

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE  
COMPLIANCE AUDIT OF SPECIFIC  
DIAGNOSIS CODES THAT  
REGENCE BLUECROSS  
BLUESHIELD OF OREGON  
(CONTRACT H3817)  
SUBMITTED TO CMS**

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## Report in Brief

Date: September 2022

Report No. A-09-20-03009

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, Regence BlueCross BlueShield of Oregon (Regence), and focused on seven groups of high-risk diagnosis codes. Our objective was to determine whether selected diagnosis codes that Regence submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

### How OIG Did This Audit

We sampled 179 unique enrollee-years with the high-risk diagnosis codes for which Regence received higher payments for 2015 and 2016. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$462,043.

## Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS

### What OIG Found

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that Regence submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, for 111 of the 179 sampled enrollee-years, the diagnosis codes that Regence submitted to CMS were not supported in the medical records and resulted in net overpayments of \$248,885. As demonstrated by the errors in our sample, the policies and procedures that Regence used 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 Regence received at least \$1.8 million of net overpayments for these high-risk diagnosis codes for 2015 and 2016.

### What OIG Recommends and Regence Comments

We recommend that Regence: (1) refund to the Federal Government the \$1.8 million of estimated net overpayments; (2) identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and (3) continue to examine its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

Regence disagreed with our findings and did not concur with our recommendations. However, Regence agreed to submit data corrections to CMS for 108 of 111 enrollee-years questioned in our draft report. Regence stated that it did not plan to submit data corrections for the remaining 3 enrollee-years and provided additional explanations as to why it believes the medical records validated the diagnosis codes. Regence also disagreed with our extrapolated repayment calculation. Furthermore, Regence disagreed that it should conduct additional audits (to identify similar instances of noncompliance) and that it should examine its compliance procedures. After reviewing Regence's comments, we maintain that our findings and recommendations are valid.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

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

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS. Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 27 major depressive disorder diagnoses into 1 group.) This audit covered Regence BlueCross BlueShield of Oregon (Regence) for contract number H3817 and focused on seven groups of high-risk diagnosis codes for payment years 2015 and 2016.<sup>2</sup> (See Appendix B for a list of related Office of Inspector General (OIG) reports on MA organizations.)

### OBJECTIVE

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

### 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

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<sup>1</sup> 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 9th revision of the ICD Coding Guidelines (ICD-9-CM) to the 10th revision (ICD-10-CM). Each revision includes different diagnosis code sets.

<sup>2</sup> All subsequent references to "Regence" in this report refer solely to contract number H3817.

fee-for-service program.<sup>3</sup> 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.<sup>4</sup>

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

- *Base rate:* Before the start of each year, each MA organization submits bids to CMS that reflect the MA organization's estimate of the monthly revenue required to cover an enrollee with an average risk profile.<sup>5</sup> 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.<sup>6</sup>
- *Risk score:* A risk score is a relative measure that reflects the additional or reduced costs that each enrollee is expected to incur compared with the costs incurred by enrollees on average. CMS calculates risk scores based on an enrollee's health status (discussed below) and demographic characteristics (such as the enrollee's age and gender). This

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<sup>3</sup> The Balanced Budget Act of 1997, P.L. No. 105-33, as modified by section 201 of the Medicare Prescription Drug, Improvement, and Modernization Act, P.L. No. 108-173, established the MA program.

<sup>4</sup> The Social Security Act (the Act) §§ 1853(a)(1)(C) and (a)(3); 42 CFR § 422.308(c).

<sup>5</sup> The Act § 1854(a)(6); 42 CFR § 422.254 *et seq.*

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



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).<sup>7</sup> Each HCC has a factor (which is a numerical value) assigned to it for use in each enrollee's risk score.

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

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

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

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

CMS multiplies the risk scores by the base rates to calculate the total monthly Medicare payment that an MA organization receives for each enrollee before applying the budget sequestration reduction.<sup>8</sup> 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.<sup>9</sup> 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 seven high-risk groups:<sup>10</sup>

- *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 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's claim). In these instances, a diagnosis indicating a history of a myocardial infarction typically should have been used.

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

<sup>9</sup> Federal regulations (42 CFR § 422.310(e)) require 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 determined that the diagnoses were supported or unsupported, we accordingly use the terms "validated" or "unvalidated" with respect to the associated HCC.

<sup>10</sup> Unless otherwise specified, the HCCs described in this report have the same name under both the Version 12 and Version 22 models.

- *Acute stroke and acute heart attack combination:* An enrollee met the conditions of both the acute stroke and acute heart attack high-risk groups in the same year.<sup>11</sup>
- *Embolism:* An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or 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.<sup>12</sup> In these instances, the diagnosis related to vascular claudication may not be supported in the medical records.
- *Major depressive disorder:* An enrollee received one major depressive disorder diagnosis (that mapped to the 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, the major depressive disorder diagnoses may not be supported in the medical records.
- *Potentially mis-keyed diagnosis codes:* An enrollee received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition (which mapped to a possibly unvalidated HCC). For example, ICD-9 diagnosis code 250.00 (which maps to the HCC for Diabetes Without Complication) could be transposed as diagnosis code 205.00 (which maps to the HCC for Metastatic Cancer and Acute Leukemia and in this example would be unvalidated). Using an analytical tool that we developed, we identified 811 scenarios in which diagnosis codes could have been mis-keyed because numbers were transposed or other data-entry errors occurred that could have resulted in the assignment of an unvalidated HCC.

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

<sup>12</sup> Vascular claudication and neurogenic claudication are different diagnoses. Vascular claudication is a condition that can result in leg pain while an individual is 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.

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

## **Regence BlueCross BlueShield of Oregon**

Regence is an MA organization based in Portland, Oregon. As of December 31, 2016, Regence provided coverage under contract number H3817 to approximately 50,000 enrollees. For the 2015 and 2016 payment years (audit period), CMS paid Regence approximately \$1 billion to provide coverage to its enrollees.<sup>13, 14</sup>

## **HOW WE CONDUCTED THIS AUDIT**

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of the seven high-risk groups during the 2014 and 2015 service years, for which Regence received increased risk-adjusted payments for payment years 2015 and 2016, respectively. Because enrollees could be categorized 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 1,427 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$3,562,144). We selected for audit a sample of 179 enrollee-years, which comprised: (1) a stratified random sample of 160 (out of 1,408) enrollee-years for the first 6 high-risk groups and (2) a nonstatistical sample of 19 enrollee-years for the remaining high-risk group.

Table 1 on the following page details the number of sampled enrollee-years (of the 179) for each of the 7 high-risk groups.

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<sup>13</sup> The 2015 and 2016 payment year data were the most recent data available at the start of the audit.

<sup>14</sup> All of the payment amounts that CMS made to Regence and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

**Table 1: Sampled Enrollee-Years for High-Risk Groups**

High-Risk Group	Number of Sampled Enrollee-Years
1. Acute stroke	36
2. Acute heart attack	30
3. Acute stroke/acute heart attack combination	4
4. Embolism	30
5. Vascular claudication	30
6. Major depressive disorder	30
<b>Total for Stratified Random Sample</b>	<b>160</b>
7. Potentially mis-keyed diagnosis codes	19
<b>Total for All High-Risk Groups</b>	<b>179</b>

Regence provided medical records as support for the selected diagnosis codes associated with the 179 enrollee-years. 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, and Appendix D contains our sample results and estimates.

## **FINDINGS**

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that Regence submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 68 of the 179 sampled enrollee-years, either the medical records validated the reviewed HCCs or we identified another diagnosis code (in CMS's systems) that supported the HCC under review. However, for the remaining 111 enrollee-years, the diagnosis codes were not supported in the medical records.

As demonstrated by the errors found in our sample, the policies and procedures that Regence used to prevent, detect, and correct noncompliance with CMS's program requirements, as

mandated by Federal regulations, could be improved. As a result, the HCCs for some of the high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Regence received at least \$1.8 million of net overpayments for these high-risk diagnosis codes for 2015 and 2016.<sup>15</sup>

## FEDERAL REQUIREMENTS

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

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

Federal regulations also state that MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes and that such data must conform to all relevant national standards (42 CFR § 422.504(l) and 42 CFR § 422.310(d)(1)). In addition, MA organizations must contract with CMS and agree to follow CMS's instructions, including the *Medicare Managed Care Manual* (the Manual) (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 according to the International Classification of Diseases, 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, the MA organizations must implement procedures to ensure that diagnoses come only from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities, and physicians (the Manual, chap. 7, § 40).

Federal regulations state that MA organizations must monitor the data that they receive from providers and submit to CMS. Federal regulations also state that MA organizations must “adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS’ program requirements . . . .” Further, MA

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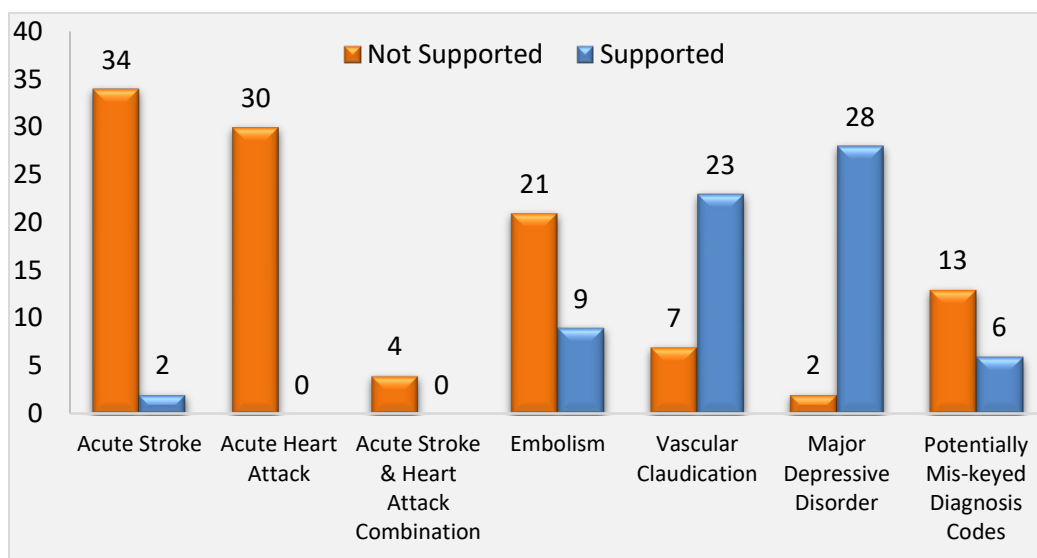
<sup>15</sup> Specifically, we estimated that Regence received at least \$1,890,855 (\$1,857,812 for the statistically sampled groups plus \$33,043 for the group of potentially mis-keyed diagnosis codes) of net overpayments. To be conservative, we recommend recovery of overpayments at the lower limit 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.

organizations must establish and implement an effective system for routine monitoring and identification of compliance risks (42 CFR § 422.503(b)(4)(vi)). (See Appendix E.)

### **MOST OF THE SELECTED HIGH-RISK DIAGNOSIS CODES THAT REGENCE SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS**

Most of the selected high-risk diagnosis codes that Regence submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. As shown in the figure below, the medical records for 111 of the 179 sampled enrollee-years did not support the diagnosis codes. In these instances, Regence should not have submitted the diagnosis codes to CMS and received the resulting net overpayments.

**Figure: Analysis of High-Risk Groups**



#### **Incorrectly Submitted Diagnosis Codes for Acute Stroke**

Regence incorrectly submitted diagnosis codes for acute stroke for 34 of 36 sampled enrollee-years. Specifically:

- For 22 enrollee-years, the medical records in each case indicated 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 medical record (for a service that occurred in 2014) indicated that the individual had acute strokes in 1998, 2000, and 2005. The independent medical review contractor noted 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]. . . . There is mention of a history of a stroke [diagnosis] but no description of residuals or sequelae that should be coded.”<sup>16</sup>

- For 11 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that “[t]he provider rules out cerebrovascular accident [diagnosis that would result in the Ischemic or Unspecified Stroke HCC] which would not be coded.”

- For the remaining 1 enrollee-year, Regence submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiplegia (which was supported in the medical records).<sup>17</sup> The independent medical review contractor noted that “the patient has hemiparesis from [a] recent stroke that should be coded with [late effects of cerebrovascular disease, hemiplegia affecting dominant side]. This would result in the assignment of HCC [Hemiplegia/Hemiparesis] . . . .” Accordingly, Regence should not have received an increased payment for the acute stroke diagnosis but instead should have received a lesser increased payment for the hemiplegia diagnosis. This error caused an overpayment.

As a result of these errors, the HCCs for Ischemic or Unspecified Stroke were not validated, and Regence received \$84,760 of overpayments for these 34 sampled enrollee-years.

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

Regence incorrectly submitted diagnosis codes for acute heart attack for all 30 sampled enrollee-years. Specifically:

- For 23 enrollee-years, the medical records in each case did not support an acute myocardial infarction diagnosis. However, we identified support for another diagnosis that should have been included in the enrollee-years’ risk scores. In some instances, the diagnosis mapped to a less severe manifestation of the related-disease group as detailed below:
  - For 18 enrollee-years, which occurred in payment year 2015, the old myocardial infarction diagnosis mapped to an HCC for a less severe manifestation of the

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<sup>16</sup> Residuals or sequelae are lasting effects after the acute phase of an illness or injury has ended.

<sup>17</sup> Hemiplegia is total or partial paralysis of one side of the body that results from disease of or injury to the motor centers of the brain.



related-disease group.<sup>18</sup> Accordingly, Regence should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the old myocardial infarction diagnosis. For example, for 1 enrollee-year, the independent medical review contractor noted that “[t]here is documentation of history of myocardial infarction [diagnosis] that results in [the] HCC [for Old Myocardial Infarction] which should have been assigned instead of the submitted [Other Acute Ischemic Heart Disease] HCC.”

- For 1 enrollee-year, which occurred in 2015, we identified support for an unspecified angina pectoris diagnosis, which mapped to an HCC for a less severe manifestation of the related-disease group.<sup>19</sup> Accordingly, Regence should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the unspecified angina pectoris diagnosis.
- For the remaining 4 enrollee-years, which occurred in payment year 2016, the old myocardial infarction diagnosis did not map to an HCC.<sup>20</sup> Accordingly, Regence should not have received an increased payment for acute myocardial infarction.
- For the remaining 7 enrollee-years, the medical records in each case did not support either an acute myocardial infarction diagnosis or a diagnosis of a less severe manifestation of the related-disease group.

As a result of these errors, the Acute Heart Attack HCCs were not validated, and Regence received \$46,130 of overpayments for these 30 sampled enrollee-years.

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

Regence incorrectly submitted diagnosis codes for all 4 of the sampled enrollee-years for which physicians had documented conditions for both the acute stroke and acute heart attack high-risk groups in the same year (footnote 10). Specifically:

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<sup>18</sup> An “old myocardial infarction” is a distinct diagnosis that represents a myocardial infarction that occurred more than 4 weeks previously and has no current symptoms directly associated with that myocardial infarction and requires no current care.

<sup>19</sup> Angina pectoris is a disease marked by brief sudden attacks of chest pain or discomfort caused by deficient oxygenation of the heart muscles, usually due to impaired blood flow to the heart.

<sup>20</sup> In contrast to the enrollee-years that occurred in 2015 (for which CMS used the Version 12 model), for 2016, CMS used only the Version 22 model, which did not include an HCC for Old Myocardial Infarction, to calculate risk scores (footnote 7).

- For 3 enrollee-years, the medical records in each case did not support an acute stroke diagnosis. Further, the medical records did not support an acute myocardial infarction diagnosis; however, we identified support for an old myocardial infarction diagnosis. Accordingly, for payment year 2015, Regence should not have received an increased payment for either the acute stroke diagnosis or the acute myocardial infarction diagnosis but should have received a lesser increased payment for the old myocardial infarction diagnosis for 2 enrollee-years.<sup>21</sup>

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted [Ischemic or Unspecified Stroke] HCC or any related HCC. There is mention of a history of a stroke [diagnosis] but no description of residuals or sequelae that should be coded.” In addition, the contractor noted that “there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of [an Acute Heart Attack] HCC . . . There is documentation of history of old myocardial infarction. . . .”

- For the remaining 1 enrollee-year, the independent medical review contractor noted that “there is no evidence of an acute stroke, however the patient has hemiparesis from an old stroke that should be coded with [late effects of cerebrovascular disease, hemiplegia affecting dominant side] and would result in the assignment of [the] HCC [for Hemiplegia/Hemiparesis].” Accordingly, Regence should not have received an increased payment for the acute stroke diagnosis but instead should have received an increased payment for the hemiplegia diagnosis.<sup>22</sup> This error caused an underpayment.

As a result of these errors, the HCCs for either Ischemic or Unspecified Stroke or Acute Heart Attack, or both, were not validated, and Regence received \$9,548 of net overpayments for these 4 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Embolism**

Regence incorrectly submitted diagnosis codes for embolism for 21 of 30 sampled enrollee-years. Specifically:

- For 14 enrollee-years, the medical records in each case did not support an embolism diagnosis.

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

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<sup>21</sup> For the remaining 1 enrollee-year, the old myocardial infarction diagnosis did not map to an HCC (for payment year 2016).

<sup>22</sup> For this enrollee-year, only the acute stroke diagnosis was not supported in the medical record.

diagnosis] code that translates to the assignment of [an Embolism] HCC. Results from the ultrasound of the lower extremity vein duplex found that there was ‘no evidence of deep venous thrombus of the right lower extremity.’ ”<sup>23</sup>

- For the remaining 7 enrollee-years, the medical records in each case indicated that the individual had previously had an embolism, but the records did not justify an embolism diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of [an Embolism] HCC. Documentation shows that the patient has a history of deep venous thrombosis [diagnosis] which should not be coded as a current diagnosis as there is no indication of an active treatment. Diagnosis of deep venous thrombosis was assessed but noted as no recurrence.”

As a result of these errors, the Embolism HCCs were not validated, and Regence received \$53,136 of overpayments for these 21 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Vascular Claudication**

Regence 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 diagnosis related to vascular claudication.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of a diagnosis that results in HCC [Vascular Disease]. There is documentation of neurogenic claudication [diagnosis] which does not result in an HCC. A diagnosis of neurogenic claudication is not the same as a diagnosis of claudication or peripheral vascular disease . . . .”

- For the remaining 1 enrollee-year, Regence 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 HCCs for Vascular Disease were not validated, and Regence received \$16,551 of overpayments for these 7 sampled enrollee-years.

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<sup>23</sup> A deep venous thrombus is a blood clot that forms in a vein deep within the body.

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

Regence incorrectly submitted diagnosis codes for major depressive disorder for 2 of 30 sampled enrollee-years. Specifically, for each of the 2 enrollee-years, the medical records did not support a major depressive disorder diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Major Depressive, Bipolar, and Paranoid Disorders] . . . . There is documentation of adjustment disorder with depressed mood [diagnosis] that does not result in an HCC.”

As a result of these errors, the HCCs for Major Depressive, Bipolar, and Paranoid Disorders were not validated, and Regence received \$5,717 of overpayments for these 2 sampled enrollee-years.

## **Potentially Mis-keyed Diagnosis Codes**

Regence submitted potentially mis-keyed diagnosis codes for 13 of 19 sampled enrollee-years. In each of these cases, the beneficiaries associated with these enrollee-years received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition.

- For 11 enrollee-years, the medical records did not support the diagnosis for the unrelated condition. Because of these errors, Regence submitted to CMS unsupported diagnosis codes that mapped to unvalidated HCCs.

For example, for 1 enrollee-year, Regence submitted five diagnosis codes for rheumatoid arthritis (714.0) and only one diagnosis code for malignant neoplasm of nipple and areola of female breast (174.0). The independent medical review contractor limited its review to the malignant neoplasm of nipple and areola of female breast diagnosis, for which it did not find support.

- For 2 enrollee-years, the medical records did not support the diagnosis for the unrelated condition. However, we identified support for another diagnosis, which mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Regence received an overpayment, in that it should not have received an increased payment for the submitted diagnosis but should have received a lesser increased payment for the other diagnosis identified.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of [the] HCC [for Vascular Disease with

Complications]. There is documentation of a small common femoral artery pseudoaneurysm [diagnosis] . . . that results in [the] HCC [for Vascular Disease].”<sup>24</sup>

Appendix F contains the HCCs that were not validated for the 13 enrollee-years (Table 5) and the HCCs for the less severe manifestation of the related-disease group that were supported for the 2 enrollee-years (Table 6).

As a result of these errors, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated, and Regence received \$33,043 of overpayments for these 13 sampled enrollee-years.

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

As demonstrated by the errors found in our sample, the policies and procedures that Regence used to prevent, detect, and correct noncompliance with CMS’s program requirements, as mandated by Federal regulations (42 CFR § 422.503(b)(4)(vi)), could be improved. (See Appendix E for the Federal regulations.)

Regence had compliance procedures to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. These procedures included educating providers to report diagnosis codes if they were actively monitored, evaluated, assessed, or treated during the face-to-face encounter and emphasized that diagnoses that are no longer active should be clearly documented as historical in the patient’s record. In addition, Regence conducted routine internal medical reviews to compare diagnosis codes from a random sample of claims with the diagnoses that were documented in the associated medical records. Regence provided guidance to its coders on how to review certain high-risk diagnoses, including diagnosis codes for acute stroke, acute heart attack, and embolism.

However, Regence did not conduct specific reviews of high-risk diagnosis codes, and those we identified as being at a higher risk for being miscoded. Although Regence performed reviews to identify risk adjustment coding errors and corrected the errors it found, its compliance procedures corrected only the errors it found in its reviews and were not designed to identify systematic errors. We therefore concluded that Regence’s compliance procedures to prevent, detect, and correct incorrect high-risk diagnosis codes could be improved.

### **REGENCE RECEIVED NET OVERPAYMENTS**

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Regence received at least

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<sup>24</sup> A pseudoaneurysm occurs when a blood vessel wall is injured and the leaking blood collects in the surrounding tissue.

\$1,890,855 of net overpayments (\$1,857,812 for the statistically sampled high-risk groups plus \$33,043 for the high-risk group with the potentially mis-keyed diagnosis codes) for 2015 and 2016. (See Appendix D for sample results and estimates.)

## **RECOMMENDATIONS**

We recommend that Regence BlueCross BlueShield of Oregon:

- refund to the Federal Government the \$1,890,855 of estimated net overpayments;
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
- continue to examine its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

## **REGENCE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, Regence disagreed with our findings and did not concur with our recommendations. However, Regence agreed to submit data corrections to CMS for 108 of 111 sampled enrollee-years questioned in our draft report. Regence stated that it did not plan to submit data corrections for the remaining 3 sampled enrollee-years and provided additional explanations as to why it believes the medical records validated the diagnosis codes. Regence also disagreed with our extrapolated repayment calculation. Furthermore, Regence disagreed that it should conduct additional audits (to identify similar instances of noncompliance) and that it should examine its compliance procedures.

After reviewing Regence's comments and for the reasons detailed below, we maintain that our findings and recommendations are valid. We revised our third recommendation to state that Regence should continue to examine its existing compliance procedures.

A summary of Regence's comments and our responses follows. Regence's comments are included in their entirety as Appendix G.<sup>25</sup>

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<sup>25</sup> Regence included an exhibit as part of its comments. This exhibit included a summary presentation of background information on CMS's payment model. Although the exhibit is not included as an appendix in our report, we considered the entirety of the document in preparing our final report and will provide Regence's comments in their entirety to CMS.

## **REGENCE DISAGREED WITH OUR FINDINGS BUT WILL SUBMIT DATA CORRECTIONS FOR 108 ENROLLEE-YEARS**

### **Regence Comments**

Regence stated that it agrees to submit data corrections to CMS for 108 of the 111 enrollee-years that we found were not supported by medical record documentation. However, Regence stated that it “disagrees that any unsupported diagnosis codes necessarily constitute overpayments.”<sup>26</sup> Regence also stated that it will be “undercompensated” by CMS for these enrollee-years because it can no longer submit to CMS the alternate diagnosis codes that OIG identified for some enrollee-years (the period for submissions is closed). Regence stated that when CMS follows its standard recoupment process, it will recoup funds associated with the data corrections without giving Regence credit for the alternate diagnosis codes that OIG identified.

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

In our estimated net overpayment amount, we accounted for the alternate diagnosis codes identified by the independent medical review contractor. Although we recognize that OIG audit findings and recommendations do not represent final determinations by CMS, we will provide CMS with our contractor’s results for its consideration. Regence should work with CMS officials on its data corrections.

## **REGENCE DISAGREED WITH OUR FINDINGS FOR 3 ENROLLEE-YEARS**

### **Regence Comments**

Regence disagreed with our findings for 3 enrollee-years (in the embolism, acute heart attack, and acute stroke high-risk groups) and stated that it does not plan to submit data corrections to CMS for these enrollee-years. Regence provided the following explanations as to why it believed the medical records supported the diagnosis codes and thus validated the HCCs for the high-risk diagnosis codes we reviewed:

- For the first enrollee-year, Regence explained why it believed the Embolism HCC was validated. Regence stated that the discharging provider documented a diagnosis of deep vein thrombosis (DVT) from the right peripherally inserted central catheter (PICC) line, which corresponds to the Embolism HCC.<sup>27, 28</sup> Regence also stated that we

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<sup>26</sup> In its comments, Regence does not refer directly to enrollee-years but to diagnosis codes associated with the enrollee-years.

<sup>27</sup> DVT is a condition in which a blood clot forms in one or more of the deep veins in the body.

<sup>28</sup> A PICC line is a long, thin tube that is inserted in a vein in the arm and passed through to the larger veins near the heart.

appeared to have relied on an ultrasound report in the record, which noted findings that “may suggest subacute venous thrombosis.” Regence said that the suggestion by one radiologist, interpreting a single diagnostic test, that there might be evidence of subacute venous thrombosis, does not undermine the DVT diagnosis based on a complete review of the patient’s presentation and records. Regence stated that even if the ultrasound report did contradict the discharging provider’s clinical diagnosis, it would not render the diagnosis assigned to this enrollee-year invalid. Regence said that a conflict between two providers’ diagnoses does not invalidate a properly documented diagnosis code.

- For the second enrollee-year, Regence explained why it believed the Acute Heart Attack HCC was validated. Regence stated that both the emergency department physician and a cardiologist diagnosed the patient with a non-ST-elevation myocardial infarction (NSTEMI), which was supported by an electrocardiogram and bloodwork.<sup>29</sup> Regence said that the same provider who documented the NSTEMI diagnosis also documented a diagnosis of syncope (i.e., fainting) in the setting of NSTEMI. Regence stated that the reference to syncope describes a manifestation of the NSTEMI diagnosis and does not negate it. Furthermore, Regence stated that the fact that a discharge diagnosis (from the inpatient medical record) differs from an emergency department diagnosis does not mean that the latter was wrong.
- For the third enrollee-year, Regence explained why it believed the Ischemic or Unspecified Stroke HCC was validated. Regence stated that the neurologist in the emergency department diagnosed the patient with a left hemispheric embolic stroke.<sup>30</sup> Regence said that after the patient was treated for this condition, the discharging provider diagnosed the patient with a transient ischemic attack.<sup>31</sup> Regence stated that when the discharge diagnosis (from the inpatient medical record) differs slightly from the diagnosis initially made in the emergency department, that does not render the initial diagnosis incorrect.

### Office of Inspector General Response

Our independent medical review contractor reviewed the medical records that Regence referred to in its comments as well as the explanations that Regence provided for these 3 enrollee-years and reconfirmed that the HCCs were not validated:

- For the first enrollee-year, the independent medical review contractor did not find support for a diagnosis that would validate the Embolism HCC. Specifically, the

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<sup>29</sup> An NSTEMI is a type of heart attack that happens when a part of the heart is not getting enough oxygen.

<sup>30</sup> An embolic stroke is a stroke caused by a blood clot or plaque debris that develops somewhere in the body other than the brain and then travels to one of the blood vessels in the brain through the bloodstream.

<sup>31</sup> A transient ischemic attack is a brief episode during which parts of the brain do not receive enough blood.



contractor found that the medical record clearly documented a PICC line thrombosis and supported a diagnosis for basilic vein thrombosis and complication of a vascular device, which does not result in an Embolism HCC. In addition, the contractor stated that the *ICD-9-CM Official Guidelines for Coding and Reporting* notes that the entire record should be reviewed to determine the specific reason for the encounter and the conditions treated. The contractor found that prophylactic administration of heparin was given for DVT as a preventive measure. The contractor added that the CMS Risk Adjustment Reviewer Guidance notes that reviewers should evaluate all listed conditions for consistency within the full provider documentation. The contractor concluded that the Embolism HCC was not validated.

- For the second enrollee-year, the independent medical review contractor did not find support for a diagnosis that would validate an Acute Heart Attack HCC. Specifically, the contractor found that the medical record did not support a diagnosis of NSTEMI and that the emergency room admit note indicated a suspected NSTEMI. However, the diagnosis was ruled out by a cardiac catheterization. Furthermore, the progress notes, the diagnostic tests, and the discharge summary indicated that there was no cardiac etiology of the patient's presenting symptom of syncope.<sup>32</sup> The contractor stated that an additional neurological evaluation was completed to determine the cause of the syncope, for which there was no conclusion. The contractor concluded that there was no support for a diagnosis code that mapped to an Acute Heart Attack HCC.
- For the third enrollee-year, the independent medical review contractor did not find support for a diagnosis that would validate the Ischemic or Unspecified Stroke HCC. Specifically, the contractor found that the medical record did not support a diagnosis of left hemispheric embolic stroke. The contractor found that the physician noted an initial impression of a "likely" and "potentially debatable" left hemispheric embolic stroke diagnosis, which should not be coded as confirmed. The contractor also found that the medical record mentioned cerebrovascular accident as a differential diagnosis and did not support a diagnosis of an acute cerebrovascular accident.<sup>33</sup> The contractor found that the admit note indicated a diagnosis of a possible cerebrovascular accident, but the remainder of the medical record—including progress notes, diagnostic test results, and discharge summary—did not support the diagnosis of a cerebrovascular accident. The contractor concluded that the Ischemic or Unspecified Stroke HCC was not validated.

Accordingly, we made no changes to our findings for these 3 enrollee-years or our recommendation that Regence refund to the Federal Government an estimated \$1.8 million of net overpayments.

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<sup>32</sup> "Etiology" is the cause or origin of a disease.

<sup>33</sup> "Cerebrovascular accident" is another term for acute stroke.

## REGENGE DISAGREED WITH OUR EXTRAPOLATED REPAYMENT CALCULATION

Regence disagreed with our extrapolated repayment calculation because it asserted that our recommended repayment amount did not ensure a payment principle known as actuarial equivalence as required by statute. Regence also stated that our audit methodology and extrapolation were flawed in several respects because: (1) we did not conduct a comprehensive review for all potentially supported diagnosis codes for the audited enrollee-years, (2) we relied on a physician's independent review in cases where two coders disagreed on whether a diagnosis code was supported, and (3) we relied on the lower bound of a 90-percent confidence interval. Finally, Regence stated that our shifting of audit standards in our compliance audits of MA organizations has made extrapolated recoveries unpredictable and unfair to audited MA organizations.

### Actuarial Equivalence of Recommended Repayment Amount

#### *Regence Comments*

Regence said that we misstated any overpayments resulting from both the audited diagnosis codes for the enrollee-years and the extrapolated amount because the calculations did not account for the Act's actuarial equivalence requirement. Regence stated that CMS is required to pay MA organizations in such a way as to ensure actuarial equivalence with what CMS would expect to pay for each beneficiary under traditional Medicare.

According to Regence, CMS relies on data from traditional Medicare and data submitted by MA organizations to calculate risk-adjusted payments. Regence noted how both sets of data contain diagnosis coding errors and stated that, to ensure actuarial equivalence when calculating payments, CMS must either: "(1) apply the same documentation (i.e., auditing) standards to both sets of data on which it relies to calculate payments to [MA organizations]; or (2) account for any differences in these standards by some other means." Regence also stated that "[r]elying on *unaudited* traditional Medicare data to determine payments to [MA organizations] in the first instance and then *auditing* [MA] data skews estimated overpayments to [MA organizations]."

Regence stated that CMS recognized the importance of the actuarial equivalence requirement to its recovery of overpayments to MA organizations. In this regard, Regence stated that in 2012 CMS notified MA organizations that it planned to calculate and apply a Fee-for-Service Adjuster (FFS Adjuster) to payment recoveries in risk adjustment data validation (RADV) audits to adjust for diagnosis coding errors in data from traditional Medicare. According to Regence, CMS "concluded that an FFS Adjuster was necessary to 'take into account how CMS payments would change if [the] perfection standard that is applied under RADV was also used when calculating risk adjustment model values' that underlie the MA payment model." Regence stated that CMS recognized that MA organizations would otherwise be underpaid in violation of the actuarial equivalence requirement. Regence also referenced a Proposed Rule that CMS

introduced in 2018 and stated that “CMS backed away from the position that an FFS adjuster is necessary in the RADV audit context, but a final rule is still pending.”

Regence concluded that “[b]ecause OIG’s recommended repayment amount here is not adjusted to ensure actuarial equivalence with traditional Medicare, the recommended repayment amount misrepresents any true overpayment to Regence.”

### *Office of Inspector General Response*

Our audit methodology correctly applied CMS requirements to properly identify the overpayment amount associated with unsubstantiated HCCs for each sample item. We used the results of the independent medical review contractor’s coding review to determine which high-risk HCCs were not substantiated and, in some instances, to identify HCCs that should have been used but were not used in the risk score calculations of the sampled enrollee-years. We followed the requirements of CMS’s risk adjustment program to determine the payment that CMS should have made for each enrollee. We used the overpayments and underpayments identified for each enrollee to determine our estimated net overpayment amount.

Regence stated that we did not consider actuarial equivalence in our overpayment calculations. To this point, and with consideration of Regence’s comments, we recognize that CMS is responsible for making operational and program payment determinations for the MA program, including the application of any FFS Adjuster requirements. Moreover, CMS has not issued any requirements that compel us to reduce our net overpayment calculations.<sup>34</sup> If CMS deems it appropriate to apply an FFS Adjuster, it will adjust our overpayment finding by whatever amount it determines necessary.

Our audits are intended to provide an independent assessment of Department of Health and Human Services (HHS) programs and operations in accordance with the Inspector General Act of 1978, 5 U.S.C. App. Thus, we believe that the steps we followed for this audit provide a reasonable basis for our findings and conclusions, including our calculation of net overpayments.<sup>35</sup>

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<sup>34</sup> In 2018, CMS proposed “not to include an FFS Adjuster in any final RADV payment error methodology” (Proposed Rule at 83 Fed. Reg. 54982, 55041 (Nov. 1, 2018)). With respect to Regence’s comment that a final rule is still pending, we reiterate that CMS has not issued any guidance that compels us to reduce our overpayment calculations.

<sup>35</sup> OIG audit findings and recommendations do not represent final determinations by CMS. Action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with CMS policies and procedures. In accordance with 42 CFR § 422.311, which addresses audits conducted by the Secretary of HHS (including those conducted by OIG), if a disallowance is taken, MA organizations have the right to appeal the determination that an overpayment occurred through the Secretary’s RADV appeals process.

## **Comprehensive Review of All Potentially Supported Diagnosis Codes for Audited Enrollee-Years**

### *Regence Comments*

Regence stated that we did not conduct a comprehensive review for all potentially supported diagnosis codes associated with a given audited enrollee-year. Regence stated that the independent medical review contractor reviewed only a subset of medical records for each enrollee-year and did not review or identify unrelated diagnosis codes that may have been supported in the medical records but were not previously reported by Regence to CMS. Regence stated that, as a result, the draft report likely exaggerates any potential overpayments and that extrapolating these results is doubly improper because it multiplies this flawed calculation across the entire contract.

### *Office of Inspector General Response*

We disagree with Regence's statements regarding our audit methodology. Specifically, it was beyond the scope of our audit to identify all possible diagnosis codes that Regence could have submitted on behalf of the sampled enrollee-years.

For this audit, our objective was to determine whether selected high-risk diagnosis codes that Regence submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements. For each of the sampled enrollee-years, Regence had previously submitted to CMS only one claim with a high-risk diagnosis code that mapped to the reviewed HCC. We asked Regence to provide a copy of that related medical record for review. We also informed Regence that it could submit up to four more medical records of its choosing that could support the reviewed HCC. These additional medical records, when originally coded, did not contain a diagnosis code that mapped to the reviewed HCC. It was entirely Regence's decision as to how many additional records (up to four) to submit to us for review. We asked our independent medical review contractor to review all of the medical records that Regence submitted to determine whether the documentation supported any diagnosis codes that mapped to the reviewed HCCs. In this regard, we considered instances in which the medical review contractor found support for a diagnosis that should have been used instead of the diagnosis that was submitted to CMS.

Accordingly, we believe that our audit methodology allowed us to calculate correctly the net overpayment amounts relevant to our objective. A valid estimate of net overpayments does not need to take into consideration all potential HCCs or underpayments within the audit period. Our estimate of net overpayments addresses only the portion of the payments related to the reviewed HCCs and does not extend to the HCCs that were beyond the scope of our audit. In accordance with our objective, and as detailed in Appendices C and D, we properly executed a statistically valid sampling methodology in that we defined our sampling frame (Regence's enrollee-years with a high-risk diagnosis) and sample unit, randomly selected our

sample, applied relevant criteria to evaluate the sample, and used statistical sampling software to apply the correct formulas to estimate the net overpayments made to Regence.

### **Reliance on a Physician's Independent Review in Cases Where Two Coders Disagreed on Whether a Diagnosis Code Was Supported**

#### *Regence Comments*

Regence stated that our audit methodology erred in relying on a physician's independent review of a medical record in cases where two coders disagreed about whether a diagnosis code was supported in that record. Regence stated that the role of a diagnosis coding review is not to second-guess the clinical diagnosis decisions of an enrollee's provider, nor are MA plans expected to scrutinize or verify a provider's clinical diagnosis of the enrollee. Regence also stated that the purpose of a diagnosis coding review is to confirm that the diagnosis codes reported to CMS are documented in the medical record, not to assess whether that diagnosis was one with which OIG would agree.

#### *Office of Inspector General Response*

We disagree that there were errors in our audit methodology. The independent medical review contractor's use of senior coders to perform coding reviews, as well as its use of a physician—who was board certified and who did not apply clinical judgment when serving as the final decisionmaker—was a reasonable method for determining whether the medical records adequately supported the reported diagnosis codes. In this regard, the independent medical review contractor reviewed all medical records that Regence provided to determine whether the diagnosis codes complied with Federal requirements.

### **Reliance on the Lower Bound of a 90-Percent Confidence Interval**

#### *Regence Comments*

Regence stated that our extrapolation methodology is statistically flawed because we relied on the lower bound of a 90-percent confidence interval rather than at least the lower bound of a 95-percent confidence interval, as CMS does in calculating RADV audit recoveries. Regence noted that a confidence interval of 95 percent is more commonly used and robust than a 90-percent confidence interval.

#### *Office of Inspector General Response*

OIG is an independent oversight agency, and therefore we do not need to mirror CMS's extrapolation methodology. Our policy is to recommend recovery at the lower limit of a two-sided 90-percent confidence interval. The lower limit of a two-sided 90-percent confidence interval provided a reasonably conservative estimate of the total amount of net overpayments to Regence for the enrollee-years and time period covered in our sampling

frame. This approach, which is routinely used by HHS for recovery calculations, results in a lower limit (the estimated overpayment amount to refund) that is designed to be less than the actual overpayment total 95 percent of the time.<sup>36</sup> For this reason, we maintain that our use of the lower limit of the two-sided 90-percent confidence interval is valid.

## **Audit Standards and Unpredictability of Extrapolated Recoveries**

### *Regence Comments*

Regence stated that extrapolating the results of this audit “would heighten a fundamental unfairness presented by [our] audit process” because we applied shifting audit standards and frameworks in the performance of our other MA compliance audits. To this point, Regence noted that in 1 audit, we audited only 2 groups of high-risk diagnosis codes, while for other audits we audited from 6 to 10 groups of high-risk diagnosis codes. Regence also stated that when “OIG extrapolates audit results across an entire contract and recommends recovery of the extrapolated amount, a fundamental unfairness exists between audited and unaudited [MA organizations].” Regence stated that when standards are inconsistent across comparable audits, the discrepancies are amplified.

### *Office of Inspector General Response*

We did not extrapolate our audit results across the entire contract. We identified our sampling frame and then limited the extrapolation to that frame. Extrapolation has long been recognized as a permissible method of calculating overpayments in Medicare. Further, current case law supports the use of extrapolation as a means to determine overpayments so long as the methodology used is statistically valid.<sup>37, 38</sup> Federal courts have consistently upheld statistical

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<sup>36</sup> HHS has used the two-sided 90-percent confidence interval when calculating recoveries in both the Administration for Children and Families and Medicaid programs. See, for example, *New York State Department of Social Services*, DAB No. 1358, 13 (1992); and *Arizona Health Care Cost Containment System*, DAB No. 2981, 4–5 (2019). In addition, HHS contractors rely on the one-sided 90-percent confidence interval, which is less conservative than the two-sided interval, for recoveries arising from Medicare FFS overpayments. See, for example, *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff’d*, 860 F.3d 335 (5th Cir. 2017); and *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 17–18 (E.D.N.Y. 2012).

<sup>37</sup> 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); and *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at \*13 (S.D. Tex. 2012).

<sup>38</sup> 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., the OIG, Office of Audit Services, statistical software RAT-STATS) to apply the correct formulas for the extrapolation.

sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.<sup>39</sup>

Using data mining techniques, discussions with medical professionals, and the results of our audits that reviewed the accuracy of diagnosis codes that MA organizations submitted to CMS, we may uncover additional high-risk groups of diagnosis codes for our audits. Not all MA organizations are the same, and we reviewed the high-risk groups applicable for the MA organizations during the time of the audits.

## **REGENCE DISAGREED WITH OUR RECOMMENDATION TO CONDUCT ADDITIONAL AUDITS OF HIGH-RISK DIAGNOSIS CODES**

### **Regence Comments**

Regence disagreed with our second recommendation—that it conduct additional “audits” of high-risk diagnosis codes to identify similar instances of noncompliance that occurred before or after the audit period and refund any overpayments. Regence noted that CMS does not require MA organizations to target particular diagnosis codes that are at heightened risk of being miscoded or to conduct condition-specific audits of provider-submitted diagnosis codes.

According to Regence, CMS recognized that MA organizations “cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the OIG, and [the U.S. Department of Justice] believe is reasonable to enforce.” Furthermore, Regence stated that CMS requires MA organizations to certify not that their data are accurate but that the data are accurate based on their “best knowledge, information, and belief.”<sup>40</sup>

Regence stated that the limited findings of our audit are not indicative of the overall accuracy of diagnosis codes that Regence submitted. Regence noted that our audit “targeted diagnosis codes that it predicted were *especially likely* to be unsupported by medical records . . . [r]ather than [taking] a random sample of enrollee-years or risk-adjusted conditions . . .” Regence stated that our “findings, by design, do not speak to the broader accuracy rate in Regence’s data submitted to CMS.” Regence stated that the results of our audit do not call for any additional internal audits.

Regence stated that, nevertheless, it conducted “quality assurance reviews that specifically sought to identify any notable coding patterns” and that it had “programs targeted at preventing systemic diagnosis coding errors, such as provider education.” Regence also stated

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<sup>39</sup> See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at \*26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at \*17 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

<sup>40</sup> Regence stated that this reference to 65 Fed. Reg. 40170, 40268 (June 29, 2000) supported its comments.

that, as the draft report recognized, “Regence provided guidance to its coders on how to review certain high-risk diagnoses, including diagnosis codes for acute stroke, acute heart attack, and embolism”—three “high-risk” codes reviewed in our audit.

## **Office of Inspector General Response**

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. However, we do not agree with Regence’s interpretation of the Federal requirements. In this regard, we believe that our second recommendation 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 noncompliance with CMS’ program requirements.” Furthermore, these regulations specify that Regence’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 to the MA organizations the responsibility for dealing with potential compliance issues.

Regarding Regence’s comment that the limited findings of our audit are not indicative of the overall accuracy of diagnosis codes that Regence submitted to CMS, we did not opine on the entirety of Regence’s compliance with Federal requirements. We limited our audit and recommendations to certain diagnosis codes that we determined to be at high risk for being miscoded. In this regard, we believe that the error rate identified in our audit (111 of 179 enrollee-years with unsupported diagnosis codes (Appendix D)) demonstrates that Regence 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 Regence identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period.

## **REGENGE DISAGREED WITH OUR RECOMMENDATION TO EXAMINE AND ENHANCE ITS COMPLIANCE PROCEDURES**

### **Regence Comments**

Regence disagreed with our third recommendation—that it examine and enhance its compliance procedures. Regence stated that the fact that we identified certain unsupported diagnosis code submissions after a medical record review does not in and of itself call into



question the sufficiency of Regence’s compliance procedures. Regence stated that its Medicare risk adjustment compliance procedures during our audit period complied with CMS program requirements and that its compliance program today continues to comply with those requirements.

Regence also stated that we did not evaluate Regence’s current compliance program and only “investigated and evaluated the . . . compliance program during the audited period . . . .” Regence stated that it will continue to look for opportunities to improve its compliance program and will consider the results of our audit in doing so.

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

We did not review Regence’s current compliance program. We limited our review to selected diagnoses and HCCs that we determined to be at high risk for noncompliance (i.e., miscoded) for our audit period. Based on the materiality of our findings—overpayments of at least \$1.8 million—we do not agree with Regence that our assessment of its compliance program was unfounded. Federal regulations at 42 CFR § 422.503(b) require MA organizations like Regence to establish and implement an effective system for routine monitoring and the identification of compliance risks. This regulation further explains that a compliance system should consider both internal monitoring and external audits. We concluded that Regence’s compliance program could be improved. The continued improvement of procedures will assist Regence 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, but we revised the wording to state that Regence should continue to examine its existing compliance procedures. We also revised our description of Regence’s policies and procedures for preventing, detecting, and correcting noncompliance with CMS’s program requirements from “not always effective” to “could be improved.”

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

### **SCOPE**

CMS paid Regence \$1,010,414,684 to provide coverage to its enrollees for 2015 and 2016. We identified a sampling frame of 1,427 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2014 and 2015 service years. Regence received \$20,859,487 in payments from CMS for these enrollee-years for 2015 and 2016. We selected for audit 179 enrollee-years with payments totaling \$2,985,347.

The 179 enrollee-years included 36 acute stroke diagnoses, 30 acute heart attack diagnoses, 4 acute stroke diagnosis and acute heart attack diagnosis combinations, 30 embolism diagnoses, 30 vascular claudication diagnoses, 30 major depressive disorder diagnoses, and 19 potentially mis-keyed diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$462,043 for our sample.

Our audit objective did not require an understanding or assessment of Regence'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 May 2019 to December 2021.

### **METHODOLOGY**

To accomplish our objective, we performed the following steps:

- We reviewed applicable Federal laws, regulations, and guidance.
- We discussed with CMS program officials the Federal requirements that MA organizations should follow when submitting diagnosis codes to CMS.
- We identified, through data mining and discussions with medical professionals at a Medicare administrative contractor, diagnosis codes and HCCs that were at high risk for noncompliance. We also identified the diagnosis codes that potentially should have been used for cases in which the high-risk diagnoses were miscoded.
- We consolidated the high-risk diagnosis codes into specific groups, which consisted of:
  - 6 diagnosis codes for acute stroke,
  - 35 diagnosis codes for acute heart attack,
  - 58 diagnosis codes for embolism,
  - 4 diagnosis codes for vascular claudication, and
  - 27 diagnosis codes for major depressive disorder.

- We developed an analytical tool that identified 811 scenarios in which either ICD-9 or ICD-10 diagnosis codes, when mis-keyed into an electronic claim because of a data transposition or other data-entry error, could result in the assignment of an incorrect HCC to an enrollee's risk score. For each of the 811 occurrences, the tool identified a potentially mis-keyed diagnosis code and the likely correct diagnosis code. Accordingly, we considered the potentially mis-keyed diagnosis codes to be high risk.
- We used CMS's systems to identify the enrollee-years on whose behalf providers documented the high-risk diagnosis codes. Specifically, we used extracts from CMS's:
  - Risk Adjustment Processing System (RAPS) to identify enrollees who received high-risk diagnosis codes from a physician during the service years;<sup>41</sup>
  - Risk Adjustment System (RAS) to identify enrollees who received an HCC for the high-risk diagnosis codes;<sup>42</sup>
  - Medicare Advantage Prescription Drug system (MARx) to identify the total Medicare payments that CMS calculated, before applying the budget sequestration reduction, for Regence for the payment years;<sup>43</sup>
  - Encounter Data System (EDS) to identify enrollees who received specific procedures;<sup>44</sup> and
  - Prescription Drug Event (PDE) file to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.<sup>45</sup>
- We interviewed Regence officials to gain an understanding of: (1) the policies and procedures that Regence followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Regence's monitoring of those diagnosis codes to prevent, detect, and correct noncompliance with Federal requirements.
- We selected for audit a sample of 179 enrollee-years, which consisted of: (1) a stratified random sample of 160 (out of 1,408) enrollee-years and (2) a nonstatistical sample of the remaining 19 enrollee-years.

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<sup>41</sup> MA organizations use the RAPS to submit diagnosis codes to CMS.

<sup>42</sup> The RAS identifies the HCCs that CMS factors into each enrollee's risk score calculation.

<sup>43</sup> The MARx identifies the payments made to MA organizations.

<sup>44</sup> The EDS contains information on each item (including procedures) and service provided to an enrollee.

<sup>45</sup> 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 179 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.<sup>46</sup>
- 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, a physician independently reviewed the medical record to make the final determination.
  - If either the first or second senior coder asked a physician for assistance, the physician’s decision became the final determination.
- We used the results of the independent medical review contractor to calculate overpayments or underpayments (if any) for each enrollee-year. Specifically, we calculated:
  - a revised risk score in accordance with CMS’s risk adjustment program and
  - the payment that CMS should have made for each enrollee-year.
- We estimated the total net overpayment made to Regence during the audit period.
- We discussed the results of our audit with Regence officials.

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

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<sup>46</sup> Our independent medical review contractor used senior coders, all of whom possessed one or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS), Certified Coding Specialist – Physician-Based (CCS-P), Certified Professional Coder (CPC), and Certified Risk Coder (CRC). RHITs have completed a 2-year degree program and have passed an American Health Information Management Association (AHIMA) certification exam. AHIMA also credentials individuals with CCS and CCS-P certifications, and the American Academy of Professional Coders credentials both CPCs and CRCs.

based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc., (Contract H1032) Submitted to CMS</i>	<a href="#">A-04-19-07084</a>	8/29/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS</i>	<a href="#">A-03-18-00002</a>	8/19/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS</i>	<a href="#">A-02-20-01009</a>	7/18/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Peoples Health Network (Contract H1961) Submitted to CMS</i>	<a href="#">A-06-18-05002</a>	5/25/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS</i>	<a href="#">A-01-19-00500</a>	2/14/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS</i>	<a href="#">A-02-18-10129</a>	1/5/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS</i>	<a href="#">A-07-19-01188</a>	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>	<a href="#">A-07-17-01173</a>	10/28/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS</i>	<a href="#">A-07-19-01187</a>	5/21/2021
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS</i>	<a href="#">A-07-16-01165</a>	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>	<a href="#">A-02-18-01028</a>	2/24/2021
<i>Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements</i>	<a href="#">A-07-17-01170</a>	4/30/2019

## **APPENDIX C: STATISTICAL SAMPLING METHODOLOGY**

### **SAMPLING FRAME**

We identified Regence enrollees who: (1) were continuously enrolled in Regence throughout all of the 2014 or 2015 service year and January of the following year, (2) were not classified as being enrolled in hospice or as having end-stage renal disease status at any time during 2014 or 2015 or in January of the following year, and (3) received a high-risk diagnosis during 2014 or 2015 that caused an increased payment to Regence for 2015 or 2016, respectively.

We presented the data for these enrollees to Regence for verification and performed an analysis of the data included in CMS's systems to determine whether the high-risk diagnosis codes increased CMS's payments to Regence. We removed any enrollees whose data could not be verified, and we classified these individuals according to the condition and the payment year (enrollee-years). Our final sampling frame consisted of 1,427 enrollee-years.

### **SAMPLE UNIT**

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

### **SAMPLE DESIGN AND SAMPLE SIZE**

The design for our statistical sample comprised six 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 (541 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 (231 enrollee-years);
- an acute stroke diagnosis and a diagnosis (that mapped to an Acute Heart Attack HCC) in the same year and that met the criteria mentioned in the previous two bullets (4 enrollee-years);
- a diagnosis that mapped to an Embolism HCC during the service year but for which an anticoagulant medication was not dispensed (134 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 (146 enrollee-years); and
- 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 (352 enrollee-years).

The specific strata are shown in Table 2.

**Table 2: Sample Design for Audited High-Risk Groups**

<b>Stratum (High-Risk Groups)</b>	<b>Frame Count of Enrollee-Years</b>	<b>CMS Payment for HCCs in Audited High-Risk Groups*</b>	<b>Sample Size</b>
1 – Acute stroke	541	\$1,305,934	36
2 – Acute heart attack	231	494,761	30
3 – Acute stroke/acute heart attack combination	4	15,176	4
4 – Embolism	134	371,087	30
5 – Vascular claudication	146	350,708	30
6 – Major depressive disorder	352	966,456	30
<b>Total – First Six Strata</b>	<b>1,408</b>	<b>\$3,504,122</b>	<b>160</b>

\* Rounded to the nearest whole dollar amount.

After we selected the 160 enrollee-years, we identified an additional group of 19 enrollee-years that represented individuals who received 1 of the 811 potentially mis-keyed diagnosis codes (each of which mapped to a potentially unvalidated HCC) and multiple instances of diagnosis codes that were likely keyed correctly.<sup>47</sup> Thus, we selected for audit a total of 179 enrollee-years.

## **SOURCE OF RANDOM NUMBERS**

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

<sup>47</sup> The entire group of 19 enrollee-years was reviewed.



## **METHOD OF SELECTING SAMPLE ITEMS**

We sorted the items in each stratum by beneficiary identification number and payment year, then consecutively numbered the items in each stratum in the stratified sampling frame. After generating 160 random numbers according to our sample design, we selected the corresponding frame items for review. We also selected all 19 nonstatistical sample items from the potentially mis-keyed group.

## **ESTIMATION METHODOLOGY**

We used the OIG, OAS, statistical software to estimate the total amount of net overpayments to Regence at the lower limit of the two-sided 90-percent confidence interval (Appendix D). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time. We also identified the overpayments from the nonstatistical sample of 19 items for the potentially mis-keyed diagnosis codes and added that amount to the estimate for the statistical sample to obtain the total net overpayments.

## APPENDIX D: SAMPLE RESULTS AND ESTIMATES

**Table 3: Sample Details and Results**

<b>Audited High-Risk Groups</b>	<b>Frame Size</b>	<b>CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)</b>	<b>Sample Size</b>	<b>CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)</b>	<b>Number of Sampled Enrollee-Years With Unvalidated HCCs</b>	<b>Net Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)</b>
1 – Acute stroke	541	\$1,305,934	36	\$89,373	34	\$84,760
2 – Acute heart attack	231	494,761	30	67,121	30	46,130
3 – Acute stroke/acute heart attack combination	4	15,176	4	15,176	4	9,548
4 – Embolism	134	371,087	30	80,389	21	53,136
5 – Vascular claudication	146	350,708	30	69,934	7	16,551
6 – Major depressive disorder	352	966,456	30	82,028	2	5,717
<b>Totals for Statistical Sample</b>	<b>1,408</b>	<b>\$3,504,122</b>	<b>160</b>	<b>\$404,021</b>	<b>98</b>	<b>\$215,842</b>
7 – Potentially mis-keyed diagnoses	19	\$58,022	19	\$58,022	13	\$33,043
<b>Totals – All</b>	<b>1,427</b>	<b>\$3,562,144</b>	<b>179</b>	<b>\$462,043</b>	<b>111</b>	<b>\$248,885</b>

**Table 4: Estimated Net Overpayments in the Sampling Frame**  
*(Limits Calculated for the 90-Percent Confidence Level)*

	<b>Estimated Net Overpayment for Statistically Sampled High-Risk Groups</b>	<b>Overpayment for High-Risk Group With Potentially Mis-keyed Diagnosis Codes</b>	<b>Total Estimated Net Overpayments</b>
Point estimate	\$2,023,469	\$33,043	\$2,056,512
Lower limit	1,857,812	33,043	1,890,855
Upper limit	2,189,125	33,043	2,222,168

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

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

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

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

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

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

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

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

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

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

## APPENDIX F: DETAILS OF POTENTIALLY MIS-KEYED DIAGNOSIS CODES

**Table 5: Potentially Mis-keyed Diagnosis Codes and Associated Overpayments**

Number of Sampled Enrollee-Years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
3	E32.9	Disease of thymus, unspecified	Other Significant Endocrine and Metabolic Disorders	F32.9	Major depressive disorder, single episode, unspecified	\$5,515
2	249.20	Secondary diabetes mellitus with hyperosmolarity, not stated as uncontrolled, or unspecified	Diabetes With Acute Complications	294.20	Dementia, unspecified, without behavioral disturbance	3,883
1	249.21	Secondary diabetes mellitus with hyperosmolarity, uncontrolled	Diabetes With Acute Complications	294.21	Dementia, unspecified, with behavioral disturbance	3,592
1	482.0	Pneumonia due to klebsiella pneumoniae	Aspiration and Specified Bacterial Pneumonias	428.0	Congestive heart failure, unspecified	5,969
1	714.9	Unspecified inflammatory polyarthropathy	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	174.9	Malignant neoplasm of breast, unspecified	3,092
1	174.9	Malignant neoplasm of breast, unspecified	Breast, Prostate, and Other Cancers and Tumors	714.9	Unspecified inflammatory polyarthritis	1,366
1	174.0	Malignant neoplasm of nipple and areola of female breast	Breast, Prostate, and Other Cancers and Tumors	714.0	Rheumatoid arthritis	1,492
1	227.4	Benign neoplasm of pineal gland	Breast, Prostate, and Other Cancers and Tumors	272.4	Hyperlipidemia, unspecified	1,469

Number of Sampled Enrollee-Years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
1	433.01	Occlusion and stenosis of basilar artery with cerebral infarction	Ischemic or Unspecified Stroke	433.10	Occlusion and stenosis of carotid artery without mention of cerebral infarction	\$4,867
1	441.01	Dissection of thoracic aorta	Vascular Disease With Complications	414.01	Coronary atherosclerosis of native coronary artery	1,798
13						\$33,043

**Table 6: Hierarchical Condition Categories (HCCs) That Were Not Validated, but We Found Support for an HCC for a Less Severe Manifestation of the Related-Disease Group**

Count of Sampled Enrollee-Years	More Severe Hierarchical Condition Category That Was Not Validated	Less Severe Hierarchical Condition Category That Was Supported
1	Diabetes With Acute Complications	Diabetes Without Complication
1	Vascular Disease With Complications	Vascular Disease

## APPENDIX G: REGENCE COMMENTS



February 24, 2022

**BY EMAIL (KITEWORKS) AND UPS OVERNIGHT**

Lori A. Ahlstrand  
Regional Inspector General for Audit Services  
Health and Human Services  
Office of Inspector General  
330 Independence Avenue SW  
Washington, DC 20201

**RE: Regence BlueCross BlueShield of Oregon's Response to OIG's Draft Report for Audit A-09-20-03009**

Dear Ms. Ahlstrand:

Regence BlueCross BlueShield of Oregon ("Regence") writes to respond to the United States Department of Health and Human Services Office of Inspector General's ("OIG's") Draft Report for Audit No. A 09-20-03009 of Regence (Contract H3817) ("Draft Report"). Regence agrees to submit data corrections for certain diagnosis codes OIG audited. Additionally, Regence will continue to explore opportunities to improve its risk adjustment compliance program, including by examining the results of OIG's audit. For the reasons discussed below, however, Regence respectfully requests that OIG withdraw the three recommendations in its Draft Report and welcomes a discussion with OIG about its response.

**I. Regence Agrees to Submit Data Corrections for 108 of the 111 Diagnosis Codes That OIG Characterized as Not Supported by Medical Records**

**A. Regence Will Submit Data Corrections but Will Be Undercompensated for the Relevant Enrollee-Years as a Result**

OIG asserted that 111 of the 179 diagnosis codes it audited were not supported by medical record documentation. Regence agrees to submit data corrections through the Centers for Medicare & Medicaid Services' ("CMS") Risk Adjustment Processing System, and Encounter Data Processing System as appropriate, for 108 of these diagnosis codes.<sup>1</sup>

For the reasons detailed later in this response, Regence disagrees that any unsupported diagnosis codes necessarily constitute overpayments. *See infra* at Section II.A. Regence also notes that after it submits the 108 data corrections and CMS recoups related payments, it will be undercompensated for the enrollee-years at issue. Regence will be undercompensated because, in some cases where OIG found that a diagnosis code submitted was not supported by medical record documentation, OIG identified another risk-adjusting diagnosis code that was

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<sup>1</sup> Regence plans to submit data corrections in accordance with its standard process for reporting and returning overpayments as defined and required under 42 C.F.R. § 422.326. Regence notes that this may result in CMS calculating a different financial impact associated with the 108 diagnosis codes from what OIG has estimated.



supported by medical record documentation. In these instances, OIG gave Regence credit for these alternate diagnosis codes in its estimate of the overpayment to Regence. But the periods for which OIG conducted its audit—2015 and 2016 Payment Years—are now closed to new diagnosis code submissions. Therefore, Regence can no longer supplement its submissions to CMS with the alternate diagnosis codes. When CMS follows its standard recoupment process, it will recoup funds associated with the data corrections Regence submits without giving Regence credit for the alternate diagnosis codes identified by OIG. The net payments from CMS in these instances will therefore be below the compensation that OIG’s audit supports.

**B. Several Diagnosis Codes That OIG Identified as Not Validated Are Supported by Medical Records Submitted to OIG**

Several of the diagnosis codes that OIG concluded were not validated are supported by medical record documentation. For these codes, Regence does not plan to submit data corrections to CMS.

**Embolism**

With respect to one enrollee-year in the embolism category, OIG concluded there was “no documentation of any condition” to support Hierarchical Condition Category (“HCC”) 105. However, the discharging provider documented a diagnosis of “[deep vein thrombosis (‘DVT’)] from the right [peripherally inserted central catheter (‘PICC’)] line,” and DVT corresponds to HCC 105.

OIG appears to have relied on an ultrasound report in the record, which noted findings that “may suggest subacute venous thrombosis.” Based on this, OIG concluded there was “documentation of a proximal and mid basilic vein thrombus . . . which does not result in an HCC and should have been assigned instead of the submitted HCC.” The suggestion by one radiologist, interpreting a single diagnostic test, that there might be evidence of a subacute venous thrombosis, does not undermine the DVT diagnosis made at discharge based on a complete review of the patient’s presentation and records. Even a confirmed basilic vein thrombosis would not rule out a diagnosis of DVT.

Even if the ultrasound report *did* contradict the discharging physician’s clinical diagnosis, it would not render the diagnosis code assigned to this enrollee-year invalid. A conflict between two providers’ diagnoses does not invalidate a properly documented diagnosis code. Coding guidance from both CMS and the American Hospital Association (“AHA”) Coding Clinic supports this understanding. “The assignment of a diagnosis code is based on the provider’s diagnostic statement that the condition exists,” and “[t]he provider’s statement that the patient has a particular condition is sufficient.”<sup>2</sup> As the AHA Coding Clinic explains, “diagnosing a patient’s condition is *solely the responsibility of the provider*,” and “[c]oders *should not be disregarding physician documentation* and deciding on their own . . . whether or not a condition should be coded.”<sup>3</sup>

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<sup>2</sup> CMS, *ICD-10-CM Official Guidelines for Coding and Reporting FY 2022* at 12; see also AHA Coding Clinic (Fourth Quarter 2016), at 147.

<sup>3</sup> AHA Coding Clinic (Fourth Quarter 2016), at 147 (emphases added).

Accordingly, the coding review should not second-guess a treating provider's diagnosis. Here, the DVT diagnosis was plainly documented. OIG's conclusion that a different diagnosis code *should have been* documented is contradicted by the record and supplants the conclusion of the diagnosing provider.

#### Acute Heart Attack

For one enrollee-year in the acute heart attack category, OIG found there was "no documentation of any condition that [would] result in the assignment of HCC 86," noting that "[t]he final discharge diagnosis was syncope (782.0) which does not result in an HCC." OIG cited the CMS Risk Adjustment Data Validation ("RADV") Medical Record Reviewer Guidance, which states that Medicare Advantage Organizations ("MAOs") should "[o]nly submit diagnoses from the ER records not overturned by inpatient record documentation."

The patient presented to the emergency department ("ED") with what an ED physician and a cardiologist diagnosed as a non-ST elevated myocardial infarction ("NSTEMI"), or an atypical myocardial infarction, which was supported by an electrocardiogram and the patient's bloodwork. The patient was admitted to the cardiovascular intensive care unit and started treatment.

OIG's reliance on guidance that MAOs should "[o]nly submit diagnoses from the ER records not overturned by inpatient record documentation" is misplaced. The NSTEMI diagnosis was not "overturned" by the member's inpatient records. The same provider who documented an NSTEMI diagnosis also documented a diagnosis of "Syncope: *In the setting of NSTEMI*" (emphasis added). The reference to syncope describes a manifestation of the NSTEMI diagnosis and does not negate it.

The fact that a discharge diagnosis differs from an ED diagnosis does not mean the latter was *wrong* or "overturned." This is not a case where a provider diagnosed a broken foot, but a later x-ray confirmed a broken ankle instead. The first two providers' NSTEMI diagnoses were supported by the records, and the existence of a later diagnosis does not negate the propriety of the initial diagnoses.

#### Acute Stroke

With respect to one enrollee-year in the acute stroke category (HCC 96), OIG noted there was "no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC or a related HCC," and "[t]he final discharge diagnosis was transient ischemic attack [(TIA)] (435.9) which does not result in an HCC."

OIG's conclusion ignores a properly supported and documented diagnosis. The neurologist in the ED diagnosed the patient with "[l]eft hemispheric embolic stroke." The medical records reflect that the patient was treated in the ED for this condition, and, after treatment, the discharging provider diagnosed TIA.

The *discharge* diagnosis differing slightly from the diagnosis initially made in the ED does not render the initial diagnosis incorrect. This is particularly true when the patient was *treated* for a stroke at the hospital. Often, the distinction between an acute stroke and TIA is only a matter of symptom duration. When there has been an intervention *expected* to improve the

symptoms experienced by a patient during the hospital visit, the reduction in symptoms does not nullify the initial presenting diagnosis. There is no evidence in the record to suggest that the acute stroke diagnosis was either improper or not adequately documented.

## II. Regence Disagrees with OIG's Extrapolated Repayment Calculation

### A. OIG's Recommended Repayment Amount Does Not Ensure Actuarial Equivalence as Required by Statute

OIG estimated that Regence received \$248,885 in net overpayments stemming from the enrollee-years and diagnosis codes audited by OIG. Using this figure, OIG extrapolated across Contract H3817 for both 2015 and 2016 Payment Years and then estimated a total of \$1.8 million in overpayments to Regence for the audited diagnosis code categories. This misstates any overpayments resulting from both the audited codes and the extrapolated amount because the calculations do not account for the Social Security Act's ("SSA's") actuarial equivalence requirement.

CMS is required to pay MAOs in such a way as to ensure "actuarial equivalence" with what CMS would expect to pay for each of the MAOs' beneficiaries under traditional Part A and Part B Medicare ("traditional Medicare"), where CMS generally compensates providers on a fee-for-service basis.<sup>4</sup> This statutory obligation requires that CMS adjust payments to MAOs based on the demographic characteristics and health status of the MAOs' beneficiaries to ensure actuarial equivalence with the expected cost of covering those beneficiaries under traditional Medicare.<sup>5</sup>

To calculate risk adjusted payments, CMS relies on two types of data: data from traditional Medicare and data submitted by MAOs. It is well understood that *both* of these types of data contain diagnosis coding errors. To ensure actuarial equivalence when calculating payments to MAOs, CMS therefore must either: (1) apply the same documentation (i.e., auditing) standards to both sets of data on which it relies to calculate payments to MAOs; or (2) account for any differences in these standards by some other means. Relying on *unaudited* traditional Medicare data to determine payments to MAOs in the first instance and then *auditing* Medicare Advantage ("MA") data skews estimated overpayments to MAOs.

CMS itself has recognized the importance of the actuarial equivalence requirement to CMS's recovery of overpayments to MAOs, including during the time period relevant to this audit. In 2012, CMS notified MAOs that it planned to calculate and apply a Fee-For-Service Adjuster ("FFS Adjuster") to payment recoveries in RADV audits to adjust for diagnosis coding

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<sup>4</sup> 42 U.S.C. § 1395w-23(b)(4)(C)(i).

<sup>5</sup> 42 U.S.C. § 1395w-24(a)(5)(A), (a)(6)(A)(i)-(iii); *see also UnitedHealthcare Ins. Co. v. Azar*, No. 16-cv-157 (D.D.C. Dec. 4, 2017), ECF No. 57-1 (government's motion for summary judgment acknowledging that there must be equivalence "between the average payments that CMS would expect to make on behalf of a given beneficiary under traditional . . . Medicare, and the payments made to [MAOs] for covering an individual with those same characteristics").



errors in traditional Medicare data.<sup>6</sup> In RADV audits, CMS audits HCCs from a sample of enrollees and extrapolates the results of that audit and any resulting recovery across the MAO's contract for a given year. CMS observed that "[i]n RADV audits, [CMS] expect[s] coding perfection from MA plans" and as such, "plans are being held to a different (higher) standard for diagnoses" than CMS applies to diagnoses in traditional Medicare.<sup>7</sup> CMS therefore concluded an FFS Adjuster was necessary to "take[] into account how CMS payments would change if [the] perfection standard that is applied under RADV was also used when calculating risk adjustment model values" that underlie the MA payment model.<sup>8</sup> CMS recognized that MAOs would otherwise be underpaid in violation of the actuarial equivalence requirement,<sup>9</sup> and demonstrated this conclusion in a simplified chart, attached as Exhibit A, that used hypothetical beneficiaries and costs to show precisely how underpayment would occur without an FFS Adjuster.

OIG's extrapolated repayment amount is comparable to CMS recoveries under RADV audits in that both are calculated on a contract-wide level without reviewing every single diagnosis code in the audit population.<sup>10</sup> Such recoveries must comply with the SSA's actuarial equivalence requirement.<sup>11</sup> Because OIG's recommended repayment amount here is not adjusted to ensure actuarial equivalence with traditional Medicare, the recommended repayment amount misrepresents any true overpayment to Regence.

<sup>6</sup> 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). In 2018, CMS backed away from the position that an FFS Adjuster is necessary in the RADV audit context, but a final rule is still pending. See Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program for All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54982 (proposed Nov. 1, 2018) (to be codified at 42 C.F.R. §§ 422, 423, 438, 498).

<sup>7</sup> *United Healthcare Ins. Co. v. Azar II*, 1:16-cv-00157-RMC (D.D.C. Oct. 2, 2017), ECF No. 44-3 at 6 (Document authored by CMS staff titled "Model Calibration Factor").

<sup>8</sup> *Id.* at 10.

<sup>9</sup> See *id.* at 8-9.

<sup>10</sup> *United Healthcare Ins. Co. v. Becerra*, 16 F.4th 867, 886 (D.C. Cir. 2021) (holding actuarial equivalence requirement inapplicable to individual diagnosis coding errors, and in doing so emphasizing it is "[s]ignificant[]" that the term "actuarial" in the SSA "necessarily implies an assessment made at the group or population level, not the individual level").

<sup>11</sup> Litigation is ongoing regarding the applicability of the actuarial equivalence requirement, and necessity of an FFS Adjuster, in the context of CMS's 2014 "Overpayment Rule," which indicates that an MAO receives an overpayment any time it submits a diagnosis code to CMS that is not supported by medical record documentation. See *United Healthcare Ins. Co.*, 16 F.4th 867 (reversing district court decision that had vacated the Overpayment Rule on the grounds that it violated the SSA's actuarial equivalence requirement because it equated individual unsupported diagnosis codes submitted by MAOs with overpayments without applying any FFS Adjuster); Petition for Writ of Certiorari, *United Healthcare Ins. Co. v. Becerra*, No. 21-1140 (arguing that D.C. Circuit's decision reflected a "clear statutory error"). But a court has yet to adjudicate whether an FFS Adjuster is required in the RADV audit context. See *United Healthcare Ins. Co.*, 16 F.4th at 871, 893 n.1 (rejecting assertion that the Overpayment Rule was inconsistent with CMS's 2012 proposal to include an FFS Adjuster in calculating RADV audit recoveries—a proposal CMS made "in direct response to concerns about actuarial equivalence," and "express[ing] no opinion on whether the [SSA's] actuarial-equivalence requirement . . . requires" an FFS Adjuster in the RADV audit context).

### **B. OIG's Audit and Extrapolation Methodology Is Flawed in Several Respects**

Regence also disagrees with OIG's extrapolated repayment amount because of several flaws in OIG's audit methodology.

- **OIG did not conduct a comprehensive review for all potentially supported diagnosis codes associated with a given audited enrollee-year.** The medical review contractors only reviewed a subset of medical records for each enrollee-year and did not review for or identify any *unrelated* diagnosis codes that may have been supported in the medical records but not previously reported to CMS. As a result, the Draft Report likely exaggerates any potential overpayment to Regence because it does not account for all additional diagnosis codes and associated HCCs for which Regence should have been compensated. Extrapolating these results is doubly improper because it multiplies this flawed calculation across the entire contract.
- **OIG's methodology errs in relying on a physician's independent review of a medical record in cases where two coders disagreed about whether a diagnosis code was supported in that record.** The role of a diagnosis coding review is *not* to second-guess the clinical diagnosis decisions of an enrollee's provider. Nor are MA plans expected to scrutinize or verify a provider's clinical diagnosis of their patient. The purpose of a diagnosis coding review is to confirm that the diagnosis codes reported to CMS are documented in the medical record, not to assess whether that diagnosis was one with which OIG would *agree*.<sup>12</sup>
- **OIG's extrapolation calculation methodology is statistically flawed because OIG relied on the lower bound of a 90 percent confidence interval, rather than at least the lower bound of a 95 percent confidence interval.**<sup>13</sup> A confidence interval of 95 percent is more commonly used and robust than a 90 percent confidence interval.<sup>14</sup> OIG should have used at least a 95 percent metric, as CMS does in calculating RADV audit recoveries.<sup>15</sup>

In addition to being methodologically flawed as described above, these aspects of OIG's Draft Report also represent unjustified departures from CMS's RADV audit methodology. Conflicting audit standards and compliance expectations, as discussed *infra* at Section II.C, provide Regence with competing and conflicting requirements for operating its compliance program.

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<sup>12</sup> See, e.g., CMS, *ICD-10-CM Official Guidelines for Coding and Reporting FY 2022* at 12; see also AHA Coding Clinic (Fourth Quarter 2016), at 147.

<sup>13</sup> See Draft Report at 31, 33.

<sup>14</sup> See Federal Judicial Center, National Academies Press, *Reference Manual on Scientific Evidence* 245 (3d ed. 2011) ("The 95% confidence level is the most popular, but some authors use 99%, and 90% is seen on occasion.").

<sup>15</sup> CMS calculates RADV audit overpayments using the lower bound of a 95 percent or 99 percent confidence interval. See CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* (Feb. 24, 2012) at 4.

**C. *OIG's Shifting Audit Standards Render Extrapolated Recoveries Unpredictable and Unfair to Audited MAOs***

Extrapolating the results of OIG's audit here would heighten a fundamental unfairness presented by OIG's audit process. As OIG notes, this is one in a "series of audits in which [OIG is] reviewing the accuracy of diagnosis codes that [MAOs] submitted to CMS,"<sup>16</sup> including at least six other condition-specific audits. Despite the related nature of the other audits in this series, OIG has applied shifting standards and frameworks to each, including using different sets of "high-risk diagnosis codes" and collecting different types of data. In one audit, OIG audited only two groups of high-risk diagnosis codes,<sup>17</sup> while in others OIG audited between six and ten<sup>18</sup> groups of high-risk diagnosis codes.

When OIG extrapolates audit results across an entire contract and recommends recovery of the extrapolated amount, a fundamental unfairness exists between audited and unaudited MAOs. When standards are inconsistent across comparable audits, the discrepancies are amplified. This makes it difficult for MAOs to predict their liabilities and introduces payment incongruities between MAOs that are not contemplated by the MA model.

**III. *Regence Disagrees with OIG's Recommendations That Regence Conduct Additional Audits of OIG's Identified Categories of Diagnosis Codes and Examine and Enhance Its Compliance Procedures***

**A. *Regence's Medicare Risk Adjustment Compliance Procedures During the Audited Period Complied with CMS Requirements***

Regence is a committed partner with the government in offering MA products and supports these programs with effective Medicare risk adjustment compliance policies and procedures. As the Draft Report recognized, during the time period subject to OIG's audit, Regence had a multi-faceted compliance program that included efforts to support the submission of accurate Medicare risk adjustment data to CMS. As described in the Draft Report:

Regence had compliance procedures to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. These procedures included educating

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<sup>16</sup> Draft Report at 1, 21.

<sup>17</sup> See Some Diagnosis Codes That Essence Healthcare, Inc. Submitted to CMS Did Not Comply with Federal Requirements, OIG Audit Report No. A-07-17-01170 (Apr. 2019).

<sup>18</sup> See Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc. (Contract H3359) Submitted to CMS, OIG Report No. A-02-18-01029 (Jan. 2022); Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS, OIG Report No. A-07-19-01188 (Nov. 2021); Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS, OIG Report No. A-07-17-01173 (Oct. 2021); Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS, OIG Report No. A-07-19-01187 (May 2021), p. 21, n. 20; Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS, OIG Report No. A-02-18-01028 (Feb. 2021).



providers to report diagnosis codes if they were actively monitored, evaluated, assessed, or treated during the face-to-face encounter and emphasized that diagnoses that are no longer active should be clearly documented as historical in the patient's record. In addition, Regence conducted routine internal medical reviews to compare diagnosis codes from a random sample of claims with the diagnoses that were documented in the associated medical records. Regence provided guidance to its coders on how to review certain high-risk diagnoses, including diagnosis codes for acute stroke, acute heart attack, and embolism.<sup>19</sup>

During the relevant time period, Regence maintained several other compliance processes.<sup>20</sup> Regence conducted annual compliance risk assessments across its Medicare program. As needed, Regence would implement required interventions to respond to identified risks, including corrective action plans and audits. Regence monitored the effectiveness of the compliance programs of its First Tier, Downstream, or Related Entities by conducting annual risk assessments and auditing a sample of entities whose programs were determined to be high-risk. Regence also conducted quality assurance reviews of select diagnosis codes submitted for risk adjustment purposes, which sought to identify any coding patterns that merited additional scrutiny. These reviews were followed by, in some cases, oversight audits of coders conducting the quality assurance reviews to support coding accuracy.

OIG cited two issues with Regence's compliance procedures. First, "Regence did not conduct specific reviews of high-risk diagnosis codes," including those identified and audited by OIG. Second, "[a]lthough Regence performed reviews to identify risk adjustment coding errors and corrected the errors it found, its compliance procedures corrected only the errors it found in its reviews and were not designed to identify systematic errors."<sup>21</sup>

No CMS rule or regulation requires MAOs to implement compliance programs targeting particular diagnosis codes that are at heightened risk of being miscoded, much less to conduct condition-specific audits of provider-submitted diagnosis codes. Even so, as the Draft Report recognizes, Regence "provided guidance to its coders on how to review certain high-risk diagnoses, including diagnosis codes for acute stroke, acute heart attack, and embolism"—three "high-risk" codes reviewed in OIG's audit. Regence conducted quality assurance reviews that specifically sought to identify any notable coding patterns. Regence had other programs targeted at preventing systemic diagnosis coding errors, such as provider education. Regence, therefore, had compliance processes in place designed to prevent the miscoding of high-risk conditions.

MAOs have significant discretion in how to design a compliance program. OIG guidance since at least 1999 has provided only that MAOs should establish an "information collection and reporting system reasonably designed to yield accurate information" and "should exercise due diligence to ensure that [their] systems are working properly," but that "[t]he exact methods

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<sup>19</sup> Draft Report at 15.

<sup>20</sup> OIG did not assess Regence's compliance procedures outside of the audited period.

<sup>21</sup> Draft Report at 15.

used . . . can be determined by the organization.”<sup>22</sup> OIG has indicated that these methods “should ordinarily [include] sample audits and spot checks of this system to verify whether it is yielding accurate information,”<sup>23</sup> but neither OIG nor CMS has ever prescribed compliance program components specific to diagnosis coding data. Regence submits that its Medicare risk adjustment compliance procedures during the time period audited by OIG complied with CMS program requirements and that Regence’s compliance program today continues to comply with those requirements.

**B. OIG’s Audit Results Do Not Call for Any Additional Auditing or Compliance Measures**

CMS has long recognized that MAOs “cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the OIG, and [the U.S. Department of Justice] believe is reasonable to enforce.”<sup>24</sup> It has always been understood that diagnosis coding errors will be found in provider-reported data—both in the MA program and in traditional Medicare.<sup>25</sup> MAOs’ annual data accuracy attestation requirement incorporates this understanding—asking MAOs to certify not that their data is accurate, but that it is accurate based on their “best knowledge, information, and belief.”<sup>26</sup> This attestation is not “an absolute guarantee of accuracy.”<sup>27</sup> The fact that OIG identified certain unsupported diagnosis code submissions after a medical record review does not in and of itself call into question the sufficiency of Regence’s compliance procedures.

Nor are OIG’s limited findings indicative of the overall accuracy of diagnosis codes submitted by Regence. OIG’s audit targeted diagnosis codes that it predicted were *especially likely* to be unsupported by medical records. Rather than take a random sample of enrollee-years or risk-adjusted conditions, OIG explains that it “identified diagnoses that were at higher risk for being miscoded,” “consolidated those diagnoses into specific groups,” and focused its audit on “seven groups of high-risk diagnosis codes for PY 2015 and 2016.”<sup>28</sup> OIG’s findings, by design, do not speak to the broader accuracy rate in Regence’s data submitted to CMS. Moreover, as discussed *supra* at II.B, OIG did not conduct a holistic review of the audited enrollee-years’ medical records for the audited years. OIG’s audit results therefore do not account for all *additional* diagnosis codes that Regence should have received credit for—they by and large only identify *unsupported* diagnosis codes for which Regence received payment.

Finally, Regence disagrees with the recommendation that Regence examine and enhance its compliance procedures because OIG did not evaluate Regence’s *current* compliance program—OIG only investigated and evaluated the effectiveness of Regence’s compliance

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<sup>22</sup> 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999).

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> See 65 Fed. Reg. 40,170, 40,268 (June 29, 2000) (recognizing that “encounter data [can] come into [MAOs] in great volume and from a number of sources, presenting significant verification challenges for the organizations”).

<sup>26</sup> 42 C.F.R. § 422.504(l)(2).

<sup>27</sup> 64 Fed. Reg. at 61,900.

<sup>28</sup> Draft Report at 1.



program during the audited period (2015 and 2016 Payment Years). Regence will continue to look—as it always has—for opportunities to improve its compliance program and will consider the results of OIG’s audit in doing so. But Regence does not agree with OIG that OIG’s audit results indicate that Regence’s compliance program is insufficient under CMS requirements, or that any particular additional auditing is required.

#### **IV. Conclusion**

For all the reasons discussed above, Regence does not concur with OIG’s recommendations that Regence: (1) refund \$1,890,855 to the Federal Government; (2) conduct additional audits of OIG’s identified “high-risk diagnoses”; and (3) examine and enhance its compliance procedures. We welcome a conversation with OIG about Regence’s responses herein.

Sincerely,



**Kathleen E. Faulk**  
Senior Vice President, Government Programs  
Regence BlueCross BlueShield of Oregon

Enclosure: Exhibit A