Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

MEDICARE ADVANTAGE COMPLIANCE AUDIT OF SPECIFIC DIAGNOSIS CODES THAT AETNA, INC. (CONTRACT H5521) SUBMITTED TO CMS

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Why OIG Did This Audit

Under the Medicare Advantage (MA) program, 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, Aetna, Inc. (Aetna), and focused on seven groups of high-risk diagnosis codes.

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

How OIG Did This Audit

We sampled 210 unique enrollee-years with the high-risk diagnosis codes for which Aetna received higher payments for 2015 through 2016. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $856,818**.**

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Aetna, Inc. (Contract H5521) 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 Aetna submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 155 of the 210 sampled enrollee-years, the medical records that Aetna provided did not support the diagnosis codes and resulted in $632,070 in overpayments. On the basis of our sample results, we estimated that Aetna received at least $25.5 million in overpayments for 2015 and 2016. As demonstrated by the errors found in our sample, Aetna's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved.

What OIG Recommends and Aetna Comments

We recommend that Aetna: (1) refund to the Federal Government the $632,070 of overpayments; (2) determine, for the remaining 159 enrollee-years in the potentially mis-keyed diagnosis code high-risk group not reviewed as part of this audit, whether the medical records in each case support the diagnosis for the unrelated condition and refund any resulting overpayments to the Federal Government; (3) 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 (4) continue to examine and improve its compliance procedures.

Aetna did not concur with our recommendations or agree with our findings for 5 enrollee-years sampled. Aetna did not state whether it agreed or disagreed with our findings for the remaining enrollee-years. Aetna also disagreed with our audit methodology, medical record review process, and use of extrapolation.

After reviewing Aetna's comments and additional information that Aetna provided, we revised the number of enrollee-years in error from 156 to 155 for this final report. We also revised the wording for our fourth recommendation. After we had issued our draft report, CMS updated regulations for audits in its risk adjustment program to specify that extrapolated overpayments could only be recouped beginning with payment year 2018. We, therefore, revised our first recommendation to request a refund of only the overpayments for the sampled enrollee-years.

The full report can be found at https://oig.hhs.gov/oas/reports/region1/11800504.asp.

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INTRODUCTION

WHY WE DID THIS AUDIT

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

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS.[2] Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 27 major depressive disorder diagnoses into 1 group.) This audit covered Aetna, Inc. (Aetna),[3] for contract number H5521 and focused on seven groups of high-risk diagnosis codes for payment years 2015 and 2016.[4]

OBJECTIVE

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

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

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

[3] CVS Health Corporation acquired Aetna on November 28, 2018.

[4] All subsequent references to "Aetna" in this report refer solely to contract number H5521.

BACKGROUND

Medicare Advantage Program

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

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

For 2022, CMS paid MA organizations $403.3 billion, which represented 45 percent of all Medicare payments for that year.

Risk Adjustment Program

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

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

- *Base rate*: Before the start of each year, each MA organization submits bids to CMS that reflect the MA organization's estimate of the monthly revenue required to cover an enrollee with an average risk profile.[7] CMS compares each bid to a specific benchmark amount for each geographic area to determine the base rate that an MA organization is paid for each of its enrollees.[8]

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

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

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

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

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

To determine an enrollee's health status for purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from acceptable data sources, including certain physicians and hospitals. MA organizations collect the diagnosis codes from providers based on information documented in the medical records and submit these codes to CMS. CMS then maps certain diagnosis codes, on the basis of similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs).[9] 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, 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. Specifically, CMS uses the diagnosis codes that the enrollee received for one calendar year (known as the service year) to determine HCCs and calculate risk scores for the following calendar year (known as the payment year). Thus, an enrollee's risk score does not change for the year in which a diagnosis is made. Instead, the risk score changes for the entirety of the year after the diagnosis has been made. Further, the risk score calculation is an additive process: As HCC factors (and, when applicable, disease interaction factors) accumulate, an enrollee's risk score increases, and the monthly risk-adjusted payment to the MA organization also increases. In this way, the risk adjustment program compensates MA organizations for the additional risk of providing coverage to enrollees expected to require more health care resources.

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[9] CMS transitioned from one HCC model to another during our audit period. As part of this transition, for 2015, CMS calculated risk scores based on both 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 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.[10] 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.[11] 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:[12]

- *Acute Stroke*: An enrollee received one 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. In these instances, a diagnosis of history of stroke (which does not map to an HCC) typically should have been used.

- *Acute Heart Attack*: An enrollee received one diagnosis that mapped to either the HCC for Acute Myocardial Infarction or to the HCC for Unstable Angina and Other Acute Ischemic Heart Disease (Acute Heart Attack HCCs) on only one physician or outpatient claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician or outpatient claim). In these instances, a diagnosis for a less severe manifestation of a disease in the related-disease group typically should have been used.

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[10] 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.

[11] 42 CFR § 422.310(e) requires MA organizations (when undergoing an audit conducted by the Secretary) to submit "medical records for the validation of risk adjustment data." For purposes of this report, we use the terms "supported" or "unsupported" to denote whether or not the reviewed diagnoses were evidenced in the medical records. If our audit determines that the diagnoses are supported or unsupported, we accordingly use the terms "validated" or "unvalidated" with respect to the associated HCC.

[12] 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.[13]

- *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) on only one claim 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 medication dispensed on his or her behalf that is frequently dispensed for a diagnosis of neurogenic claudication.[14] 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 (that 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 832 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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[13] 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 HCC or an 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).

[14] 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."

Aetna, Inc.

Aetna is an MA organization based in Hartford, Connecticut. As of December 31, 2016, Aetna provided coverage under contract number H5521 to 692,958 enrollees. For the 2015 and 2016 payment years (audit period), CMS paid Aetna approximately $12.7 billion to provide coverage to its enrollees.[15, 16]

On November 28, 2018, CVS Health Corporation (CVS Health) acquired Aetna. CVS Health is a diversified health company based in Woonsocket, Rhode Island.

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 Aetna received increased risk-adjusted payments for payment years 2015 and 2016, respectively. Because enrollees could be classified into more than one high-risk group or could have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment year, which we refer to as "enrollee-years."

We identified 14,948 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes ($40,108,178). We selected for audit a sample of 210 enrollee-years, which comprised: (1) a stratified random sample of 180 (out of 14,759) enrollee-years for the first six high-risk groups and (2) a non-statistical sample of 30 (out of 189) enrollee-years for the remaining high-risk group.

Table 1 on the following page details the number of sampled enrollee-years for each high-risk group.

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[15] The 2015 and 2016 payment year data were the most recent data available at the start of the audit.

[16] All of the payment amounts that CMS made to Aetna and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

Table 1: Sampled Enrollee-Years

High Risk Group	Number of Sampled Enrollee Years
1. Acute Stroke	30
2. Acute Heart Attack	30
3. Acute Stroke/Acute Heart Attack Combination	30
4. Embolism	30
5. Vascular Claudication	30
6. Major Depressive Disorder	30
Total for Stratified Random Sample	**180**
7. Potentially Mis-keyed Diagnosis Codes	30
Total for All High-Risk Groups	**210**

Aetna provided medical records as support for the selected diagnosis codes associated with 199 of the 210 sampled enrollee-years.[17] 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. For the HCCs that were not validated, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or if we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

Appendix A contains the details of our audit scope and methodology, Appendix C contains our statistical sampling methodology, Appendix D contains our sample results and estimates, and Appendix E contains the Federal regulations regarding MA organizations' compliance programs.

FINDINGS

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that Aetna submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 55 of the 210 sampled enrollee-years, the medical records validated the reviewed HCCs, or we identified another diagnosis code (on CMS's systems) that

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[17] Aetna could not locate medical records for the remaining 11 sampled enrollee-years.

mapped to the HCC under review. For the remaining 155 enrollee-years, however, either the medical records that Aetna provided did not support the diagnosis codes or Aetna could not locate the medical records to support the diagnosis codes and the associated HCCs were therefore not validated. As a result, Aetna received $632,070 in overpayments. On the basis of our sample results, we estimated that Aetna received at least $25,579,799 in overpayments for 2015 and 2016.[18] Because of Federal regulations that limit the use of extrapolation in Risk Adjustment Data Validation (RADV) audits for recovery purposes to payment years 2018 and forward, we are reporting the overall estimated overpayment amount but are recommending a refund of $632,070 in overpayments.[19]

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

FEDERAL REQUIREMENTS

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

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

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

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[18] Specifically, we estimated that Aetna received at least $25,579,799 ($25,303,632 for the statistically sampled groups plus $276,167 for the group of potentially mis-keyed diagnosis codes) in overpayments. To be conservative, we estimated 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.

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

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, MA organizations must implement procedures to ensure that diagnoses come only from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities, and physicians (the Manual, chap. 7, § 40).

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

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

Most of the selected high-risk diagnosis codes that Aetna 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 155 of the 210 sampled enrollee-years did not support the diagnosis codes. In these instances, Aetna should not have submitted the diagnosis codes to CMS and received the resulting overpayments.

Figure: Analysis of High-Risk Groups
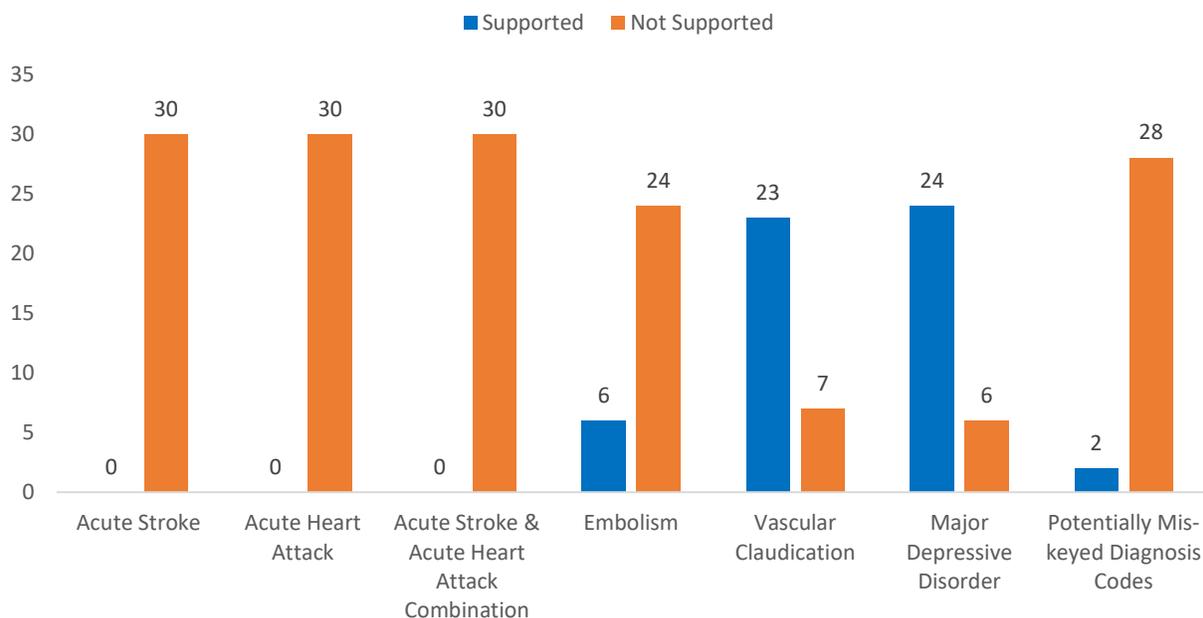
Incorrectly Submitted Diagnosis Codes for Acute Stroke

Aetna incorrectly submitted diagnosis codes for acute stroke for all 30 sampled enrollee-years. Specifically:

- For 21 enrollee-years, the medical records indicated in each case that the individual had previously had a stroke, but the records did not justify an acute stroke diagnosis at the time of the physician's service.

    For example, for 1 enrollee-year, the independent medical review contractor noted that "there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC or a related HCC. There is mention of a history of a stroke [diagnosis] but no description of residuals or sequelae that should be coded."[20]

- For 8 enrollee-years, the medical records in each case did not contain sufficient information to support an acute stroke diagnosis.

    For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC or a related HCC."

- For the 1 enrollee-year remaining, Aetna could not locate any medical records to support the acute stroke diagnoses; therefore, the HCCs for Acute Stroke were not validated.

As a result of these errors, the HCC for Ischemic or Unspecified Stroke were not validated, and Aetna received $85,739 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Heart Attack

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

- For 16 enrollee-years, the medical records in each case did not support the submitted diagnosis code that mapped to an Acute Heart Attack HCC. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Aetna should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the other diagnosis identified.

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

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 HCC [Unstable Angina and Other Acute Ischemic Heart Disease]. There is documentation of a past medical history of myocardial infarction [diagnosis] that results in HCC [Angina Pectoris/Old Myocardial Infarction]."

- For 8 enrollee-years, the medical records indicated in each case that the individual had an old myocardial infarction diagnosis, but the records did not support the submitted diagnosis code that mapped to an Acute Heart Attack HCC (at the time of the physician's service).[21] In these instances, the old myocardial infarction diagnosis did not map to an HCC.[22]

  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 HCC [Unstable Angina and Other Acute Ischemic Heart Disease]. There is documentation of a past medical history of [a] myocardial infarction [diagnosis] that does not result in an HCC."

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

  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 HCC [Unstable Angina and Other Acute Ischemic Heart Disease]."

As a result of these errors, the Acute Heart Attack HCCs were not validated, and Aetna received $54,936 in overpayments for these 30 sampled enrollee-years.

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

[22] The risk scores for these 8 enrollee-years were based solely upon CMS's Version 22 model. Under this model, an old myocardial infarction diagnosis did not map to an HCC.

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

For 30 sampled enrollee-years, Aetna had submitted diagnosis codes in which physicians had documented conditions for both the acute stroke and acute heart attack high-risk groups in the same year (footnote 13). However, we found errors for all 30 of the enrollee-years because the medical records in each case did not support either the acute stroke diagnosis, the acute myocardial infarction diagnosis, or both.

Table 2 details the findings for the 30 enrollee-years for which the medical records did not support the submitted diagnosis codes.

Table 2: Acute Stroke and Acute Heart Attack Combination Findings

Count of Enrollee-Years	Acute Stroke HCC		Acute Heart Attack HCC	
	Medical Record Validated HCC	**Support for Different HCC Found**	**Medical Record Validated HCC**	**Support for Different HCC Found**
11	No	No	No	Yes – Angina Pectoris/Old Myocardial Infarction
8	No	No	No	No
4[*]	No	No	No	Yes – Angina Pectoris/Old Myocardial Infarction (Version 12)/Angina Pectoris (Version 22)
4	No	No	Yes	Not Applicable
2	No	No	No	Yes – Angina Pectoris
1[†]	Yes	No	No	No
* For 1 of these 4 enrollee-years, Aetna did not submit a medical record for the acute stroke diagnosis code. For another one of these enrollee-years, Aetna could not locate any medical records for either the acute stroke or acute myocardial infarction diagnosis codes. † For this enrollee-year, we found support for another diagnosis for the acute stroke HCC on CMS's systems. As a result, we consider the acute stroke HCC a non-error.				

As a result of these errors, the HCCs for either Ischemic or Unspecified Stroke or Acute Heart Attack, or both, were not validated, and Aetna received $110,266 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

Aetna incorrectly submitted diagnosis codes for embolism for 24 of 30 sampled enrollee-years. Specifically:

- For 16 enrollee-years, the medical records did not support a diagnosis that mapped to an Embolism HCC.

  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 Vascular Disease]."

- For 4 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not justify a diagnosis that mapped to an Embolism HCC at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor noted that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Vascular Disease with Complications]. There is mention of a past medical history of pulmonary embolism [diagnosis] that does not result in an HCC."[23]

- For the 4 enrollee-years remaining, Aetna could not locate any medical records in each case to support the embolism diagnosis; therefore, the Embolism HCC was not validated.

As a result of these errors, the Embolism HCCs were not validated, and Aetna received $69,511 in overpayments for these 24 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Vascular Claudication

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

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

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

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[23] A pulmonary embolism is the blocking of an artery of the lung (pulmonary artery) by a collection of solid material brought through the bloodstream—usually a blood clot. Blood clots are clumps that occur when blood hardens from a liquid to a solid.

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

As a result of these errors, the HCCs for Vascular Disease were not validated, and Aetna received $16,335 in overpayments for these 7 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder

Aetna incorrectly submitted diagnosis codes for major depressive disorder for 6 of 30 sampled enrollee-years. Specifically:

- For 4 enrollee-years, the medical records in each case did not support a major depressive disorder diagnosis.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of HCC [Major Depressive, Bipolar, and Paranoid Disorders]. There is documentation of depression [diagnosis] which does not result in an HCC [for Major Depressive, Bipolar, and Paranoid Disorders]."[24]

- For the 2 enrollee-years remaining, Aetna could not locate any medical records in each case to support the major depressive disorder diagnosis; therefore, the HCCs for Major Depressive Disorder were not validated.

As a result of these errors, the HCCs for Major Depressive, Bipolar, and Paranoid Disorders were not validated, and Aetna received $19,116 in overpayments for these 6 sampled enrollees-years.

Potentially Mis-keyed Diagnosis Codes

Aetna submitted potentially mis-keyed diagnosis codes for 28 of 30 sampled enrollee-years. In each of these cases, the enrollees associated with the enrollee-years received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition. Specifically:

- For 21 enrollee-years, the medical records in each case did not support the diagnosis for the unrelated condition. Because of these errors, Aetna submitted to CMS unsupported diagnosis codes that mapped to unvalidated HCCs.

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[24] Depression is a feeling of sadness or a decreased interest or pleasure in activities that becomes a disorder when it is intense enough to interfere with functioning.

For example, for 1 enrollee-year, Aetna submitted 9 diagnosis codes for diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled (250.00)[25] and only 1 diagnosis code for acute myeloid leukemia, without mention of having achieved remission (205.00).[26] The independent medical review contractor limited its review to the acute myeloid leukemia, without mention of having achieved remission diagnosis, for which it did not find support.

- For 5 enrollee-years, the medical record 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, Aetna 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, Aetna submitted a diagnosis code for metastatic cancer and acute leukemia. The independent medical review contractor noted that "there is no documentation of any condition that will result in the assignment of HCC [Metastatic Cancer and Acute Leukemia]. There is mention of [a] chronic myeloid leukemia [diagnosis][27] that results in HCC [Lung, Upper Digestive Tract, and Other Severe Cancers] which should have been assigned instead of the submitted HCC." Accordingly, Aetna should not have received an increased payment for the Metastatic Cancer and Acute Leukemia HCC but should have received a lesser increased payment for the Lung, Upper Digestive Tract, and Other Severe Cancers HCC.

- For 2 enrollee-years, Aetna could not locate any medical records in each case to support the potentially mis-keyed diagnosis code; therefore, the HCC associated with the potentially mis-keyed diagnosis code was not validated.

Appendix F contains the HCCs that were not validated for the 28 enrollee-years (Table 6) and the HCCs for the less severe manifestation of the related-disease group that were supported for the 5 enrollee-years (Table 7).

As a result of these errors, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated, and Aetna received $276,167 in overpayments for these 28 sampled enrollee-years. We did not review the remaining 159 enrollee-years that we identified as having a potentially mis-keyed diagnosis code.

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[25] Diabetes mellitus is a disorder in which the body does not produce enough or respond normally to insulin, causing blood sugar levels to be abnormally high.

[26] Acute myeloid leukemia is a cancer of the blood and bone marrow.

[27] Chronic myeloid leukemia is a slowly progressing disease in which cells that normally would develop into the types of white blood cells called neutrophils, basophils, eosinophils, and monocytes become cancerous and replace normal cells in the bone marrow.

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

As demonstrated by the errors found in our sample, the policies and procedures that Aetna had 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.

Aetna had compliance policies and procedures in place to determine whether the diagnosis codes that it received from its providers and then submitted to CMS to calculate risk-adjusted payments were correct. One of these prevention techniques included education related to risk adjustment that Aetna made available to contracted providers. However, Aetna officials informed us that the providers were not required to participate in the available education.

Aetna's compliance policies and procedures to detect and correct Medicare noncompliance included an annual risk assessment in which Aetna reviewed, ranked, and prioritized regulatory risks. From this assessment, Aetna developed an annual workplan to prioritize its Medicare monitoring and auditing activities. Aetna also had procedures to perform periodic reviews by which it identified the diagnoses reported on the underlying medical records and compared those results to the claims to identify any discrepancies. Although these procedures did not specifically target high-risk diagnoses (as identified in this report) for review, we note that Aetna provided guidance to its reviewers that outlined the process of coding acute stroke and acute myocardial infarction diagnoses in accordance with CMS documentation and ICD-9 guidelines.

Based on our assessment of the policies and procedures that were in place for our audit period and because the diagnosis codes for 155 of the 210 sampled enrollee-years (including all 90 enrollee-years in the acute stroke, acute heart attack, and acute stroke and acute heart attack combination high-risk groups[28]) were not supported by the medical records, Aetna's compliance procedures to prevent, detect, and correct high-risk diagnoses could be improved.

AETNA RECEIVED OVERPAYMENTS

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Aetna received at least $25,579,799 in overpayments ($25,303,632 for the statistically sampled high-risk groups plus $276,167 for the potentially mis-keyed diagnosis codes) for 2015 and 2016 (Appendix D).

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[28] We sampled 30 enrollee-years from each of the Acute Stroke, Acute Heart Attack, and Acute Stroke and Acute Heart Attack Combination high-risk groups (for a total of 90 enrollee-years). The medical records did not validate the audited HCCs for all 60 of the sampled enrollee-years in the Acute Stroke and Acute Heart Attack high-risk groups. For each of the 30 sampled enrollee-years in the Acute Stroke and Acute Heart Attack Combination group, either the acute stroke or acute heart attack HCC (or both) was not validated (Table 2).

Because of Federal regulations that limit the use of extrapolation in RADV audits for recovery purposes to payment years 2018 and forward, we are reporting the estimated overpayment amount but are recommending a refund of only the $632,070 in overpayments that Aetna received for the 210 sampled enrollee-years. (See footnote 19.)

RECOMMENDATIONS

We recommend that Aetna, Inc.:

- refund to the Federal Government the $632,070 of overpayments;

- determine, for the remaining 159 enrollee-years in the potentially mis-keyed diagnosis code high-risk group not reviewed as part of this audit, whether the medical records in each case support the diagnosis for the unrelated condition and refund any resulting overpayments to the Federal Government;

- 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.

AETNA COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Aetna stated that it did not agree with some of our findings and did not concur with our recommendations. Specifically, Aetna did not agree with our findings for 5 of the 156 enrollee-years in error in our draft report. For these 5 enrollee-years, Aetna explained why the medical records it gave us validated the reviewed HCCs. Aetna did not state whether it agreed or disagreed with our findings for the HCCs related to the remaining 151 enrollee-years. With respect to our methodology, Aetna said that it saw "numerous flaws," including our "apparent expectation for perfect coding in the [Medicare Advantage] program" and "approach to medical record review." Aetna also stated that it understood that we would make changes to this final report from the draft report, including the removal of our recommendation related to extrapolation, and that we declined its request to make formal comments on the changes to this final report.

After considering Aetna's comments and additional information it provided, we reduced the number of enrollee-years in error from 156 to 155 and adjusted our calculation of overpayments for this final report. We also revised the wording for our fourth recommendation. After we issued our draft report, CMS updated its regulations for RADV audits to specify that extrapolated overpayments could be recouped beginning with payment

year 2018 only. (See footnote 19.) Because our audit period covered payment years 2015 and 2016, we revised the amount in our first recommendation to reflect only the overpayments for the 155 sampled enrollee-years.

Aetna is correct in that we declined its request to make formal comments on this final report. We made two changes that were not in our draft report: (1) as explained just above, we revised the amount in our first recommendation to reflect only the overpayments for the sampled items, and (2) we revised our fourth recommendation to state that Aetna should "continue" to examine its existing compliance procedures. Accordingly, Aetna has had the opportunity to comment on every aspect of our report. We maintain that our remaining recommendations are valid.

Aetna's comments are included in their entirety as Appendix G.

AETNA DID NOT CONCUR WITH THE OIG RECOMMENDATION THAT IT REFUND OVERPAYMENTS

Aetna Did Not Agree With OIG's Findings for 5 Sampled Enrollee-Years

Aetna Comments

Aetna disagreed with our findings related to 5 sampled enrollee-years (Table 3) and explained that the medical records it provided to us validated the reviewed HCCs.

Table 3: Summary of Enrollee-Years for Which Aetna Disagreed With Our Findings

High Risk Group	Number of Sampled Enrollee Years
Acute Stroke/Acute Heart Attack Combination	2
Embolism	1
Vascular Claudication	2
Total	5

For example, for 1 enrollee-year (sample 111), Aetna disagreed with our independent medical review contractor's conclusion that there was no documentation to support a condition that would result in the assignment of the HCC for Acute Stroke. Aetna stated that the "OIG second-guessed the treating [emergency department] physician's diagnosis of stroke even though the diagnosis was entirely reasonable at the time of the care . . . and the medical records were robust . . . OIG simply applied a standard that was more rigorous than what the coding guidelines required."

OIG Response

For 4 of the 5 enrollee-years for which Aetna disagreed with the results of our independent medical review contractor's coding review, our contractor reaffirmed that the HCCs were not validated and upheld its original decisions. For sample 111, our contractor stated: "Even though a diagnosis of stroke is noted, there is contradictory information in the medical record. The head CT scan results indicate no acute abnormality. The patient received a critical care evaluation in the emergency room but there is no documentation that the patient was admitted as an inpatient for further evaluation as noted in [Aetna's] rebuttal. The diagnosis of stroke was not confirmed. The ICD-9-CM Official Guidelines for Coding and Reporting indicate that uncertain diagnoses are not to be coded for outpatient services."[29]

For the remaining 1 enrollee-year (from the embolism high-risk group), our independent medical review contractor reversed its original decision after reviewing the explanation that Aetna submitted. Specifically, Aetna cited the medical record's reference to the fact that the enrollee had a filter inserted and that filters are only placed in individuals who have had and have ongoing risk of embolism and for whom long-term anticoagulation is not an option.[30] Our contractor stated "[t]here is documentation of chronic pulmonary embolism [diagnosis] which results in [the] HCC [for Vascular Disease with Complications]. This condition was assessed and treatment evaluated."

Accordingly, we reduced the number of enrollee-years in error from 156 (in our draft report) to 155 for this final report. We also revised our findings and reduced the associated monetary recommendation. Our independent medical review contractor confirmed that Aetna's written comments and additional explanations had no impact on the decisions that our contractor made for other sampled enrollee-years and stated that there were no "systemic issues identified" in its reviews.

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[29] A computed tomography scan (better known as a CT scan or CAT scan) is often one of the first tests done in a stroke evaluation. A CT scan uses X-rays to take pictures of the skull and brain that are then used by computers to create an image of the brain to show areas of abnormalities in the brain that can help determine the type of stroke.

[30] A vena cava filter is a metal device placed in a vein to prevent blood clots in the lungs (pulmonary embolism). Patients may need a filter if they have blood clots in their veins and can't take blood-thinning medications (anticoagulants).

Aetna Stated That OIG's Audit Departed From the Congressional Design and Historical Implementation of the Medicare Advantage Program

Aetna Comments

Aetna said that our audit departed from the Congressional design and historical implementation of the MA program to which Aetna made several related points:

- Aetna said that our audit of "specific diagnosis codes" departed from the "historical aim" of the MA program, which has been to achieve overall payment accuracy for which the over reporting of some diagnosis codes offsets the underreporting of others. Aetna stated that our audit approach: (1) distorts CMS's risk-adjustment process because we "expect perfect coding for specific diagnoses by looking at only those diagnoses in isolation" and (2) was "unworkable at scale" because "[t]he volume of data in the MA program is already tremendous" and "an MA program that looks at large volumes of diagnosis codes chosen by OIG would put those administrative burdens squarely on the [MA organizations]." To these points, Aetna stated that "Congress has never adopted OIG's apparent approach, and for good reason."

- Aetna did not agree with our methodology of only selecting specific diagnoses for audit. Aetna noted that we, unlike CMS, did not look "at all the diagnosis codes in each [medical] record to determine which were correct, and which were not." Instead, according to Aetna, we "began with fact patterns that supposedly showed overreporting of specific diagnoses, and then used analytics to . . . fit those fact patterns." Further, Aetna said that we "limited the evidence" that it "could present in support of the diagnosis." Aetna also stated that we did not attempt to measure overall payment accuracy or account for factual differences between the enrollee-years within the samples. Aetna said, "OIG's approach slanted the playing field towards the finding of alleged overpayments in the audit."

- Aetna also stated the "CMS attestation and compliance regulations do not support— much less require—the OIG audit structure." Aetna acknowledged that the "attestation regulation requires that [MA organizations] certify 'based on the best knowledge, information, and belief' to the 'accuracy, completeness, and truthfulness of relevant data that CMS requests.'" Aetna also acknowledged that the compliance regulation requires MA organizations to have an operative and productive compliance program. However, Aetna also stated that neither regulation speaks "to how OIG should structure its audit" or supports our recommendation for "self-auditing of specific diagnosis codes."

OIG Response

Our audit of diagnosis codes that are at a high risk for being miscoded did not depart from the Congressional design and historical implementation of the MA program.

- While we acknowledge that Federal requirements mandate that payments to MA organizations be based on the anticipated cost of providing Medicare benefits to a given enrollee,[31] we do not agree with Aetna's assertion that underreported and overreported diagnosis codes offset each other to achieve payment accuracy. Further, these requirements do not prohibit audits of specific diagnosis codes, especially for diagnoses that we have determined to be at high risk for being miscoded.

- As Aetna stated, we began "with fact patterns that supposedly showed overreporting of specific diagnoses." Specifically, we identified diagnoses that were at a higher risk for being miscoded. However, we did not "limit the evidence" that Aetna could provide in support of the diagnoses. Because we designed our audit to review the diagnosis codes that Aetna had submitted to CMS, we allowed Aetna to provide any medical record of its choosing that conformed to CMS's risk-adjustment requirements as support for the audited HCC. Furthermore, Aetna's description of our overpayment calculations as skewed is not accurate. A valid estimate of overpayments does not need to take into consideration all potential HCCs or underpayments within the audit period. Our estimate of overpayments addresses only the portion of payments related to the reviewed HCCs and does not extend to HCCs that were beyond the scope of our audit.

- Further, we disagree with Aetna's statement that our audit is "unworkable at scale" and Aetna's assertion that we misunderstood the attestation and compliance regulations. 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.[32] We recognize, as Aetna said, that CMS has never required that MA organizations ensure perfect coding for all claims. We also acknowledge that Aetna cannot "reasonably be expected to know that every piece of data is correct."

Our audit revealed a significant error rate (155 of 210 enrollee-years) with unsupported diagnosis codes (see Appendix D) for the high-risk areas we audited. Federal regulations require MA organizations to implement procedures for "promptly responding to compliance issues as they are raised" and to correct "such problems promptly and thoroughly to reduce the potential for recurrence" (42 CFR § 422.503(b)(4)(vi)(G)). (See Appendix E.) As such, Aetna is responsible for addressing the issues that resulted in that significant error rate. Further, we selected our sample from a 2-year period that identified 14,948 enrollee-years. Thus, correcting these issues are "workable at scale," and will also assist Aetna in attaining better assurance with regard to the accuracy, completeness, and truthfulness of the risk adjustment data that it submits in the future.

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

[32] 79 Fed. Reg. 29844, 29926 (May 23, 2014).

Accordingly, we maintain our recommendation for Aetna to 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 as valid.

Aetna Stated That Aspects of OIG's Audit Were Slanted in Favor of Finding Alleged Overpayments

Aetna Comments

Aetna stated that aspects of our audit were slanted in favor of identifying overpayments. Specifically, Aetna stated that our selection of "distant" audit years created a data validation problem because the "loss of [medical] records [by some providers] prevented Aetna from adducing medical record support for physician diagnosis coding that was undisputedly authentic." Aetna also stated that we instructed it "to flag only the page numbers and text of the medical records [as] directed by [the] OIG" and that it was unclear as to whether we "reviewed [the] pages [of the medical records] outside of those flagged" in order to identify underpayments.

Aetna said that although we indicated that we included the financial impact of HCCs that should have been submitted but were not, "the risk adjustment submission process was not open to allow Aetna to submit additional HCCs for these codes." Further, Aetna stated that we used pharmacy data to populate our sample, but "would not permit Aetna to use any pharmacy data to show that diagnoses codes were supported."

OIG Response

We do not fully agree with Aetna's statements.

CMS's RADV Submission Instructions, issued to MA organizations, recognizes that "there may be extraordinary circumstances that prevent an MA Organization . . . from submitting medical records for the audited enrollee(s) and CMS-HCC(s) in accordance with . . . audit requirements."[33] However, CMS also notes in these instructions that "extraordinary circumstances do not typically include ordinary issues encountered during the process of requesting medical records and attestations from providers." We worked with Aetna officials during our audit to extend the medical record collection timeframe to account for any collection difficulties. Moreover, Aetna did not convey to us that it had confronted any extraordinary circumstances for the 11 enrollee-years for which it was not able to provide us medical records.

We did not review the pages of the medical records outside of those flagged to identify underpayments. Each of the sampled enrollee-years had one claim with a diagnosis that was at

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

high risk for being miscoded. We asked Aetna to provide the medical records for those claims and, at its option, up to four additional medical records as support for the audited HCC for each enrollee-year. Because the claims associated with these additional medical records—when Aetna initially submitted them to CMS—did not have a diagnosis code that mapped to the audited HCC, we asked Aetna to flag the page number of the medical record for which it believed support existed for the relevant diagnosis. Our objective did not extend to diagnosis codes not previously submitted by Aetna or to HCCs that were beyond the scope of our audit; accordingly, we did not review the pages outside of those flagged to identify potential underpayments.

With regard to Aetna's statement that it could not make submissions to CMS for the HCCs that we determined should have been submitted, 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.[34] Aetna should work with CMS officials regarding any underpayments that we identified for this audit. In addition, we used prescription drug event data as a means to identify enrollee-years with diagnoses that were at high risk for being miscoded. To determine whether the associated HCC was validated, we only reviewed the medical records that conformed to CMS's requirements (inpatient, outpatient, or physician) as support for the audited HCC.

Aetna Stated That Numerous Aspects of OIG's Medical Record Review Process Were Unclear, Unfair, or Potentially Unlawful

Aetna Comments

Aetna had numerous concerns regarding our independent medical review contractor's review process. With regard to these concerns, Aetna made several points:

- Aetna stated that "OIG did not identify the name of its independent medical record review contractor." Aetna also said that it did not "have any way of evaluating whether the contractor was qualified, applied consistent standards across its work for OIG and other clients, and was free from conflicts of interest."

- Aetna stated that "OIG did not confirm all of its medical record review standards for Aetna, or promulgate any of them through notice-and-comment rulemaking." Specifically, Aetna stated that it needed to know how our independent medical review contractor applied the ICD-10 coding guidelines and if the contractor augmented "those guidelines with [any] additional coding resources." To this point, Aetna said that even if we provided this explanation, "the audit process would have still been unfair and

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[34] Action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures. In accordance with 42 CFR § 422.311, which addresses audits conducted by the Secretary (including those conducted by OIG), if a disallowance is taken, MA organizations have the right to appeal the determination that an overpayment occurred through the Secretary's RADV appeals process.

potentially unlawful because neither OIG nor CMS published the standards through notice-and-comment rulemaking." Aetna further stated: "If CMS were to recoup OIG's alleged overpayment from Aetna, then OIG's underlying medical records review standards would constitute requirements or policies establishing substantive legal standards governing the payment for services . . .. Neither the ICD-10 coding guidelines, nor the Medicare Managed Care manual, nor any other standards used by OIG and the independent reviewer have been promulgated by regulation under 42 U.S.C. § 1395hh(a)(1). . .. The lack of notice and comment had real-world consequences that diminished the integrity of the audit."

- Aetna stated that "OIG acted arbitrarily and capriciously by overriding physician diagnoses based on subsequent treatments, patient choices, and OIG's clinical preferences." Specifically, Aetna asserted that our independent medical review contractor relied upon decisions made by enrollees or the conclusions drawn by any subsequent treating physicians "to find that diagnoses by treating physicians in the sample were unsupported."

OIG Response

We do not agree with Aetna's assertion that aspects of our medical record review process were unclear, unfair, or potentially unlawful. Specifically:

- It is not our practice to name our independent medical review contractor. However, our audit process included measures to ensure that there were no conflicts of interest among the parties involved in the audit. Identifying our contractor by name would not provide information about our contractor's qualifications beyond what we state in this audit report. Furthermore, during the course of our audit, we informed Aetna that our medical reviews were performed by professional coders credentialed by the American Health Information Management Association (AHIMA) and the American Academy of Professional Coders (AAPC).[35] These coders were experienced in coding ICD-9-CM and ICD-10-CM diagnosis codes for hospital inpatient, outpatient, and physician medical records.

- With regard to Aetna's assertion that we did not confirm our "medical record review standards," our independent medical review contractor reviewed each medical record that Aetna provided in conformance with CMS's risk-adjustment program to determine

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[35] Our independent medical review contractor used senior coders all of whom possessed one or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS), Certified Coding Specialist – Physician-Based (CCS-P), Certified Professional Coder (CPC), CPC – Instructor, and Certified Risk Adjustment Coder (CRC). RHITs have completed a 2-year degree program and have passed an AHIMA certification exam. AHIMA also credentials individuals with CCS and CCS-P certifications and the AAPC credentials both CPCs and CRCs. This information also appears in a footnote in Appendix A of both our draft and final reports.

whether support existed for a diagnosis code that mapped to the audited HCC. As explained just above, experienced coders performed these reviews and in doing so used the following coding and documentation standards: (1) the CMS's *Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance*,[36] (2) *2011 ICD-9-CM Official Guidelines for Coding and Reporting*,[37] (3) *2015 ICD-10-CM Official Guidelines for Coding and Reporting*,[38] (4) the American Hospital Association (AHA), Coding Clinic for ICD-9-CM, and (5) the AHA Coding Clinic for ICD-10-CM and ICD-10-PCS.[39] These standards are legally binding on an MA organization based not only on regulation, but also on its contract with CMS. Federal regulations state that MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes and that such data must conform to all relevant national standards.[40] In addition, MA organizations that contract with CMS must agree to follow CMS's instructions.

We disagree with Aetna's assertion that we should have put our "medical record review process" through notice-and-comment rulemaking and that, by not doing so, diminished the integrity of our audit. Our application of the regulatory requirements through a review of the medical records that Aetna provided does not constitute creation of a new payment rule. Rather, we designed our audits to determine whether Aetna adhered to those regulatory requirements and when we identified errors, we recommended that those errors be corrected. No new regulatory requirements were imposed; thus, there was no need for notice-and-comment rulemaking.

- Our independent medical review contractor did not override the treating physicians' diagnoses. Instead, our contractor separately reviewed each medical record that Aetna provided to us to determine whether support existed for a diagnosis that mapped to audited HCCs. As explained in our audit methodology (Appendix A), this coding review followed a specific process for which our contractor used both skilled senior coders and physicians (when necessary). The coders and physicians did not make clinical judgments, rely upon decisions made by enrollees, or only rely upon conclusions drawn by any subsequent treating physicians. This process was not arbitrary and capricious; rather, it was reasonable to accomplish our audit objective.

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[36] CMS, *Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance As of 9/27/2017*. Accessed on Apr. 18, 2023.

[37] *ICD-9-CM Official Guidelines for Coding and Reporting Effective October 1, 2011*. Accessed on Apr. 18, 2023.

[38] *ICD-10-CM Official Guidelines for Coding and Reporting FY 2015*. Accessed on Apr. 18, 2023.

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

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

Aetna Stated That OIG Had No Statutory Authority To Extrapolate Overpayments

Aetna Comments

Aetna had numerous concerns regarding our extrapolation of overpayments and statistical sampling methodology. With regard to these concerns, Aetna made several points:

- Aetna stated that we do not have the statutory authority to collect extrapolated overpayments from MA organizations through audits. In this regard, Aetna referenced the Inspector General Act (IGA) and other Federal requirements to state that we have the authority to conduct audits and that CMS can collect the improper payments that we identify in those audits. Aetna also stated that the Social Security Act and Federal regulations do not provide authority for us to calculate or collect "extrapolated overpayments, now or in the future" and that we "previously glossed over the gap between [our] audit authority under the IGA and [our] recommendations on extrapolated overpayments in [our MA organization] audit reports." Thus, according to Aetna, if we cannot "calculate or collect extrapolated overpayments, then public recommendations on the calculation or collection of extrapolated overpayments serve only to confuse the public and cause reputational harm to [MA organizations]."

- Aetna stated that "OIG's extrapolation methodology and recommendation in the Draft Report are inconsistent with the statutory actuarial equivalence requirement." Aetna said: "In 2012, CMS gave public notice that it would achieve actuarial equivalence in RADV audits by applying a [FFS] Adjuster when determining the final payment recovery amount." Then, in 2018, "CMS published a proposed rule in which it signaled that it would not use the FFS Adjuster because it had conducted a FFS Adjuster Study that suggested that 'errors in FFS claims data . . . do not have any systematic effect on the payments made to MA organizations.'" Aetna also stated: "The FFS Adjuster Study was flawed [and] CMS still needs a FFS Adjuster to comply with the statutory actuarial equivalence requirement."

  Aetna also said that we did not adjust our "audit findings for the payment error rate in original [FFS] Medicare for the specific diagnosis codes" we chose. According to Aetna, our "failure to do so is inconsistent with the statutory actuarial equivalence requirement" and any CMS recoupment of our recommended overpayment would be "arbitrary and capricious."

- Aetna stated that "OIG uses a less statistically sound confidence interval than CMS" and although OIG "applied the lower bound of a 90[-percent] confidence interval to calculate its extrapolated overpayment amount in the Draft Report[,] CMS follows the more common and statistically sound approach of using the lower limit of a 99[-percent] confidence interval in RADV audits." Aetna concluded that "OIG should align its approach with CMS, or at least explain its reasons for applying a different approach."

OIG Response

We do not fully agree with Aetna's assertions that we do not have statutory authority to calculate or collect extrapolated overpayments or that our statistical sampling methodology is inconsistent with the law and less statistically sound than CMS's. Specifically:

- We do not have statutory authority to collect extrapolated overpayments; however, our monetary recommendation points not to OIG collecting but rather to Aetna refunding overpayments to the Federal Government. As Aetna also discusses, action officials at CMS—not OIG—will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures.

  Aetna's assertion that we do not have statutory authority under the IGA to calculate extrapolated overpayments is inaccurate. Neither Federal statute nor any other authority limits our ability to use sampling techniques with extrapolation to calculate overpayments or recommend a recovery based on extrapolation. Moreover, extrapolation has long been recognized as a permissible method of calculating overpayments in Medicare. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.[41] The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.[42] 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 our statistical sampling software to apply the correct formulas for the extrapolation. Thus, we did not revise the amount in our first recommendation based on Aetna's comments; rather, we revised the amount in response to the updated regulations that CMS published after we issued our draft report. (See footnote 19.) We are reporting the estimated overpayment amount based on extrapolation but are recommending a refund of only the amounts associated with sampled enrollee-years.

- With regard to Aetna's comment about the statutory equivalence requirement, our audit methodology correctly applied CMS requirements to properly identify the

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[41] 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).

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

overpayment amount associated with the unvalidated HCCs for each sample item. Specifically, we used the results of our independent medical review contractor's review to determine which HCCs were not validated and, in some instances, to identify HCCs that should have been used but were not used in the associated enrollees' risk score calculations. We followed CMS's risk adjustment program requirements to determine the payment that CMS should have made for each enrollee and to estimate overpayments. With respect to Aetna's comment regarding actuarial equivalence in our overpayment calculations, after we issued our draft report, CMS stated that it "will not apply an adjustment factor (known as an FFS Adjuster) in RADV audits."[43] In the context of CMS's requirements and updated guidance, we recognize that CMS—not OIG—is responsible now for making operational and program payment determinations for the MA program.

As stated above, for this final report our recommendation to refund overpayments is limited to the overpayments associated with the 210 sampled enrollee-years, rather than to an estimate. However, the results of our sampling—and our estimate of overpayments (Appendix D)—provide a reasonable basis for our findings and conclusions.

- With regard to Aetna's comment that we use a less statistically sound confidence interval than CMS, OIG is an independent oversight agency; therefore, our estimation methodology does not need to mirror CMS's estimation methodology. Our policy recommends recovery at the lower limit of a two-sided 90-percent confidence interval. The lower limit of a two-sided 90-percent confidence interval provides a reasonably conservative estimate of the total amount overpaid to Aetna for the enrollee-years and time period covered in our sampling frame. This approach, which is routinely used by HHS for recovery calculations,[44] results in a lower limit (the estimated overpayment amount) that is designed to be less than the actual overpayment total 95 percent of the time. However, as previously discussed, we are not recommending recovery of the extrapolated amount for this audit.

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[43] 88 Fed. Reg. 6643 (Feb. 1, 2023).

[44] For example, HHS has used the two-sided 90-percent confidence interval when calculating recoveries in both the Administration for Child and Families and Medicaid programs. See *New York State Department of Social Services*, HHS Departmental Appeals Board (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 *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).

AETNA DID NOT CONCUR WITH THE OIG'S NON-MONETARY RECOMMENDATIONS

Aetna Comments

Aetna stated that although it did not concur with our non-monetary recommendations, it "will continue to evaluate and evolve its compliance program." Aetna stated that it "has invested tremendous time, effort, and resources into strengthening its compliance program prior to and since the audit period." Aetna also stated that it does not believe that we considered the evolution of its compliance program in the seven years since the audit period ended. For these reasons, Aetna also stated that it did not concur with our recommendations to perform additional reviews for: (1) the remaining 159 enrollee-years in the potentially mis-keyed diagnosis code high-risk group or (2) similar instances of high-risk diagnoses that occurred before or after the audit period.

Aetna noted that we have identified "similarly high rates of incorrect coding of the same diagnoses" in our audits of MA organizations. To this point, Aetna said that our solution is for MA organizations "to attain perfect coding of the specific diagnoses through more oversight of their internal processes." Aetna stated that this "recommendation is unlikely to yield the outcome sought by [the] OIG" because, according to Aetna, "providers are the root cause of the vast majority of coding errors, and there are legal and practical limits to the power of [MA organizations] to force providers to improve their coding practices." To this point, Aetna stated that the Secretary should secure "changes in provider behavior in original [FFS] Medicare" to drive change and address "root causes in the MA program."

OIG Response

We did not review the evolution of Aetna's compliance program. We limited our review to selected diagnoses that we determined to be at high risk for being miscoded for our audit period. Our audit revealed a significant error rate (155 of 210 enrollee-years). (See Appendix D.) Federal regulations at 42 CFR section 422.503(b) require MA organizations like Aetna 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.

In this regard, we disagree with Aetna's assertion that our recommendations to improve internal processes made to MA organizations, including Aetna, seek an outcome of perfect coding. As we state above, we recognize that CMS has never required that MA organizations ensure perfect coding for all claims and acknowledge that Aetna cannot "reasonably be expected to know that every piece of data is correct." However, Aetna's statement that the Secretary should secure changes in provider behavior in the original FFS Medicare does not alter its obligation under Federal requirements to implement an effective compliance program.

We concluded that Aetna's compliance program could be improved. The continued improvement of procedures will assist Aetna 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 recommendation to examine its existing compliance procedures is valid, but we revised the wording to state that Aetna should continue to examine those procedures. We made no changes to our other two recommendations that Aetna perform additional reviews.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid Aetna $12,742,735,669 to provide coverage to its enrollees for 2015 and 2016. We identified a sampling frame of 14,948 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2014 and 2015 service years; Aetna received $255,440,001 in payments from CMS for these enrollee-years for 2015 and 2016. We selected for audit 210 enrollee-years with payments totaling $5,241,537.

The 210 enrollee-years included 30 acute stroke diagnoses, 30 acute myocardial infarction diagnoses, 30 acute stroke and acute myocardial infarction diagnosis combinations, 30 embolism diagnoses, 30 vascular claudication diagnoses, 30 major depressive disorder diagnoses, and 30 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 $856,818 for our sample.

Our audit objective did not require an understanding or assessment of Aetna'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 November 2018 through December 2022.

METHODOLOGY

To accomplish our objective, we performed the following steps:

- We reviewed applicable Federal laws, regulations, and guidance.

- We discussed with CMS program officials the Federal requirements that MA organizations should follow when submitting diagnosis codes to CMS.

- We identified, through data mining and discussions with medical professionals at a 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 included:

  - 6 diagnosis codes for acute stroke,
  - 35 diagnosis codes for acute heart attack,
  - 51 diagnosis codes for embolism,
  - 4 diagnosis codes for vascular claudication, and

- o 29 diagnosis codes for major depressive disorder.

- We developed an analytical tool that identified 832 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 832 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:

  - o Risk Adjustment Processing System (RAPS)[45] to identify enrollees who received high-risk diagnosis codes from a physician during the service years,

  - o Risk Adjustment System (RAS)[46] to identify enrollees who received an HCC for the high-risk diagnosis codes,

  - o Medicare Advantage Prescription Drug System (MARx)[47] to identify enrollees for whom CMS made monthly Medicare payments to Aetna, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C),

  - o Encounter Data System (EDS)[48] to identify enrollees who received specific procedures, and

  - o Prescription Drug Event file[49] to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.

- We interviewed Aetna officials to gain an understanding of: (1) the policies and procedures that Aetna followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Aetna's monitoring of those diagnosis codes to prevent, detect and correct noncompliance with Federal requirements.

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[45] MA organizations use the RAPS to submit diagnosis codes to CMS.

[46] The RAS identifies the HCCs that CMS factors into each enrollee's risk score calculation.

[47] The MARx identifies the payments made to MA organizations.

[48] The EDS contains information on each item (including procedures) and services provided to enrollees.

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

- We selected for audit a sample of 210 enrollee-years, which consisted of: (1) a stratified random sample of 180 (out of 14,759) enrollee-years and (2) a non-statistical sample of 30 (out of 189) enrollee-years.

- We used an independent medical review contractor to perform a coding review for the 210 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.[50]

- 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:

    o If the first senior coder found support for the diagnosis code on the medical record, the HCC was considered validated.

    o 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.

    o 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:

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

    o the payment that CMS should have made for each enrollee-year.

- We estimated the total overpayment made to Aetna during the audit period.

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[50] Our independent medical review contractor used senior coders, all of whom possessed one or more of the following qualifications and certifications: RHIT, CCS, CCS-P, CPC, and CRC. RHITs have completed a 2-year degree program and have passed an AHIMA certification exam. AHIMA also credentials individuals with CCS and CCS-P certifications, and the American Academy of Professional Coders credentials both CPCs and CRCs.

- We limited the total overpayment that we recommended for recovery to the sampled enrollee-years.[51]

- We discussed the results of our audit with Aetna officials on April 26, 2022.

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

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

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS	A-07-20-01197	8/3/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS	A-07-20-01202	7/10/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. (Contract H3952) Submitted to CMS	A-03-20-00001	5/31/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS	A-05-19-00013	4/4/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring Life & Health Insurance Company, Inc. (Contract H4513) Submitted to CMS	A-07-19-01192	3/28/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS	A-02-20-01008	3/24/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS	A-09-21-03011	3/16/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring of Tennessee, Inc. (Contract H4454) Submitted to CMS	A-07-19-01193	12/22/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross & Blue Shield of Rhode Island (H4152) Submitted to CMS	A-01-20-00500	11/16/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That California Physicians' Service, Inc. (Contract H0504) Submitted to CMS	A-09-19-03001	11/10/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract R5826) Submitted to CMS	A-05-19-00039	9/30/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (Contract H3916) Submitted to CMS	A-03-19-00001	9/29/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS	A-07-19-01195	9/29/2022

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS	A-09-20-03009	9/13/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS	A-02-20-01009	7/18/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health Network (Contract H1961) Submitted to CMS	A-06-18-05002	5/25/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS	A-01-19-00500	2/14/2022
Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS	A-07-17-01169	2/3/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS	A-02-18-01029	1/5/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS	A-07-19-01188	11/5/2021
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS	A-07-17-01173	10/28/2021
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS	A-07-19-01187	5/21/2021
Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS	A-07-16-01165	4/19/2021
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS	A-02-18-01028	2/24/2021
Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements	A-07-17-01170	4/30/2019

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified Aetna enrollees who: (1) were continuously enrolled in Aetna 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 Aetna for 2015 or 2016, respectively.

We presented the data for these enrollees to Aetna for verification and performed an analysis of the data included on CMS's systems to ensure that the high-risk diagnosis codes increased CMS's payments to Aetna. After we performed these steps, our finalized sampling frame consisted of 14,948 enrollee-years.

SAMPLE UNIT

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

SAMPLE DESIGN

The design for our statistical sample comprised of 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 hospital claim (4,258 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 (3,622 enrollee-years);

- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) 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 (49 enrollee-years);

- a diagnosis (that mapped to an Embolism HCC) on only one claim during the service year but did not have an anticoagulant medication dispensed on his or her behalf (2,515 enrollee-years);

- a vascular claudication diagnosis (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 (1,648 enrollee-years); or

- 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 (2,667 enrollee-years).

The specific strata are shown in Table 3.

Table 3: Sample Design for Audited High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee-Years	CMS Payment for HCCs in Audited High-Risk Groups*	Sample Size
1 – Acute Stroke	4,258	$11,444,792	30
2 – Acute Heart Attack	3,622	8,336,440	30
3 – Acute Stroke / Acute Heart Attack Combination	49	234,649	30
4 – Embolism	2,515	7,209,545	30
5 – Vascular Claudication	1,648	4,110,338	30
6 – Major Depressive Disorder	2,667	7,774,353	30
Total – First Six Strata	**14,759**	**$39,110,118**	**180**
* Rounded to the nearest whole dollar amount.			

After we selected the 180 enrollee-years, we identified an additional group of 189 enrollee-years, from which we non-statistically selected 30 enrollee-years that represented individuals who received 1 of the 832 potentially mis-keyed diagnosis codes (which mapped to a potentially unvalidated HCC) and multiple instances of diagnosis codes for unrelated conditions that were likely keyed correctly. Thus, we selected for audit a total of 210 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.

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the items in each stratum in the stratified sampling frame. After generating 180 random numbers according to our sample design, we selected the corresponding frame items for review. We also selected a non-statistical sample of 30 items from the potentially mis-keyed group.

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to estimate the total amount of overpayments to Aetna 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 non-statistical sample of 30 potentially mis-keyed diagnosis codes and added that amount to the estimate for the statistical sample to obtain the total overpayments.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Details and Results

Audited High-Risk Groups	Frame Size	CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With Unvalidated HCCs	Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)
1 – Acute Stroke	4,258	$11,444,792	30	$86,029	30	$85,739
2 – Acute Heart Attack	3,622	8,336,440	30	73,200	30	54,936
3 – Acute Stroke/Acute Heart Attack Combination	49	234,649	30	137,045	30	110,266
4 – Embolism	2,515	7,209,545	30	88,347	24	69,511
5 – Vascular Claudication	1,648	4,110,338	30	71,215	7	16,335
6 – Major Depressive Disorder	2,667	7,774,353	30	90,946	6	19,116
Totals for Statistical Sample	**14,759**	**$39,110,118**	**180**	**$546,782**	**127**	**$355,903**

7 - Potentially Mis-keyed Diagnoses	189	$998,060	30	$310,036	28	$276,167
Totals – All	**14,948**	**$40,108,178**	**210**	**$856,818**	**155**	**$632,070**

Table 5: Estimated Overpayments in the Sampling Frame
(Limits Calculated at the 90-Percent Confidence Level)

	Estimated Overpayment for Statistical Sample	Overpayment for Potentially Mis-keyed Diagnosis Group	Total Estimated Overpayments
Point Estimate	$27,405,914	$276,167	$27,682,081
Lower Limit	25,303,632	276,167	25,579,799
Upper Limit	29,508,197	276,167	29,784,364

**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 6: 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	
10	205.00	Acute myeloid leukemia, without mention of having achieved remission	Metastatic Cancer and Acute Leukemia	250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled	$159,455
5	482.0	Pneumonia due to klebsiella pneumoniae	Aspiration and Specified Bacterial Pneumonias	428.0	Congestive heart failure, unspecified	27,947
3	714.9	Unspecified inflammatory polyarthropathy	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	174.9	Malignant neoplasm of breast (female), unspecified	10,020
2	200.00	Reticulosarcoma, unspecified site, extranodal and solid organ sites	Lymphatic, Head and Neck, Brain, and Other Major Cancers	250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled	9,943
1	205.02	Acute myeloid leukemia, in relapse	Metastatic Cancer and Acute Leukemia	250.02	Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled	21,967
1	996.56	Mechanical complication due to peritoneal dialysis catheter	Dialysis Status	996.65	Infection and inflammatory reaction due to other genitourinary device, implant, and graft	10,323
1	200.62	Anaplastic large cell lymphoma, intrathoracic lymph nodes	Lymphatic, Head and Neck, Brain, and Other Major Cancers	250.62	Diabetes with neurological manifestations, type	8,969

Number of Sampled Enrollee-Years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	Overpayment
					II or unspecified type, uncontrolled	
1	205.80	Other myeloid leukemia, without mention of having achieved remission	Lung, Upper Digestive Tract, and Other Severe Cancers (Version 12 model) and Lung and Other Severe Cancers (Version 22 model)	250.80	Diabetes with other specified manifestations, type II or unspecified type, not stated as uncontrolled	8,468
1	482.42	Methicillin resistant pneumonia due to Staphylococcus aureus	Aspiration and Specified Bacterial Pneumonias	428.42	Chronic combined systolic and diastolic heart failure	6,038
1	518.81	Acute respiratory failure	Cardio-Respiratory Failure and Shock	581.81	Nephrotic syndrome in diseases classified elsewhere	5,158
1	200.60	Anaplastic large cell lymphoma, unspecified site, extranodal and solid organ sites	Lymphatic, Head and Neck, Brain, and Other Major Cancers	250.60	Diabetes with neurological manifestations, type II or unspecified type, not stated as uncontrolled	4,515
1	714.4	Chronic postrheumatic arthropathy	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	174.4	Malignant neoplasm of upper-outer quadrant of female breast	3,364
28						$276,167

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Aetna, Inc. (H5521) Submitted to CMS (A-01-18-00504)

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Table 7: 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
2	Metastatic Cancer and Acute Leukemia	Lung, Upper Digestive Tract, and Other Severe Cancers
2	Metastatic Cancer and Acute Leukemia	Lymphatic, Head and Neck, Brain, and Other Major Cancers
1	Metastatic Cancer and Acute Leukemia	Breast, Prostate, Colorectal and Other Cancers and Tumors

♥CVS Health.

March 1, 2023

Curtis M. Roy
Regional Inspector General for Audit Services
Office of Audit Services, Region 1
JFK Federal Building
15 New Sudbury Street, Room 2425
Boston, MA, 02203

       Re: Response to OIG Draft Report Number: A-01-18-00504

Dear Mr. Roy,

       I write on behalf of CVS Health Corporation and Aetna, in response to the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), draft report *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Aetna, Inc. (Contract H5521) Submitted to CMS*.

       Aetna appreciates the opportunity to respond to the Draft Report and we are committed to the integrity of the Medicare Advantage (MA) program. We strive to maintain a candid and collaborative approach with OIG as we continuously look for ways to enhance our MA operations.

       Nevertheless, we see numerous flaws in OIG's methodology. The most problematic of these flaws is OIG's apparent expectation for perfect coding in the MA program. CMS has explained that Medicare Advantage Organizations (MAOs) "cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the OIG, and DOJ believe is reasonable to enforce."[1] This aligns with industry practice. The methodology's flaw conflicts with a fundamental assumption of the risk adjustment system: the overreporting of some diagnosis codes offsets the underreporting of others, which achieves overall payment accuracy.

       Perfect coding is not attainable because coding is highly individualized and variable. OIG finds uniform coding errors because the OIG methodology is designed to produce that outcome. What is more, providers are the root cause of the vast majority of coding errors, which we diligently address through coding reviews, provider training and education, and other compliance efforts. The Secretary has more powerful tools for securing changes in provider behavior, and the expanded use of those tools in original Medicare is the ultimate key to driving change in the MA

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[1] *Medicare Program: Medicare+Choice Program*, 65 Fed. Reg. 40,170, 40,268 (June 29, 2000).

♥CVS Health.

program.

Another major flaw lies in OIG's approach to medical record review. OIG frequently relies on decisions by enrollees and conclusions drawn by subsequent treating physicians to render invalid the underlying diagnosis by the initial treating physician who recommended the treatment to the enrollee. Yet it is the initial treating physician who diagnoses the MA enrollee by evaluating the available information and applying clinical judgment. The enrollee may reject or accept the initial treating physician's recommendation for reasons that have nothing to do with the physician's underlying diagnosis. It is arbitrary and capricious for OIG to reject as unsupported the diagnosis coded by the initial treating physician when the diagnosis was within the standard of care when made. It is likewise arbitrary and capricious for OIG to reject as unsupported the diagnosis coded by the initial treating physician based on the subsequent absence of certain facts, without at least accounting for why else those facts may have failed to materialize.

Notwithstanding our methodological concerns, we are pleased that OIG recognized that "Aetna had compliance policies and procedures in place [during the audit period] to determine whether the diagnosis codes that it received from its providers and then submitted to CMS to calculate risk-adjusted payments were correct[,]" including provider education, an annual risk assessment, an annual workplan, and periodic reviews. We are equally pleased that OIG noted that Aetna "provided guidance to its reviewers that outlined the process of coding acute stroke and acute myocardial infarction diagnoses in accordance with CMS documentation and ICD-9 guidelines." Aetna has invested tremendous time, effort, and resources into improving its compliance program prior to and since the audit period, and will continue to do so going forward. Nonetheless, we disagree with the audit approach and recommendations in the Draft Report, as set forth in Attachment A attached to this letter.

Aetna's comments are limited to the Draft Report. We understand that the final report will include changes, including the removal of recommendations related to extrapolation. We therefore requested an opportunity to submit a formal comment to OIG on the changes in the final report. OIG declined our request. We maintain our right to comment publicly on any aspects of the final report that are different from the Draft Report.

Sincerely,

Patrick Jeswald
Vice President
Chief Compliance Officer, Medicare

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Attachment A

Aetna, Inc. offers Medicare Advantage (MA) plans to Medicare beneficiaries under Contract H5521 with the Centers for Medicare & Medicaid Services (CMS), which administers the MA program under the Social Security Act. The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) audited Contract H5521 for alleged overpayments to Aetna under the Inspector General Act of 1978 (IGA).

OIG structured its audit in ways that depart from the historical statutory and regulatory design and CMS implementation of the MA program, including the Medicare Risk Adjustment Data Validation (RADV) program. OIG compounded those structural flaws in its audit by tilting the medical records review component of the audit in favor of identifying alleged overpayments to Aetna. OIG originally extrapolated those alleged overpayments to Aetna at the contract level, notwithstanding OIG's lack of authority under the IGA to extrapolate overpayments. We understand that OIG no longer plans to extrapolate at the contract level based on the recent policy decision by the Secretary to begin pursuing extrapolation in plan year 2018. Regardless of the plan year, OIG has no statutory authority to extrapolate overpayments.

To appreciate how far afield OIG's recommendations would take the MA program, some context is helpful. The MA program is an increasingly popular choice for seniors, with nearly half (48%) of all Medicare beneficiaries choosing MA plans rather than original, fee-for-service (FFS) Medicare in 2022.[1] The MA program has succeeded because it helps both MA enrollees and CMS; enrollees may obtain supplemental benefits that are not covered by original Medicare, while CMS may shift financial risk for the healthcare costs of the enrollees to Aetna and other Medicare Advantage Organizations (MAOs) that offer MA plans.

Congress designed the MA program to shift financial risk to MAOs through a risk-adjustment payment regime. Under that regime, CMS makes fixed monthly payments to the MAO for each enrollee.[2] CMS later adjusts the total monthly payments to account for the health status of the enrollees; CMS does so by looking at the diagnoses made by the enrollees' providers.[3] The MAO must pay for all covered services under the MA plan, regardless of whether the MAO agrees with the providers' diagnoses, or the diagnoses result in a risk adjustment payment.[4]

In the risk adjustment process, the overreporting of some diagnosis codes offsets the

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[1] Meredith Freed et al., *Medicare Advantage in 2022: Enrollment Update and Key Trends*, The Henry J. Kaiser Family Foundation (Aug. 25, 2022), https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/.

[2] 42 U.S.C. §§ 1395w–23(a)(1)(A), (a)(1)(B); 42 C.F.R. § 422.304(a) (2021).

[3] *See* 42 U.S.C. § 1395w–23(a)(1)(C); 42 C.F.R. §§ 422.308(c)(1), 422.310(d)(3) (2021).

[4] 42 U.S.C. §1395w–22(a)(1)(A); 42 C.F.R. § 422.100(a) (2021); *see generally* 42 C.F.R. § 422.308 (2021).

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underreporting of others.[5] Historically, neither Congress nor CMS has required MAOs ensure perfection in provider coding through audits or other mechanisms. CMS has instead conducted RADV audits for overall coding accuracy.

Another tenet of the risk adjustment payment regime is actuarial equivalence. CMS must pay MAOs in a manner that is actuarially equivalent to what CMS would pay under original Medicare.[6] If CMS achieves actuarial equivalence, then CMS is paying the MAOs consistent with the statutory mandate.

Instead of aligning its audit of CMS Contract H5521 with these core features of the MA program, OIG went in the opposite direction. OIG structured its audit to identify alleged overpayments for specific diagnosis codes that it deemed high risk, without regard to overall coding accuracy, actuarial equivalence, or the assumptions of the risk adjustment model that some codes will be overreported while others will be underreported. OIG justified the flawed audit structure through counter-textual interpretations of the CMS attestation and compliance regulations.

As stated above, OIG compounded the structural flaws in its audit by tilting its medical records review in favor of finding alleged overpayments. OIG used coders from an independent medical review contractor for the review. The coders overrode the diagnoses made by treating physicians when subsequent treatments deviated from what OIG expected to see, or when enrollees chose alternative treatments for reasons independent of the merits of the treating physician's diagnosis. Disagreements among coders were viewed as ties and resolved by physicians working for the review vendor. OIG did not promulgate any coding standards for the audit through a notice-and-comment process. While OIG disclosed that coders would apply the ICD-10 coding guidelines, OIG did not disclose whether they relied upon any supplemental coding resources.

OIG then set out to extrapolate its alleged overpayment findings at the CMS contract level. OIG has apparently reversed course on extrapolation for 2016. But the fact remains that OIG has no authority under the IGA to extrapolate and apply its audit findings on a contract-wide basis. OIG therefore has no basis to recommend extrapolation, now or in the future.

OIG ultimately recommended in its Draft Report that Aetna review 159 enrollee-years from the audit sample for potentially mis-keyed diagnosis codes, audit specified diagnoses for time periods before and after the audit period, and examine Aetna's existing compliance procedures to make improvements. We understand that OIG will recommend in the final report that Aetna refund alleged overpayments that OIG identified in the audit sample. Aetna has already submitted deletes for any audit samples it agrees with as targeted by the OIG, but Aetna continues to disagree with

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[5] Wakely Consulting Group, MEDICARE RADV: REVIEW OF CMS SAMPLING AND EXTRAPOLATION METHODOLOGY (2018), p. 10 (noting that the "Fiscal Year (FY) 2016 Department of Health and Human Services (HHS) Agency Financial Report … implies that supported but not reported coding errors represent a material offset to unsupported coding errors.")

[6] 42 U.S.C. § 1395w–23(a)(1)(C)(i).

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several examples as set forth herein.

Aetna has strengthened its compliance procedures and will, of course, continue to enhance those procedures going forward. But Aetna does not concur with OIG's other recommendations in its Draft Report for the reasons explained above and below.

I. **The OIG audit departed from the congressional design and historical implementation of the MA program**

A. **CMS makes uniform monthly payments and aggregate risk adjustments for health status, while OIG looked at specific diagnosis codes**

CMS makes uniform monthly payments to MAOs for providing covered benefits to enrollees and uses data from MAOs to adjust the total payments each year.[7] The uniform monthly payments align with the projected average cost of providing benefits to an enrollee, and are risk-adjusted in the aggregate based on the health status of enrollees evidenced through diagnosis coding.[8] In the risk-adjustment process, the overreporting of some diagnosis codes offsets the underreporting of others,[9] and the historical aim has been to achieve overall payment accuracy, as opposed to perfect coding of specific diagnoses or groups of diagnoses.

OIG's Draft Report departs from that historical aim. Namely, OIG's audit approach was to expect perfect coding for specific diagnoses by looking at only those diagnoses in isolation. First, such an approach would treat MAOs like providers in original Medicare that CMS pays based on the volume of particular services. But treating MAOs like providers in original Medicare ignores that overreported diagnosis codes are offset by underreported diagnosis codes in the MA program, and the singling out of particular diagnosis codes distorts the risk adjustment process.

Second, OIG's audit approach is unworkable at scale. The volume of data in the MA program is already tremendous; one MAO may receive millions of claims from providers annually, and each claim may contain multiple diagnosis codes. The volume of information in the underlying medical records is even more difficult for MAOs to extract and use. Historically, the risk-adjustment process has avoided significant administrative burdens by offsetting underreported and overreported diagnosis codes to achieve overall payment accuracy. In contrast, an MA program that looks at large volumes of diagnosis codes chosen by OIG would put those administrative burdens squarely on the MAOs.

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[7] 42 U.S.C. §§ 1395w-23(a)(1)(A)-(C); 42 C.F.R. §§ 422.310(b), (d)(3) (2021).

[8] 42 U.S.C. §§ 1395w–23(a)(1)(C); *see* 42 CFR §§ 422.254, 422.308(c) (2021).

[9] Wakely Consulting Group, MEDICARE RADV: REVIEW OF CMS SAMPLING AND EXTRAPOLATION METHODOLOGY (2018), p. 10 (noting that the "Fiscal Year (FY) 2016 Department of Health and Human Services (HHS) Agency Financial Report … implies that supported but not reported coding errors represent a material offset to unsupported coding errors.").

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Congress has never adopted OIG's apparent approach, and for good reason.

B.   CMS audits for overall payment accuracy, while OIG audited specific diagnoses

In prior RADV audits, CMS has taken a sample of enrollee records and done a two-way record review.[10] In other words, CMS has looked at all the diagnosis codes in each record to determine which were correct, and which were not. The incorrect codes are factored into a general error rate for all diagnosis coding, without regard to a particular diagnosis code or group of codes.

OIG took a different approach in its audit of Aetna. It ran analytics to populate a sample with specific diagnosis codes and facts that supposedly show the codes were overreported. OIG, for example, populated its sample with claims where the physician diagnosed the enrollee with embolism, and the enrollee never received a prescription for an anti-coagulant. OIG similarly populated its sample with vascular claudication claims where medication for neurogenic claudication (unrelated to vascular claudication) was dispensed.[11] Again, OIG did not build a random sample and review all the diagnoses codes in the sample; OIG began with fact patterns that supposedly showed overreporting of specific diagnoses, and then used analytics to populate the sample to fit those fact patterns.

As discussed below, OIG compounded the partiality of its sampling methodology by imposing parameters for the subsequent medical records review that limited the evidence that Aetna could present in support of the diagnosis by the treating provider.

At no point did OIG attempt to measure overall payment accuracy, or account for any factual differences between the enrollee-years within the samples. OIG's approach slanted the playing field towards the finding of alleged overpayments in the audit.

C.   OIG disregarded the statutory actuarial equivalence requirement

Congress requires CMS to adjust the payments to MAOs based on the health status of the enrollees to "ensure actuarial equivalence" with what CMS pays directly to providers in original Medicare.[12] Two modes of payment are "actuarially equivalent when their present values are equal

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[10] 42 U.S.C. § 1395w-23(a)(3); 42 C.F.R. § 422.311(a) (2021). The U.S. Department of Justice (DOJ) has taken a similar position in False Claims Act (FCA) litigation, arguing that two-way reviews of diagnoses codes are proper and one-way reviews are not. *See United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1175 (9th Cir. 2016).

[11] OIG, A-01-18-00504, MEDICARE ADVANTAGE COMPLIANCE AUDIT OF SPECIFIC DIAGNOSIS CODES THAT AETNA INC. (CONTRACT H5521) SUBMITTED TO CMS (2022), pp. 24-25.

[12] 42 U.S.C. § 1395w-23(a)(1)(C)(i) ("[CMS] shall adjust the payment amount … for such risk factors as age, disability status, gender, institutional status, and such other factors as [CMS] determines to be appropriate, including adjustment for health status … so as to ensure actuarial equivalence. [CMS] may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.").

under a given set of actuarial assumptions."[13] Aetna's position has always been that any calculation of a payment error rate in an audit of a MA contract must include an adjustment to account for the payment error rate found in original Medicare. The failure to make such an adjustment results in the application of a more exacting standard to the MA program, which violates the actuarial equivalence requirement, and may also result in the underpayment of MAOs, undermining the purpose of the risk adjustment system.[14]

OIG did not adjust its audit findings to account for the overall payment error rate in original Medicare. Nor did OIG adjust its audit findings for the payment error rate in original Medicare for the specific diagnosis codes chosen by OIG. OIG's failure to do so is inconsistent with the statutory actuarial equivalence requirement, and any CMS recoupment of OIG's recommended overpayment would violate the statute and put Aetna at risk of a "systemic underpayment." It is arbitrary and capricious to make a recommendation that would violate a statutory requirement.

> **D.   The CMS attestation and compliance regulations do not support—much less require—the OIG audit structure**

OIG asserts that the CMS attestation and compliance regulations at 42 C.F.R. § 422.504(l) and 42 CFR § 422.503(b)(4)(vi), respectively, support its audit structure. Aetna disagrees.

The attestation regulation requires that MAOs certify "based on best knowledge, information, and belief" to the "accuracy, completeness, and truthfulness of relevant data that CMS requests."[15] It does not impose a self-auditing mandate, alone or with the Overpayment Rule.[16] Nor does it impose a reasonable diligence or negligence standard for overpayments, alone or with the Overpayment Rule.[17]

CMS has explained 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 DOJ believe is reasonable to

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[13] *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 185 (D.D.C. 2018) (quoting *Stephens v. U.S. Airways Grp., Inc.*, 644 F.3d 437, 440 (D.C. Cir. 2011)), *rev'd on other grounds*, *UnitedHealthcare Ins. Co. v. Becerra*, 9 F.4th 868, 892-93 (D.C. Cir. 2021).

[14] *See* American Academy of Actuaries, Comment Letter on RADV Sampling and Error Calculation Methodology (Jan. 21, 2011) ("This type of data inconsistency … may also create systematic underpayment, undermining the purpose of the risk-adjustment system and potentially resulting in payment inequities."). Indeed, OIG recognized in a prior audit that the error rate in original Medicare could have a potential impact and opted against extrapolation at the CMS contract level. OIG, A-06-09-00012, RISK ADJUSTMENT DATA VALIDATION OF PAYMENTS MADE TO PACIFICARE OF TEXAS FOR CALENDAR YEAR 2007 (CONTRACT NUMBER H4590) (May 2012), p. ii.

[15] 42 C.F.R. § 422.504(l) (2021).

[16] *See UnitedHealthcare*, 16 F.4th at 884.

[17] *UnitedHealthcare*, 330 F. Supp. 3d at 190 (vacating definition of "identified"), *rev'd on other grounds, UnitedHealthcare*, 16 F.4th at 892-93.

enforce."[18] OIG has similarly commented that "[t]he requirement that the CEO or CFO certify as to the accuracy, completeness and truthfulness of [risk adjustment] data, based on best knowledge, information and belief, does not constitute an absolute guarantee of accuracy. Rather, it creates a duty on the [MAO] to put in place an information collection and reporting system reasonably designed to yield accurate information."[19]

The attestation regulation does not speak to how OIG should structure its audit. Nor does it support OIG's recommendation that Aetna audit the diagnoses codes chosen by OIG for the time periods before and after the OIG audit period of 2015–2016. Nor does it impose a legal obligation on Aetna to conduct any sort of self-audit in the wake of OIG's audit report.

The compliance regulation states that MAOs must "[h]ave administrative and management arrangements satisfactory to CMS," including "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."[20] It further states that MAOs must establish and implement an "effective system for routine monitoring and identification of compliance risks," as well as a "system for promptly responding to compliance issues as they are raised … ."[21]

The compliance regulation requires that Aetna operate an "effective" compliance program, meaning one that is operative and productive.[22] It does not speak to how OIG should structure its audit. Nor does it require that the Aetna compliance program incorporate the widespread self-auditing of specific diagnosis codes chosen by OIG, or ensure that providers achieve perfection in diagnosis coding. The OIG recommendation for self-auditing of specific diagnosis codes goes beyond the natural construction and application of the compliance regulation.

E.   CMS has never required and industry practice has never been perfect coding

As discussed above, CMS has never required that MAOs ensure perfect coding for all claims. [23] Nor has industry practice ever been perfect coding. Perfect coding is impossible to attain because coding involves professional judgment, and different coding professionals may

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[18] *Medicare Program: Medicare+Choice Program*, 65 Fed. Reg. 40,170, 40,268 (June 29, 2000).

[19] *Publication of the OIG's Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans*, 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999).

[20] 42 C.F.R. § 422.503(b)(4)(vi) (2021) (emphasis added).

[21] 42 C.F.R. §§ 422.503(b)(4)(vi)(F), (G) (2021).

[22] *Effective,* MERRIAM-WEBSTER ONLINE DICTIONARY, https://www.merriam-webster.com/thesaurus/effective (last visited Feb. 14, 2023) (listing "operative" and "productive" as synonyms of "effective").

[23] 65 Fed. Reg. 40,169, 40,268 (June 29, 2000); 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999). Nothing in the Secretary's final RADV rule changed the long-held CMS position that perfect coding is not required.

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reach different conclusions on the coding of the same claims.[24]   This variability is well-documented in relevant literature.[25]   It is also within the common experience of the healthcare industry.[26]   Yet OIG conducted its audit under the assumption that there is one correct coding outcome for every claim in a sample that is determined by OIG.   OIG ignores both the fact-intensive nature of coding and the range of acceptable conclusions that different coders may reach after reviewing the medical records for the same claim.

One telling feature of OIG's methodology is that it yields a comparable outcome nearly every time OIG audits an MAO.   OIG has completed 18 audits of MAOs since January 2021 and found similarly high rates of incorrect coding of the same diagnoses nearly every time.[27]   Coding is highly individualized and variable, yet OIG has found the entire industry is coding the same diagnoses in the same incorrect way.   OIG's solution is for MAOs to attain perfect coding of the specific diagnoses through more oversight of their internal processes and contracted providers.   But that recommendation is unlikely to yield the outcome sought by OIG for two reasons.   First, OIG's uniform audit findings are the product OIG's skewed methodology, and perfect coding is impracticable in any event.   Second, providers are the root cause of the vast majority of coding errors, and there are legal and practical limits to the power of MAOs to force providers to improve their coding practices.   The Secretary has more powerful tools for securing changes in provider behavior in original Medicare, and the expanded use of those tools in original Medicare is the ultimate key to driving change and addressing root causes in the MA program.

II.   Additional aspects of the OIG audit were slanted in favor of finding alleged overpayments

A.   OIG selected audit years that created a data validation problem for Aetna

OIG audited contract years 2015 and 2016, which means that the audit period began in 2015 (8 years ago) and ended in 2016 (7 years ago).   Aetna took all reasonable steps to ensure that records for the audit period were available for use by not only OIG but also Aetna itself.   Aetna, for example, complied with the requirement at 42 C.F.R. § 422.504(d)(2) that its provider contracts

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[24] CMS, REGIONAL TECHNICAL ASSISTANCE RISK ADJUSTMENT (2008), p. 6-3   ("Throughout the ICD-9-CM publication, there are notes and cross references to assist the coder in arriving at *the most accurate code* according to official coding guidelines." (emphasis added)).

[25] CMS, MEDICAL RECORD REVIEWER GUIDANCE (2019), pp. 24-25, 59 (describing situations that require RADV Auditors to make nuanced decisions on a "case-by-case" basis).

[26] CMS, REGIONAL TECHNICAL ASSISTANCE RISK ADJUSTMENT (2008), p. 6-6 (explaining that providers' assessments of co-existing conditions may vary and, in turn, impact diagnosis codes); ICD-10-CM OFFICIAL GUIDELINES FOR CODING AND REPORTING (2022), p. 12 ("The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis.").

[27] *See e.g.,* CMS, A-06-18-05002, MEDICARE ADVANTAGE COMPLIANCE AUDIT OF SPECIFIC DIAGNOSIS CODES THAT PEOPLES HEALTH NETWORK (CONTRACT H1961) SUBMITTED TO CMS (2022), pp. 8-9   (finding similar coding validation rates for same diagnoses).

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include a provision obligating the provider to retain "records" for a minimum timeframe of 10 years. Aetna also exhausted all reasonable efforts to obtain records in the possession, custody, or control of its contracted providers. But Aetna does not control all actions by its contracted providers. And in the past 7 years, some of those providers ceased to exist, or failed to meet their contractual obligation to retain records, or encountered *force majeure* events that resulted in the loss of records. The loss of records prevented Aetna from adducing medical record support for physician diagnosis coding that was undisputedly authentic. Yet OIG did not give Aetna the benefit of the doubt. The choice by OIG to audit distant years, coupled with circumstances outside the control of Aetna, combined to further slant the audit towards finding alleged overpayments.

B. Aetna was barred from reopening audit years and identifying underpayments

The audit sought to identify only overpayments, and OIG went so far as to instruct Aetna to flag only the page numbers and text of the medical records directed by OIG. Indeed, it is unclear whether OIG even reviewed pages outside of those flagged, for both codes that it found unsupported and codes that treating physicians should have submitted and did not. The result was to eliminate or reduce the offsetting of overreported codes with underreported codes and generate an alleged overpayment. While OIG indicated that it included the financial impact of HCCs that should have been submitted in its analyses, the risk adjustment submission process was not open to allow Aetna to submit additional HCCs for these codes. As a result, the OIG effectively penalized Aetna for codes that did not meet OIG's coding standards while Aetna was prevented from recovering additional amounts owed.

C. OIG used pharmacy data in a one-sided way

OIG used pharmacy data to determine whether the parameters for OIG's sample were met. OIG, however, would not permit Aetna to use any pharmacy data to show that diagnoses codes were supported. The use of pharmacy data to populate the sample—but not to validate any diagnoses codes—naturally steered the audit towards the finding of an alleged overpayment.

III. Numerous aspects of the OIG medical record review process were unclear, unfair, and/or potentially unlawful

A. OIG did not disclose its reviewer, much less the reviewer's initial decisions

OIG did not identify the name of its independent medical record review contractor. Aetna received only the final determination by the contractor on each claim. Aetna therefore has no way of evaluating the contractor's decision-making process as a whole, including the assessments made by the contractor at the initial levels of review. Nor does Aetna have any way of evaluating whether the contractor was qualified, applied consistent standards across its work for OIG and other clients, and was free from conflicts of interest. Aetna requests that OIG disclose all such information pursuant to the Data Quality Act and generally accepted government auditing standards because, in the instance that CMS acts upon OIG's final report, the information will bear

on Aetna's discussions.[28]

B. OIG did not confirm all of its medical record review standards for Aetna, or promulgate any of them through notice-and-comment rulemaking

OIG stated in its report that MAOs and their network providers are to submit diagnosis codes consistent with ICD-10 coding guidelines.[29] But the ICD-10 coding guidelines only go so far and do not supply all of what providers and MAOs need in order to make coding judgments.[30] Even CMS has tacitly recognized the limits of the ICD-10 coding guidelines by referring MAOs and providers to supplemental resources, including those published by the American Health Information Management Association (AHIMA), the American Medical Association (AMA), the American Hospital Association (AHA), and the American Academy of Professional Coders (AAPC).[31] Those resources have their own limits,[32] and are sometimes inconsistent.[33]

For these reasons, OIG should have done more than identify the ICD-10 coding guidelines as a standard for the medical record review process. At a bare minimum, Aetna needed to know how the independent reviewer would apply the ICD-10 coding guidelines, including whether the independent reviewer would augment those guidelines with additional coding resources.

Of course, even if OIG had told Aetna how the independent reviewer would apply the ICD-

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[28] Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. 106-554, § 515 (2001) (referred to as the Data Quality Act or the Information Quality Act); U.S. GOV'T ACCOUNTABILITY OFF., GOVERNMENT AUDITING STANDARDS 2018 REVISION: TECHNICAL UPDATE APRIL 2021 (2021).

[29] OIG, A-01-18-00504, MEDICARE ADVANTAGE COMPLIANCE AUDIT OF SPECIFIC DIAGNOSIS CODES THAT AETNA INC. (CONTRACT H5521) SUBMITTED TO CMS (Dec. 13, 2022), p.1, n.1 .

[30] ICD-10-CM OFFICIAL GUIDELINES FOR CODING AND REPORTING (2022), p. 16 (describing how coders should proceed in the absence of guidance); CMS, MEDICAL RECORD REVIEWER GUIDANCE (2019), p.16 ("It is critical to understand all guidance pertaining to these documentation issues will be considered on a case-by-case basis. The guidance and examples are not exhaustive in content. … [M]edical records can be unique … .").

[31] ICD-10-CM OFFICIAL GUIDELINES FOR CODING AND REPORTING (2022) (noting that the guidelines have been approved by the AHA, AHIMA, CMS, and NCHS); *see also* CMS, MEDICAL RECORD REVIEWER GUIDANCE (2019), p. 55 ("[c]ode assignment may be based on other physician [documentation] . . . This information is consistent with the [AHIMA] documentation guidelines."); CMS, REGIONAL TECHNICAL ASSISTANCE RISK ADJUSTMENT (2008), p. 6-2 ("ICD-9-CM diagnosis codes are 3- to 5-digit codes used to describe the clinical reason for a patient's treatment. They do not describe the service performed, just the patient's medical condition. For any classification system to be reliable, the application of the codes must be consistent across users. Therefore, CMS, the [AHA], the [AHIMA], and the National Center for Health Statistics (NCHS) together have developed coding guidelines.").

[32] CMS, MEDICAL RECORD REVIEWER GUIDANCE (2019), p.7.

[33] OIG, A-03-14-00010, CMS DID NOT ADEQUATELY ADDRESS DISCREPANCIES IN THE CODING CLASSIFICATION FOR KWASHIORKOR (2017), p.1 ("[w]e reviewed the medical records for 2,145 inpatient claims at 25 providers and found that all but 1 claim incorrectly included the diagnosis code for Kwashiorkor . . . [t]he ICD-CM coding classification contained a discrepancy between the tabular list and the alpha index on the use of diagnosis code 260 . . . CMS did not have adequate policies and procedures in place to address this discrepancy.").

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10 coding guidelines, the audit process would have still been unfair and potentially unlawful because neither OIG nor CMS published the standards through notice-and-comment rulemaking. If CMS were to recoup OIG's alleged overpayment from Aetna, then OIG's underlying medical records review standards would constitute requirements or policies establishing substantive legal standards governing the payment for services. No such requirements can take effect unless they are promulgated by the Secretary by regulation under 42 U.S.C. § 1395hh(a)(1).[34] Neither the ICD-10 coding guidelines, nor the Medicare Managed Care Manual, nor any other standards used by OIG and the independent reviewer have been promulgated by regulation under § 1395hh(a)(1).[35]

The lack of notice and comment had real-world consequences that diminished the integrity of the audit. If OIG had put its medical record review standards through a notice-and-comment process, then Aetna and other MAOs would have submitted their comments long before any audits. OIG would have considered and incorporated, or, at minimum, responded to the comments. The result would have been a more transparent and better overall medical record review process.

C.   The OIG process was prescriptive in ways that were arbitrary and capricious

OIG directed Aetna to support the diagnoses in the 210 enrollee-years in the audit sample by providing "the specific medical record support for the diagnosis code for the one specific date of service identified," including the "specific PDF page no. and specific text" for any supporting inpatient records. Outpatient records were not subject to the same instruction. The instruction turned the process into a hunt for specific words in the inpatient records, and impeded Aetna's efforts to show how the diagnoses were supported by the records as a whole.

The RADV medical records review process is fairer. CMS does not restrict MAOs to identifying specific page numbers and text from medical records for one specific date of service chosen by CMS. Furthermore, MAOs receive additional opportunities to identify medical record support. OIG's prescriptive approach was arbitrary and capricious, and further skewed the audit in favor of identifying alleged overpayments.

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[34] 42 U.S.C. § 1395hh(a)(2); *Azar v. Allina Health Serv.*, 139 S. Ct. 1804, 1814 (2019); HHS, Memorandum from CMS Chief Legal Officer Kelly M. Cleary on Impact of *Allina* on Medicare Payment Rules (Oct. 31, 2019), p. 2.

[35] A CMS recoupment would also be unlawful because neither the U.S. Constitution nor the Medicare statute authorizes OIG or CMS to delegate the promulgation of regulatory standards to private, non-governmental entities. *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 565-68 (D.C. Cir. 2004) ("subdelegations to outside parties are assumed to be improper absent an affirmative showing of congressional authorization"); *Texas v. Rettig*, 993 F.3d 408, 413 (5th Cir. 2021) (Ho, J., dissenting), *cert. denied*, 142 S. Ct. 1308, 1309 (2022) (Alito, J., concurring) ("[I]f the determinations … have any future effect, review should be granted in an appropriate case.").

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D. **OIG acted arbitrarily and capriciously by overriding physician diagnoses based on subsequent treatments, patient choices, and OIG's clinical preferences**

The physicians who initially treat MA enrollees are the ones who diagnose MA enrollees by evaluating the available information about the enrollee and applying clinical judgment. Subsequent treating physicians may make different diagnoses at later points in time, when more information is available. Regardless of what an initial or subsequent treating physician recommends for treatment, the enrollee is the one who ultimately decides whether to accept and act on the recommendation. The enrollee may reject their physician's recommendation for physical, mental, philosophical, or financial reasons that have nothing to do with whether the physician's underlying diagnosis is supported. Alternatively, the enrollee may accept the recommendation, and choose to implement it through new and different providers or coverage or funding mechanisms for reasons that likewise have nothing to do with whether the physician's underlying diagnosis is unsupported. Neither the decisions by the enrollee nor the conclusions drawn by any subsequent treating physicians render invalid the underlying diagnosis by the physician who recommended the treatment to the enrollee. OIG, however, relied on such facts—as well as OIG's own *post hoc* clinical preferences—to find that diagnoses by treating physicians in the sample were unsupported.[36]

One example is OIG's targeting of diagnoses of major depressive disorder because the enrollee was not receiving a prescription drug associated with major depressive disorder through their Medicare Part D Plan. An enrollee may refuse to fill a prescription for such a drug because the enrollee is noncompliant, or may fill the prescription but use other coverage (e.g., veterans benefits) to pay for the drug, or may pay out of pocket for the drug.[37] The medication may also be contraindicated for that enrollee. In none of those scenarios is there a reason to conclude that the diagnosis of major depressive disorder was unsupported.

Another example is OIG's finding that diagnoses of stroke in the emergency department (ED) were unsupported. In Sample 111, the enrollee presented to the ED with an altered mental status and inability to respond verbally. The ED physician called a stroke alert, documented that the member was nonverbal and could not follow commands, obtained a CT scan showing no acute abnormality, and documented a final diagnosis of stroke and altered mental status. OIG conceded that stroke was the final diagnosis in the ED, but asserted that it was never confirmed and therefore deemed it unsupported.[38] OIG second-guessed the treating ED physician's diagnosis of stroke

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[36] OIG, A-01-18-00504, MEDICARE ADVANTAGE COMPLIANCE AUDIT OF SPECIFIC DIAGNOSIS CODES THAT AETNA INC. (CONTRACT H5521) SUBMITTED TO CMS (2022), p. 24.

[37] *See, e.g.*, OIG, ADVISORY OP. NO. 14-05 (2014) (approving direct-to-patient product sales program offering brand name drugs at a discount and allowing patients to pay for the drug out of pocket); OIG, ADVISORY OP. NO. 07-04 (2007) (approving patient assistance program that provides free outpatient prescription drugs entirely outside the Part D benefit).

[38] OIG, A-01-18-00504, MEDICARE ADVANTAGE COMPLIANCE AUDIT OF SPECIFIC DIAGNOSIS CODES THAT AETNA

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even though the diagnosis was entirely reasonable at the time of the care. Obviously, the treating ED physician did not have the benefit of later inpatient treatment.

OIG's finding for Sample 111 is striking because an ED physician is an acceptable physician specialty type for the submission of risk adjustment data to CMS, the submission of the diagnosis coding for the enrollee's presentation to the ED is now mandatory under encounter data submission requirements, the coding met the applicable guidelines, and the medical records were robust. There was no reason to question the ED physician's clinical judgment in the moment, nor was there any deficiency in the diagnosis coding for the presentation to the ED. OIG simply applied a standard that was more rigorous than what the coding guidelines required and what would have applied in original Medicare.

It is arbitrary and capricious for OIG to reject as unsupported the diagnosis coded by the treating physician when the diagnosis was within the standard of care when made. It is likewise arbitrary and capricious for OIG to reject as unsupported the diagnosis coded by the treating physician based on the subsequent absence of certain facts, without at least accounting for all alternative reasons why those facts may have failed to materialize.

E.   The so-called tie-breaker is arbitrary and capricious

OIG did not give weight to the diagnoses coded by treating physicians when OIG's coders split on the question of whether the diagnoses were supported. OIG treated splits between coders as ties, and looked to the independent reviewer's physicians to break the ties instead of the treating physician.[39] The lack of weight given to the diagnosis by the treating physician is arbitrary and capricious because the treating physician has more education, training, and skills than the coders, and was closer to the patient than the coders or the independent reviewer's physician. If one of OIG's coders agrees with the treating physician's diagnosis, then the diagnosis is plainly valid and there is no tie.

IV.   OIG should, at a minimum, reverse its findings for certain enrollee-years based on the support for the diagnoses in the medical record

Aetna has submitted a list of enrollee-years for OIG to reconsider, consistent with OIG's instructions at the exit conference. We summarize the clinical and coding issues in Exhibit A and ask OIG to reverse its findings concerning these enrollee-years.

V.   OIG has no statutory authority to extrapolate overpayments and, even if it did, its methodology in the Draft Report is inconsistent with the law and unsound

As noted above, OIG has indicated to Aetna that it will not try to extrapolate at the contract level in this audit based on the recent policy decision by the Secretary to begin pursuing

INC. (CONTRACT H5521) SUBMITTED TO CMS (2022), p. 10.

[39] *Id*. at p. 20.

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extrapolation in plan year 2018. Regardless of the plan year, OIG has no statutory authority to extrapolate overpayments. Aetna explains why below.

A. OIG has no statutory authority to calculate or collect extrapolated overpayments

OIG audited Aetna under the IGA. The IGA does not authorize OIG to calculate or collect extrapolated overpayments from MAOs through audits.

The Secretary and the CMS Administrator previously asserted in sub-regulatory guidance that the Secretary (including OIG) has the authority under the IGA and 42 C.F.R. part 422, subpart G, to "conduct RADV audit activity."[40] The Secretary did not squarely affirm that interpretive rule in the final RADV rule published on February 1, 2023. Instead, the Secretary stated that OIG "undertakes audits of MAOs, similar to RADV audits, as part of its oversight functions[,]" and "CMS can collect the improper payments identified during those HHS-OIG audits, including the extrapolated amounts calculated by the OIG."[41]

In the Draft Report, OIG did not purport to exercise regulatory authority under 42 C.F.R. Part 422, subpart G through the IGA or otherwise.[42] And we do not believe that OIG could ever do so for two reasons. First, Congress delegated authority to the Inspector General and not the Secretary in the IGA.[43] Second, the statutory authority for subpart G is the Social Security Act, not the IGA.[44] The Inspector General has no authority under the Social Security Act.

We also disagree that the Social Security Act and 42 C.F.R. part 422, subpart G, authorize contract-wide extrapolation in audits of MAOs.[45] There is no statutory authority for OIG or CMS

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[40] *Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*, 79 Fed. Reg. 29,844, 29,934 (May 23, 2014) ("The Secretary (including the Office of Inspector Genera (OIG)—pursuant to OIG's authority under the Inspector General Act of 1978, 5 U.S.C. App.) clearly has the authority to conduct RADV audit activity.").

[41] *Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021*, 88 Fed. Reg. 6,643, 6,645 n.6 (Feb. 1, 2023).

[42] *See* OIG, A-01-18-00504, MEDICARE ADVANTAGE COMPLIANCE AUDIT OF SPECIFIC DIAGNOSIS CODES THAT AETNA INC. (CONTRACT H5521) SUBMITTED TO CMS (2022), at cover letter and "Office of Inspector General" page.

[43] IGA §§ 2 – 4, 6.

[44] 42 C.F.R. § 422.300 (2021) ("This subpart is based on sections 1106, 1128J(d), 1853, 1854, and 1858 of the [Social Security] Act.").

[45] The Secretary previously conceded that HHS lacks such authority by seeking the authority from Congress. *See Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations for 2011: Hearings Before the H.R. Comm. on Appropriations*, 111th Cong. pt. 7, at 14 (2010) (written statement of HHS Deputy Secretary William Corr); CMS, FISCAL YEAR 2011 PERFORMANCE BUDGET (2010), at 177 (describing proposal that would "[c]larify in statute that CMS can extrapolate the error rate found in the risk adjustment validation (RADV) audits to the entire MA plan payment for a given year when recouping overpayments."). The Secretary now takes the

to calculate or collect extrapolated overpayments, now or in the future.[46]

OIG has previously glossed over the gap between its audit authority under the IGA and its recommendations on extrapolated overpayments in its MAO audit reports, positing that there is no statutory constraint on OIG's ability to make such recommendations to CMS.[47]   But that would miss the point here. If neither CMS nor OIG can calculate or collect extrapolated overpayments, then public recommendations on the calculation or collection of extrapolated overpayments serve only to confuse the public and cause reputational harm to MAOs.

B.   OIG's extrapolation methodology and recommendation in the Draft Report are inconsistent with the statutory actuarial equivalence requirement

Even if CMS has the authority to implement OIG recommendations, CMS must still comply with the Social Security Act, applicable regulations, and the Administrative Procedure Act. If the recommendations themselves would be contrary to law or arbitrary and capricious, then CMS cannot implement them. The fact that OIG made the recommendations is immaterial.

The Draft Report is a prime example. CMS must comply with the statutory actuarial equivalence requirement with respect to the original Medicare and MA payment methodologies.[48] OIG's extrapolation methodology and recommendation in the Draft Report are inconsistent with the statute because they do not account for the error rate in the original Medicare program. Specifically, they do not account for the fact that the FFS data from the original Medicare program that CMS used to develop the MA risk adjustment model was unaudited and therefore included a certain number of unsupported codes.   The adoption and collection of OIG's extrapolated

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position that the failure of Congress to expressly prohibit extrapolation shows that the Secretary has the authority to extrapolate. *Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021*, 88 Fed. Reg. 6,643, 6,651 (Feb. 1, 2023). But "[t]hat theory has it backwards as a matter of basic separation of powers and administrative law" because an agency "may only take action that Congress has *authorized*." *Bais Yaakov of Spring Valley v. F.C.C.*, 852 F.3d 1078, 1082 (D.C. Cir. 2017). The Secretary's failure to identify specific statutory provisions authorizing contract-wide extrapolation in the MA program—coupled with his reliance on decades-old case law on extrapolation in original Medicare that predates the MA program—is a clear sign that the Secretary's change of position lacks good grounds.

[46] We do not read 42 U.S.C. § 1395ddd(f)(3), which places limits on the use of extrapolation by program integrity contractors, to apply to risk adjustment in the MA program. In 2010, Congress amended § 1395ddd to add subsection (h)(9), which sets forth special rules for the use of recovery audit contractors (RACs) in the MA program. The special rules do not authorize the RACs to engage in program integrity activities related to MA risk adjustment at all.

[47] OIG, A-07-19-01195, MEDICARE ADVANTAGE COMPLIANCE AUDIT OF SPECIFIC DIAGNOSIS CODES THAT BLUECROSS BLUESHIELD OF TENNESSEE (CONTRACT H7917) SUBMITTED TO CMS (2022), at p. 23 ("With respect to BCBST's comments that the Inspector General Act of 1978, 5 U.S.C. App does not authorize us to extrapolate, we note that neither the statute nor any other authority limits our ability to recommend a recovery to CMS based on extrapolation.").

[48] 42 U.S.C. §§ 1395w-23(b)(4)(C)-(D), 1395w-24(a)(5)(A), (a)(6)(A)(i)-(iii).

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overpayment would violate the statute.

In 2012, CMS gave public notice that it would achieve actuarial equivalence in RADV audits by applying a FFS Adjuster when determining the final payment recovery amount. CMS represented that it would first determine an estimated payment error rate for the MA contract and then apply a 99 percent confidence interval (CI). If the CI for the point estimate was above zero, then CMS would determine the final payment recovery amount by setting a preliminary payment recovery amount at the lower bound of the 99 percent CI for the MA contract's point estimate, and applying the FFS Adjuster as an offset. If the FFS Adjuster amount was greater than the preliminary payment recovery amount, then the final payment recovery amount was zero.[49]

CMS reasoned in 2012 that "[t]he FFS Adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error rate (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims). The actual amount of the adjuster will be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data."[50]

Six years later, CMS published a proposed rule in which it signaled that it would not use the FFS Adjuster because it had conducted a FFS Adjuster Study that suggested that "errors in FFS claims data do not have any systematic effect on the risk score calculated by the CMS-HCC risk adjustment model, and therefore do not have any systematic effect on the payments made to MA organizations."[51]

The FFS Adjuster Study was flawed; CMS still needs a FFS Adjuster to comply with the statutory actuarial equivalence requirement. As Aetna explained in its comment letter on the rulemaking, the CMS FFS Adjuster Study "fails to address the fundamental data inconsistency issue (use of unaudited FFS data), relies on flawed analysis premised on inappropriate data and methodological errors, is inconsistent with CMS's prior findings, and departs from core actuarial principles."[52] Aetna showed the impact of the data inconsistency issue by asking CMS to:

> Consider a simplified, hypothetical example where all FFS beneficiaries move to an MA plan, and this represents all MA enrollment. In theory, the average risk score across all MA plan members, applying risk factors developed using unaudited FFS data, should be the same as the average risk score across all FFS beneficiaries

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[49] CMS, NOTICE OF FINAL PAYMENT ERROR CALCULATION METHODOLOGY FOR PART C MEDICARE ADVANTAGE RISK ADJUSTMENT DATA VALIDATION CONTRACT-LEVEL AUDITS (February 24, 2012), at p. 4-5.

[50] *Id*.

[51] *Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for years 2020 and 2021*, 83 Fed. Reg. 54,982, 55,040 (Nov. 1, 2018).

[52] Aetna incorporates the administrative record for the final CMS rule, including Aetna's comment letter and all attachments thereto, into this OIG audit response by reference.

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(i.e., a "1.0") to maintain actuarial equivalence. If unsubstantiated diagnoses were removed from the MA payments as part of RADV audits, and the FFS Adjuster were zero, MA beneficiary risk scores would average something less than 1.0, and the MA plan would be paid commensurately less despite enrolling the same population as the FFS program—an impermissible result that destroys the actuarial equivalence required by law.

The Secretary finalized the RADV rule without a FFS Adjuster on February 1, 2023.[53] Perhaps recognizing the serious flaws in the FFS Adjuster Study, the Secretary rationalized the omission of the FFS Adjuster on two legal grounds. First, the Secretary posited that the statutory actuarial equivalence requirement does not "apply to the obligation to return improper payments for MAO diagnosis codes that are unsupported by medical records."[54] Second, he asserted that "it would be unreasonable to interpret the Act as requiring a minimum reduction in payments in one provision (the coding pattern provision), while at the same time prohibiting CMS in an adjacent provision (the actuarial equivalence provision) from enforcing those longstanding documentation requirements (by requiring an offset to the recovery amount calculated for CMS audits)."[55] We disagree strongly with the Secretary's reading of the Act and believe that his omission of a FFS Adjuster from the RADV rule was not only contrary to law, but also arbitrary and capricious for the reasons that we detailed in our comment letter.

The adoption and collection of OIG's extrapolated overpayment in the Draft Report would be contrary to law and arbitrary and capricious for the same reasons.

C.   **OIG uses a less statistically sound confidence interval than CMS in the Draft Report**

OIG applied the lower bound of a 90% confidence interval to calculate its extrapolated overpayment amount in the Draft Report. CMS follows the more common and statistically sound approach of using the lower limit of a 99% confidence interval in RADV audits.[56] OIG does not explain its reasons for choosing the 90% confidence interval instead of the 99% confidence interval that CMS would otherwise apply in a RADV audit. In general, OIG should align its approach with CMS, or at least explain its reasons for applying a different approach.

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[53] 88 Fed. Reg. 6,643, 6,644 (February 1, 2023).

[54] *Id*. at 6,656.

[55] *Id*. at 6,657.

[56] CMS, HHS Risk Adjustment Data Validation (HHS-RADV) White Paper (Dec. 6, 2019), at p. 6; Milliman, MEDICARE ADVANTAGE RADV FFS ADJUSTER: WHITE PAPER (Aug. 23, 2019), http://assets.milliman.com/ektron/Medicare_Advantage_RADV_FFS_adjuster_8-23-2019.pdf; *see also* 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.").

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VI.   Aetna does not concur with OIG's recommendations but will continue to evaluate and evolve its compliance program

Aetna has invested tremendous time, effort, and resources into strengthening its compliance program prior to and since the audit period. Aetna is pleased that OIG recognized that "Aetna had compliance policies and procedures in place [during the audit period] to determine whether the diagnosis codes that it received from its providers and then submitted to CMS to calculate risk-adjusted payments were correct[,]" including provider education, an annual risk assessment, an annual workplan, and periodic reviews. Aetna is equally pleased that OIG noted that Aetna "provided guidance to its reviewers that outlined the process of coding acute stroke and acute myocardial infarction diagnoses in accordance with CMS documentation and ICD-9 guidelines."

Notwithstanding Aetna's efforts, OIG found that Aetna's compliance procedures during the audit period "could be improved," and recommended that Aetna "examine its existing compliance procedures to identify areas where improvements can be made … ."

Aetna engages in continuous process improvement across its MA operations, and its compliance program is no exception. The compliance program has evolved greatly in the seven years since the audit period ended, and Aetna does not believe that OIG's recommendation takes into account that evolution. Aetna, however, remains committed to continuous process improvement and will look for new and different ways to enhance its compliance program in the future.

OIG further recommended in the Draft Report "that Aetna … (2) determine, for the remaining 159 enrollee-years in the potentially mis-keyed diagnosis code high-risk group not reviewed as part of this audit, whether the medical records in each case support the diagnosis for the unrelated condition and refund any resulting overpayments to the Federal Government; [and] (3) identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after [OIG's] audit period and refund any resulting overpayments to the Federal Government[.]" We understand that OIG will also recommend in the final report that Aetna refund alleged overpayments that OIG identified in the audit sample.

Aetna does not concur with the additional recommendations for the reasons that Aetna has stated above. In addition, Aetna does not concur with recommendation (3) because the transition to the ICD-10 coding regime largely mitigated any mis-keying of diagnoses.

Conclusion

We thank OIG for the opportunity to respond to its Draft Report and we request that OIG revise its Draft Report to account for the arguments discussed herein.

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Sample 111: OIG targeted date of service 09/09/2015 for HCC 96/100: ICD code 434.91; Cerebral artery occlusion; unspecified with cerebral infarction.

> **Aetna's Conclusion**: This diagnosis code is supported based on the emergency department physician's Primary Impression of cerebrovascular accident (CVA) and subsequent admission to the hospital as an inpatient. The definitive diagnosis in the emergency department setting from a face-to-face visit with a valid provider type follows the ICD-9-CM Official Guidelines for Coding and Reporting, Section IV. Diagnostic Coding and Reporting Guidelines for Outpatient Services. As per the CPT guidance for emergency department services, an emergency department is defined as an organized hospital-based facility for the provision of unscheduled episodic services to patients who present for immediate medical attention.

> **Detail:** The enrollee presented to the emergency department for evaluation of sudden onset of weakness followed by a subsequent unresponsive and catatonic episode. The physician noted in the physical exam the enrollee was nonverbal and could not follow commands. A CT was performed and showed no acute abnormality; however, the provider noted the final diagnosis was stroke and altered mental status followed by admission. The ER physician performed a comprehensive history and exam and utilized medical decision of high complexity to determine treatment and care for the enrollee, which is supported by his documentation.

> **Reference:** 111-01-PHY.pdf; pages 2-4

Sample 114: OIG targeted date of service 2/25/2015 for HCC 96/100: ICD code 434.91; Cerebral artery occlusion; unspecified with cerebral infarction.

> **Aetna's Conclusion**: This diagnosis code is supported based on the physicians' clinical documentation.

> **Detail:** The enrollee presented for an initial evaluation for numbness/weakness in the right hand and right side of the face. The enrollee reported all problems began in a prior hospital stay for kidney failure, pneumonia, and heart problems. The review of systems noted upper extremity weakness on the right side as well as tingling on the right side. Within the neurological exam, the physician documents decreased sensation in a right V1 distribution. The physician documented in his assessment the diagnosis of stroke with a plan for MRI Brain without Gad w/anesthesia and further notating "abnormal."

> **Reference**: 114-01-PHY.pdf; pages 3-5

Sample 130 OIG targeted date of service 10/28/2014 for HCC 104/107: ICD code 416.2; Chronic pulmonary embolism

> **Aetna's Conclusion**: This diagnosis code is supported based on physicians' clinical documentation and coding.

> **Detail:** The enrollee presented for a follow-up outpatient visit. The enrollee is status post-surgery for breast cancer in April 2014. The physician documented a chronic pulmonary embolism in the assessment, further, the plan notes to continue current therapies. The past medical history documents blood clots and the surgical history notes that there has been a "filter placed/blood clots."

The enrollee was on aspirin and Plavix. The history of present illness documents the enrollee as having shortness of breath with exertion. The provider noted the diagnosis of chronic pulmonary embolism which is supported by the fact the enrollee had a filter inserted. Filters are only placed in individuals who have had and have an ongoing risk of embolism and for whom long term anticoagulation is not an option. The enrollee has a cardiac stent and is on dual antiplatelet therapy. Anticoagulants are contraindicated. The provider documents chronic pulmonary embolism in their assessment.

Reference: 130-01-PHY.pdf; pages 2-4

Sample 152: OIG targeted date of service 10/20/2014 for HCC 105/108: ICD code 443.9; Peripheral vascular disease, unspecified.

Aetna's Conclusion: This diagnosis code is supported based on the physicians' clinical documentation and coding.

Detail: The enrollee presented for an outpatient visit. The provider documents vascular changes in the assessment as well as Diabetes with neuro/vascular changes. On physical examination the provider documents the following Class B findings: negative hair growth, skin texture is shiny with noted discoloration, diminished dorsalis pedis and posterior tibial pulses bilaterally, delayed capillary refill, and skin temperature is cool. Both feet demonstrate dry sandy plantar texture with hyperkeratotic tissue and dryness of heels with open fissures. The assessment of the provider documents "Diabetes with neuro changes/vascular changes."–Indexing to Diabetes with vascular changes yields code 250.70 (DM with peripheral circulatory complications HCC 18/18). Indexing further directs the coder to "Use Additional Code" for peripheral angiopathy (443.81) which is the same HCC for which this sample was targeted.

Reference: 152-01-PHY.pdf; pages 2-3

Sample 171: OIG targeted date of service 06/30/2014 for HCC 105/108: ICD code 443.9; Peripheral vascular disease, unspecified.

Aetna's Conclusion: The diagnosis is supported based on the physicians' clinical documentation and coding. An ABI of 0.9 or lower is an indication of peripheral arterial disease.

Detail: The enrollee presented for an outpatient visit for bilateral lower extremity pain. The provider documented lower extremity pain concerning for peripheral vascular disease prompting the order for the vascular study.   The Bilateral Lower Extremity Arterial & Noninvasive Physiologic Study documents ABI of 0.8 on the right and 0.75 on the left. ABIs are abnormal bilaterally. The provider documented in the Impression mild to moderate atherosclerotic disease. Utilizing ICD Coding standards, indexing for the documented diagnosis would direct the coder to select code 443.9, peripheral vascular disease, unspecified.

Reference: 171-01-PHY.pdf; pages 2-3