations. The quality review process identified and made corrections, if needed. We do not believe that providing the results of those internal IRR reviews would provide additional information, as the results of the quality review process are reflected in the coding determinations that serve as the bases for our findings.

- Our independent medical review contractor used the following coding and documentation standards: (1) the CMS-published Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance,⁴⁴ (2) 2011 ICD-9-CM Official Guidelines for Coding and Reporting,⁴⁵ (3) 2015 ICD-10-CM Official Guidelines for Coding and

⁴³ 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 Adjustment 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. This information also appears in a footnote in Appendix A of both our draft and final reports.

⁴⁴ 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 Nov. 18, 2022.

⁴⁵ *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. Accessed on Nov. 18, 2022.

Reporting,⁴⁶ (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.⁴⁷ We provided Cigna information regarding the coding guidelines and guidance during the course of our audit.

- As explained in our audit methodology (Appendix A), the coding review followed a specific process to determine whether there was support for a diagnosis code and the associated HCC. At the conclusion of this process, we used only the final coding review determination for each sampled enrollee-year to calculate overpayments or underpayments (if any). We provided Cigna the final coding review determinations for each sampled enrollee-year.
- The independent medical review contractor used both skilled coders and physicians (when necessary) to review medical record documentation in accordance with the relevant CMS guidance,⁴⁸ which states, “**reviewers** should evaluate all listed conditions for consistency within the full provider documentation” (emphasis added). The coders and physicians did not make clinical judgments, but rather applied coding rules to accurately assign applicable ICD codes that translated to HCCs. Physician input was not an assessment of clinical support; rather, it constituted an assessment of documented evidence in support of the assignment of diagnosis codes. We believe that the use of a physician to serve as the final decision maker (i.e., tiebreaker), was a reasonable method for determining whether the medical records adequately supported the reported diagnosis codes.

Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General Used an Arbitrary Date Range That Prohibited Cigna From Submitting Documentation That Would Substantiate a Diagnosis

Cigna stated that our “narrowly defined documentation requirements conflicted” with our sampling methodology. Specifically, Cigna stated that we developed “parameters for when a diagnosis would be considered a high risk of noncompliance” but prohibited Cigna from submitting documentation from the same time periods as were contained within those parameters. Cigna also stated that because of this conflict, “records that would substantiate a diagnosis were not accept[ed] if outside of the narrow time frame of the audit.” Cigna offered

⁴⁶ *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 Nov. 18, 2022.

⁴⁷ The “PCS” acronym in the ICD-10-PCS refers to the Procedure Coding System, which is a medical classification coding system that tracks various health interventions taken by medical professionals. See also footnote 1.

⁴⁸ CMS, Contract-Level Risk Adjustment Data Validation, Medical Record Reviewer Guidance, for reviews 3/20/2019. 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/Medical-Record-Reviewer-Guidance.pdf>. Accessed on Nov. 18, 2022.

examples of cases in which enrollees received diagnoses near the end of one calendar year and treatments or prescriptions the following calendar year. Cigna argued that “[t]his disregard of documentation and support for a diagnosis code based on an arbitrary date range . . . ignores the fact that for MA [enrollees] and their plan providers, the end of a calendar year does not change how providers deliver care.”

Office of Inspector General Response

Cigna incorrectly linked the methodology we used to develop the sampling frame with CMS’s medical record documentation requirements. As explained in Appendix C, our sampling methodology identified specific diagnoses that occurred only once during the service year along with other information that we took into consideration. Although the dates associated with this other information may have spanned consecutive calendar years, they helped us determine whether the identified diagnoses were at high risk for being miscoded. Thus, our sampling methodology has no correlation to CMS’s medical record documentation requirements.

With respect to the medical record documentation, CMS uses the diagnosis codes that the enrollee received for one calendar year (known as the service year) to determine HCCs and calculate risk scores for the following calendar year (known as the payment year). Accordingly, the medical record documentation that we considered for each enrollee-year involved only the service year associated with the scope of the audit (service years 2015 and 2016).

Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General Used Problematic Standards To Determine the Validity of Diagnoses

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna stated that OIG used “problematic and arbitrary” standards “to supplant its medical knowledge years later for that of . . . treating providers.” Cigna added that it knows of “no CMS guidance suggesting that the health status of [an enrollee] . . . is disproved solely by whether a provider prescribes a certain course of treatment or whether [an enrollee] elects to follow through with such treatment.” As an example, Cigna cited a sampled enrollee-year in which the individual had been diagnosed with prostate cancer and who had elected to undergo “watchful waiting with monitoring of his PSA levels.”⁴⁹ Cigna stated that “[i]dentifying such a diagnosis as unsupported was clinically inaccurate . . . and this finding results in OIG and its MAC consultant supplanting the member’s personal choices with their own.”

In addition, Cigna stated that we “ignored information regarding [enrollees] seeking care outside of the Medicare program.” For example, Cigna cited a sampled enrollee-year in which the individual “was diagnosed with and treated for prostate cancer in 2006, and continued to

⁴⁹ “Watchful waiting” involves closely watching a patient’s condition but not giving treatment unless symptoms appear or change.

be prescribed Lupron for his prostate cancer in 2016.”⁵⁰ In addition, the enrollee was obtaining followup care through the Department of Veterans Affairs (VA). Because this individual filled the prescription using a means other than the Cigna MA plan and “was obtaining oncology follow-up care through the VA, OIG invalidated the diagnosis.”

Office of Inspector General Response

We disagree with Cigna’s characterizations of the standards used during the medical review process. We used a reasonable approach to identify diagnoses that were at higher risk for being miscoded. This approach involved, among other things, discussions with medical professionals regarding the treatment of certain conditions; and used that information to identify enrollee-years with high-risk diagnosis codes. This sampling methodology has no correlation to the CMS medical record documentation requirements that our independent medical review contractor used to determine whether or not the diagnoses were supported.

For this audit, our objective was to determine whether selected high-risk diagnosis codes that Cigna submitted to CMS for use in CMS’s risk adjustment program complied with Federal requirements. For each of the sampled enrollee-years, we asked Cigna to provide up to five medical records of its choosing to support the reviewed HCC. We asked our independent medical review contractor to review all the medical records that Cigna provided to determine whether the information documented in the medical records supported any diagnoses that mapped to the reviewed HCC. During its review, the independent medical review contractor did not make clinical judgments, but rather used applicable coding and documentation standards to accurately assign the appropriate diagnosis codes that translate to HCCs.

With respect to Cigna’s example of the individual who had been diagnosed and treated for prostate cancer through the VA, the associated enrollee-year is one for which we reviewed the additional explanations provided by Cigna for this final report. Specifically, our independent medical review contractor reviewed the additional information that Cigna provided and determined that there was no documentation that the individual was being actively treated for prostate cancer, stating that “the patient had a radical prostatectomy in the past. There is no evidence of active cancer.”⁵¹

More generally, our audit does not supplant provider decision making or enrollee choice. We acknowledge that providers have choices in prescribing courses of treatment, and that enrollees also have choices regarding treatment, some of which are outside of the Medicare program. Nevertheless, Medicare requirements are clear that in order for a diagnosis code that has been submitted to CMS to be appropriately included in the calculation of the risk score, the diagnosis needs to be documented in, and supported by, an acceptable medical record.

⁵⁰ Lupron is a type of hormone therapy that doctors typically use in combination with other treatments to treat people with prostate cancer.

⁵¹ In a radical prostatectomy operation, the surgeon removes the entire prostate gland as well as some of the tissue around it.

CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY DID NOT CONCUR WITH THE OFFICE OF INSPECTOR GENERAL’S RECOMMENDATION TO PERFORM ADDITIONAL REVIEWS BEFORE OR AFTER THE AUDIT PERIOD

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna did not concur with our second recommendation—that it perform additional reviews to determine whether similar instances of high-risk diagnoses occurred before or after the audit period. According to Cigna, “MA regulations do not require the sort of audits that OIG recommends and do not require data perfection.” Cigna also stated that this recommendation holds MA organizations to standards that are “unknown, vague, and nonexistent.” Further, Cigna stated that if it “undertook an audit similar to OIG’s, it could not result in ‘risk adjustment payment integrity and accuracy’” because “a payment audit designed to target errors without considering and recognizing diagnoses that are supported but not previously submitted, does not ensure payment accuracy and is improper.”

Office of Inspector General Response

We do not agree with Cigna’s interpretation of the Federal requirements. Contrary to Cigna’s assertions, we maintain that our recommendation that Cigna review whether similar instances of high-risk diagnoses occurred before or after our audit period remains valid and conforms to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (Appendix E)).

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

With respect to Cigna’s comments stating that audits like ours do not result in payment accuracy, we note that our findings are not indicative of the overall accuracy of diagnosis codes that Cigna submitted to CMS. We limited our audit and recommendations to certain diagnosis codes that we determined to be at high risk for being miscoded. We believe that the error rate identified in our audit (200 of 300 enrollee-years (see Appendix D)) demonstrates that Cigna has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope. Accordingly, we maintain the validity of our recommendation that Cigna

identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period.

CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY DID NOT CONCUR WITH THE OFFICE OF INSPECTOR GENERAL’S RECOMMENDATION THAT IT ENHANCE ITS EXISTING COMPLIANCE PROCEDURES

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna did not concur with our third recommendation—that it continue to examine its existing compliance procedures for diagnoses that are at high risk for being miscoded and enhance those procedures as necessary. Specifically, Cigna stated that it “has a strong and effective compliance program that is designed to comply with all relevant legal and regulatory requirements,” and that it had made numerous changes to its compliance program since 2015 and 2016. In addition, Cigna said that it has “put forth significant effort to educate providers regarding the appropriate use of some of the specific codes targeted by OIG in this audit.” Further, Cigna noted that in 2021, it underwent a CMS program audit that had no findings related to Cigna’s compliance program. Cigna also cited a recent OIG contract-level RADV audit (of another contract) that described Cigna’s policies and procedures as generally effective.⁵²

Cigna also stated that we made “potentially misleading statements” with regard to the Federal regulations that MA organizations are required to follow regarding compliance programs. Cigna said that it believed that we have “expanded [CMS’s] MA compliance program requirements” because we did not take into consideration that CMS gives MA organizations “broad discretion to design their own compliance and risk adjustment data accuracy programs,” and that MA organizations “are not held to a standard of guaranteeing the accuracy of the risk adjustment data that [are] submitted.”

Finally, Cigna stated that “[t]he fact that OIG identified supposedly unsupported diagnoses . . . does not indicate that Cigna’s compliance program is ineffective, particularly when measured by MA program guidance.”

Office of Inspector General Response

Cigna’s response implied that we opined on the effectiveness of its entire compliance program. That was not our intention or our focus for this audit. Rather, we limited our audit to selected diagnoses that we determined to be at high risk for being miscoded. Our audit revealed a significant error rate for some of these high-risk groups. Although a prior CMS program audit did not result in any findings, and although the OIG contract-level RADV audit—which had a different objective than this audit—found Cigna’s policies and procedures to be

⁵² *Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS.* Available online at <https://oig.hhs.gov/oas/reports/region3/31800002.pdf>. Accessed on Nov. 18, 2022. See also Appendix B of this report.

generally effective, we continue to believe that Cigna should enhance its compliance procedures with respect to these high-risk groups of diagnoses.

Moreover, although we acknowledge that CMS gives discretion to MA organizations when designing a compliance plan, Federal regulations also require MA organizations to implement procedures for “promptly responding to compliance issues as they are raised” and to “[correct] such problems promptly and thoroughly to reduce the potential for recurrence” (42 CFR § 422.503(b)(4)(vi)(G)). The continued improvement of Cigna’s existing procedures and internal data quality reviews (based on the results of this audit) will assist Cigna in attaining better assurance with regard to the “accuracy, completeness and truthfulness” of the risk adjustment data that it submits in the future. Accordingly, we maintain that our third recommendation is valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid Cigna \$2,140,237,283 to provide coverage to its enrollees for 2016 and 2017. We identified a sampling frame of 8,667 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2015 and 2016 service years. Cigna received \$134,347,953 in payments from CMS for these enrollee-years for 2016 and 2017. We selected for audit 300 enrollee-years with payments totaling \$4,939,748.

The 300 enrollee-years included 30 acute stroke diagnoses, 30 acute heart attack diagnoses, 60 major depressive disorder diagnoses, 30 embolism diagnoses, 30 vascular claudication diagnoses, 30 lung cancer diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, and 30 prostate cancer diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$720,395 for our sample.

Our audit objective did not require an understanding or assessment of Cigna'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 August 2019 through April 2022.

METHODOLOGY

To accomplish our objective, we performed the following steps:

- We reviewed applicable Federal laws, regulations, and guidance.
- We discussed with CMS program officials the Federal requirements that MA organizations should follow when submitting diagnosis codes to CMS.
- We identified, through data mining and discussions with medical professionals at a MAC, diagnosis codes and HCCs that were at high risk for noncompliance. We also identified the diagnosis codes that potentially should have been used for cases in which the high-risk diagnoses were miscoded.
- We consolidated the high-risk diagnosis codes into specific groups, which included:
 - 74 diagnosis codes for acute stroke,
 - 38 diagnosis codes for acute heart attack,
 - 29 diagnosis codes for major depressive disorder,
 - 85 diagnosis codes for embolism,
 - 4 diagnosis codes for vascular claudication,
 - 24 diagnosis codes for lung cancer,

- 65 diagnosis codes for breast cancer
 - 20 diagnosis codes for colon cancer, and
 - 2 diagnosis codes for prostate cancer.
- We used CMS’s systems to identify the enrollee-years on whose behalf providers documented the high-risk diagnosis codes. Specifically, we used extracts from CMS’s:
 - Risk Adjustment Processing System (RAPS)⁵³ to identify enrollees who received high-risk diagnosis codes from a physician during the service years,
 - Risk Adjustment System (RAS)⁵⁴ to identify enrollees who received an HCC for the high-risk diagnosis codes,
 - Medicare Advantage Prescription Drug System (MARx)⁵⁵ to identify enrollees for whom CMS made monthly Medicare payments to Cigna, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C),
 - Encounter Data System (EDS)⁵⁶ to identify enrollees who received specific procedures, and
 - Prescription Drug Event (PDE) file⁵⁷ to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.
 - We interviewed Cigna officials to gain an understanding of: (1) the policies and procedures that Cigna followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Cigna’s monitoring of those diagnosis codes to identify and detect noncompliance with Federal requirements.
 - We selected for audit a stratified random sample of 300 enrollee-years (Appendix C).

⁵³ MA organizations use the RAPS to submit diagnosis codes to CMS.

⁵⁴ The RAS identifies the HCCs that CMS factors into each enrollee’s risk score calculation.

⁵⁵ The MARx identifies the payments made to MA organizations.

⁵⁶ The EDS contains information on each item (including procedures) and service provided to enrollees.

⁵⁷ The PDE file contains claims with prescription drugs that have been dispensed to enrollees through the Medicare Part D (prescription drug coverage) program.

- We used an independent medical review contractor to perform a coding review for the 300 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.⁵⁸
- The independent medical review contractor’s coding review followed a specific process to determine whether there was support for a diagnosis code and the associated HCC:
 - If the first senior coder found support for the diagnosis code on the medical record, the HCC was considered validated.
 - If the first senior coder did not find support on the medical record, a second senior coder performed a separate review of the same medical record:
 - If the second senior coder also did not find support, the HCC was considered to be not validated.
 - If the second senior coder found support, then a physician independently reviewed the medical record to make the final determination.
 - If either the first or second senior coder asked a physician for assistance, the physician’s decision became the final determination.
- We used the results of the independent medical review contractor to calculate overpayments or underpayments (if any) for each enrollee-year. Specifically, we calculated:
 - a revised risk score in accordance with CMS’s risk adjustment program and
 - the payment that CMS should have made for each enrollee-year.
- We estimated the total overpayment made to Cigna during the audit period.

⁵⁸ 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 Adjustment 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.

- We limited the total overpayment that we recommended for recovery to the sampled enrollee-years.⁵⁹
- We discussed the results of our audit with Cigna officials on February 28, 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.

⁵⁹ Federal regulations at 42 CFR § 422.311 state: “the Secretary annually conducts RADV audits to ensure risk-adjusted payment integrity and accuracy.” Recovery of improper payments from MA organizations will be conducted in accordance with the Secretary’s payment error extrapolation and recovery methodologies. CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years. 88 Fed. Reg. 6643, 6655 (Feb. 1, 2023).

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring of Tennessee, Inc. (Contract H4454) Submitted to CMS</i>	<u>A-07-19-01193</u>	12/22/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BCBS of Rhode Island (Contract H4152) Submitted to CMS</i>	<u>A-01-20-00500</u>	11/16/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That California Physicians' Service, Inc. (Contract H0504) Submitted to CMS</i>	<u>A-09-19-03001</u>	11/10/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract R5826) Submitted to CMS</i>	<u>A-05-19-00039</u>	9/30/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (H3916) Submitted to CMS</i>	<u>A-03-19-00001</u>	9/29/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS</i>	<u>A-07-19-01195</u>	9/29/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Inter Valley Health Plan, Inc. (Contract H0545), Submitted to CMS</i>	<u>A-05-18-00020</u>	9/26/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS</i>	<u>A-09-20-03009</u>	9/13/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc., (Contract H1032) Submitted to CMS</i>	<u>A-04-19-07084</u>	8/29/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS</i>	<u>A-03-18-00002</u>	8/19/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS</i>	<u>A-02-20-01009</u>	7/18/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health (Contract H1961) Submitted to CMS</i>	<u>A-06-18-05002</u>	5/25/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS</i>	<u>A-01-19-00500</u>	2/14/2022

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

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified Cigna enrollees who: (1) were continuously enrolled in Cigna throughout all of the 2015 or 2016 service year and January of the following year, (2) were not classified as being enrolled in hospice or as having end-stage renal disease status at any time during 2015 or 2016 or in January of the following year, and (3) received a high-risk diagnosis during 2015 or 2016 that caused an increased payment to Cigna for 2016 or 2017, respectively.

We presented the data for these enrollees to Cigna for verification and performed an analysis of the data included on CMS's systems to ensure that the high-risk diagnosis codes increased CMS's payments to Cigna. After we performed these steps, our finalized sampling frame consisted of 8,667 enrollee-years.

SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2016 or 2017.

SAMPLE DESIGN AND SAMPLE SIZE

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

- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on only one physician claim during the service year but did not have that diagnosis on a corresponding inpatient or outpatient hospital claim (1,399 enrollee-years);
- a diagnosis (that mapped to an Acute Heart Attack HCC) on only one physician or outpatient claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician or outpatient claim (609 enrollee-years);
- a major depressive disorder diagnosis (that mapped to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) on only one claim during the service year but did not have an antidepressant medication dispensed on his or her behalf (4,869 enrollee-years);
- a diagnosis (that mapped to an Embolism HCC) on only one claim during the service year but did not have an anticoagulant medication dispensed on his or her behalf (256 enrollee-years);

- a diagnosis related to vascular claudication (that mapped to the HCC for Vascular Disease) on only one claim during the service year (a diagnosis that had not been documented during the 2 years that preceded the service year), but had medication for neurogenic claudication dispensed on his or her behalf (442 enrollee-years);
- a lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the lung cancer diagnosis administered within a 6-month period before or after the diagnosis (119 enrollee-years);
- a breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the breast cancer diagnosis administered within a 6-month period before or after the diagnosis (448 enrollee-years);
- a colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (243 enrollee-years); or
- a prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors), for an individual 74 years old or younger, on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (282 enrollee-years).

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

Table 3: Sample Design for Audited High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee-Years	CMS Payment for HCCs in Audited High-Risk Groups	Sample Size
1 – Acute stroke	1,399	\$2,853,179	30
2 – Acute heart attack	609	1,121,163	30
3 – Major depressive disorder	4,869	11,853,541	60
4 – Embolism	256	638,640	30
5 – Vascular claudication	442	903,526	30
6 – Lung cancer	119	759,024	30
7 – Breast cancer	448	515,140	30
8 – Colon cancer	243	563,755	30
9 – Prostate cancer	282	329,439	30
Total	8,667	\$19,537,407	300

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We sorted the items in each stratum by beneficiary identification number and then consecutively numbered the items in each stratum in the stratified sampling frame. After generating 300 random numbers according to our sample design, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

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

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Details and Results

Audited High-Risk Groups	Frame Size	CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With Unvalidated HCCs	Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)
1 – Acute stroke	1,399	\$2,853,179	30	\$66,086	29	\$62,466
2 – Acute heart attack	609	1,121,163	30	51,144	29	41,309
3 – Major depressive disorder	4,869	11,853,541	60	143,843	3	7,247
4 – Embolism	256	638,640	30	71,322	22	51,125
5 – Vascular claudication	442	903,526	30	59,197	7	12,872
6 – Lung cancer	119	759,024	30	190,116	28	169,930
7 – Breast cancer	448	515,140	30	33,276	28	31,104
8 – Colon cancer	243	563,755	30	64,177	28	56,923
9 – Prostate cancer	282	329,439	30	41,234	26	35,396
Total	8,667	\$19,537,407	300	\$720,395	200	\$468,372

**Table 5: Estimated Overpayments in the Sampling Frame
(Limits Calculated for a 90-Percent Confidence Interval)**

Point Estimate	\$6,897,950
Lower Limit	\$6,247,399
Upper Limit	\$7,548,502

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

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

Any entity seeking to contract as an MA organization must

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

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

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

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

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

(3) Implement the operation of the compliance program;

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

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

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

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

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

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

- (G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.
- (1) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.
 - (2) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.
 - (3) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.



July 11, 2022

Thomas A. Young
Managing Director
Medicare Compliance Officer
Cigna Medicare

500 Great Circle Road
Nashville, Tennessee 37228
Email: Thomas.Young@healthspring.com

U.S. Department of Health & Human Services
Office of Inspector General
Office of Audit Services, Region VII
Attn: James Korn
Regional Inspector General for Audit Services
601 East 12th Street, Room 0429
Kansas City, MO 64106

Re: Response to Draft Report Number: A-07-19-01192

Cigna HealthSpring Life & Health Insurance Company, 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 Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Cigna (contract H4513) Submitted to CMS.^{1/} Through contract H4513, Cigna provides healthcare and prescription drug benefits to more than 115,000 Medicare Advantage (“MA”) beneficiaries in Texas.

We are a committed partner to OIG, the Centers for Medicare & Medicaid Services (“CMS”), and the MA program. We believe the MA program serves Medicare beneficiaries so well because of the partnership between CMS and MA organizations (“MAOs”) like Cigna. In the spirit of that partnership, we previously 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 program.

We believe that the basic premise of OIG’s audit is inconsistent with risk adjustment data validation regulations and CMS standards for data accuracy. OIG’s sampling methodology targeted diagnoses that were already suspected to not be supported and did not include looking for unreported, unrelated diagnoses. OIG ignored the fact that there may be supported diagnoses not submitted to CMS.

^{1/} OIG, DRAFT – Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Cigna-HealthSpring Life & Health Insurance Company, Inc. (Contract H4513) Submitted to CMS, A-07-19-01192 (April 2022) (“Draft Report”).

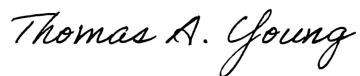
As a result, OIG's audit was skewed toward identifying "overpayments" and was not an unbiased audit seeking to promote payment integrity and accuracy.

We believe these issues affected the audit results. In particular, we do not believe the audit results reflect the strength of Cigna's compliance activities. Cigna has a strong and effective compliance program that is designed to comply with all relevant legal and regulatory requirements. Cigna's current compliance program recently received positive feedback from both CMS and OIG. In Cigna's contract-level RADV audit of H5410 in 2021, OIG 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." Also in 2021, Cigna underwent a CMS Program Audit and there were no findings related to the effectiveness of Cigna's compliance program.

As we describe in detail below, Cigna requests that OIG revise its Draft Report and withdraw its 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 Draft Report to discuss our feedback and how it might be incorporated into the Final Report.

Thank you for your consideration.

Sincerely,



Thomas A. Young
Medicare Compliance Officer

CC: Aparna Abburi, President, Medicare and Care Allies
Erin Wessling, Chief Counsel

Attachments

EXECUTIVE SUMMARY

Cigna appreciates the opportunity to respond to the Draft Report provided by OIG. Through contract H4513, Cigna provides healthcare and prescription drug benefits to more than 115,000 MA beneficiaries in Texas.

We believe that the basic premise of OIG’s audit is inconsistent with risk adjustment data validation (“RADV”) regulations and CMS standards for data accuracy and that the audit methodology was flawed. These issues affected the audit results.

- OIG’s audit was skewed toward identifying “overpayments” and was not an unbiased audit seeking to ensure payment integrity and accuracy.
- OIG’s sampling methodology targeted diagnoses that were already suspected to not be supported and the review did not include looking for unreported, unrelated diagnoses. This type of biased review cannot produce a comprehensive picture of accuracy because it deliberately ignores the fact that there may be supported diagnoses not submitted to CMS.
- The audit methodology shared with us does not discuss how OIG and its contractor identified or evaluated potential underpayments. In general, the overall intent of MAO payment audits is to determine whether the MAO has been accurately paid. However, targeting nine specific diagnoses to the exclusion of anything that had previously not been submitted, artificially inflates the proposed “overpayment.” OIG should have considered the previously unreported diagnosis codes when considering and calculating its proposed “overpayment.”
- The flaws in OIG’s audit methodology are evidenced by the fact that no MAO has performed well during any of the audits targeting high-risk diagnoses. Even MAOs like Cigna, that have had very high accuracy ratings in contract-level RADVs, have scored much lower because of many flaws in the methodology. In fact, OIG shared that Cigna’s performance is in the “upper echelon” of MAOs under review in this audit series.
- We believe that 6 of the sampled enrollee-years that OIG and its contractor did not validate should have been validated under the applicable statutes, regulations, and CMS guidance. Our review also indicates that OIG and its contractor did not capture 19 previously unreported diagnoses that accurately reflect our enrollees’ health status.
- OIG determined whether a diagnosis was at high-risk for noncompliance and was valid based on what a provider decided to recommend to a member, whether a member decided to seek recommended treatment within an OIG-defined period of time, and where or how a member sought treatment. This is inherently problematic and arbitrary. By applying these arbitrary standards of medical practice and “health status,” OIG supplants its medical knowledge for that of members’ treating providers and in turn applies arbitrary payment standards to Cigna.
- OIG’s narrowly defined documentation timing standards conflicted with its sampling methodology. Specifically, OIG included members’ diagnoses in its sample based on whether a provider recommended and a member followed up with treatment within an OIG-defined period of time. But, when OIG’s defined period of time for treatment (for example, 6 months after a cancer diagnosis) fell outside of the audit time (2015 and 2016 dates of service), OIG refused to

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

consider documentation outside of the audit time, even if the records were from a patient visit two or three days removed from when the original diagnosis was reached. By rigidly adhering to an artificially limited time period, and refusing to consider records from subsequent visits based solely on how the calendar fell, OIG improperly limited Cigna's ability to offer substantiating proof.

- OIG's extrapolation of potential overpayments is not appropriate or authorized by Congress.

In addition to these flaws in the OIG's audit methodology, Cigna does not agree with OIG's recommendation to conduct additional audits related to the high-risk diagnoses and Cigna does not agree with OIG's recommendation that Cigna examine existing compliance procedures.

For these reasons, discussed in greater detail below, we respectfully request OIG recalculate its estimated overpayment amount to account for these errors and withdraw its recommendations for extrapolation, additional auditing, and compliance program review.

I. Cigna Does Not Concur with OIG's Findings Because the Audit Design and Intent is Inconsistent with RADV Regulations and Standards for Data Accuracy.

We respectfully request that OIG withdraw its findings given that its overall audit design and intent are inconsistent with risk adjustment data validation regulations and CMS standards for data accuracy. Specifically, (a) OIG's audit does not ensure payment accuracy; (b) OIG's sampling and review methodology was improperly skewed toward identifying "overpayments"; (c) OIG ignores the long-standing principle that MAOs are not required to have perfect data; and (d) OIG fails to recognize that perfection in risk adjustment data is not possible.

a. OIG's Audit Does Not Ensure Payment Accuracy

MA regulations at 42 C.F.R. §§ 422.2 and 422.311(a) establish that a payment audit of an MAO conducted by the Secretary of HHS ensures the integrity and accuracy of risk adjustment payment data. Over the last fifteen years, CMS has developed and proposed multiple audit and sampling methodologies and has undergone multiple rounds of industry engagement, in an attempt to establish a sampling methodology that ensures payment integrity and accuracy. However, OIG's audit was not designed to ensure risk adjustment payment integrity and accuracy.

OIG's audit methodology was so targeted that it could not equally identify overpayments and underpayments. In particular, the sample frame targeted nine specific diagnosis categories that OIG hypothesized, prior to conducting the audit, are likely to be at high risk for noncompliance based on medical claims data and prescription drug claims data, and therefore likely to have resulted in an "overpayment." This biased targeting resulted in findings that do not ensure accuracy because the audit was not designed to look at payment accuracy, which would include both overpayments and underpayments. OIG neither (1) simultaneously conducted an audit of members for which Cigna was most likely underpaid (i.e., members with no or few submitted HCCs), nor (2) allowed Cigna to demonstrate support for and receive credit for diagnosis codes that had not previously been submitted to CMS for the audited members that were unrelated to the target diagnosis codes ("net new").

These issues affected the audit results. In our view, the issues indicate 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. And, as discussed in more detail below, this reinforces our concern that the proposed overpayment figure used by OIG cannot be an adequate basis for a valid extrapolation.

The flaws in OIG's targeted audit methodology are evidenced by the fact that no MAO has performed well during any of the audits targeting high-risk diagnoses. Even MAOs like Cigna, which recently completed a contract-level RADV audit of H5410 that resulted in a 97% payment accuracy rate finding, are scoring much lower because of the flawed audit methodology. In fact, OIG shared that Cigna's performance is in the "upper echelon" of MAOs under review in this audit series. Further, it indicates that if OIG's targeted audit was designed for payment accuracy, as required by 42 C.F.R. § 422.311(a), then the findings would be different and would be a much more accurate reflection of the MAO's risk adjustment data validation.

Finally, the timing of the audit also makes payment accuracy unachievable as a practical matter. This audit covered dates of service in 2015 and 2016. The five and six year gap between the encounters at issue and the audit creates a significant data validation issue for Cigna. 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 OIG to assess payment accuracy via a RADV-styled audit of targeted high-risk diagnoses.

b. *OIG's Sampling and Review Methodology was Improperly Skewed Towards Identifying "Overpayments"*

i. **Sampling Methodology**

OIG's sampling methodology targeted diagnoses that were already suspected to not be supported and as a result, OIG's audit was not an unbiased audit seeking to promote payment integrity and accuracy. OIG's audit was first biased towards overpayment by creating a universe of members who had only certain diagnoses, then OIG and a Medicare Administrative Contractor ("MAC") (as discussed below) limited that universe to instances where such diagnoses did not have evidence of Medicare-reimbursed follow-up care which the OIG determined to be an indication that the diagnosis was at high-risk of noncompliance, and then identified a sample from that limited universe. OIG only focused on samples that it viewed to be high-risk diagnoses so that it could only identify a potential overpayment. OIG did not simultaneously create a sample of members for whom it would seek to identify under-reported diagnoses or underpayments. As a result, OIG skewed any potential findings to only identify overpayments and exclude all other diagnoses.

Further, OIG's development of its sampling methodology was arbitrary and relied on a source that lacks sufficient MA experience. OIG relied on medical professionals from a MAC to identify HCCs that were at a high risk for noncompliance.^{2/} As CMS describes, "a MAC is private health care insurer that

encounter data. [/] MACs do not process MA claims or

MACs are assigned to CMS-established jurisdictions, and there are currently 12 MACs that focus on Parts A and B FFS claims. No MAC is assigned to evaluate the MA risk adjustment system. OIG did not explain why it consulted a MAC, disclose the MAC it consulted, indicate whether the MAC it consulted had expertise to assist OIG in determining which diagnoses submitted by an MA plan may be "high risk for noncompliance," or disclose the type of or qualifications of medical professionals employed by the MAC that OIG relied upon. This lack of transparency results in Cigna being unable to evaluate how the standards it, and its contracted treating providers, are being held to, were developed or the qualifications of the entity developing such standards. Further, given that MACs have expertise in identifying potential errors in FFS data, OIG's reliance on a MAC and its recognition of a MAC's familiarity with FFS errors further

^{2/} See Draft Report, Appendix A: Audit Scope and Methodology, page 19.

^{3/} See CMS, "What's a MAC?" at [https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC#:~:text=A%20Medicare%20Administrative%20Contractor%20\(MAC,%2DService%20\(FFS\)%20beneficiaries.](https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC#:~:text=A%20Medicare%20Administrative%20Contractor%20(MAC,%2DService%20(FFS)%20beneficiaries.)

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

underscores the need for a FFS Adjuster. But as discussed below in *Section II.e*, OIG did not apply a FFS Adjuster to any of its findings.

In addition, OIG's sampling methodology arbitrarily used the lack of Medicare prescription drug data or a member's decision to not seek follow up care that was evidenced in Medicare data within an OIG-invented timeframe to flag diagnoses as being at high risk for noncompliance. By developing and applying this sampling methodology, OIG was replacing its clinical expertise for that of members' treating providers. Further, OIG's reliance on the lack of Medicare prescription drug data to flag and potentially invalidate a provider-reported diagnosis stands in stark contrast to MA risk adjustment rules, which do not recognize pharmacies and prescription drug data as acceptable sources for risk adjustment data.

ii. Review Methodology

OIG's review of medical records was also skewed to only identify overpayments. Once OIG identified the sample of members that it considered to have the targeted high-risk diagnoses, OIG's reviewers only reviewed the limited acceptable medical records for such members for evidence of the targeted high-risk diagnosis or a related diagnosis. OIG ignored the fact that for each identified member, there may be supported diagnoses not previously submitted to CMS (i.e., "underpayments"), creating additional bias toward identifying "overpayments." As OIG is aware, an MAO cannot reopen payment years to add diagnoses that it determines were not previously reported. The payment years subject to this audit were closed multiple years ago. By OIG limiting its review to only instances of potential "overpayments," OIG knew that Cigna would be unable, on its own, to demonstrate that it was not in fact "overpaid" because Cigna is not able to submit diagnoses identified in 2021 as support for dates of services in 2015 and 2016. The only way for Cigna to be credited for such previously unreported codes, and for this audit to ensure payment accuracy, is for OIG to take such diagnoses into account.

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 requires that plans only be responsible for the accuracy of the coding of the diagnosis as provided by a practitioner.^{4/} 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 statement, as documented.^{5/} For that reason, CMS has not permitted the certified coders conducting its medical record reviews to attempt to assess the clinical validity of diagnoses.^{6/} 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 was required to serve as a tie-breaker when at least one coder already determined a code to be supported. The fact that a practitioner submitted the code to the MAO

^{4/} 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.

^{5/} 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.")

^{6/} 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.")

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

and at least one coder found it to be supported should not require a physician tie-breaker unless that physician was questioning the clinical validity of the provider's diagnostic statements.^{7/}

Further, in direct conflict with the Coding Guidelines and the Coding Clinic, as discussed in *Section II.c.v*, OIG's review methodology was specifically designed to question a provider's diagnostic statement, as documented, because OIG's methodology was clinically targeted to determine whether a given member was prescribed or received care that OIG determined should have been provided.

c. OIG Disregards that MAOs Are Not Required to Have Perfect Data

The perfection standard posited by the Draft Report reflects either a misunderstanding of CMS regulations or a rejection of the data standards set by CMS. 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"^{8/} and "in recognition of the fact that [MA organizations] cannot reasonably be expected to know that every piece of data is correct."^{9/} CMS also recognized at the time that "it would be unfair and unrealistic to hold [MA organizations] to a '100 percent accuracy' certification standard."^{10/} CMS has since reiterated that there is no requirement "to verify every diagnosis submitted by every provider."^{11/} OIG, itself, also has recognized that an MA organization's attestation "does not constitute an absolute guarantee of accuracy."^{12/}

The Draft Report also cites 42 C.F.R. § 422.503(b)(vi), which requires organizations to adopt an "effective" compliance program, to suggest that because OIG concluded that some HCCs were not valid, Cigna should evaluate its compliance program to ensure compliance with 42 C.F.R. § 422.503(b)(vi). 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."^{13/}

^{7/} Because the information has not been provided to date, we do not know how many records 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 Humana, Inc. (Contract H1036) Submitted to CMS, A-07-16-01165*, 15 n.14 (Apr. 2021).

^{8/} 65 Fed. Reg. 40170, 40250 (June 29, 2000).

^{9/} *Id.* at 40268.

^{10/} *Id.*

^{11/} 79 Fed. Reg. 29843, 29925 (May 23, 2014).

^{12/} 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 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).

^{13/} 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

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

A perfection standard also would conflict with the “same methodology” requirement in 42 U.S.C. § 1395w-23(b)(4)(D). This provision mandates 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. Similarly, as discussed in greater detail below in connection with the extrapolation methodology used to prepare the Draft Report, a perfection standard also would violate the actuarial equivalence requirement in 42 U.S.C. § 1395w-23(a)(1)(C)(i).^{14/} Finally, we note that the federal courts uniformly decline to require perfection as a standard of measure in the Medicare program.^{15/}

d. *Perfection in Risk Adjustment Is Not Possible.*

The perfection standard reflected in the Draft Report also is inconsistent with the realities and limitations of attempting to perform a risk adjustment function. As CMS has recognized, risk adjustment data “come into [MAOs] in great volume and from a number of sources.”^{16/} In particular, an overwhelming majority of the risk adjustment data for our Texas contract (more than 64%) were submitted by the healthcare providers that treated our enrolled beneficiaries. Although we 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 MAO. Diagnosis coding is an inherently subjective process and there often are substantial differences in interpretation and opinion among health care practitioners and certified coders regarding a broad array of coding issues. CMS generally does not require providers to use any particular diagnostic or clinical criteria and allows providers to use their best professional judgment.^{17/} OIG is aware of these differences in interpretation as evidenced by its review methodology that included multiple reviewers for coding disagreements. “One 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.”^{18/} 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 health care industry.^{19/}

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.”).

^{14/} See *infra* at Section II.e.

^{15/} 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)).

^{16/} 65 Fed. Reg. at 40628.

^{17/} 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).

^{18/} Kimberly O'Malley, *Measuring Diagnoses: ICD Code Accuracy*, 40 Health Serv. Res. 1620 (2005).

^{19/} 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*, A03-14-00010 (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.”).

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

We do not think it is correct to automatically conclude that a diagnosis 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 MAOs 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.^{20/}

Additionally, obtaining medical records from providers is often very challenging. For many of our provider partners who seek to provide such records, responding to medical record requests for visits that occurred five to six years prior can be administratively burdensome, and such burden has been further exacerbated by the COVID-19 public health emergency and staff shortages. For MAOs, the consolidation of hospital systems and large provider groups and the increasing number of providers who are publicly traded or private investor-backed has led to some large groups and health systems refusing to respond to records requests in a timely fashion, if at all, especially when they know that an MAO requires their participation in certain areas to satisfy network adequacy requirements. MAOs have very little leverage, and almost no recourse, when providers do not provide the medical records requested, even though the consequence of a provider's lack of cooperation is significant for the MAO, as is demonstrated by the Draft Report.

* * *

OIG designed and conducted an audit that was inconsistent with RADV regulations and CMS standards for data accuracy. By not focusing on payment accuracy and reviewing for both "overpayments" and "underpayments," OIG skewed any potential results towards identifying "overpayments." Further, OIG ignored long-standing principles that perfection in risk adjustment data is not possible and MAOs are not required to have perfect data. For these reasons, we respectfully request OIG withdraw its findings and reconsider its audit design and methodology.

II. Cigna Does Not Concur with OIG's Estimated and Extrapolated Repayment Amount and Respectfully Requests OIG Recalculate to Address Errors in OIG's Analysis of Certain Enrollee-Years, Remove The Impact of Underlying Biases, and Ensure Actuarial Equivalence

We respectfully request OIG withdraw its recommended repayment amount and recalculate it, when possible, to (a) address errors in OIG's analysis of certain enrollee-years; (b) include previously unreported diagnoses; (c) remove the impact of underlying biases; and (c) ensure actuarial equivalence.

- a. *OIG's Recommended Repayment Amount is Incorrect Because Certain Sample Enrollee-years that OIG Found to be Unsupported are Supported by Documentation in the Relevant Medical Records*

^{20/} 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").

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

We believe that 6 of the sampled enrollee-years that OIG and its contractor did not validate should have been validated under the applicable statutes, regulations, and CMS guidance. Discussions of these enrollee-years are attached at **Exhibit A**. Please note that these exhibits contain protected health information and are not eligible for public disclosure.

b. OIG's Recommended Repayment Amount is Incorrect Because It Does Not Consider Previously Unreported Diagnoses

Similarly, our review indicates that OIG and its contractor did not capture 19 other previously unreported diagnoses that accurately reflect our enrollees' health status. This includes diagnoses that are related to the targeted high-risk categories and some that are unrelated. A list of these enrollee-years are attached at **Exhibit B**. Though documented, OIG did not validate any of these diagnosis codes.

For a number of reasons, discussed above, we are concerned that the audit methodology was not structured to equally identify both overpayments and underpayments. In particular, the audit methodology shared with us does not discuss how OIG and its contractor identified or evaluated potential underpayments, including the additional diagnoses we identified in our review. In general, the overall intent of payment audits is to determine whether the MAO has been paid accurately. However, targeting nine specific diagnoses to the exclusion of anything that previously had not been submitted artificially inflates the proposed "overpayment." When calculating a proposed "overpayment" amount, OIG should have sought to determine accuracy, which must offset any proposed "overpayments" by underpayments.

c. OIG's Review Methodology was Needlessly Opaque and Did Not Adequately Identify the Independent Medical Review Contractor or the Coding and Documentation Standards Applied during the Medical Record Review. OIG Should Update its Draft Report to Include Additional Information Regarding its Medical Record Review.

i. OIG did not provide information regarding its independent medical review contractor or the credentials of reviewers.

We request that OIG provide additional information regarding its review. For example, OIG has not identified the "independent medical record review contractor." Given the importance of this audit, we believe we have the right to know who is performing the review so we can evaluate whether there is a conflict of interest, assess the contractor's credentials, coding policies, procedures, and training, and see if the positions taken are consistent with prior work undertaken by the contractor, or statements made by it.

Further, Cigna 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. 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. It also does not appear the individuals conducting each level of review were consistently subject to inter-rater reliability ("IRR") (which we believe to be a standard practice in CMS audits). If they were subject to IRR, we should have the ability to evaluate the results of such reviews. We believe 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.

ii. OIG did not provide the coding and document standards applied during its review.

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

MAOs, and their network providers, are expected to submit diagnosis codes in accordance with ICD-10 coding guidelines. But, because of the lack of specificity, CMS has directed providers and plans to rely on coding and documentation guidance from industry experts such as the American Health Information Management Association (AHIMA), the American Medical Association (AMA), the American Hospital Association (AHA), and the American Academy of Professional Coders (AAPC). The scope of these resources is quite broad, they are not always consistent with one another, and they change over time. For example, while ICD-10 greatly increased the codes and descriptive nature of such codes when compared to ICD-9, ICD-10 still does not have a code for every specific diagnosis that a provider may make. There are many times where providers must decide whether the medical diagnosis that they are making aligns with one ICD-10 versus another, and coding sources do not consistently align the same diagnosis with the same ICD-10. Further, the sources that CMS recommends providers rely on often do not respond to questions in a timely manner (e.g., the AHA Coding Clinic, a well-respected source, takes more than six months to respond). Because of these inconsistencies and variations, OIG should identify the specific coding and documentation standards that were used to evaluate the targeted high-risk diagnoses, as required by relevant auditing standards.

iii. **Any coding and documentation standards applied during OIG’s review were not validly established.**

Even if OIG were to provide its coding and document standards, any standards applied during OIG’s 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.^{21/} The Supreme Court has explained that this obligation is broad and is likely to invalidate many policies found only in the Medicare manuals.^{22/} 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.”^{23/} In late 2020, 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.”^{24/}

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 2018 proposed rule that the RADV coding and documentation guidance defines “the

^{21/} 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.

^{22/} *See Allina Health*, 139 S. Ct. at 1814.

^{23/} 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).

^{24/} 45 C.F.R. § 1.3(a)(2). Although HHS has proposed to rescind this regulation, it has not finalized that proposal, and the regulation therefore remains binding on the agency.

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

payment standard” for MA risk adjustment payments.^{25/} 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 AMA, AHIMA, the AAPC, and others, which do not involve public input, are not always consistent with each other, and change without notice. The Medicare statute and the APA do not allow CMS to delegate its responsibility to establish risk adjustment standards to private, non-governmental entities.^{26/} OIG’s potential reliance on these standards is improper for all of the reasons stated.

iv. OIG’s narrowly defined documentation requirements conflicted with OIG’s sampling methodology such that records that would substantiate a diagnosis were not acceptable if outside of the narrow time frame of the audit.

For many of the targeted high-risk diagnoses, OIG’s determining factor for whether such diagnosis should be in the sample was whether a subsequent or previous claim or diagnosis was submitted to the MAO and then to CMS. For example:

- Diagnoses for lung, breast, colon, and prostate cancer were considered suspect by OIG and therefore included in the potential sample, if CMS had not received evidence of “surgical therapy, radiation treatments, or chemotherapy treatment drugs administered within a 6-month period before or after the diagnosis.”
- Acute heart attack diagnoses from outpatient providers were included in the potential sample if the diagnosis was not also reported from an inpatient hospital encounter either 60 days prior or after the diagnosis in question.
- Acute stroke diagnoses from outpatient providers were included in the potential sample if the diagnosis was not also reported by either another outpatient encounter or an inpatient encounter.
- Both major depressive disorder and embolism diagnoses were included in the potential sample if the diagnosed member did not fill a prescription drug associated with the condition through their Medicare Part D plan, with no specific time frame set forth.

OIG developed the parameters for when a diagnosis would be considered a high risk of noncompliance; however, OIG’s documentation requirements relating to timing prohibited Cigna from submitting documentation that would substantiate a diagnosis. For example, records for members diagnosed with cancer in late 2016 who later sought treatment in early 2017 would not be reviewed by OIG even though such treatment was obtained within OIG’s arbitrarily defined 6-month window. Further,

^{25/} 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.”).

^{26/} 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”).

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

for members who were diagnosed with major depressive disorder or embolism late in a plan year and filled a related prescription early in the following plan year, records for such a prescription fill would both be time barred as being outside of the audit time period and not considered to be a valid source of risk adjustment data. This disregard of documentation and support for a diagnosis code based on an arbitrary date range in such a targeted audit ignores the fact that for MA members and their plan providers, the end of a calendar year does not change how providers deliver care. Further, as discussed directly below, when, where or whether a member elects to obtain follow-up care is not a valid basis to determine that a documented diagnosis is not supported.

v. **OIG Determining Whether a Diagnosis is Valid Based on What a Provider Decides to Recommend to a Member, Whether a Member Decides to Seek Recommended Treatment, or Where or How a Member Seeks Recommended Treatment is Inherently Problematic and Arbitrary.**

We know of no CMS guidance suggesting that the health status of a member that is reported through a diagnosis submitted by their treating provider is disproved solely by whether a provider prescribes a certain course of treatment or whether a member elects to follow through with such treatment. We believe that, absent indicia of fraud, the treating provider's notation of a diagnosis should be given wide latitude and deference, especially when significant time has passed from when the patient was seen and when the OIG reviewer evaluates the medical record. And we do not believe "indicia of fraud" includes a provider deciding to not prescribe treatment identified by OIG as being appropriate or by a member electing to not follow up. By applying these arbitrary standards of medical practice and "health status," OIG seeks to supplant its medical knowledge years later for that of members' treating providers.

As we discussed, OIG identified diagnoses that were at high risk of noncompliance by consulting with medical professionals at an MAC. How are a non-clinical federal agency and a randomly selected federal contractor well-suited to determine clinical guidelines that will identify whether a member has a given diagnosis assigned by the member's treating provider? If a member's provider decides not to prescribe a drug because such drug would interact poorly with the member's other drugs, this audit would identify the diagnosis as at high risk of noncompliance based on the provider's clinical decision making. Identifying such diagnoses as unsupported would be clinically inaccurate and such a finding would result in OIG and its MAC consultant supplanting the provider's clinical decision making with their own. OIG does not have this authority.

Further, if a provider counseled a member on treatment options all of the following common situations would result in the OIG considering the provider's diagnosis as being at "high risk of noncompliance:" (1) the member elected to not follow up, (2) the member was not able to afford the cost share charged for their prescribed prescription so they did not fill the prescription, (3) the member elected to fill a prescription through their Veterans Affairs ("VA") pharmacy, (4) the member paid cash and used a discount card (e.g., GoodRx, SingleCare, etc.), and (5) the member elected to use widely available manufacturer coupons (which continue to be offered by manufacturers to Part D members, sometimes with OIG's approval^{27/}). All of these situations result in an MA plan not receiving a claim or PDE for the

^{27/} See e.g., OIG Advisory Opinion No. 14-05 (Jul. 21, 2014) (approving manufacturer's direct-to-patient product sales program that offers a brand name drug (for which there is a generic equivalent) at a discount much lower than the manufacturer's wholesale acquisition cost, allowing the patient to pay for the drug out of pocket with no charge to the insurer); OIG Advisory Opinion No. 07-04 (Mar. 30, 2007) (approving pharmaceutical company patient assistance program that provides

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

member filling a prescribed drug, but do not suggest that a member does not have a diagnosis that their provider assigned to them. Identifying such diagnoses as unsupported would be clinically inaccurate and such a finding would result in OIG and its MAC consultant supplanting the member's personal choices with their own. OIG does not have this authority.

For example, Cigna member assigned as "audit sample #11-280" was diagnosed with prostate cancer in 2014. The member was informed of the diagnosis and discussed treatment options with his provider, and elected to undergo watchful waiting with monitoring of his PSA levels. In 2015, the provider continued to monitor the member's PSA levels in June and documented in September that the member will continue to be monitored. Current American Society of Clinical Oncology guidelines state that men with low-volume Gleason prostate cancer (which this member had) may be considered for active surveillance, and that is what the member and his provider elected. The OIG invalidated the diagnosis of prostate cancer. Identifying such a diagnosis as unsupported was clinically inaccurate, as summarized on **Exhibit A**, and this finding results in OIG and its MAC consultant supplanting the member's personal choices with their own.

Additionally, OIG ignored information regarding members seeking care outside of the Medicare program. The most blatant example of this is care provided through the VA. Cigna, like many MAOs, offers MA plans to many veterans who receive benefits from the Veterans Health Administration as well as an MA plan. Such members may elect to see providers under either benefit. Under OIG's audit, diagnoses that are documented by the member's provider are at "high risk of noncompliance" if such member seeks follow up care at the VA, because such care does not produce a Medicare claim. Invalidation on such basis is clinically inaccurate.

For example, Cigna member assigned as "audit sample #11-292" was diagnosed with and treated for prostate cancer in 2006, and continued to be prescribed Lupron for his prostate cancer in 2016. Further, in 2016, the member was prescribed an additional drug to treat prostate cancer (Casodex) and his treating provider noted that that member was obtaining oncology follow-up care through the VA. As OIG is well aware,^{28/} Lupron is a widely used drug to treat prostate cancer, covered under a member's medical benefit and not under Part D. Even though the member was actively being treated with Lupron and Casodex, and was obtaining oncology follow-up care through the VA, OIG invalidated the diagnosis. Identifying such a diagnosis as unsupported was clinically inaccurate, as summarized on **Exhibit A**.

vi. Cigna understands some of the coding and documentation standards applied during this 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.^{29/} The risk adjustment system relies on the ICD-CM diagnosis codes only as a proxy for such statuses.^{30/} Often, however, the coding and documentation standards published by the AHA, AHIMA, the AAPC, etc. turn on formalities or criteria that do not address the beneficiary's health status. Such standards also have the effect of preventing Cigna and other plans from presenting important, credible evidence regarding their members' health statuses.

free outpatient prescription drugs to financially needy Part D enrollees entirely outside of the Part D benefit); OIG Advisory Opinion No. 06-04 (Apr. 18, 2006) (same).

^{28/} See OIG, *Medicare Reimbursement for Lupron*, OEI-03-03-00250, January 2004.

^{29/} See Draft Report at 1, 2, 3, and 6.

^{30/} See *id.* at 1 ("To determine the health status of enrollees, CMS relies on ... diagnosis codes ...").

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

Cigna has submitted detailed comments to OIG and CMS previously relating to examples of how the coding and documentation standards applied during RADV audits, including this type of audit, are inconsistent with the statute that establishes payment based on health status. Some examples include the limited definition of a “medical record,”^{31/} limitations on physician^{32/} and provider and source types,^{33/} the signature requirement,^{34/} exclusion of attestations for all matters other than signatures, and inaccurate clinical guidelines.^{35/}

In this specific audit, the exclusion of prescription data as a validation source when OIG itself used the lack of prescription data to determine whether certain diagnoses were considered high-risk for noncompliance, is arbitrary and further demonstrates the inaccuracy of the audit results. Additionally, the fact that RADV guidance currently precludes MAOs 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), is particularly problematic given that the RADV rules for the Affordable Care Act expressly allow for the use of prescription data in risk adjustment.^{36/}

We believe many of the above issues would have been addressed if the RADV rules and payment standards for MA had been established through notice and comment, and OIG had followed them. 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.”^{37/} 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. Because this dialogue has not taken place as it applies to documentation standards, it is inappropriate for OIG to rely on such standards in this audit.

d. *Extrapolation of Potential Overpayments is Inappropriate and Not Authorized by Congress*

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.^{38/}

Significantly, Congress addressed 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

^{31/} CMS, *Risk Adjustment User Group 2007/2008 – February 2008 Questions & Answers* (Feb. 13, 2008).

^{32/} Gregory C. Pope, et al., *Diagnostic Cost Group Hierarchical Condition Category Models for Medicare Risk Adjustment – Final Report*, ES-11 to ES-13 (Dec. 21, 2000) (prepared for the Health Care Financing Administration pursuant to Contract No. 500-95-048) (“Final HCC Report”).

^{33/} *Id.* at 5-6 and 5-8.

^{34/} See, e.g., 74 Fed. Reg. 54634, 54675 (Oct. 22, 2009).

^{35/} Compare AHA Coding Clinic 3Q 1993, with AHA Coding Clinic Q1 2019.

^{36/} 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).

^{37/} *Allina Health*, 139 S. Ct. at 1816.

^{38/} 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. pt. 7 at 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).

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

has failed to correct the payment error.”^{39/} Neither of these conditions have been met here. Because of the many faults in the sampling and review methodology of this audit, discussed in detail above, we believe it is not possible to accurately identify a sustained or high level of payment error with the targeted methodology used by OIG in this audit. Further, Cigna did not fail to correct a payment error after receiving documented educational intervention by OIG or CMS. Instead, five to six years after diagnoses were reported by treating providers, OIG elected to work with an undisclosed MAC to develop a list of diagnoses and criteria for such diagnoses that OIG and the MAC determined were high risk. Cigna only received notice of what conditions OIG and the MAC considered high risk when it received the audit notice in 2019.^{40/}

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.^{41/} At the time, the regulations applied only to audits conducted by CMS.^{42/} Four years later, however, the regulations were amended to apply to all RADV audits conducted by any component of HHS, including OIG.^{43/} The preamble explained that the amendments were intended to clarify that the RADV regulations applied to RADV audits conducted by OIG pursuant to its authority under the Inspector General Act.^{44/} The preamble also addressed the statistical sampling and extrapolation methodologies to be used during such audits.^{45/} It stated that audits would be conducted using the methodology published by CMS in February 2012,^{46/} unless an updated methodology was published after opportunity for stakeholder comment.^{47/} To date, no update has been made to that methodology.^{48/} 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.^{49/} And, as discussed further below, the February 2012 methodology adopted the use of a “FFS adjuster” to function as “an offset” to “account[] for the fact that the documentation standard used in RADV audits ... is different from the documentation standard used” in the FFS program.^{50/} OIG’s proposed extrapolation disregarded this necessary adjustment.

^{39/} 42 U.S.C. § 1395ddd(f)(3).

^{40/} As OIG is aware, while Cigna received notice of the audit in 2019, the audit was postponed because of the COVID-10 Public Health Emergency and the burden that record collection would place on health professionals during the PHE.

^{41/} 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).

^{42/} 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 ...”). We note, however, that OIG generally adhered to CMS’s RADV policies in place at that time.

^{43/} 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 ...”).

^{44/} See 79 Fed. Reg. 29843, 29934 (May 23, 2014).

^{45/} See *id.* at 29927-28 (discussing the Final RADV Methodology).

^{46/} 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”)

^{47/} See *supra* n.45

^{48/} 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.

^{49/} 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.

^{50/} Final RADV Methodology at 4-5.

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

OIG's audit was designed to analyze targeted high-risk diagnoses that OIG expected to fail. As discussed earlier, this process is contrary to the data validation processes set forth in the February 2012 methodology. We are not aware of an analysis establishing that OIG's approach is superior to the final audit methodology that HHS adopted through the 2014 rulemaking, and warrants extrapolation. For these reasons, extrapolation is inappropriate and unauthorized by Congress.

e. *OIG's Estimated and Extrapolated Repayment Amount is Incorrect Because it is Not Adjusted to Ensure Actuarial Equivalence*

Statute and regulation require CMS to pay MAOs an amount that is "actuarially equivalent" to the expected cost that CMS would have otherwise incurred had it provided required Medicare benefits directly to the MAO's enrollees.^{51/} CMS does this by making risk-adjusted payments to MAOs that are based on actuarially sound calculations of the expected cost of providing traditional Medicare benefits to enrollees with differing health statuses.^{52/}

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."^{53/} 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 in payment inequities."^{54/} More recently, most qualified statisticians and actuaries to consider the question concluded that a significant FFS adjuster was essential to meeting the statutory requirement of actuarial equivalence.^{55/}

CMS developed the MA risk adjustment model using FFS claims data from the traditional Medicare program. The FFS claims data is unaudited and contains numerous errors that CMS must account for when determining whether similar errors for MA enrollees resulted in an overpayment. In 2012, CMS published a notice stating that it would incorporate the FFS error rate into its methodology for calculating recovery amounts for unsupported HCCs identified during its RADV audits. CMS said that it would first identify a "payment recovery amount" based on the value of supported and unsupported HCCs identified during its review.^{56/} Then, "to determine the final payment recovery amount, CMS [would] apply a Fee-for-Service

^{51/} 42 U.S.C. § 1395w-24(a)(5)(A), (a)(6)(A)(i)-(iii).

^{52/} 42 U.S.C. § 1395w-23(b)(4)(C), (D).

^{53/} 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 Guide lines, E. Centers for Medicare & Medicaid Services, V. Agency Quality Assurance Policies, Standards and Processes (Oct. 1, 2002).

^{54/} 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).

^{55/} 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).

^{56/} CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation for Contract-Level Audits*, at 3-4 (Feb. 24, 2012).

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

Adjuster (“FFS Adjuster”) amount as an offset to the preliminary recovery amount.” The FFS Adjuster would be based “on a RADV-like review of records submitted to support [traditional Medicare] claims data.”^{57/}

CMS tried to shift away from this principle in 2014 when it implemented a rule stating that MAOs receive an “overpayment” when they submit any diagnosis code to CMS that is not sufficiently supported by underlying medical records, without adjusting for error rates in traditional Medicare data.^{58/} This rule was struck down when a federal district court found that it violated the actuarial equivalence mandate by defining “overpayment” as the payment of funds to MAOs based on unsupported diagnosis codes without applying a FFS Adjuster or other mechanism to maintain actuarial equivalence.^{59/} Although the district court’s ruling was partially overturned by the D.C. Circuit’s finding that actuarial equivalence does not apply to the overpayment rule,^{60/} the D.C. Circuit itself distinguished the overpayment rule from the actuarial equivalence standard that applies to CMS’ calculation and disbursement of monthly payments to MAOs^{61/} and from RADV audits, which more broadly impact payments to MAOs because such audits are designed to require repayment for all unsupported diagnosis codes.^{62/}

Amidst this litigation, CMS issued a proposed rule in 2018 suggesting that diagnosis coding errors in unaudited traditional Medicare data do not systematically impact payments to MAOs.^{63/} Many MAOs and numerous other parties, including actuarial and statistical experts, submitted comments to CMS explaining that the 2018 proposal does not satisfy the actuarial equivalence requirement. CMS was required to take action on this rule in November 2021 but instead, CMS extended its deadline for an additional year to November 2022 as it continues to contemplate how to handle this significant issue and potential significant change in practice and policy.^{64/} As a result, the proposed rule remains subject to the administrative rulemaking process.

The actuarial equivalence requirement extends to OIG’s estimation and extrapolation of a potential “overpayment” amount in this audit. OIG did not apply a FFS Adjuster to account for errors in the data used to create the risk adjustment payment model. The lack of FFS Adjuster violates important principles of administrative law, in particular the requirement for prospective notice and comment rulemaking. It also would mark a departure from OIG’s past audit practices. In prior contract-level RADV audits, OIG

^{57/} *Id.*

^{58/} See 79 Fed. Reg. 29844, 29921 (May 23, 2014), implementing 42 C.F.R. § 422.326.

^{59/} *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 187–90 (D.D.C. 2018). The court concluded that by measuring overpayments without adjusting for error rates in traditional Medicare, “The consequence is inevitable: while CMS pays for all diagnostic codes, erroneous or not, submitted to traditional Medicare, it will pay less for Medicare Advantage coverage because essentially no errors would be reimbursed.” *Id.* at 187. This position was reaffirmed on January 27, 2020 when the same court denied the government’s request to reconsider the court’s prior holding. *Azar*, No. 16-cv-157 (RMC), 2020 WL 417867 (D.D.C. Jan. 27, 2020).

^{60/} See *UnitedHealthcare Inc. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), *cert. denied*, No. 21-1140, 2022 WL 2203436 (U.S. June 21, 2022).

^{61/} See *id.* at 884.

^{62/} See *id.* at 892. Cigna does not agree with the D.C. Circuit’s decision regarding the overpayment rule because actuarial equivalence in the MA risk adjustment system is statutorily required and cannot be achieved or maintained without it applying to all payment contexts within the risk adjustment system, but in any event, the D.C. Circuit’s decision by its own terms was limited to the overpayment rule and “expresses no opinion” with respect to actuarial equivalence in RADV audits. *Id.* at 893 n.1.

^{63/} 83 Fed. Reg. 54982, 55041 (Nov. 1, 2018).

^{64/} See CMS, *Extension of Timeline To Finalize a Rulemaking*, 86 Fed. Reg. 58,245.

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

acknowledged that the actuarial equivalence requirement made it inappropriate 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 [MAOs]. 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 MAO] refund only the overpayments identified for the sampled beneficiaries rather than refund the estimated overpayments and (2) added a recommendation that [the MAO] work with CMS to determine the correct contract-level adjustments for the estimated overpayments.^{65/}

OIG made similar statements in two prior audits involving Cigna affiliates.^{66/} Because the relevant circumstances have not changed since those prior audits, the APA requires, in our view, that OIG follow the same approach in this audit.^{67/}

Considering this history, it is not possible for OIG to determine whether Cigna received an overpayment without establishing an actuarially sound methodology that takes into account diagnosis coding errors in the FFS data. As a result, OIG's estimated and extrapolated repayment amount is both legally and actuarially unsound.

f. *OIG's Extrapolated Repayment Amount Relies on a Confidence Interval that is Too Conservative and Inconsistent with CMS RADV Audit Practice*

OIG acknowledged it was taking a conservative position by using the lower limit of a two-sided 90-percent confidence interval to calculate the extrapolated repayment amount, rather than the statistically valid and more robust practice of using the lower limit of a 95-percent or 99-percent confidence interval.^{68/} OIG provides no explanation for its decision to do so, which is unusual because CMS uses the lower limit of a 99-percent confidence interval when calculating extrapolated repayment amounts for its Medicare Advantage RADV audits.

* * *

For the reasons discussed here, we believe that OIG's estimated and extrapolated repayment amounts are incorrect. We respectfully request OIG withdraw its recommended repayment amount and recalculate it to (a) address errors in OIG's analysis of certain enrollee-years; (b) include previously unreported diagnoses; (c) remove the impact of underlying biases; (d) disregard unwarranted extrapolation, and (d) ensure actuarial equivalence.

^{65/} 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).

^{66/} 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-0710-01082, iii (May 2013).

^{67/} See, e.g., *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 31 (D.D.C. 1997).

^{68/} Draft Report at 8.

III. Cigna Does Not Concur with OIG’s Recommendation that Cigna Conduct Additional Auditing Related to the High-Risk Diagnoses Included in the Audit and Respectfully Requests that OIG Update its Draft Report to Withdraw this Recommendation

OIG recommends that Cigna “identify, for the high-risk diagnoses included in [the Draft Report], similar instances of noncompliance that occurred before or after [the] audit period and refund any resulting overpayments to the Federal Government[.]”^{69/} However, MA regulations do not require the sort of audits that OIG recommends and do not require data perfection. By making this recommendation, OIG is holding MAOs to standards that are unknown, vague, and nonexistent. Further, if Cigna undertook an audit similar to OIG’s, it could not result in “risk adjustment payment integrity and accuracy”^{70/} because Cigna would not be permitted to submit diagnosis codes that it determined were supported but not previously submitted given that all plan years other than 2021, and 2022 are closed for resubmissions.

As discussed above in *Section I*, a payment audit designed to target errors without considering and recognizing diagnoses that are supported but not previously submitted, does not ensure payment accuracy and is improper. For OIG to recommend that Cigna repeat such an audit across multiple years on its own is excessively penal. We respectfully request that OIG withdraw its recommendation that Cigna conduct additional audits.

IV. Cigna Does Not Concur with OIG’s Recommendation that Cigna Examine Existing Compliance Procedures and Respectfully Requests that OIG Update its Draft Report and Withdraw its Recommendation

OIG recommends that Cigna “continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements...and take the necessary steps to enhance those procedures.”^{71/}

However, Cigna has a strong and effective compliance program that is designed to comply with all relevant legal and regulatory requirements. In fact, in 2021, when conducting a contract-level RADV audit of H5410, OIG 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.” Also in 2021, Cigna underwent a CMS Program Audit and there were no findings related to Cigna’s compliance program.

During its audit, OIG reviewed Cigna’s diagnosis data from 2015 and 2016, and issued a finding regarding the overall effectiveness of policies and procedures that are in place today. But as part of its ongoing efforts to further strengthen its compliance program, Cigna has made numerous changes to that program over the last several years. This is standard practice for a company like Cigna. The current policies and procedures have no bearing on 2015 and 2016 dates of service and as such, there is no basis for findings related to Cigna’s current compliance program. It is beyond the scope of OIG’s audit to make recommendations related to Cigna’s current compliance activities.

OIG’s audit was not designed to determine whether Cigna’s current practices would have addressed the issues potentially identified in 2015/2016 data. Cigna’s current compliance program

^{69/} Draft Report at 18.

^{70/} See 42 C.F.R. §422.311(a).

^{71/} Draft Report at 18.

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

recently received positive feedback from both CMS and OIG. Cigna's recent contract-level RADV in Florida found a 97% coding accuracy rate and included positive statements regarding Cigna's compliance program. Also in 2021, Cigna underwent a CMS Program Audit and there were no findings related to Cigna's compliance program.

The Draft Report cites 42 C.F.R. § 422.503(b)(vi), which requires organizations to adopt an "effective" compliance program. But, as stated above, OIG has "recognize[d that] the implementation of an effective compliance program may not entirely eliminate fraud, abuse and waste from an organization."^{72/} OIG's Draft Report makes two potentially misleading statements in this respect.^{73/}

First, the Draft Report states that "[f]ederal regulations state that [MAOs] must monitor the data that they receive from providers and submit to CMS."^{74/} However, this statement is incomplete. CMS gives MAOs broad discretion to design their own compliance and risk adjustment data accuracy programs and has declined to require MAOs to implement any specific oversight measures.

Second, the Draft Report also states that federal regulations "state that [MAOs] are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes."^{75/} This statement is again incomplete because it fails to account for the qualified attestation standard that CMS explicitly adopted. MAOs are not held to a standard of guaranteeing the accuracy of the risk adjustment data that is submitted. Instead, MAOs have to attest that the submissions are accurate to their best knowledge, information and belief.

Relying on these misleading broad characterizations of CMS regulations, OIG has inappropriately expanded the MA compliance program requirements. CMS is undoubtedly aware of industry-wide trends related to the high-risk diagnoses audited by OIG. Nevertheless, CMS has not opted to take any action to implement regulations or additional requirements, let alone the broad recommendations OIG makes in its Draft Report. 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.

OIG's recommendations based on 2015 and 2016 dates of service also fail to consider changes in medical documentation practices that have occurred over the last 6 to 7 years. During that time, MAOs, including Cigna, have put forth significant effort to educate providers regarding the appropriate use of some of the specific codes targeted by OIG in this audit (e.g., when to use acute stroke versus history of stroke, heart attack versus history of a heart attack). OIG's recommendation ignores this effort and the likely effect of this effort on coding in 2022.

Additionally, at the end of 2015, which was after many of the service dates at issue in the audit, providers transitioned from ICD-9 to ICD-10 coding. The more specific diagnosis codes available under ICD-10 changed physician diagnosis coding practices so that they were more easily able to identify "history of" codes as being the appropriate code to report for their applicable patients. As a result, the related

^{72/} 64 Fed. Reg. 61894, 61895 (Nov. 15, 1999).

^{73/} 64 Fed. Reg. at 61900. The Draft Report also appears to suggest that perfection is required by 42 C.F.R. § 422.310(d)(I), 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." However, 310(d)(1) does not establish or reference any standards that require 100% accuracy in order for a compliance program to be effective.

^{74/} Draft Report at 9.

^{75/} Draft Report at 8.

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

compliance functions required today are entirely different from those needed to ensure compliance under ICD-9.

It also seems that, simply by virtue of the fact that it discovered supposedly unsupported diagnosis codes through its targeted audit, OIG believes Cigna's compliance policies and procedures must not have been effective. But as we have discussed throughout our comments, perfection is not the standard that CMS imposes and OIG has long recognized that. The fact that OIG identified supposedly unsupported diagnoses, through its skewed audit sampling and review methodology, does not indicate that Cigna's compliance program is ineffective, particularly when measured by MA program guidance.

V. Conclusion

For the reasons described, we believe that the overall intent and design of OIG's audit is contrary to MA regulations and the goal of payment accuracy audits. Cigna respectfully requests OIG withdraw its recommendations and update its Draft Report to account for the inherent bias in such a targeted audit. Cigna further requests that OIG revise its Draft Report and withdraw its recommendations that Cigna (a) refund to the Federal Government \$6,281,045 of estimated overpayments, (b) identify similar instances of noncompliance outside of the audit period and refund any resulting overpayments, and (c) examine existing compliance procedures to identify where improvements can be made to ensure diagnosis codes that are at high risk for being miscoded comply with Federal requirements.