

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE COMPLIANCE
AUDIT OF SPECIFIC DIAGNOSIS CODES
THAT ANTHEM COMMUNITY
INSURANCE COMPANY, INC.
(CONTRACT H3655)
SUBMITTED TO CMS**

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Office of Inspector General

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Report in Brief

Date: May 2021

Report No. A-07-19-01187

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



Why OIG Did This Audit

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

To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS. Some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.

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

How OIG Did This Audit

We sampled 203 unique enrollee-years with the high-risk diagnosis codes for which Anthem 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 \$599,842.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) 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 Anthem submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 123 of the 203 enrollee-years, the diagnosis codes that Anthem submitted to CMS were not supported in the medical records and resulted in \$354,016 of net overpayments for the 203 enrollee-years.

These errors occurred because the policies and procedures that Anthem had to detect and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. On the basis of our sample results, we estimated that Anthem received at least \$3.47 million of net overpayments for these high-risk diagnosis codes in 2015 and 2016.

What OIG Recommends and Anthem Comments

We recommend that Anthem refund to the Federal Government the \$3.47 million of net overpayments; identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and enhance its compliance procedures to focus on diagnosis codes that are at high risk for being miscoded by (1) determining whether these diagnosis codes (when submitted to CMS for use in CMS's risk adjustment program) comply with Federal requirements and (2) educating its providers about the proper use of these diagnosis codes.

Anthem did not concur with our findings and recommendations. Anthem disagreed with our findings for 2 specific enrollee-years and provided additional explanations. Anthem also did not agree with the methodologies that we used to review the selected diagnoses and to calculate the \$3.47 million of net overpayments. Anthem also said that our report reflected misunderstandings of legal and regulatory requirements underlying the MA program.

After reviewing Anthem's comments and the information provided, we maintain that all of our findings and recommendations remain valid. We followed a reasonable audit methodology, properly executed our sampling methodology, and correctly applied applicable Federal requirements underlying the MA program.

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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, sex, 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 codes¹ from their providers and submit these codes to CMS. We are auditing MA organizations because some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS. Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 28 major depressive disorder diagnoses into 1 group.) This audit covered Anthem Community Insurance Company, Inc. (Anthem), for contract number H3655² and focused on seven groups of high-risk diagnosis codes.

OBJECTIVE

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

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

² All subsequent references to "Anthem" in this report refer solely to contract number H3655.

BACKGROUND

Medicare Advantage Program

The MA program³ offers beneficiaries managed care options by allowing them to enroll in private health care plans rather than having their care covered through Medicare's traditional fee-for-service (FFS) program. Beneficiaries who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

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

For 2019, CMS paid MA organizations \$273.8 billion, which represented 34 percent of all Medicare payments for that year.

Risk Adjustment Program

Federal requirements mandate that payments to MA organizations be based on the anticipated cost of providing Medicare benefits to a given enrollee and, in doing so, also account for variations in the demographic characteristics and health status of each enrollee.⁴

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.⁵ 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.⁶

³ 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.

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

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

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

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

To determine an enrollee's health status for purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from face-to-face encounters with a physician (in an office or in an inpatient or outpatient setting). MA organizations collect the diagnosis codes that physicians document on the medical records and submit these codes to CMS. CMS then maps certain diagnosis codes, on the basis of similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs).⁷ Each HCC has a factor (which is a numerical value) assigned to it for use in each enrollee's risk score.

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

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

The risk adjustment program is prospective; CMS uses the diagnosis codes that the enrollee received for one year (known as the service year) to determine HCCs and calculate risk scores for the following year (known as the payment year). Thus, an enrollee's risk score does not change for the year in which a diagnosis is made. Instead, the risk score changes for the entirety of the year after the diagnosis has been made. Further, the risk score calculation is an additive process: As HCC factors (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

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

organizations for the additional risk for providing coverage to enrollees expected to require more health care resources.

CMS multiplies the risk scores by the base rates to calculate the total monthly payment that an MA organization receives for each enrollee. Miscoded diagnoses submitted to CMS may result in HCCs that are not validated and incorrect enrollee risk scores, which may lead to improper payments (overpayments) from CMS to MA organizations. Conversely, correctly coded diagnoses that MA organizations do not submit to CMS may lead to improper payments (underpayments).

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:

- *Acute stroke*: An enrollee received one acute stroke diagnosis (which maps to the HCC for Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim. 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 claim but did not have that diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician's claim). A diagnosis for a less severe manifestation of a disease in the related-disease group typically should have been used.
- *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.⁸
- *Embolism*: An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease With Complications (Embolism HCCs) but did not have an anticoagulant medication dispensed on his or her behalf. An anti-coagulant medication is typically used to treat an embolism. 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.

⁸ We combined these enrollees into one group because an individual's risk scores could have been further increased if that enrollee also had a COPD diagnosis (which was not part of our audit). If our audit identified an error that invalidated either the acute stroke or acute heart attack HCC, then the disease interaction factor would also be identified as an error. By combining these enrollees in one group, we eliminated the possibility of including the disease interaction factor twice in overpayment calculations (if any).

- *Vascular claudication*: An enrollee received one diagnosis related to vascular claudication (which maps to the HCC for Vascular Disease) but had medication dispensed on his or her behalf that is frequently dispensed for a diagnosis of neurogenic claudication.⁹ In these instances, the vascular claudication diagnoses may not be supported in the medical records.
- *Major depressive disorder*: An enrollee received a major depressive disorder diagnosis (which maps to the HCC entitled Major Depressive, Bipolar, and Paranoid Disorders) on one claim during the service year but did not have an antidepressant medication dispensed on his or her behalf. In these instances, the major depressive disorder diagnoses may not be supported in the medical records.
- *Potentially mis-keyed diagnosis codes*: An enrollee received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition (which mapped to a possibly unvalidated HCC). For example, ICD-9 diagnosis code 250.00 (which maps to the HCC for Diabetes Without Complication) could be transposed as diagnosis code 205.00 (which maps to the HCC for Metastatic Cancer and Acute Leukemia and in this example would be unvalidated). Using an analytical tool that we developed, we identified 832 scenarios in which diagnosis codes mis-keyed because of data transposition or other data entry errors could have resulted in the assignment of an unvalidated HCC.

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

Anthem Community Insurance Company, Inc.

Anthem is an MA organization based in Indianapolis, Indiana. As of December 31, 2016, Anthem provided coverage under contract number H3655 to approximately 137,000 enrollees. For the 2015 through 2016 payment years (audit period), CMS paid Anthem approximately \$2.3 billion to provide coverage to its enrollees.

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 through 2015 service years, for which Anthem received increased risk-adjusted payments for payment years 2015 through 2016, respectively. Because enrollees could have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment

⁹ Vascular claudication and neurogenic claudication are different diagnoses. Vascular claudication is a condition that can result in leg pain while walking and is caused by insufficient blood flow. Neurogenic claudication is a condition that can also result in leg pain but is caused by damage to the neurological system, namely the spinal cord and nerves.

year, which we refer to as “enrollee-years.” We identified 3,139 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$7,298,047). We selected for audit a sample of 203 enrollee-years, which comprised (1) a stratified random sample of 159 (out of 3,095) enrollee-years for the first 6 high-risk groups and (2) 44 enrollee-years for the remaining high-risk group.

Table 1 breaks out the numbers of sampled enrollee-years (of the 203) associated with each of the 7 high-risk groups.

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	9
4. Embolism	30
5. Vascular claudication	30
6. Major depressive disorder	30
Total for Stratified Random Sample	159
7. Potentially mis-keyed diagnosis codes	44
Total for All High-Risk Groups	203

Anthem provided medical records as support for the selected diagnosis codes associated with the 203 enrollee-years. We used an independent medical review contractor to review the medical records to determine whether the selected diagnosis codes that Anthem submitted to CMS were supported. If the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

Appendix A contains the details of our audit scope and methodology, Appendix B contains our statistical sampling methodology, and Appendix C contains our sample results and estimates.

FINDINGS

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that Anthem submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 80 of the 203 sampled enrollee-years, the medical records supported the diagnosis codes that Anthem submitted to CMS. For the remaining 123 enrollee-years, however, the diagnosis codes were not supported in the medical records.

These errors occurred because the policies and procedures that Anthem had to detect and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. As a result, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Anthem received at least \$3.47 million of net overpayments for 2015 and 2016.¹⁰

FEDERAL REQUIREMENTS

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

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

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

CMS requires all submitted diagnosis codes to be documented on 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 ICD Coding Guidelines (42 CFR § 422.310(d)(1) and 45 CFR §§ 162.1002(b)(1) and (c)(2)-(3)). Further, the MA organizations must implement procedures to ensure that diagnoses come only from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities, and physicians (the Manual chap. 7 § 40).

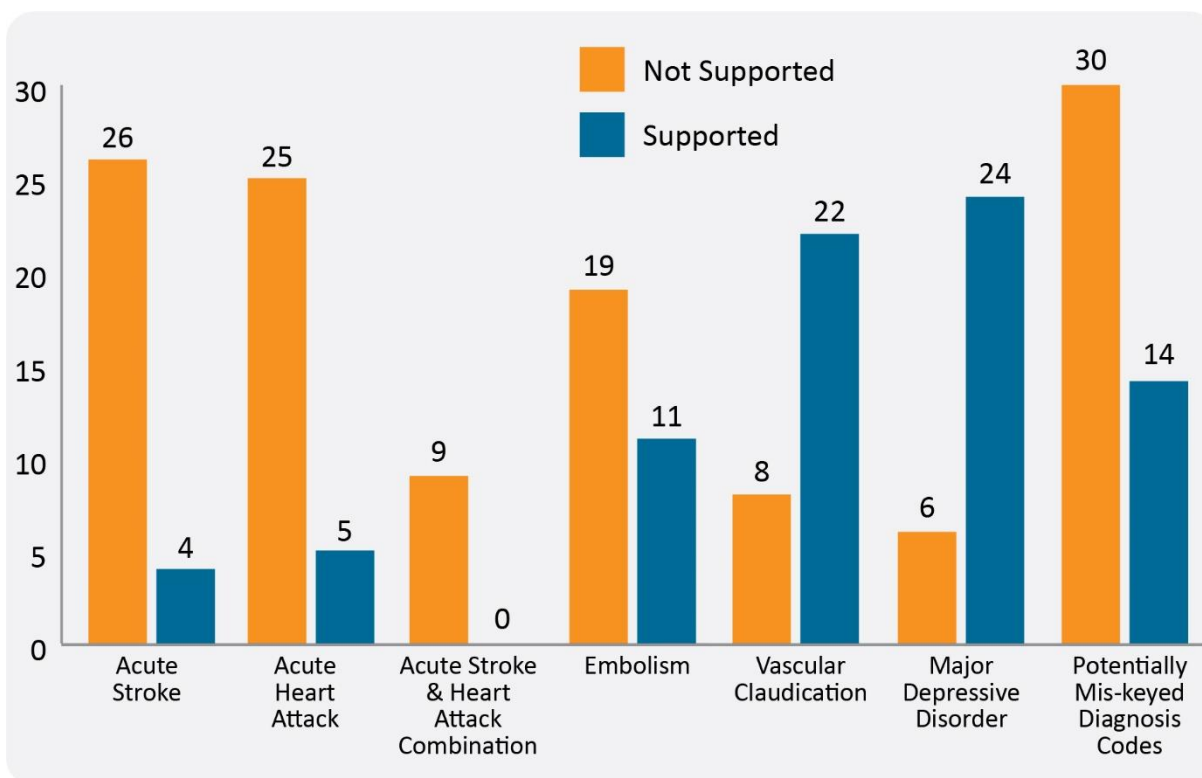
¹⁰ Specifically, we estimated that Anthem received at least \$3,468,954 of net overpayments (\$3,317,947 for the statistically sampled groups plus \$151,007 for the group of potentially mis-keyed diagnosis codes).

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

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

Most of the selected high-risk diagnosis codes that Anthem 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 123 of the 203 sampled enrollee-years did not support the diagnosis codes. In these instances, Anthem should not have submitted the diagnosis codes to CMS and received the resulting net overpayments.

Figure: Analysis of High-Risk Groups



Incorrectly Submitted Diagnosis Codes for Acute Stroke

Anthem incorrectly submitted diagnosis codes for acute stroke for 26 of 30 sampled enrollee-years. Specifically:

- For 24 enrollee-years, the medical records did not support an acute stroke diagnosis.
 - For 16 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 medical record (for a service that occurred in 2015) indicated that the individual had an acute stroke in 1999. 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 [Ischemic or Unspecified Stroke]. . . . There is mention of a history of a stroke [diagnosis] but no description of residuals or sequelae that should be coded."

- For 7 enrollee-years, the medical records did not contain sufficient information to support an acute stroke diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that the "[p]rovider noted a possibility of an acute [stroke] as one of the differential diagnoses. Cannot be coded as a confirmed diagnosis. Moreover, the progress notes from the inpatient admission have documentation of an MRI [magnetic resonance imaging] report that was negative for acute [stroke]."

- For 1 enrollee-year, Anthem submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiparesis (which was supported in the medical records). The independent medical review contractor noted that "the patient has hemiparesis from an old [stroke] that should have been coded with [late effects of cerebrovascular disease, hemiplegia affecting nondominant side] and would result in the assignment of HCC [Hemiplegia/Hemiparesis]." Accordingly, Anthem should not have received an increased payment for the acute stroke diagnosis but instead should have received a lesser net increased payment for the hemiplegia diagnosis.

- For the remaining 2 enrollee-years, Anthem could not locate any medical records to support the acute stroke diagnoses; therefore, the HCCs for Ischemic or Unspecified Stroke were not validated.

As a result of these errors, the HCCs for Ischemic or Unspecified Stroke were not validated, and Anthem received \$60,678 of net overpayments for these 26 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Heart Attack

Anthem incorrectly submitted diagnosis codes for acute heart attack for 25 of 30 sampled enrollee-years. Specifically:

- For 19 enrollee-years, the medical records did not support an acute myocardial infarction diagnosis. However, we identified support for an old myocardial infarction diagnosis, which is a less severe manifestation of the related-disease group.
 - For 11 enrollee-years, which occurred in 2015, the old myocardial infarction diagnosis mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Anthem should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the old myocardial infarction diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor noted that “[t]he patient presented to undergo a [c]olonoscopy. There is no mention of [diagnoses for acute myocardial infarction or angina]. The medical record does mention a history of [myocardial infarction] in 1995.”

- For the remaining 8 enrollee-years, which occurred in 2016, the old myocardial infarction diagnosis did not map to an HCC.¹¹ Anthem should not have received an increased payment for acute myocardial infarction.
- For the remaining 6 enrollee-years, the medical records did not support either an acute myocardial infarction diagnosis or an old myocardial infarction diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor noted that “[t]he patient underwent EGD [upper GI endoscopy] for gastric pain. There is no mention of [a]cute [myocardial infarction] or [a]ngina.”

As a result of these errors, the Acute Heart Attack HCCs were not validated, and Anthem received \$37,209 of net overpayments for these 25 sampled enrollee-years.

¹¹ In contrast to the enrollee-years that occurred in 2015 (for which CMS used the Version 12 model), for 2016, CMS used only the Version 22 model, which did not include an HCC for Old Myocardial Infarction, to calculate risk scores (footnote 7).

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

For 9 sampled enrollee-years, Anthem 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 8). However, we found errors for all 9 of the enrollee-years because the medical records did not support either the acute stroke diagnosis, the acute myocardial infarction diagnosis, or both. Specifically:

- For 8 enrollee-years, the medical records did not support an acute stroke diagnosis. Further, the medical records did not support an acute myocardial infarction diagnosis; however, we identified support for an old myocardial infarction diagnosis, which is a less severe manifestation of the related-disease group. Accordingly, for payment year 2015, Anthem should not have received an increased payment for either the acute stroke diagnosis or the acute myocardial infarction diagnosis but should have received a lesser increased payment for the old myocardial infarction diagnosis for 7 enrollee-years.¹²

For example, for 1 enrollee-year, the medical record indicated that the individual had an acute stroke in 1990 and a myocardial infarction in the 1980s. The independent medical review contractor noted that “[t]here is no evidence of an acute stroke or any related condition that would result in an assignment of the [Ischemic or Unspecified Stroke] 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.” In addition, the contractor noted that “there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of [an Acute Heart Attack] HCC. There is documentation of a history of myocardial infarction.”

- For the 1 remaining enrollee-year, the medical records supported an acute myocardial infarction diagnosis but did not support the acute stroke diagnosis. The independent medical review contractor noted that the HCC for “[Acute Heart Attack] was substantiated based on assessment of acute myocardial infarction.” However, the contractor also noted that “there is no documentation of any condition that will result in an assignment . . . that translates to the assignment of HCC [Ischemic or Unspecified Stroke].” Accordingly, Anthem should not have received an increased payment for the acute stroke diagnosis.

As a result of these errors, either the HCCs for Ischemic or Unspecified Stroke or Acute Heart Attack were not validated, and Anthem received \$31,126 of net overpayments for these 9 sampled enrollee-years.

¹² For the remaining enrollee-year, the old myocardial infarction diagnosis did not map to an HCC (for payment year 2016).

Incorrectly Submitted Diagnosis Codes for Embolism

Anthem incorrectly submitted diagnosis codes for embolism for 19 of 30 sampled enrollee-years. Specifically, the medical records did not support an embolism diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor noted “[t]here is no anticoagulant listed in the current medications list. Provider has noted . . . ‘No evidence for DVT [deep vein thrombosis].’”

As a result of these errors, the Embolism HCCs were not validated, and Anthem received \$46,598 of overpayments for these 19 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Vascular Claudication

Anthem incorrectly submitted diagnosis codes for vascular claudication for 8 of 30 sampled enrollee-years. Specifically, the medical records did not support a vascular claudication diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor noted that the “patient is seen in a pre-op clearance visit for upcoming TKR [total knee replacement] procedure. No active treatment noted for a past medical history of PVD [peripheral vascular disease].”

As a result of these errors, the HCCs for Vascular Disease were not validated, and Anthem received \$16,612 of overpayments for these 8 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder

Anthem incorrectly submitted diagnosis codes for major depressive disorder for 6 of 30 sampled enrollee-years. Specifically, the medical records did not support a major depressive disorder diagnosis for each of the 6 enrollee-years.¹³

For example, for 1 enrollee-year, the independent medical review contractor noted that the “[p]rovider has documented a diagnosis of mild depression . . . which does not result in HCC. A diagnosis of [m]ajor depression is not specified anywhere in the record.”

As a result of these errors, the HCCs for Major Depressive, Bipolar, and Paranoid Disorders were not validated, and Anthem received \$10,786 of overpayments for these 6 sampled enrollee-years.

¹³ In five of these cases, the independent medical review contractor identified support for a diagnosis code for a lesser form of depression, which does not map to an HCC.

Potentially Mis-keyed Diagnosis Codes

Anthem submitted potentially mis-keyed diagnosis codes for 30 of 44 enrollee-years. In each of these cases, the enrollee-years received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition. Table 5 in Appendix E contains the potentially mis-keyed diagnosis codes that we identified for the 30 enrollee-years.

- For 26 enrollee-years, the medical records did not support the reviewed diagnosis code. Because of these errors, Anthem submitted unsupported diagnosis codes that mapped to unvalidated HCCs to CMS.

For example, for 1 enrollee-year, Anthem submitted four diagnosis codes for diabetes mellitus (250.00) and only one diagnosis code for acute myeloid leukemia (205.00) to CMS. The independent medical review contractor limited its review to the acute myeloid leukemia diagnosis, for which it did not find support. Thus, the Metastatic Cancer and Acute Leukemia HCC was not validated.

- For 4 enrollee-years, the medical records did not support the diagnosis code submitted to CMS; however, we found support for another diagnosis code that mapped to a different HCC.

For example, for 1 enrollee-year, Anthem submitted 21 diagnosis codes for diabetes mellitus (250.00) and only 1 diagnosis code for acute myeloid leukemia (205.00) to CMS. 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 [Metastatic Cancer and Acute Leukemia]. Provider has documented Burkitt’s lymphoma . . . which results in HCC [Lymphoma and Other Cancers].” Accordingly, Anthem should not have received an increased payment for the Metastatic Cancer and Acute Leukemia HCC, but it should have received a lesser increased payment for the Lymphoma and Other Cancers HCC.

Appendix E contains the 30 HCCs that were not validated (Table 5) and the additional HCCs that were supported for the 4 enrollee-years (Table 6).

As a result of these errors, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated, and Anthem received \$151,007 of net overpayments for these 30 sampled enrollee-years.

THE POLICIES AND PROCEDURES THAT ANTHEM USED TO DETECT AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS WERE NOT ALWAYS EFFECTIVE

The errors we identified occurred because the policies and procedures that Anthem had to detect and correct noncompliance with CMS’s program requirements, as mandated by Federal regulations (42 CFR § 422.503(b)(4)(vi) (Appendix D)), were not always effective.

Anthem had compliance procedures to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. These procedures included a comparison of diagnosis codes from specific claims to the diagnoses that were documented on the associated medical records. Anthem's procedures included guidance on how its reviewers should address certain high-risk diagnoses, including diagnosis codes that mapped to acute stroke, acute heart attack, and embolism HCCs. If Anthem detected compliance problems, its procedures called for Anthem to make corrections on the reviewed claims and expand its review to other claims not initially selected. However, these compliance procedures were not always effective because Anthem did not identify high-risk diagnosis codes as problematic unless that diagnosis code appeared on a specific claim that was selected for review.

Anthem's compliance procedures also included outreach to help educate its providers on several topics, including medical management and quality of care. The outreach occasionally provided guidance on listing valid diagnosis codes on claims; however, this guidance did not address steps to ensure that the correct diagnosis codes were used. In this regard, the outreach was not effective for high-risk diagnosis codes.

ANTHEM RECEIVED NET OVERPAYMENTS

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Anthem received at least \$3,468,954 (\$3,317,947 for the statistically sampled groups plus \$151,007 for the group of potentially mis-keyed diagnosis codes) of net overpayments for these high-risk diagnosis codes in 2015 and 2016 (Appendix C).

RECOMMENDATIONS

We recommend that Anthem Community Insurance Company, Inc.:

- refund to the Federal Government the \$3,468,954 of net overpayments;
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
- enhance its compliance procedures to focus on diagnosis codes that are at high risk for being miscoded by
 - determining whether these diagnosis codes (when submitted to CMS for use in CMS's risk adjustment program) comply with Federal requirements and
 - educating its providers about the proper use of these diagnosis codes.

ANTHEM COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Anthem did not concur with our findings and recommendations. Anthem disagreed with our findings for 2 specific enrollee-years and provided additional explanations as to why it believed the medical records validated the HCCs. Anthem requested that we identify the extent to which these two errors were replicated more broadly across our analysis. Anthem also did not agree with the methodologies that we used to review the selected diagnoses and to calculate net overpayments. Moreover, Anthem said that our report reflected misunderstandings of legal and regulatory requirements underlying the MA program and that our recommendations were “inconsistent with the Social Security Act’s . . . actuarial equivalence mandate and with HHS [Department of Health and Human Services] and [CMS] data accuracy requirements.”

After reviewing Anthem’s comments and the information provided, we maintain that all of our findings and recommendations remain valid. We added Appendix E to this final report to clarify some of our findings.

A summary of Anthem’s comments and our responses follows. Anthem’s comments appear in their entirety as Appendix F.

ANTHEM DID NOT AGREE WITH HOW THE OFFICE OF INSPECTOR GENERAL CHARACTERIZED ITS AUDIT RESULTS

Anthem Comments

Anthem stated that the manner in which we characterized our audit results could be misleading. Specifically, our statement (at the beginning of our “Findings” section above) that “[m]ost of the selected diagnosis codes that Anthem submitted to CMS for use in CMS’s risk adjustment program did not comply with Federal requirements” could, according to Anthem, be misinterpreted and could suggest that we made this conclusion about all diagnosis codes Anthem has submitted to CMS.

Anthem requested that we revise the statement to “make unmistakably clear” that we are referring only to the selected diagnosis codes sampled in Anthem’s contract H3655 for 2014 and 2015 dates of service.

Office of Inspector General Response

We disagree with Anthem’s assertion. Our objective and our explanation of the scope of our audit (Appendix A) make it clear that our audit considered only *selected* diagnoses that Anthem, under contract number H3655, submitted to CMS. We conveyed our findings and recommendations (i.e., our audit results) within the framework of these limitations. However, we have slightly revised the statement in question to remove any possible misinterpretation of the magnitude or scope of our findings.

ANTHEM DID NOT AGREE WITH FINDINGS FOR TWO SPECIFIC SAMPLED ENROLLEE-YEARS

Anthem Comments

Anthem did not agree with our findings for 2 specific sampled enrollee-years because, it said, the associated “medical record examples that OIG [Office of Inspector General] highlights in its [d]raft [r]eport do not support OIG’s conclusions that the [HCC] under review is unvalidated.” Anthem provided explanations to support its positions:

- For the first enrollee-year, Anthem stated that our independent medical review contractor did not validate the HCC for Major Depressive, Bipolar, and Paranoid Disorders because the medical record documented only a diagnosis of mild depression, which does not map to an HCC. Anthem stated that this determination is a misinterpretation and that the HCC should be validated because “the provider documented ‘mild depression,’ and in the context of the entire medical record and consistent with clinical diagnostic standards, the term ‘mild’ should be read to modify major depressive disorder.” Anthem noted that the American Psychiatric Association’s *Diagnostic and Statistical Manual of Mental Disorders V (DSM-V)* states “that major depressive disorder can be either mild, moderate, or severe - that there is no separate diagnosis in the DSM-V for ‘mild depression.’”¹⁴
- For the second enrollee-year, Anthem stated that our independent medical review contractor did not validate the Embolism HCC because the medical record did not list an anticoagulant on the current medications list and because there was no evidence of a DVT after an ultrasound. Anthem said that our contractor’s determination was incorrect because the medical record stated that the “provider documented that it was ‘unsafe’ to prescribe the [enrollee] anticoagulant therapy,” and noted the “presence of an ‘IVC [inferior vena cava] filter’ . . . which is an intervention . . . in patients for whom anticoagulation therapy was contraindicated.” Lastly, Anthem stated that although an ultrasound found no current DVT, the medical record demonstrated that the enrollee was being actively monitored and treated for the condition.

Anthem requested that we reconsider our findings for these 2 sampled enrollee-years, identify the extent to which these errors were replicated more broadly across our analysis, and modify our monetary recommendation accordingly.

¹⁴ The DSM-V is an official archive of all conditions that are formally recognized as mental disorders, which clinicians and researchers use to diagnose and classify these conditions.

Office of Inspector General Response

Our independent medical review contractor reviewed the explanations that Anthem provided for these 2 enrollee-years and reconfirmed that the HCCs are unvalidated.

- For the first enrollee-year, the independent medical review contractor did not find support for the HCC for Major Depressive, Bipolar, and Paranoid Disorders. Specifically, the contractor reviewed Anthem’s comments and rereviewed the medical record and stated that “[t]here is no documentation in the medical record that supports the diagnosis of major depressive disorder. The provider documented mild depression that would be accurately assigned to . . . [the diagnosis of depressive disorder, not elsewhere classified].” This diagnosis code does not map to an HCC.
- For the second enrollee-year, the independent medical review contractor did not find support for the Embolism HCC. Specifically, the contractor reviewed Anthem’s comments and rereviewed the medical record and stated that the American Hospital Association (AHA) has “indicate[d] that coding of deep vein thrombosis (DVT) is based on the documentation of acute, chronic or a history of the diagnosis. Patients with a filter may have any of these diagnoses and ‘if the DVT has resolved, it may be reported as a personal history of venous thrombosis and embolism.’”¹⁵ To this point, the contractor stated that “there is no documentation to support acute, chronic or active [DVT]. The provider noted on [the medical record], ‘[n]o evidence for DVT’ and an ultrasound of the left extremity did not show any evidence of an acute or chronic deep vein thrombosis.” Finally, the contractor said that the medical record did support the diagnosis for personal history of venous thrombosis and embolism, which does not map to an HCC.

In addition, our contractor “confirmed that there is no impact on decisions made for other sample items as a result of Anthem’s arguments, and no quality systemic issues exist.” Accordingly, we made no changes to our recommendation that Anthem refund to the Federal Government an estimated \$3.47 million of net overpayments.

ANTHEM DID NOT AGREE WITH THE METHODOLOGIES THAT THE OFFICE OF INSPECTOR GENERAL USED TO REVIEW THE SELECTED DIAGNOSES

Anthem Comments

Anthem stated that our review methodologies were “skewed improperly toward identifying ‘overpayments.’” In this regard, Anthem made three related points:

- Anthem stated that we did not review all medical records from the specific years for the sampled enrollee-years; Anthem stated that instead, our sampling methodology

¹⁵ AHA Coding Clinic, Vol. 28, 1st Quarter, No. 1, 2011.

“targeted only those encounters for which OIG already suspected that the underlying medical record would not support an HCC uniquely reported on that date of service.” Anthem also stated that our “methodology improperly ignored the fact that there may be additional supported HCCs not previously submitted to CMS [on] other records for the sampled years for each enrollee.” Further, Anthem noted that “[a]t OIG’s request, Anthem submitted only one record to OIG for the majority of the sampled members and two records for a very small subset of those members.”

- In addition, Anthem stated that we did not account for the possibility of additional, unrelated HCCs that were supported in the medical records but that had not been previously submitted to CMS. Specifically, Anthem noted that we directed our independent medical review contractor to review only specific HCCs for the sampled enrollee-years.
- Anthem also said that our audit population “was skewed by excluding enrollees for whom no risk adjustment data was [sic] submitted to CMS” and asserted that our review methodology created an “additional systematic bias toward identifying ‘overpayments.’”

Anthem stated that as a result of our review methodologies, “OIG’s actual and extrapolated repayment calculations are inflated and its extrapolated repayment calculation is statistically unsupported.” Accordingly, Anthem contested our monetary recommendation and requested that we revise our calculations to address these “biases.”

Office of Inspector General Response

Our objective was to determine whether selected high-risk diagnosis codes that Anthem submitted to CMS for use in CMS’s risk adjustment program complied with Federal requirements. For each of the sampled enrollee-years, Anthem had previously submitted to CMS only one claim with a high-risk diagnosis code that mapped to the reviewed HCC. We asked Anthem to provide a copy of that related medical record for review. Recognizing that other medical records could support the diagnosis, we also informed Anthem that it could submit up to four more medical records of its choosing that could support the reviewed HCC. These additional medical records, when originally coded, did not contain a diagnosis code that mapped to the reviewed HCC. It was Anthem’s decision alone as to how many more records (up to four) to submit to the OIG for each of its members.

We asked our independent medical review contractor to review all medical records that Anthem submitted to determine whether the documentation supported any diagnosis codes that mapped to the reviewed HCCs. In this regard, we considered instances in which the medical review contractor found a diagnosis or HCC that should have been used instead of the diagnosis or HCC that was submitted to CMS, and on that basis we made our determinations appropriately.

The identification of: (1) all possible diagnosis codes that Anthem could have submitted on behalf of the sampled enrollee-years and (2) enrollees for whom Anthem did not submit any risk-adjusted diagnosis codes was beyond the scope of our audit.

Moreover, Anthem’s description of our net overpayment calculations as skewed and biased is not accurate. A valid estimate of net overpayments does not need to take into consideration all potential HCCs or underpayments within the audit period. Our estimate of net overpayments addresses only the portion of the payments related to the reviewed HCCs and does not extend to the HCCs that were beyond the scope of our audit. In accordance with our objective and as detailed in Appendices B and C, we properly executed a statistically valid sampling methodology in that we defined our sampling frame (Anthem enrollee-years with a high-risk diagnosis) and sample unit, randomly selected our sample, applied relevant criteria to evaluate the sample, and used statistical sampling software to apply the correct formulas to estimate the net overpayments made to Anthem.

ANTHEM DID NOT AGREE WITH THE EXTRAPOLATION METHODOLOGY THAT THE OFFICE OF INSPECTOR GENERAL USED TO CALCULATE THE RECOMMENDED NET OVERPAYMENT AMOUNT

Anthem Comments

Anthem disagreed with how we calculated the net overpayment amount that we recommended for Anthem to refund to the Federal Government. Specifically, Anthem stated that our use of the lower bound of a 90-percent confidence interval was not as “statistically valid and . . . robust” as using the lower bound of a 95-percent or 99-percent confidence interval. In this respect, Anthem noted that CMS uses the lower bound of the 99-percent confidence interval level for its risk-adjusted data validation (RADV) audits and requested that we use the same approach.¹⁶

Anthem also stated that although we removed 19 enrollee-years from our sample (because we could not reconcile certain risk adjustment data to the original CMS payments), we incorrectly included these enrollee-years in our overpayment calculations. Anthem asked that we take steps to address any statistical bias introduced due to the inclusion of the unreconciled 19 enrollee-years in the extrapolation calculation.

Office of Inspector General Response

Our estimation methodology does not need to mirror CMS’s estimation methodology. We believe that the lower limit of a two-sided 90-percent confidence interval provides a reasonably conservative estimate of the total amount overpaid to Anthem for the enrollee-years and time

¹⁶ CMS RADV audits consist of reviews of medical record documentation that audited MA organizations provide to substantiate the diagnosis codes that MA organizations submit to CMS. RADV audits are the primary tools that CMS uses to identify improper payments made to MA organizations.

period covered in our sampling frame. This approach, which is routinely used by HHS for recovery calculations,¹⁷ results in a lower limit (the estimated overpayment amount to refund) that is less than the actual overpayment amount 95 percent of the time.

In addition, Anthem’s statement that we removed the 19 enrollee-years but included them in our overpayment calculations is not correct. As we explained at the exit conference, we did not include these enrollee-years in either our sample or in any of our calculations.

ANTHEM DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL’S APPLICATION OF CMS REQUIREMENTS FOR CALCULATIONS OF OVERPAYMENTS

Anthem Comments

Anthem said that our actual and extrapolated calculations of overpayments violated certain CMS requirements that are mandated under the MA program. Specifically, Anthem stated that our audit methodology did not account for a payment principle known as “actuarial equivalence,” which, according to Anthem, is mandated by the Act.

Anthem cited the provision of the Act that mandates that risk-adjusted payments be made in a manner that ensures “actuarial equivalence” between CMS payments for health care coverage under MA and CMS payments under Medicare’s traditional FFS program. Anthem stated that “[b]ecause CMS developed the Medicare Advantage risk adjustment model using unaudited [FFS] claims data from the traditional Medicare program—which CMS has acknowledged contain high levels of erroneous diagnoses—CMS must account for those traditional Medicare data errors when measuring whether similar erroneous diagnoses for Medicare Advantage enrollees result in an overpayment.”

Anthem said that to account for the “traditional Medicare data errors” in audits of HCCs at MA organizations, CMS published a notice in 2012 stating that “it would first identify a ‘payment recovery amount’ based on the value of supported and unsupported HCCs identified during its review . . . [t]hen ‘to determine the final payment recovery amount, CMS [would] apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount.’” Anthem also said that a Federal district court decision concluded “that CMS systematically devalues MAO [MA organization] payments when it uses unaudited traditional Medicare data to set MAO payment rates while measuring MAO ‘overpayments’ based on audited patient records.” In this regard, Anthem said that without accounting for diagnosis coding errors in

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

traditional Medicare data (e.g., an FFS Adjuster), it is not possible to determine whether an MA organization (such as Anthem) has been overpaid as a result of any diagnosis coding errors.¹⁸

Anthem also noted that “CMS issued a proposed rule in 2018 suggesting that diagnosis coding errors in unaudited traditional Medicare data do not systematically impact payments to MAOs . . . and released a corresponding study purporting to support this premise.” Anthem added that this rule is not final and said that “CMS’s proposal does not satisfy the actuarial equivalence requirement of the [Act].”

Anthem requested that we withdraw our overpayment calculation until CMS issues an actuarially sound overpayment methodology that considers coding errors in the traditional Medicare program, and “[a]t that time, OIG should apply that actuarially sound methodology to this audit to calculate any repayment that might be due.”

Office of Inspector General Response

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

We used the results of the independent medical review contractor’s coding review to determine which of the high-risk HCCs were not substantiated and, in some instances, to identify HCCs that should have been used but were not used in the sampled enrollees’ risk score calculations. We followed the requirements of CMS’s risk adjustment program to determine the payment that CMS should have made for each enrollee. We used the overpayments and underpayments identified for each enrollee to estimate net overpayments.

Anthem stated that we did not consider actuarial equivalence in our overpayment calculations. To this point, we recognize that CMS is responsible for making operational and program payment determinations for the MA program, including the application of any FFS Adjuster requirements. Moreover, CMS has not issued any requirements that compel us to reduce our net overpayment calculations.¹⁹ Thus, we believe that the steps that we followed for this audit provided reasonable assurance with regard to the findings and recommendations, including our estimation of net overpayments.²⁰

¹⁸ *UnitedHealthcare Ins. C. v. Azar II*, 330 F. Supp. 3d 173 (D.D.C. 2018).

¹⁹ In 2018, CMS proposed “not to include an FFS adjuster in any final RADV payment error methodology.” (Proposed Rule at 83 Fed. Reg. 54982, 55041.)

²⁰ OIG audit findings and recommendations do not represent final determinations by CMS. Action officials at CMS will determine whether a potential overpayment exists and will recoup any overpayments consistent with its policies and procedures. If a disallowance is taken, MA organizations have the right to appeal the determination that an overpayment occurred through the CMS RADV appeals process.

ANTHEM CONTENDED THAT THE OFFICE OF INSPECTOR GENERAL’S RECOMMENDATION TO PERFORM ADDITIONAL REVIEWS BEFORE OR AFTER THE AUDIT PERIOD DOES NOT CONFORM TO MEDICARE ADVANTAGE REGULATIONS

Anthem Comments

Anthem disagreed with our second recommendation to perform additional reviews to determine whether similar instances of high-risk diagnoses occurred before or after the audit period because, according to Anthem, “Medicare Advantage regulations do not require the sort of audits that OIG recommends.”

Anthem stated that MA regulations “do not require MAOs to ensure data perfection as the [d]raft [r]eport implies.” In this respect, Anthem said that “[t]he government has long acknowledged that MAOs are not expected to submit perfect risk adjustment data” and that “OIG has issued non-binding guidance stating that MAOs should establish an ‘information collection and reporting system reasonably designed to yield accurate information.’”²¹ Moreover, Anthem stated that CMS recognizes that MA organizations submit encounter data “in great volume from a number of sources” and that for the certification of these data, CMS holds MA organizations responsible for making good faith efforts to certify their accuracy, completeness, and truthfulness.

In this respect, Anthem stated that our citations of Federal regulations for MA organizations like Anthem to monitor the data that they receive from providers and submit to CMS were incomplete and misleading. Specifically, Anthem stated that our citations did not address the “broad discretion” that CMS provided to MA organizations to design their own compliance programs and did not “account for the qualified ‘good faith’ attestation standard that CMS explicitly adopted.” Thus, according to Anthem, our recommendation “dramatically expands the minimal Medicare Advantage compliance program requirements.”

In addition, with respect to the potentially mis-keyed diagnosis codes that we identified, Anthem said that it was unable to replicate our methodology for this finding because we have “not provided the underlying algorithm for identifying additional issues of those codes beyond the audited population.”

Office of Inspector General Response

We do not agree with Anthem’s interpretation of the Federal requirements. We recognize that MA organizations have the latitude to design their own, federally mandated, compliance programs. We also recognize that CMS applies a “good faith attestation” standard when MA organizations certify the great volume of data that they submit to CMS for use in the risk adjustment program. However, contrary to Anthem’s assertions, we believe that our recommendation for Anthem to review whether similar instances of high-risk diagnoses

²¹ Anthem cited 64 Fed. Reg. 61893, 61900 (Nov. 15, 1999).

occurred before or after our audit period conforms to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (Appendix D)).

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

We believe that the error rates identified in this report demonstrate that Anthem has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope. Accordingly, we stand by our recommendation that Anthem review whether similar instances of high-risk diagnoses occurred before or after our audit period.

With regard to the algorithm for the mis-keyed diagnoses, before the issuance of our draft report we provided Anthem with a spreadsheet detailing the 832 scenarios used in our analytical tool. In addition, for this final report we made minor clarifications to some of the language in this finding.

ANTHEM DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL’S RECOMMENDATION TO ENHANCE ITS EXISTING COMPLIANCE AND EDUCATION PROGRAMS

Anthem Comments

Anthem stated that our recommendation for Anthem to enhance its existing compliance procedures was based on an inaccurate and unfounded perception that its compliance program was not always effective. Anthem stated that although we found unsupported diagnosis codes, its “compliance and education programs comply with all legal and Medicare Advantage regulatory requirements” and added that we did not identify any specific deficiencies in those compliance and education programs.

Anthem noted that our review was limited to 2014 and 2015 dates of service and the compliance functions in place to monitor claims data for those years, and because of that limitation, “it is beyond the scope of the audit to arrive at a recommendation for current practices, which were not subject to OIG’s audit.”

Anthem stated that we acknowledged the effectiveness of its compliance program “in that [the program] alerted Anthem to potential problems and allowed Anthem to correct for them.” In addition, Anthem said that we did not identify any material flaws in its compliance and education programs, and “the mere fact that OIG identified some data inaccuracies . . . does not mean that Anthem’s compliance or education programs are deficient.” In this regard, Anthem also stated that it is not clear how it “could possibly identify any diagnosis code as ‘problematic’ without selecting and reviewing the claim information.” Anthem said that we “did not employ such a standard” and added that Anthem is “unable to identify unsupported diagnosis codes without reviewing claims data and corresponding medical records.”

Anthem said that our third recommendation “attempts to impose a requirement that substantially exceeds the auditing and monitoring required under existing regulations.” Because, according to Anthem, its “compliance and education are robust, effective, and comply with all applicable legal and regulatory requirements,” and also “extends beyond these processes [mentioned in the report],” Anthem requested that we withdraw this recommendation.

Office of Inspector General Response

Anthem’s response implied that we opined on the effectiveness of its entire compliance program. That was not our intention or our focus for this audit. Rather, we limited our review to selected diagnoses that we had determined to be at higher risk of being miscoded. Our audit revealed a significant error rate for some of these areas. In this regard, Anthem acknowledged that it is not clear how it could identify problematic diagnosis codes without selecting and reviewing the claim information. Accordingly, we do not believe that Anthem’s policies and procedures in place during our audit period were always effective for preventing or detecting and correcting these errors. Moreover, in its comments on our draft report, Anthem did not specify any current practices that it had implemented that would prevent the errors we identified. Thus, we continue to believe that Anthem can make improvements through an enhancement of its compliance procedures to focus on diagnosis codes that are at high risk for being miscoded.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid Anthem \$2,302,439,515 to provide coverage to its enrollees for 2015 and 2016. We identified a sampling frame of 3,139 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2014 and 2015 service years; Anthem received \$47,687,659 in payments from CMS for these enrollee-years for 2015 and 2016. We selected for audit 203 enrollee-years with payments totaling \$3,618,496.

The 203 enrollee-years included 30 acute stroke diagnoses, 30 acute heart attack diagnoses, 9 acute stroke diagnosis and acute heart attack diagnosis combinations, 30 embolism diagnoses, 30 vascular claudication diagnoses, 30 major depressive disorder diagnoses, and 44 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 \$599,842.

Our audit objective did not require an understanding or assessment of Anthem'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 October 2018 through August 2020.

METHODOLOGY

To accomplish our objective, we performed the following steps:

- We reviewed applicable Federal laws, regulations, and guidance.
- We discussed with CMS program officials the Federal requirements that MA organizations should follow when submitting diagnosis codes to CMS.
- We 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,
 - 58 diagnosis codes for embolism,
 - 4 diagnosis codes for vascular claudication, and
 - 28 diagnosis codes for major depressive disorder.

- We developed an analytical tool that identified 832 scenarios in which diagnosis codes that, 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:
 - Risk Adjustment Processing System (RAPS)²² to identify enrollees who received high-risk diagnosis codes from a physician during the service years,
 - Risk Adjustment System (RAS)²³ to identify enrollees who received an HCC for the high-risk diagnosis codes,
 - Medicare Advantage Prescription Drug (MARx)²⁴ to identify the total payments that CMS made to Anthem for the payment years, and
 - Prescription Drug Event (PDE)²⁵ to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.
- We interviewed Anthem officials to gain an understanding of (1) the policies and procedures that Anthem followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Anthem’s monitoring of those diagnosis codes to identify and detect noncompliance with Federal requirements.
- We selected for audit a sample of 203 enrollee-years that included (1) a stratified random sample of 159 enrollee-years and (2) 44 enrollee-years as identified by our analytical tool.
- We used an independent medical review contractor to perform a coding review for the 203 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.

²² MA organizations use the RAPS to submit diagnosis codes to CMS.

²³ The RAS identifies the HCCs that CMS factors into each enrollee’s risk score calculation.

²⁴ The MARx identifies the payments made to MA organizations.

²⁵ The PDE file contains claims with prescription drugs that have been dispensed to enrollees through the Medicare Part D (prescription drug coverage) program.

- The independent medical review contractor’s coding review followed a specific process to determine whether there was support for a diagnosis code and the associated HCC:
 - If the first senior coder found support for the diagnosis code on the medical record, the HCC was considered validated.
 - If the first senior coder did not find support on the medical record, a second senior coder performed a separate review of the same medical record:
 - If the second senior coder also did not find support, the HCC was considered to be not validated.
 - If the second senior coder found support, then a physician independently reviewed the medical record to make the final determination.
 - If either the first or second senior coder asked a physician for assistance, the physician’s decision became the final determination.
- We used the results of the independent medical review contractor to calculate overpayments or underpayments for each enrollee-year. Specifically, we calculated:
 - a revised risk score in accordance with CMS’s risk adjustment program and
 - the payment that CMS should have made for each enrollee-year.
- For the 7 high-risk groups covered by our audit, we estimated the total net overpayment made to Anthem during the audit period.
- We discussed the results of our audit with Anthem officials on March 6, 2020.

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

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

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

We presented the data for these enrollees to Anthem 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 Anthem. We removed any enrollees whose managed care data could not be verified and we classified these individuals according to the condition and the payment year (enrollee-years). Our finalized sampling frame consisted of 3,139 enrollee-years.

SAMPLE UNIT

The sample unit was 1 enrollee-year.

SAMPLE DESIGN

The design for our statistical sample comprised of six strata of enrollee-years with either:

- an acute stroke diagnosis (which maps to the HCC Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim (733 enrollee-years),
- a diagnosis that mapped to an acute heart attack HCC on only one physician claim but did not have that diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician claim (838 enrollee-years),
- an acute stroke diagnosis and a diagnosis that mapped to an acute heart attack HCC in the same year and met the criteria mentioned in the previous two bullets (9 enrollee-years),
- a diagnosis that mapped to an embolism HCC but for which an anticoagulant medication was not dispensed (416 enrollee-years),
- a vascular claudication diagnosis (which maps to HCC for Vascular Disease) but for which medication was dispensed for neurogenic claudication (715 enrollee-years), or

- a major depressive disorder diagnosis (which maps to the HCC entitled Major Depressive, Bipolar, and Paranoid Disorders) on one claim during the service year but for which antidepressant medication was not dispensed (384 enrollee-years).

The specific strata are shown in Table 2.

Table 2: 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	733	\$1,702,837	30
2 – Acute heart attack	838	1,714,919	30
3 – Acute stroke/acute heart attack combination	9	42,667	9
4 – Embolism	416	1,095,661	30
5 – Vascular claudication	715	1,570,234	30
6 – Major depressive disorder	384	958,505	30
Total – First Six Strata	3,095	\$7,084,823	159

*Rounded to the nearest whole dollar amount.

After we selected the 159 enrollee-years, we identified an additional group of 44 enrollee-years (for a total of 203 sampled 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 that were likely keyed correctly.

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the items in each stratum by the combination of the enrollee identifier and the payment year under review in the stratified sampling frame. We generated the random numbers for our sample according to our sample design, and we then selected the corresponding frame items for review. We also selected all 44 items from the potentially mis-keyed group.

ESTIMATION METHODOLOGY

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

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 3: Sample 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 Incorrect Diagnosis Codes	Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)
1 – Acute stroke	733	\$1,702,837	30	\$69,747	26	\$60,678
2 – Acute heart attack	838	1,714,919	30	65,620	25	37,209
3 – Acute stroke/acute heart attack combination	9	42,667	9	42,667	9	31,126
4 – Embolism	416	1,095,661	30	74,930	19	46,598
5 – Vascular claudication	715	1,570,234	30	63,744	8	16,612
6 – Major depressive disorder	384	958,505	30	69,910	6	10,786
Totals for Statistical Sample	3,095	\$7,084,823	159	\$386,618	93	\$203,009
7 – Potentially mis-keyed diagnoses	44	\$213,224	44	\$213,224	30	\$151,007
Totals – All	3,139	\$7,298,047	203	\$599,842	123	\$354,016

**Table 4: 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	\$3,733,187	\$151,007	\$3,884,194
Lower limit	3,317,947	151,007	3,468,954
Upper limit	4,148,427	151,007	4,299,434

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

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

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

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

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

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

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

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

(3) Implement the operation of the compliance program;

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

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

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

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

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

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

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

APPENDIX E: BREAKOUT OF POTENTIALLY MIS-KEYED DIAGNOSIS CODES

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

Number of Sampled Enrollee-years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
6	482.0	Pneumonia Due to Klebsiella Pneumoniae	Aspiration and Specified Bacterial Pneumonias	428.0	Congestive Heart Failure, Unspecified	\$23,747
5	E32.9	Disease of Thymus, Unspecified	Other Significant Endocrine and Metabolic Disorders	F32.9	Major Depressive Disorder, Single Episode, Unspecified	10,084
4	205.00	Acute Myeloblastic Leukemia, Not 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	55,304
3	714.9	Unspecified Inflammatory Polyarthritis	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	174.9	Malignant Neoplasm of Breast, Non-Specified	8,304
2	441.00	Dissection of Aorta, Unspecified Site	Vascular Disease With Complications	414.00	Coronary Atherosclerosis of Unspecified Type of Vessel, Native or Graft	3,514
2	249.20	Secondary Diabetes Mellitus With Hyperosmolarity, Not Stated as Uncontrolled, or Unspecified	Diabetes With Acute Complications	294.20	Dementia, Unspecified, Without Behavioral Disturbance	8,860
2	200.00	Reticulosarcoma, Unspecified Site, Extranodal and Solid Organ Sites	Lymphatic, Head and Neck, Brain, and Other Major Cancers	250.00	Diabetes Without Complication	9,224

Number of Sampled Enrollee-years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
1	250.10	Diabetes With Ketoacidosis, Type II or Unspecified Type, Not Stated as Uncontrolled	Diabetes With Acute Complications	205.10	Acute Myeloid Leukemia, Without Mention of Having Achieved Remission	2,003
1	174.0	Malignant Neoplasm of Nipple and Areola of Female Breast	Breast, Prostate, and Other Cancers and Tumors	714.0	Rheumatoid Arthritis	1,364
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	17,961
1	146.0	Malignant Neoplasm of Tonsil	Colorectal, Bladder, and Other Cancers	416.0	Primary Pulmonary Hypertension	4,545
1	493.20	Chronic Obstructive Asthma Non-Specified	Chronic Obstructive Pulmonary Disease	493.02	Extrinsic Asthma With (Acute) Exacerbation	2,708
1	820.8	Closed Fracture of Unspecified Part of Neck of Femur	Hip Fracture/Dislocation	802.8	Closed Fracture of Other Facial Bones	3,389
30						\$151,007

**Table 6: Hierarchical Condition Categories (HCCs) That Were Not Validated;
However, Support Was Found for a Different HCC**

Count of Sampled Enrollee-Years*	Hierarchical Condition Category That Was Not Validated	Hierarchical Condition Category That Was Supported
2	Vascular Disease With Complications	Vascular Disease (Version 12 and Version 22 models)
1	Metastatic Cancer and Acute Leukemia	Lung, Upper Digestive Tract, and Other Severe Cancers (Version 12 model) and Lung and Other Severe Cancers (Version 22 model)
1	Metastatic Cancer and Acute Leukemia	Lymphatic, Head and Neck, Brain and Other Major Cancers (Version 12 model) and Lymphoma and Other Cancers (Version 22 model)

*The 4 enrollee-years identified in Table 6 are a subset of the enrollee-years in Table 5.



October 16, 2020

BY EMAIL

Patrick J. Cogley
 Regional Inspector General for Audit Services
 Health and Human Services
 Office of Inspector General
 330 Independence Avenue SW
 Washington, DC 20201

RE: Anthem’s Response to OIG’s Draft Report for Audit A-07-19-01187

Dear Mr. Cogley:

Anthem, Inc. (“Anthem”) writes to respond to the United States Department of Health and Human Services (“HHS”) Office of Inspector General’s (“OIG’s”) Draft Report for Audit No. A-07-19-01187 of the Community Insurance Company (Contract H3655) (“Draft Report”). For the reasons described below, Anthem respectfully requests that OIG withdraw its recommendations that Anthem repay an extrapolated amount of \$3,468,954, conduct additional audits beyond OIG’s sample and make repayments based on those audits, and change its compliance procedures. As written, these recommendations are inconsistent with the Social Security Act’s (“SSA’s”) actuarial equivalence mandate and with HHS and Centers for Medicare & Medicaid Services (“CMS”) data accuracy requirements. Anthem therefore requests that OIG revise its report to address these issues.¹

I. Anthem Requests that OIG Modify the Draft Report’s Characterization of its Audit Results

In its Draft Report, OIG states that “[m]ost of the selected diagnosis codes that Anthem submitted to CMS for use in CMS’s risk adjustment program did not comply with Federal requirements.”² To outside readers, this statement has the potential to be seriously misinterpreted—it is not limited in scope temporally or by contract, and could be read to suggest that OIG drew this conclusion about *all* diagnosis codes Anthem has submitted to CMS. Anthem therefore requests that OIG clarify its statement that “[m]ost of the selected diagnosis codes that Anthem submitted to CMS for use in CMS’s risk adjustment program did not comply” to make

¹ Anthem also wishes to notify OIG of two additional factual inaccuracies in its Draft Report: First, the Draft Report states that Anthem is “based in Mason, Ohio.” Draft Report at 5. Although the contract OIG audited provides coverage to Medicare Advantage beneficiaries in Ohio, Anthem’s corporate headquarters are in Indianapolis, Indiana. Second, the Draft Report states that “[a]s of December 31, 2016, Anthem provided coverage under contract number H3655 to approximately 149,500 enrollees.” Draft Report at 4. As of December 31, 2016, there were 136,863 members enrolled under Contract H3655. Anthem notes, however, that this membership number is measured on one date in time, and that enrollment under any particular contract may change throughout a given year.

² Draft Report at 7.

unmistakably clear that OIG is referring only to the select diagnosis codes that OIG sampled in its audit of Contract H3655 for 2014 and 2015 dates of service.

II. Anthem Requests that OIG Recalculate Its Estimated and Extrapolated Repayment Amounts to Address Errors in OIG’s Analysis of Certain Enrollee-Years, to Remove Underlying Statistical Biases, and to Ensure Actuarial Equivalence

Anthem respectfully submits that OIG’s recommended repayment amount is incorrect because it (1) incorporates OIG’s inaccurate findings for certain enrollee-years; (2) is based on audit sampling and review methodologies that are improperly skewed toward identifying “overpayments”; (3) is not adjusted to ensure the statutorily required actuarial equivalence between expected costs in Medicare Advantage and traditional Medicare; (4) improperly accounts for unreconciled diagnoses; and (5) is derived from an insufficiently robust confidence interval inconsistent with CMS Risk Adjustment Data Validation (“RADV”) audits.

A. *The Recommended Repayment Amount is Incorrect Because Certain Sample Enrollee-Years OIG Finds Unvalidated are Supported by Documentation in the Relevant Medical Records*

Some of the individual medical record examples that OIG highlights in its Draft Report do not support OIG’s conclusions that the Hierarchical Condition Category (“HCC”) under review is unvalidated. Specifically, for two medical records OIG references in its findings related to OIG’s major depressive disorder and embolism audit categories, the medical record documentation supports the HCC.

1. Major Depressive Disorder

In its Draft Report, OIG identifies one enrollee-year in the major depressive disorder category as unvalidated because “the independent medical review contractor noted that the [p]rovider has documented a diagnosis of mild depression . . . which does not result in [an] HCC,” and that “[a] diagnosis of [m]ajor depression is not specified anywhere in the record.”³ OIG’s independent medical review contractor has misinterpreted the medical record. The provider documented “mild depression,” and in the context of the entire medical record and consistent with clinical diagnostic standards, the term “mild” should be read to modify major depressive disorder.

The most widely accepted definitions of mental health conditions can be found in the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders V (“DSM-V”). The DSM-V states that major depressive disorder can be either mild, moderate, or severe—there is no separate diagnosis in the DSM-V for “mild depression.”⁴ In this case, the provider wrote “296.21[,] mild depression” in the medical record. ICD-9-CM code 296.21 corresponds with “Major Depressive Disorder, Single Episode, Mild,” making it clear that the

³ Draft Report at 12.

⁴ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 160-62 (5th ed. 2013); see also American Psychiatric Association, “What Is Depression?” (using the term “depression” to refer to major depressive disorder).

provider diagnosed mild major depressive disorder. The provider’s diagnosis is further supported by other documentation in the medical record, including the patient’s symptoms of depressed mood, difficulty sleeping, fatigue, the indication in the medical record that these symptoms were affecting the patient’s daily functioning, and the provider’s documented recommendation that the patient “resume social interaction.”

It is therefore clear based on a holistic review of the medical record and the applicable diagnostic criteria that the provider’s reference to “mild depression” was simply a shorthand for major depressive disorder, mild, which was the diagnosis code submitted to CMS by Anthem. For these reasons, this record supports a diagnosis of major depressive disorder. To interpret the medical record otherwise would ignore the unambiguous use by the provider of the correct diagnosis code as well as the provider’s clear documentation of symptoms and treatment consistent with the corresponding diagnosis.

2. *Embolism*

For an enrollee-year OIG highlights in the embolism category of its Draft Report, OIG finds that “the independent medical review contractor noted ‘[t]here is no anticoagulant listed in the current medications list,’” and that a provider found “[n]o evidence for [deep vein thrombosis]” after an ultrasound.⁵ OIG apparently concludes, therefore, that ICD-9-CM code 453.40 (acute venous embolism and thrombosis of unspecified deep vessels of lower extremity) was not properly coded. But in the same medical record, the provider documented that it was “unsafe” to prescribe the patient anticoagulant therapy because of a history of subdural hematoma. Thus, the fact that the patient was not being treated with anticoagulant therapy should not have been relied upon by the independent medical review contractor to conclude that the patient’s record did not support diagnosis code 453.40. Additionally, the medical record notes the presence of an “IVC filter” (an inferior vena cava filter), which is an intervention for the management of deep vein thrombosis, especially in patients for whom anticoagulation therapy is contraindicated. Here it is almost certain that the indication for the implantation of an IVC filter was deep vein thrombosis in a setting where anticoagulation therapy was contraindicated. The patient was therefore being actively managed for risk of pulmonary embolism, a complication of deep vein thrombosis, just like a patient receiving anticoagulation therapy. Finally, although an ultrasound found no current deep vein thrombosis, the patient’s record otherwise demonstrates that her provider was actively monitoring and treating the condition. For these reasons, this record supports diagnosis code 453.40.

Because these diagnosis codes are in fact supported, Anthem asks OIG to reconsider its findings with respect to the corresponding HCCs and modify its recommended repayment and extrapolation amounts accordingly. Additionally, to the extent either of these errors is replicated more broadly across OIG’s analysis, Anthem respectfully requests that OIG reconsider the findings of its independent medical review contractor and OIG’s recommended repayment and extrapolation amounts.

⁵ Draft Report at 12.

B. *OIG’s Sampling and Review Methodologies Were Improperly Skewed Toward Identifying “Overpayments”*

Anthem also contests OIG’s recommended repayment amount because OIG’s audit sample was skewed toward identifying “overpayments.” Specifically, OIG’s audit did not involve a review of all records from the sampled years for the enrollees included in the audit sample, but instead targeted only those encounters for which OIG already suspected that the underlying medical record would not support an HCC uniquely reported on that date of service.⁶ This methodology improperly ignored the fact that there may be additional supported HCCs not previously submitted to CMS in other records for the sampled years for each enrollee. At OIG’s request, Anthem submitted only one record to OIG for the majority of the sampled members and two records for a very small subset of those members. OIG’s audit sample therefore included far fewer than the full set of records for each enrollee in the audited years.

OIG’s audit population also was skewed by excluding enrollees for whom no risk adjustment data was submitted to CMS. This methodology ignored the fact that there may be supported HCCs not submitted to CMS for those enrollees and created an additional systematic bias toward identifying “overpayments.”

Nor did OIG account for (or even seek to identify) all of the potential HCCs that were not previously submitted to CMS but that were supported by medical records that OIG reviewed even though OIG itself recognizes in the Draft Report that “correctly coded diagnoses that MA organizations do not submit to CMS may lead to . . . underpayments.”⁷ In some cases where OIG found an HCC unvalidated but concluded that a lesser, related HCC was supported in the medical record, OIG took that lower-confirmed HCC into consideration. And in a few, limited instances—specifically, in the “potentially miskeyed diagnoses” category and in one single other record—OIG reviewed and confirmed additional, *unrelated* HCCs that were not previously submitted to CMS. But in the “potentially miskeyed diagnoses” category, OIG accounted for only the HCC that it had already suspected was originally miscoded; OIG did not holistically review these records and add *all* unrelated but supported HCCs. And OIG did not, throughout the rest of the audit sample, account for additional, unrelated HCCs supported by the medical record but previously unreported. In fact, OIG generally designed its audit not to look for unreported risk adjusting diagnosis codes, only collecting and auditing medical records for particular encounters and only reviewing within those records the specific conditions targeted by its audit.⁸

Because the sampling methodology was skewed improperly toward identifying “overpayments” and because the medical record review process was structured largely to avoid accounting for additional HCCs that had not been previously reported for those members, OIG’s actual and extrapolated repayment calculations are inflated and its extrapolated repayment

⁶ See, e.g., Draft Report at 1.

⁷ Draft Report at 4.

⁸ OIG provided an example of this audit practice during its March 6, 2020 conference call with Anthem regarding the audit methodology and findings (“the Exit Conference”), stating that if an OIG auditor reviewed a record to support an acute stroke diagnosis code, the auditor would not account for the value of a diabetes diagnosis for which a diagnosis code had not previously been submitted to CMS.

calculation is statistically unsupported. Anthem respectfully requests that OIG revise its repayment calculations to address these biases.

C. *The Recommended Repayment Amount Also is Incorrect Because it is Not Adjusted to Ensure Actuarial Equivalence*

The SSA requires CMS to pay Medicare Advantage organizations (“MAOs”) an amount that is “actuarially equivalent” to the expected cost that CMS would have otherwise incurred had it provided required Medicare benefits directly to the MAOs’ enrollees. Actuarial equivalence measures whether different benefit packages have “the same value, based on the estimated spending that would be incurred by the insurer.”⁹ Because the SSA ties Medicare Advantage compensation to the expected cost of providing traditional Medicare benefits to an enrollee of average risk, the “actuarial equivalence” mandate requires CMS to base risk-adjusted payments on actuarially sound calculations of the expected cost of providing traditional Medicare benefits to enrollees with differing health status.¹⁰ That conclusion is confirmed by the SSA’s separate requirement that CMS report to Congress on the “actuarial soundness” of the agency’s proposed risk adjustment methodology.¹¹ Because CMS developed the Medicare Advantage risk adjustment model using unaudited Fee-for-Service claims data from the traditional Medicare program—which CMS has acknowledged contain high levels of erroneous diagnoses—CMS must account for those traditional Medicare data errors when measuring whether similar erroneous diagnoses for Medicare Advantage enrollees result in an overpayment.¹²

In 2012, CMS published a notice stating that it was incorporating this requirement into its methodology for calculating recovery amounts for unsupported HCCs identified during its RADV audits. Specifically, CMS said that it would first identify a “payment recovery amount” based on the value of supported and unsupported HCCs identified during its review.¹³ Then, “to determine the final payment recovery amount, CMS [would] apply a Fee-for-Service Adjuster (‘FFS Adjuster’) amount as an offset to the preliminary recovery amount,” and base the FFS Adjuster “on a RADV-like review of records submitted to support [traditional Medicare] claims data.”¹⁴

⁹ U.S. Department of Health & Human Services, *Payment for Medicare Advantage Plans: Policy Issues and Options* (June 2009).

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

¹¹ *See* 42 U.S.C. § 1395w-23(b)(4)(C), (D).

¹² *See generally* Wakely Consulting Group, *Actuarial Report on CMS’ November 1, 2018 Proposed Rule* (Aug. 27, 2019) (enclosure to Letter from Anthony Mader, Vice President, Public Policy, Anthem, Inc., to Seema Verma, Administrator, Ctrs. for Medicare & Medicaid Servs. (Aug. 28, 2019), available at <https://beta.regulations.gov/comment/CMS-2018-0133-0260>).

¹³ CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation for Contract-Level Audits*, at 3–4 (Feb. 24, 2012).

¹⁴ *Id.* at 4–5.

This announcement is consistent with internal CMS documents that acknowledge that without applying a FFS Adjuster to calculated repayment amounts, audited MAOs are underpaid.¹⁵ In a CMS presentation titled “Model Calibration Factor,” for example, CMS explained that “[i]n RADV audits, we expect coding perfection from [MAOs],” while “[i]n [traditional] Medicare, some portion of diagnoses on [traditional Medicare] claims are not documented in medical records.”¹⁶ As a result, for RADV audits, MAOs “are being held to a different (higher) standard for diagnoses.”¹⁷ CMS said that these different document standards matter because traditional Medicare data were used to calculate MA payments and the “[i]nclusion of undocumented diagnoses tends to reduce risk adjustment vales.”¹⁸ CMS then used numerical examples to demonstrate that MAOs would be underpaid (i.e., MAOs’ costs would exceed CMS reimbursement) if MAOs were audited to a standard of data perfection without properly calibrating the overpayment amount to account for traditional Medicare data errors.¹⁹

But CMS departed from this principle in 2014, implementing a Medicare Advantage Overpayment Rule stating that MAOs receive an “overpayment” when they submit any individual diagnosis code to CMS that is insufficiently supported by underlying medical records, without adjusting for error rates in traditional Medicare data.²⁰ In September 2018, a federal district court in *UnitedHealthcare Ins. Co. v. Azar II* (“*Azar*”), 330 F. Supp. 3d 173 (D.D.C. 2018), vacated CMS’s Medicare Advantage Overpayment Rule because the rule violated the SSA’s actuarial equivalence mandate by defining “overpayment” as the payment of funds to MAOs based on unsupported diagnosis codes, while not applying the same documentation standards to the traditional Medicare data used to calculate payments to MAOs.²¹ In doing so, the court concluded that CMS systematically devalues MAO payments when it uses unaudited traditional Medicare data to set MAO payment rates while measuring MAO “overpayments” based on audited patient records.²² On January 27, 2020, the same court reaffirmed this position in denying the government’s request to reconsider the court’s prior holding.²³

¹⁵ See *Azar*, 1:16-cv-00157-RMC (D.D.C. Oct. 2, 2017) (ECF 44-3) (Document authored by CMS titled “Model Calibration Factor”); *Azar*, 1:16-cv-00157-RMC (D.D.C. Oct. 2, 2017) (ECF 44-4) (Document authored by CMS titled “Three RADV Policy Issues”).

¹⁶ *Azar* 1:16-cv-00157-RMC (D.D.C. Oct. 2, 2017) (ECF 44-3) at 6.

¹⁷ *Id.*

¹⁸ *Id.* at 7.

¹⁹ *Id.* at 8–9.

²⁰ 42 C.F.R. § 422.326.

²¹ *Azar*, 330 F. Supp. 3d at 187–90.

²² *Id.* at 186–87 (“[T]he ‘expected’ value of payments from CMS for healthcare costs [to MAOs] will be lower than the ‘expected’ payments CMS itself will make under traditional Medicare, since CMS does not audit or engage in similar self-examination for accuracy of its own records. The consequence is inevitable: while CMS pays for all diagnostic codes, erroneous or not, submitted to traditional Medicare, it will pay less for Medicare Advantage coverage because essentially no errors would be reimbursed.”).

²³ *Azar*, Case No. 16-cv-157 (RMC), 2020 WL 417867 (D.D.C. Jan. 27, 2020).

Thus, as *Azar* made clear, it is not possible to determine whether Anthem has been overpaid as a result of any diagnosis coding errors without accounting for diagnosis coding errors in traditional Medicare data. While CMS issued a proposed rule in 2018 suggesting that diagnosis coding errors in unaudited traditional Medicare data do not systematically impact payments to MAOs²⁴ and released a corresponding study purporting to support this premise,²⁵ the court in *Azar* found that CMS’s study “does not persuade” and concluded that the government had failed to “adequately respond” to criticisms of the study raised during litigation.²⁶ The proposed rule itself remains subject to the administrative rule-making process and is not final. Consistent with the court’s holding in *Azar*, Anthem submits that CMS’s proposal does not satisfy the actuarial equivalence requirement of the SSA. Anthem and numerous other parties, including actuarial and statistical experts, have submitted comments explaining this view to CMS in connection with the proposed rule.²⁷

These Medicare Advantage program requirements, which apply to CMS’s audits and overpayment determinations, are equally applicable to OIG’s audits and calculation of estimated repayment amounts for the same program. Thus, by defining each unsupported diagnosis code as an “overpayment” without accounting for the fact that the traditional Medicare data on which those payments are based are not subject to the same documentation and validation standards, OIG’s actual and extrapolated repayment calculations violate the “actuarial equivalence” mandate that underpins the Medicare Advantage program. Anthem firmly believes, consistent with the principles articulated in *Azar*, that OIG is unable to determine whether Anthem has been overpaid without first establishing an actuarially sound overpayment methodology that takes into account diagnosis coding errors in the traditional Medicare program. Anthem accordingly requests that OIG withdraw its overpayment calculation until such time as CMS issues an actuarially sound overpayment methodology that takes into account coding errors in the traditional Medicare program (e.g., a FFS Adjuster). At that time, OIG should apply that actuarially sound methodology to this audit to calculate any repayment that might be due.

²⁴ Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program for All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54982 (proposed Nov. 1, 2018) (to be codified at 42 C.F.R. §§ 422, 423, 438, 498) (“Proposed Rule”).

²⁵ CMS, *Fee for Service Adjuster & Payment Recovery for Contract Level Risk Adjustment Data Validation Audits* (Oct. 26, 2018), available at <https://tinyurl.com/ve3737d>; CMS, *Addendum to the Fee-For-Service Adjuster Study* (June 28, 2019).

²⁶ *Azar*, 2020 WL 417867, at *1, *5.

²⁷ See Public Comments on Proposed Rule (e.g., Anthem Letter dated August 28, 2019, *supra* n.12; Cigna Letter dated August 28, 2019, available at <https://www.regulations.gov/document?D=CMS-2018-0133-0254>; CVSHealth Letter dated August 28, 2019, available at <https://www.regulations.gov/document?D=CMS-2018-0133-0259>; Humana Letter dated August 28, 2019, available at <https://www.regulations.gov/document?D=CMS-2018-0133-0257>; Kaiser Permanente Letter dated August 28, 2019, available at <https://www.regulations.gov/document?D=CMS-2018-0133-0267>; and UnitedHealth Group Letter dated August 28, 2019, available at <https://www.regulations.gov/document?D=CMS-2018-0133-0263>).

D. *OIG’s Extrapolated Repayment Calculation Should Be Revised to Exclude the Diagnoses that OIG Was Unable to Reconcile*

During the Exit Conference, OIG reported to Anthem that nineteen of the enrollee-years included in its sample were excluded because OIG was unable to reconcile the CMS payment for the associated HCCs. But when calculating the extrapolated repayment amount, OIG still extrapolated to these unreconciled enrollee-years. Without information about the specific enrollee-years and HCCs subject to this exclusion, Anthem is unable to determine the extent to which this may have biased the extrapolated “overpayment” calculation. At a minimum, the inclusion of these enrollee-years in the extrapolation incorrectly inflated the overall repayment amount. Additionally, if there is something systematically different about these records that led to the failure to reconcile (i.e., if there is something not truly random about these records), this factor could have increased the bias in the extrapolated amount.

Anthem respectfully requests that OIG provide additional detail on the unreconciled enrollee-years, adjust the extrapolated payment amount to exclude these enrollee-years, and take steps to address any statistical bias introduced as a result of these enrollee-years having been removed from the sample of the audited population.

E. *OIG’s Extrapolated Repayment Amount Relies on a Confidence Interval that is Too Low and Inconsistent with CMS RADV Audit Practice*

OIG used the lower bound of a 90% confidence interval to calculate the extrapolated repayment amount,²⁸ rather than the statistically valid and more robust practice of using the lower bound of a 95% or 99% confidence interval.²⁹ In CMS’s most recent disclosure of its methodology for calculating extrapolated repayment amounts for its RADV audits, CMS stated that it uses the lower bound of a 99% confidence interval.³⁰ Anthem respectfully requests that OIG recalculate the extrapolated “overpayment” amount using the lower bound of the more statistically robust 99% confidence interval consistent with CMS practice for RADV audits.

III. *Anthem Requests that OIG Withdraw Its Recommendation that Anthem Undertake Additional Auditing for the Condition Categories Subject to OIG’s Audit*

OIG recommends that Anthem “identify, for the high-risk diagnoses included in [the Draft Report], similar instances of noncompliance that occurred before or after [the] audit period and refund any resulting overpayments to the Federal Government[.]”³¹ As further set forth below, MAOs are not required to audit to the standard that OIG suggests. Medicare Advantage regulations do not require the sort of audits that OIG recommends and certainly do not require MAOs to ensure data perfection as the Draft Report implies. Moreover, for the reasons

²⁸ Draft Report at 20.

²⁹ 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.”).

³⁰ CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* (Feb. 24, 2012) at 4.

³¹ Draft Report at 14.

explained above, individually identified potentially unverified diagnosis codes are not necessarily “overpayments,” and, even if Anthem were to undertake additional audits, OIG has not provided Anthem with the information necessary to identify additional “potentially miskeyed diagnoses” similar to those audited by OIG here.

A. MAOs Are Not Required to Achieve Data Perfection

The government has long acknowledged that MAOs are not expected to submit perfect risk adjustment data. For example, it has stated that MAOs “cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the OIG, and [the U.S. Department of Justice] believe is reasonable to enforce.”³² OIG has issued non-binding guidance stating that MAOs should establish an “information collection and reporting system reasonably designed to yield accurate information.”³³ This guidance affords MAOs broad discretion in designing compliance mechanisms and does not address any of the complexities of the risk adjustment model, nor does it address the legal developments described *supra* at II.C. And, as the federal district court acknowledged in *Azar*, there is a disconnect when the government “treats diagnosis codes as categorically valid for its own purposes under traditional Medicare,” but then requires “Medicare Advantage insurers to certify ‘based on best knowledge, information and belief’ that the information they provide to CMS, including all diagnosis codes, is ‘accurate, complete, and truthful.’”³⁴

This understanding is reflected in MAOs’ annual data accuracy attestation requirements. MAOs are required to certify that their risk adjustment data is accurate based on their “best knowledge, information, and belief.”³⁵ CMS has acknowledged that “[t]he requirement that the CEO or CFO certify as to the accuracy, completeness and truthfulness of data, based on best knowledge, information and belief, does not constitute an absolute guarantee of accuracy.”³⁶ CMS has stated that MAOs “will be held responsible for making *good faith efforts* to certify the accuracy, completeness, and truthfulness of encounter data submitted.”³⁷ This “good faith” standard is not defined by CMS or OIG but it recognizes “that encounter data [can] come into [MAOs] in great volume from a number of sources, presenting significant verification challenges for the organizations.”³⁸

³² 65 Fed. Reg. 40,169, 40,268 (June 29, 2000).

³³ 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999) (noting also that MAOs “should exercise due diligence to ensure that these systems are working properly” but that “[t]he exact methods used . . . can be determined by the organization[,] and that these methods “should ordinarily [include] sample audits and spot checks of this system to verify whether it is yielding accurate information”).

³⁴ *Azar*, 330 F. Supp. 3d at 179–80.

³⁵ 42 C.F.R. § 422.504(l)(2).

³⁶ 64 Fed. Reg. at 61,900.

³⁷ 65 Fed. Reg. at 40,268 (emphasis added).

³⁸ *Id.* Notably, OIG’s Draft Report appears at times to conflate the source of diagnosis codes in a manner that suggests MAOs have more information than they actually do about the accuracy of the risk adjustment data submitted to CMS. *See, e.g.*, Draft Report at 3 (“MA organizations collect the diagnosis codes that physicians document on the medical records and submit th[o]se codes to CMS.”); *id.* at 10 (“Anthem had submitted diagnosis codes in which physicians had documented conditions . . .”). Providers document patient encounters in their

OIG's Draft Report makes two potentially misleading statements in this respect. *First*, the Draft Report states that “[f]ederal regulations state that [MAOs] must monitor the data that they receive from providers and submit to CMS.”³⁹ But this statement is incomplete and therefore misleading. Aware of the high volume of diagnosis codes that are submitted to MAOs, CMS gives MAOs broad discretion to design their own compliance and risk adjustment data accuracy programs and has declined to require MAOs to implement any specific oversight measures. *Second*, the Draft Report also states that federal regulations “state that [MAOs] are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes.”⁴⁰ But again, this statement is incomplete and therefore inaccurate because it fails to account for the qualified “good faith” attestation standard that CMS explicitly adopted.

Relying on these misleading broad characterizations of CMS regulations, OIG's recommendation dramatically expands the minimal Medicare Advantage compliance program requirements.⁴¹ It also disrupts the guidance that Anthem has consistently received and relied upon from its regulators by asking Anthem to review all diagnosis code submissions that fall into the same seven categories audited by OIG for dates of service both before and after the two-year period audited by OIG. CMS is certainly aware of industry-wide trends pertaining to the seven categories audited by OIG through CMS's years of RADV audits, communications with MAOs, and review of the traditional Medicare data it uses to calculate MAO payments. But CMS has not opted to take *any* steps to implement regulations in response to these trends, let alone the expansive steps OIG proposes in its Draft Report. Anthem therefore respectfully requests that OIG withdraw this recommendation as inconsistent with existing Medicare Advantage guidance.

B. *Individually Identified Potentially Unverified Diagnosis Codes Would Not Necessarily Be Overpayments*

As noted *supra* at II.C, even if Anthem were to identify unsupported diagnosis codes through the type of review OIG recommends, individual unsupported codes would not necessarily be overpayments. An overpayment based on the type of audits that OIG recommends could be calculated only by applying an overpayment methodology that takes into account diagnosis coding errors in the traditional Medicare program (e.g., a FFS Adjuster) to ensure consistency with the actuarial equivalence requirements of the SSA.

medical records and submit claims to MAOs with diagnosis codes based on those encounters. MAOs then extract diagnosis codes from provider claims data to submit to CMS. Contrary to OIG's description in the Draft Report, the majority of the diagnosis codes MAOs submit to CMS come from the claims data submitted to MAOs by providers and are not identified by MAOs following a review of patient medical records. Recognizing that MAOs are not the original source of most risk adjustment data, CMS applies a “good faith” standard to the annual data accuracy attestation, having expressly acknowledged that MAOs are not guaranteeing through that attestation absolute accuracy. OIG's Draft Report, and in particular its audit recommendations, appear to be in direct conflict with this express guidance from CMS.

³⁹ Draft Report at 8.

⁴⁰ *Id.* at 8.

⁴¹ CMS's minimal compliance requirements are consistent with (1) the fact that HCC coefficients are based on unaudited traditional Medicare data and (2) the implausibility of expecting MAOs to audit more than a small subset of the vast amount of data submitted to CMS that is generated by healthcare providers who are neither employed by Anthem nor under the direction and control of Anthem.

C. *Anthem Lacks the Information Necessary to Replicate OIG’s Audit Procedures for One Audited Category: “Potentially Miskeyed” Diagnoses*

Although OIG has provided Anthem with the list of “potentially miskeyed” diagnosis codes for which it searched for the purpose of this audit, OIG has not provided the underlying algorithm for identifying additional instances of those codes beyond the audited population. Without this additional information, Anthem would be unable to replicate OIG’s methodology for identifying “potentially miskeyed” diagnoses even if Anthem conceded that such measures were necessary.

IV. *Anthem Requests that OIG Withdraw Its Recommendation that Anthem Make Changes to Its Existing Compliance and Education Programs*

OIG recommends that Anthem “enhance its compliance procedures to focus on diagnosis codes that are at high risk for being miscoded by determining whether these diagnosis codes (when submitted to CMS for use in CMS’s risk adjustment program) comply with Federal requirements and educating its providers about the proper use of these diagnosis codes.”⁴² This recommendation is based on OIG’s inaccurate and unfounded perception that while Anthem “had compliance procedures to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct,” which included provider education regarding the HCCs that OIG audited, “these compliance procedures were not always effective because Anthem did not identify high-risk diagnosis codes as problematic unless that diagnosis code appeared on a specific claim that was selected for review.”⁴³

Anthem requests that OIG withdraw this recommendation because Anthem’s compliance and education programs comply with all legal and Medicare Advantage regulatory requirements and OIG did not identify any specific deficiencies in those programs through its audit. Moreover, OIG’s audit was limited to 2014 and 2015 dates of service and the compliance functions in place to monitor claims data for those years. To the extent the Draft Report can be read to include findings about Anthem’s *current* compliance program, there is no basis for such findings. On the face of the Draft Report, it is beyond the scope of the audit to arrive at a recommendation for current practices, which were not subject to OIG’s audit.

A. *Anthem’s Compliance Program is Robust, Effective, and Compliant with Applicable Legal and Regulatory Requirements*

As OIG itself acknowledges, “Anthem had compliance procedures to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct” and these procedures “included guidance on how its reviewers should address certain high-risk diagnoses, including diagnosis codes that mapped to acute stroke, acute heart attack and embolism HCCs.”⁴⁴ Additionally, OIG acknowledges that “[i]f Anthem detected compliance problems, it made corrections on the reviewed claims and expanded its review to other claims

⁴² Draft Report at 14.

⁴³ *Id.* at 13-14.

⁴⁴ Draft Report at 13.

not initially selected.”⁴⁵ OIG recognizes that “Anthem’s compliance procedures also included outreach in order to help educate its providers on several topics, including medical management and quality of care.”⁴⁶ OIG thus acknowledges that Anthem’s compliance program was effective in that it alerted Anthem to potential problems and allowed Anthem to correct for them. And Anthem’s robust compliance program extends beyond these processes. For example, during the audited time period Anthem conducted multiple types of audits and maintained a host of policies and procedures governing data collection and submission.

As explained *supra* at III.A, MAOs are not expected or required to implement the specific types of compliance measures recommended by OIG. Instead, CMS regulations require MAOs to “[a]dopt 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.”⁴⁷ CMS has acknowledged that its requirements are “broad and general[.]” and stated that it expects MAOs to use their “discretion . . . to design their compliance plan structure to meet the unique aspects of each organization.”⁴⁸ OIG’s recommendation attempts to impose a requirement that substantially exceeds the auditing and monitoring required under existing regulations and Anthem therefore respectfully requests that OIG withdraw this recommendation.

B. *OIG Has Failed to Identify Any Material Flaws in Anthem’s Compliance Program*

OIG seems to infer simply by virtue of the fact that it discovered unsupported diagnosis codes through its audit that Anthem’s compliance and education programs must have been deficient. But as noted *supra* at III.A, perfection is not the standard that CMS imposes and OIG has long recognized that fact. Thus, the mere fact that OIG identified some data inaccuracies—particularly through a skewed audit sample, *see supra* at II.B—does not mean that Anthem’s compliance or education programs are deficient when measured by existing Medicare Advantage program guidance.

The closest OIG comes to identifying anything specifically wrong with Anthem’s compliance program is OIG’s statement that Anthem’s provider education program “did not address steps to ensure that the correct diagnosis codes were used” and therefore “was not effective for high-risk diagnosis codes.”⁴⁹ It is unclear what this statement means and therefore not clear how Anthem could implement this guidance even if it were required to do so. As noted *supra* at III.A, however, MAOs are afforded broad discretion in designing compliance programs and there are no legal requirements that provider education materials include specific instructions. Additionally, OIG acknowledges that “Anthem had compliance procedures to

⁴⁵ *Id.*

⁴⁶ *Id.* at 14.

⁴⁷ 42 C.F.R. § 422.503(b)(4)(vi). This requirement is not specific to the collection or submission of risk adjustment data.

⁴⁸ 65 Fed. Reg. at 40,265.

⁴⁹ *Id.*

determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct” and that “[i]f Anthem detected compliance problems, it made corrections on the reviewed claims and expanded its review to other claims not initially selected.”⁵⁰

OIG also appears to base its recommendation that Anthem enhance its compliance and education policies in part on its conclusion that “Anthem did not identify high-risk diagnosis codes as problematic unless that diagnosis code appeared on a specific claim that was selected for review.”⁵¹ But it is not clear how Anthem could possibly identify any diagnosis code as “problematic” without selecting and reviewing the claim information. OIG’s own audit did not employ such a standard; like Anthem, OIG selects and reviews specific claims to determine whether medical records include sufficient supporting documentation for the diagnosis codes submitted to CMS. Anthem similarly is unable to identify unsupported diagnosis codes without reviewing claims data and corresponding medical records.

Because Anthem’s compliance and education programs are robust, effective, and comply with all applicable legal and regulatory requirements—and because OIG has not identified any material flaws in any of these programs—Anthem respectfully requests that OIG withdraw this recommendation.

V. Conclusion

For the reasons explained herein, Anthem does not concur with OIG’s three proposed recommendations and respectfully requests that OIG withdraw each one. Anthem welcomes the opportunity to further discuss OIG’s methodology, findings, and anticipated recommendations. Anthem reserves all rights to challenge any current or revised recommendations.

Sincerely,

A handwritten signature in black ink that reads "William H. Roth". The signature is written in a cursive, flowing style.

William Roth
President, Medicare
Anthem, Inc.

⁵⁰ *Id.* at 13.

⁵¹ *Id.* at 14.