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Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health and Life Insurance Company (Contract H1608) Submitted to CMS

REPORT HIGHLIGHTS

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Why OIG Did This Audit

- Under the Medicare Advantage (MA) program, CMS makes monthly payments to MA organizations according to a system of risk adjustment that depends on the health status of each enrollee. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources than to healthier enrollees, who would be expected to require fewer health care resources.
- To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS. Some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.
- This audit examined whether Coventry Health and Life Insurance Company's submission of selected diagnosis codes to CMS, for use in CMS's risk adjustment program, complied with Federal requirements.

What OIG Found

For the 10 high-risk groups covered by our audit, most of Coventry's submissions of the selected diagnosis codes to CMS for use in CMS's risk adjustment program did not comply with Federal requirements.

- For 249 of 300 sampled enrollee-years, the diagnosis codes that Coventry submitted to CMS were not supported by medical records and resulted in $752,587 in net overpayments. On the basis of our sample results, we estimated that Coventry received at least $6.9 million in net overpayments for 2018 and 2019.
- As demonstrated by the errors we identified, Coventry's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved.

What OIG Recommends

We made three recommendations to Coventry, including that it refund to the Federal Government the $6.9 million of estimated net overpayments, identify similar instances of noncompliance after our audit period and refund any resulting overpayments to the Federal Government, and continue to examine its existing compliance procedures to identify areas for improving compliance with Federal requirements. The full recommendations are in the report.

Coventry disagreed with some of our findings and all of our recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

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

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS.[2] Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 54 breast cancer diagnoses into 1 group.) This audit covered Coventry Health and Life Insurance Company (Coventry) for contract number H1608 and focused on 10 groups of high-risk diagnosis codes for payment years 2018 and 2019.[3, 4]

OBJECTIVE

Our objective was to determine whether Coventry's submission of selected diagnosis codes to CMS, for use in CMS's risk adjustment program, complied with Federal requirements.

BACKGROUND

Medicare Advantage Program

The MA program offers people eligible for Medicare managed care options by allowing them to enroll in private health care plans rather than having their care covered through Medicare's

[1] The providers code diagnoses using the International Classification of Diseases (ICD), Clinical Modification, *Official Guidelines for Coding and Reporting*. The ICD is a coding system that is used by physicians and other health care providers to classify and code all diagnoses, symptoms, and procedures.

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

[3] All subsequent references to "Coventry" in this report refer solely to contract number H1608.

[4] The 2018 and 2019 payment year data were the most recent data available at the start of the audit.

traditional fee-for-service program.[5] Individuals who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers including hospitals and physicians.

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

For 2023, CMS paid MA organizations $466.7 billion, which represented 45 percent of all Medicare payments for that year.

Risk Adjustment Program

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

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

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

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

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

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

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

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

process results in an individualized risk score for each enrollee, which CMS calculates annually.

To determine an enrollee's health status for purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from acceptable data sources, including certain physicians and hospitals. MA organizations collect the diagnosis codes from providers based on information documented in the medical records and submit these codes to CMS. CMS then maps certain diagnosis codes, on the basis of similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs).[9] Each HCC has a factor (which is a numerical value) assigned to it for use in each enrollee's risk score.

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

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

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

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

[9] During payment years 2018 and 2019, CMS calculated risk scores based on the Version 22 and the Version 23 CMS-HCC models.

sequestration reduction.[10] Thus, if the factors used to determine an enrollee's risk score are incorrect, CMS will make an improper payment to an MA organization. Specifically, if medical records do not support the diagnosis codes that an MA organization submitted to CMS, the HCCs are not validated, which causes overstated enrollee risk scores and overpayments from CMS.[11] Conversely, if medical records support the diagnosis codes that an MA organization did not submit to CMS, validated HCCs may not have been included in enrollees' risk scores, which may cause those risk scores to be understated and may result in underpayments.

High-Risk Groups of Diagnoses

Using data mining techniques and discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. For this audit, we focused on 10 high-risk groups:

- *Acute stroke*: An enrollee received one acute stroke diagnosis that mapped to the HCC for Ischemic or Unspecified Stroke on only one physician claim during the service year but did not have an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim. In these instances, a diagnosis of history of stroke (which does not map to an HCC) typically should have been used.

- *Acute myocardial infarction*: An enrollee received one acute myocardial infarction diagnosis that mapped to the HCC for Acute Myocardial Infarction on only one physician or outpatient claim during the service year but did not have an acute myocardial infarction diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician or outpatient claim). In these instances, a diagnosis indicating a history of myocardial infarction (which does not map to an HCC) typically should have been used.

- *Embolism*: An enrollee received one embolism diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease With Complications (Embolism HCCs) on only one claim during the service year but did not have an anticoagulant medication dispensed on his or her behalf. An anticoagulant medication is typically used to treat an embolism. In these instances, a diagnosis of history of embolism (an indication that the provider is evaluating a prior acute embolism diagnosis, which does not map to an HCC) typically should have been used.

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

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

- *Sepsis*: An enrollee received one sepsis diagnosis that mapped to the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock on only one physician or outpatient claim during the service year but did not have a sepsis diagnosis on a corresponding inpatient hospital claim. A sepsis diagnosis generally results in an inpatient hospital admission.

- *Pressure Ulcer*: An enrollee received one pressure ulcer diagnosis that mapped to either the HCC for Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone or to the HCC for Pressure Ulcer of Skin with Full Thickness Skin Loss (Pressure Ulcer HCCs) on only one claim during the service year but did not have a pressure ulcer diagnosis on another claim during the prior and subsequent service years. Individuals diagnosed with the most severe types of pressure ulcers generally receive treatment on multiple occasions.

- *Lung cancer*: An enrollee received one lung cancer diagnosis that mapped to the HCC for Lung and Other Severe Cancers on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period either before or after the diagnosis. In these instances, a diagnosis of history of lung cancer (which does not map to an HCC) typically should have been used.

- *Breast cancer*: An enrollee received one breast cancer diagnosis that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of breast cancer (which does not map to an HCC) typically should have been used.

- *Colon cancer*: An enrollee received one colon cancer diagnosis that mapped to the HCC for Colorectal, Bladder, and Other Cancers on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of colon cancer (which does not map to an HCC) typically should have been used.

- *Prostate cancer:* An enrollee 74 years old or younger received one prostate cancer diagnosis that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of prostate cancer (which does not map to an HCC) typically should have been used.

- *Ovarian cancer*: An enrollee received one ovarian cancer diagnosis that mapped to either the HCC for Lymphoma and Other Cancers or to the HCC for Metastatic Cancer and Acute Leukemia (Ovarian Cancer HCCs) on only one claim during the service year but did not have surgical therapy or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of ovarian cancer (which does not map to an HCC) typically should have been used.

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

COVENTRY HEALTH AND LIFE INSURANCE COMPANY

Coventry is an MA organization based in Saint Louis, Missouri.[12] As of December 31, 2019, Coventry provided coverage under contract number H1608 to 197,971 enrollees. For the 2018 and 2019 payment years (audit period), CMS paid Coventry approximately $3.5 billion to provide coverage to its enrollees.[13]

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to 1 of the 10 high-risk groups during the 2017 and 2018 service years, for which Coventry received increased risk-adjusted payments for payment years 2018 and 2019, respectively. Because enrollees could be classified into more than one high-risk group or could have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment year, which we refer to as "enrollee-years."

We identified 4,026 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes ($9,262,313). We selected for audit a stratified random sample of 300 enrollee-years as shown on the following page in Table 1.

[12] Coventry Health Care Inc., the parent entity of Coventry Health and Life Insurance Company, was acquired by Aetna Inc., on May 7, 2013. Aetna Inc., was subsequently acquired by CVS Health on November 28, 2018. Although we are addressing this report to CVS Health, we use "Coventry" throughout this report and in our findings and recommendations.

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

Table 1: Sampled Enrollee-Years
(Strata for Sample Design Based on High-Risk Groups)

High Risk Group	Number of Sampled Enrollee Years
1. Acute Stroke	30
2. Acute myocardial infarction	30
3. Embolism	30
4. Sepsis	30
5. Pressure Ulcer	30
6. Lung Cancer	30
7. Breast Cancer	30
8. Colon Cancer	30
9. Prostate Cancer	30
10. Ovarian Cancer	30
Total for All High-Risk Groups	**300**

Coventry provided medical records as support for the selected diagnosis codes associated with 288 of the 300 enrollee-years.[14] We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. For the HCCs that were not validated, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or if we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group, we included the financial impact of the resulting HCC (if any) in our calculation of net overpayments.

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

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

FINDINGS

With respect to the 10 high-risk groups covered by our audit, most of Coventry's submissions of the selected diagnosis codes to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 51 of the 300 sampled enrollee-years, the medical records validated the reviewed HCCs. For the remaining 249 enrollee-years, however, either the

[14] Coventry could not locate medical records for the remaining 12 sampled enrollee-years.

medical records that Coventry provided did not support the diagnosis codes or Coventry could not locate the medical records to support the diagnosis codes; therefore, the associated HCCs were not validated and resulted in $752,587 in net overpayments.

As demonstrated by the errors found in our sample, Coventry's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that Coventry received at least $6,995,522 in net overpayments for 2018 and 2019.[15]

FEDERAL REQUIREMENTS

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

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

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

CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap. 7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7, § 40). The diagnosis must be coded according to the International Classification of Diseases, Clinical Modification, *Official Guidelines for Coding and Reporting*) (42 CFR § 422.310(d)(1) and 45 CFR §§ 162.1002(c)(2)-(3)). Further, MA organizations must implement procedures to ensure that diagnoses come only from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities, and physicians (the Manual, chap. 7, §§ 40 and 120.1.1).

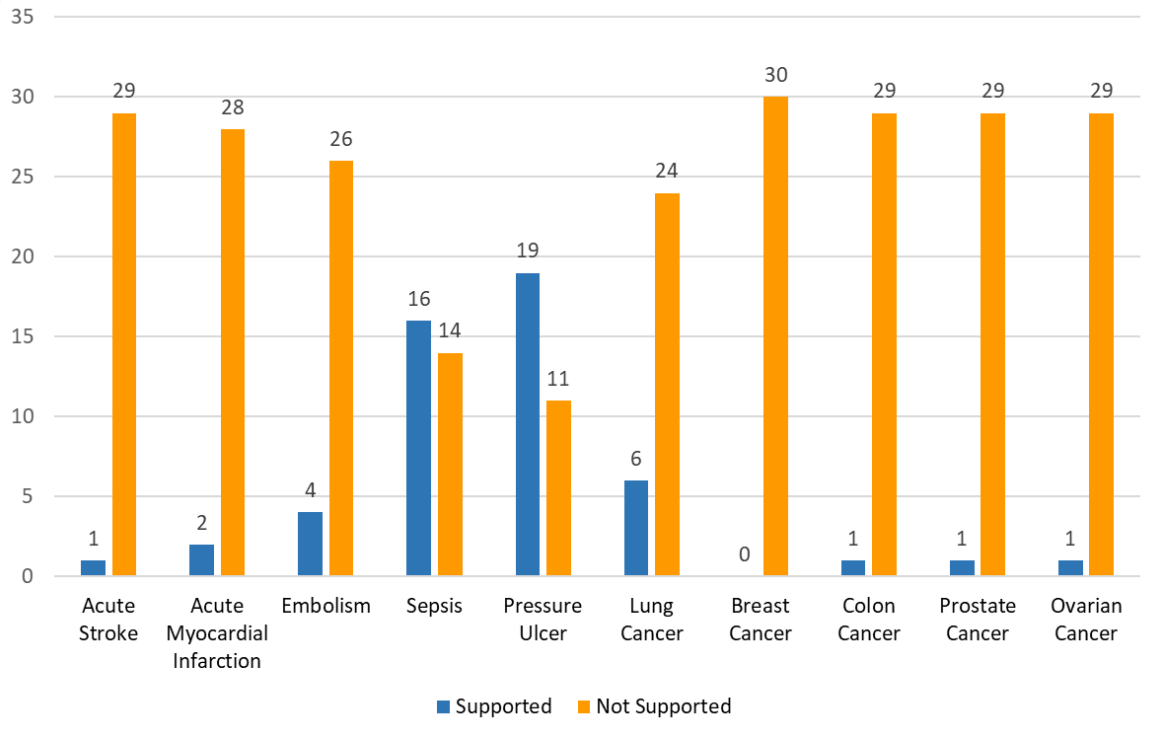
[15] To be conservative, we estimate net overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

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

MOST OF COVENTRY HEALTH AND LIFE INSURANCE COMPANY'S SUBMISSIONS OF THE SELECTED HIGH-RISK DIAGNOSIS CODES TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Most of Coventry's submissions of the selected high-risk diagnosis codes to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, as shown in the figure below, for 249 of the 300 sampled enrollee-years either the medical records that Coventry provided did not support the diagnosis codes or Coventry could not locate the medical records to support the diagnosis codes. In these instances, Coventry 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

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

- For 17 enrollee-years, the medical records indicated in each case that the individual had previously had a stroke, but the records did not support an acute stroke diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Ischemic or Unspecified Stroke]. There is documentation of a past medical history of cerebrovascular accident [diagnosis] which does not result in an HCC."[16]

- For 9 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.

- For 2 enrollee-years, the medical records that Coventry provided to support the reviewed HCC were radiology reports signed and credentialed by radiologists. For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources, which include face-to-face encounters with a provider, physician, or other practitioner. Because the records for these 2 enrollee-years did not meet CMS's requirements for acceptable data sources, the HCC for Ischemic or Unspecified Stroke was not validated.

- For the remaining 1 enrollee-year, Coventry could not locate any medical records to support the acute stroke diagnosis; therefore, the HCC for Ischemic or Unspecified Stroke was not validated.

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and Coventry received $53,823 in overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Myocardial Infarction

Coventry incorrectly submitted diagnosis codes for acute myocardial infarction for 28 of 30 sampled enrollee-years. Specifically:

- For 15 enrollee-years, the medical records indicated in each case that the individual had an old myocardial infarction diagnosis, but the records did not support an acute

[16] A cerebrovascular accident is also known as a stroke.

myocardial infarction diagnosis at the time of the physician's service.[17]

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Acute Myocardial Infarction]. Although the medical record lists a diagnosis of acute myocardial infarction, it is noted as 'subsequent episode of care' with no indication of an active treatment plan. A past medical history of a myocardial infarction [diagnosis] does not result in an HCC."

- For 7 enrollee-years, the medical records in each case did not support an acute myocardial infarction diagnosis.

- For 6 enrollee-years, the medical records in each case did not support an acute myocardial infarction diagnosis, however, for each of these enrollee-years, we identified support on CMS's systems for the diagnosis of other and unspecified angina pectoris, which mapped to an HCC for a less severe manifestation of the related-disease group.[18] Accordingly, Coventry should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the other diagnosis identified.[19]

As a result of these errors, the HCC for Acute Myocardial Infarction was not validated, and Coventry received $47,952 in overpayments for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

Coventry incorrectly submitted diagnosis codes for embolism for 26 of 30 sampled enrollee-years. Specifically:

- For 10 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Embolism HCC.

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

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

[19] For 1 of these enrollee-years, there was no financial impact because, due to the enrollee being a long-term institutional resident, the factor used in the enrollee's risk score for the acute myocardial infarction diagnosis was the same as the factor for the angina pectoris diagnosis. Therefore, the increased payment that Coventry received for the acute myocardial infarction diagnosis was the same as the increased payment it should have instead received for the angina pectoris diagnosis.

- For 9 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not support a diagnosis that mapped to an Embolism HCC at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Vascular Disease]. There is documentation of a past medical history of deep vein thrombosis [diagnosis] which does not result in an HCC."[20]

- For 5 enrollee-years, Coventry could not locate any medical records to support the embolism diagnosis; therefore, the Embolism HCCs were not validated.

- For the remaining 2 enrollee-years, the medical records that Coventry provided to support the reviewed HCC were radiology reports signed and credentialed by radiologists. For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources, which include face-to-face encounters with a provider, physician, or other practitioner. Because the records for these 2 enrollee-years did not meet CMS's requirements for acceptable data sources, the Embolism HCCs were not validated.

As a result of these errors, the Embolism HCCs were not validated, and Coventry received $75,741 in overpayments for these 26 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Sepsis

Coventry incorrectly submitted diagnosis codes for sepsis for 14 of 30 sampled enrollee-years. Specifically:

- For 9 enrollee-years, the medical records in each case did not support a sepsis diagnosis.

- For 3 enrollee-years, Coventry could not locate any medical records to support the sepsis diagnosis; therefore, the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock was not validated.

- For the remaining 2 enrollee-years, the medical records indicated in each case that the individual had previously had sepsis, but the records did not support a sepsis diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock]. There is

[20] Deep vein thrombosis occurs when a blood clot forms in one or more of the deep veins of the body, usually in the legs.

documentation of a past medical history of sepsis [diagnosis] which does not result in an HCC. The medical documentation states that a diagnosis of sepsis due to urinary tract infection has been resolved from a prior hospitalization."

As a result of these errors, the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock was not validated, and Coventry received $44,245 in overpayments for these 14 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Pressure Ulcer

Coventry incorrectly submitted diagnosis codes for pressure ulcer for 11 of 30 sampled enrollee-years. Specifically:

- For 5 enrollee-years, the medical records in each case did not support a diagnosis that mapped to a Pressure Ulcer HCC.[21]

- For 5 enrollee-years, the medical records in each case did not support a pressure ulcer diagnosis. However, for each of these enrollee-years, we identified support on CMS's systems for another diagnosis that mapped to the HCC for Chronic Ulcer of Skin, Except Pressure, which is a less severe manifestation of the related-disease group. Accordingly, Coventry should not have received an increased payment for the pressure ulcer diagnosis but should have received a lesser increased payment for the other diagnosis identified.

- For the remaining 1 enrollee-year, Coventry submitted a pressure ulcer of other site, stage 3, diagnosis code (which was not supported in the medical records) instead of a diagnosis code for pressure ulcer of other site, stage 4, diagnosis code (which was supported in the medical records). The independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Pressure Ulcer of Skin with Full Thickness Skin Loss]. There is documentation of pressure ulcer of other site, stage 4 [diagnosis] that results in [the] HCC [for Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone] which should have been assigned instead of the submitted HCC." This error caused an underpayment.

As a result of these errors, the Pressure Ulcer HCCs were not validated, and Coventry received $62,319 in net overpayments for these 11 sampled enrollee-years.

[21] For 1 of these enrollee-years, the inpatient hospital medical record that Coventry provided to support the reviewed HCC did not meet Medicare requirements regarding the inclusion of a discharge summary. For purposes of medical review, hospital inpatient medical records must include a signed discharge summary (Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance).

Incorrectly Submitted Diagnosis Codes for Lung Cancer

Coventry incorrectly submitted diagnosis codes for lung cancer for 24 of 30 sampled enrollee-years. Specifically:

- For 15 enrollee-years, the medical records indicated in each case that the individual had previously had lung cancer, but the records did not support a lung cancer diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Lung and Other Severe Cancers]. There is documentation of a past medical history of lung cancer [diagnosis] which does not result in an HCC. The enrollee underwent left lung resection in 2012."

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

- For 2 enrollee-years, the medical records in each case did not support a lung cancer diagnosis. However, for each of these enrollee-years, we identified support on CMS's systems for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Coventry should not have received an increased payment for the lung cancer diagnosis but should have received a lesser increased payment for the other diagnosis identified.

- For the remaining 1 enrollee-year, the medical record that Coventry provided to support the reviewed HCC was a physical therapy record signed and credentialed by a physical therapist assistant. For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources, which include face-to-face encounters with a provider, physician, or other practitioner. Because the record for this enrollee-year did not meet CMS's requirements for acceptable data sources, the HCC for Lung and Other Severe Cancers was not validated.

  However, for this enrollee-year, we identified support on CMS's systems for another diagnosis that mapped to the HCC for Lymphoma and Other Cancers, which is a less severe manifestation of the related-disease group. Accordingly, Coventry should not have received an increased payment for the lung cancer diagnosis but should have received a lesser increased payment for the other diagnosis identified.

As a result of these errors, the HCC for Lung and Other Severe Cancers was not validated, and Coventry received $181,489 in overpayments for these 24 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

Coventry incorrectly submitted diagnosis codes for breast cancer for all 30 sampled enrollee-years. Specifically:

- For 27 enrollee-years, the medical records indicated in each case that the individual had previously had breast cancer, but the records did not support a breast cancer diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Breast, Prostate, and Other Cancers and Tumors]. There is documentation of a past medical history of breast cancer [diagnosis] which does not result in an HCC. The enrollee had a right mastectomy in 1995 with no evidence of recurrence."

- For 2 enrollee-years, the medical records did not support a breast cancer diagnosis.[22]

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

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Coventry received $36,938 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

Coventry incorrectly submitted diagnosis codes for colon cancer for 29 of 30 sampled enrollee-years. Specifically:

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

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Colorectal, Bladder, and Other Cancers]. There is documentation of a past

[22] For 1 of these enrollee-years, the medical record that Coventry provided to support the reviewed HCC did not meet Medicare requirements regarding provider signature. For purposes of determining whether the diagnoses were supported, the services provided or ordered as shown on the medical records must be authenticated by a signature, and the credentials for the provider must appear on the medical record, in accordance with CMS policies (Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance).

medical history of colon cancer [diagnosis] with a colon resection in 2005 which does not result in an HCC."

- For 4 enrollee-years, the medical records in each case did not support the submitted colon cancer diagnosis, however, we identified support on CMS's systems for another diagnosis that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors, which is a less severe manifestation of the related-disease group. Accordingly, Coventry should not have received an increased payment for the submitted colon cancer diagnosis but should have received a lesser increased payment for the other diagnosis identified.

- For 3 enrollee-years, the medical records in each case did not support a colon cancer diagnosis.

- For the remaining 1 enrollee-year, Coventry could not locate any medical records to support the colon cancer diagnosis; therefore, the HCC for Colorectal, Bladder, and Other Cancers was not validated.

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and Coventry received $65,425 in overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

Coventry incorrectly submitted diagnosis codes for prostate cancer for 29 of 30 sampled enrollee-years. Specifically:

- For 25 enrollee-years, the medical records indicated in each case that the individual previously had prostate cancer, but the records did not support a prostate cancer diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Breast, Prostate, and Other Cancers and Tumors]. There is documentation of a past medical history of prostate cancer [diagnosis] which does not result in an HCC. The patient is status post prostatectomy in 2005 and completed radiation therapy in 2011."[23]

- For 3 enrollee-years, the medical records in each case did not support a prostate cancer diagnosis.

[23] A prostatectomy is a surgical procedure for the partial or complete removal of the prostate. It may be performed to treat prostate cancer.

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

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Coventry received $35,433 in overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Ovarian Cancer

Coventry incorrectly submitted diagnosis codes for ovarian cancer for 29 of 30 sampled enrollee-years. Specifically:

- For 17 enrollee-years, the medical records indicated in each case that the individual had previously had ovarian cancer, but the records did not support an ovarian cancer diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Lymphoma and Other Cancers]. There is documentation of a past medical history of ovarian cancer [diagnosis] which does not result in an HCC. The provider has documented the patient underwent a partial hysterectomy in 1972 with no evidence of recurrence."

- For 7 enrollee-years, the medical records in each case did not support an ovarian cancer diagnosis. However, for each of these enrollee-years, we identified support on CMS's systems for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Coventry should not have received an increased payment for the ovarian cancer diagnosis but should have received a lesser increased payment for the other diagnosis identified.

- For 3 enrollee-years, the medical records in each case did not support an ovarian cancer diagnosis.

- For 1 enrollee-year, the medical record that Coventry provided to support the reviewed HCC was a specimen collection report that does not reflect a face-to-face visit. For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources, which include face-to-face encounters with a provider, physician, or other practitioner. Because the record for this enrollee-year did not meet CMS's requirements for acceptable data sources, the Ovarian Cancer HCC was not validated.

- For the remaining 1 enrollee-year, Coventry did not provide a legible copy of the medical record; therefore, the Ovarian Cancer HCC was not validated.

As a result of these errors, the Ovarian Cancer HCCs were not validated, and Coventry received $149,222 in overpayments for these 29 sampled enrollee-years.

Summary of Incorrectly Submitted Diagnosis Codes

In summary and with respect to the 10 high-risk groups covered by our audit, Coventry received $752,587 in net overpayments for 249 of the 300 sampled enrollee-years.

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

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

Coventry had compliance procedures to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. Specifically, Coventry had preventative techniques, including a provider education program designed to promote accurate diagnosis coding. Further, Coventry provided instructions to providers on the appropriate coding of a condition as either active (i.e., current) or historical and the proper coding of certain risk adjustment diagnoses, including all diagnosis groups reviewed in our audit.

In addition, Coventry's compliance procedures for detection and correction of incorrectly submitted diagnosis codes included periodic reviews of sampled claims comparing the diagnoses that Coventry submitted to CMS to the diagnoses documented in the associated medical records. When Coventry identified an unsupported diagnosis, it had procedures to correct that diagnosis code on CMS's risk adjustment system. Coventry also had procedures to review the results of its analysis to identify providers with coding compliance issues. Coventry gave those providers additional education and training, and implemented corrective action plans when continued noncompliance was detected. Coventry also had procedures to assess the coding accuracy of its internal coders and, based on the results of the assessments, provide training specific to the coders' understanding of coding polices and guidelines.

We acknowledge that Coventry had compliance procedures designed to ensure that diagnosis codes comply with Federal requirements. Additionally, Coventry indicated that it engages in a continuous process to improve its compliance program. However, based on our assessment of the procedures that were in place during our audit period, and because the diagnosis codes for 249 of the 300 sampled enrollee-years were not supported by the medical records, we believe that Coventry's compliance procedures to prevent, detect, and correct incorrect high-risk diagnosis codes could be improved.

Regarding the 12 sampled enrollee-years for which Coventry could not locate any medical records to support the diagnosis codes it submitted to CMS, Coventry officials stated that Coventry made multiple attempts to retrieve the medical records, to no avail. Coventry explained that in most instances the providers were not able to locate the medical records, and in other instances the providers did not respond to the medical record request or Coventry was unable to contact the provider.

COVENTRY HEALTH AND LIFE INSURANCE COMPANY 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 Coventry received at least $6,995,522 in net overpayments for our audit period (See footnote 15 and Appendix D for sample results and estimates.)

RECOMMENDATIONS

We recommend that Coventry Health and Life Insurance Company:

- refund to the Federal Government the $6,995,522 of estimated net overpayments;[24]

- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred after our audit period and refund any resulting overpayments to the Federal Government; and

- continue to examine its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

COVENTRY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Coventry, through CVS Health, disagreed with some of our findings and all of our recommendations. Specifically, Coventry did not agree with our findings for 23 of the 259 enrollee-years identified as errors in our draft report and provided

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

additional information for our consideration.[25] Coventry did not state whether it agreed or disagreed with our findings for the remaining 236 enrollee-years.

Coventry stated that our audit methodology was skewed in favor of finding alleged overpayments and that it did not concur with our recommendation that it refund estimated net overpayments. Additionally, Coventry did not concur with our recommendation to identify similar instances of noncompliance that occurred after our audit period. Lastly, Coventry did not concur with our recommendation regarding its compliance program but stated that it will look for ways to evaluate and improve its MA compliance program.

After reviewing Coventry's comments and the additional information it provided, we reduced the number of enrollee-years identified as in error from 259 to 249 and adjusted our calculation of estimated net overpayments. Accordingly, we reduced the recommended refund in our first recommendation from $7,217,966 to $6,995,522 for this final report. We maintain that our second and third recommendations remain valid.

A summary of Coventry's comments and our responses follows. Coventry's comments are included in Appendix F.

COVENTRY DID NOT AGREE WITH OIG'S RECOMMENDATION THAT COVENTRY REFUND ESTIMATED NET OVERPAYMENTS

Coventry Did Not Agree With OIG's Findings for 23 Sampled Enrollee-Years

Coventry Comments

Coventry did not agree with our draft report findings for 23 sampled enrollee-years and asked that we reverse our findings concerning these enrollee-years (as shown in Table 2 on the following page).

[25] This information was included in an attachment to Coventry's comments. We excluded the attachment from this report because it contained personally identifiable information. We are separately providing Coventry's comments and attachments in their entirety to CMS.

Table 2: Summary of Enrollee-Years for Which Coventry Disagreed With Our Findings

High Risk Group	Number of Sampled Enrollee Years
Acute Stroke	1
Acute Myocardial Infarction	3
Sepsis	8
Pressure Ulcer	7
Lung Cancer	2
Colon Cancer	1
Ovarian Cancer	1
Total	**23**

For 21 sampled enrollee-years, Coventry provided explanations supporting its position that previously submitted medical records validated the audited HCCs. For the remaining 2 sampled enrollee-years, Coventry previously indicated that it could not locate medical records. For these 2 enrollee-years, Coventry provided medical records and explanations supporting its position that those records validated the audited HCCs.

OIG Response

For the 21 enrollee-years for which Coventry provided explanations supporting its position that previously submitted medical records validated the audited HCCs, our independent medical review contractor reviewed the documentation.

- For 11 of the 21 enrollee-years, our contractor reaffirmed that the HCCs were not validated. For example, for 1 enrollee-year from the sepsis high-risk group, our contractor upheld its original decision upon reconsideration and stated:

  > "The provider noted sepsis, among other diagnoses, as a preliminary diagnosis that required further work-up. The rebuttal itself notes a 'suspected infection.' Based on the ICD-10-CM Official Guidelines for Coding and Reporting, possible or uncertain diagnoses are not to be coded as confirmed in an outpatient setting."

- For the remaining 10 enrollee-years, our contractor reversed its original decision and stated that the HCCs were validated.[26] As a result, we reduced the number of enrollee-years in error from 259 (as reported in our draft report) to 249. We also revised our findings and reduced the associated monetary recommendation. Our contractor completed a quality review of the 10 enrollee-years for which it reversed its original decision and reported that it did not identify any systemic issues.

[26] The 10 enrollee-years were in the following high-risk groups: sepsis (4), pressure ulcer (4), lung cancer (1), and colon cancer (1).

For the 2 sampled enrollee-years for which Coventry provided medical records that it previously stated it could not locate, our independent medical review contractor reviewed the documentation and found that the HCCs were not validated.

Coventry Stated That OIG's Audit Methodology Violated Key Requirements of the Medicare Advantage Program

Coventry Comments

Coventry stated that our audit methodology violated "key requirements of the MA program, including actuarial equivalence." Coventry stated that "[t]he overarching purpose of the risk-adjustment scheme, including adjusting for individual enrollees' different health statuses, is to 'ensure actuarial equivalence' with original Medicare." According to Coventry, actuarial equivalence means that "CMS should pay [MA organizations] the same amount for each enrollee that it would expect to pay to cover that enrollee in [Fee-For-Service (FFS)] Medicare." Coventry stated, "[t]o achieve actuarial equivalence, what matters is *overall* payment accuracy," which, according to Coventry, is reflected in CMS's prior Risk Adjustment Data Validation (RADV) audit methodology, where "the overreporting of some diagnosis codes is offset by the underreporting of others."

In this respect, Coventry stated that OIG "used a fundamentally different methodology" than what CMS used for its RADV audits in that we "did not build a representative sample of enrollee diagnosis codes from across the full range of reported diagnoses." Instead, "OIG identified diagnosis codes that were at particularly high risk of being miscoded in one direction—miscoding that generates alleged *over*payments… ." To these points, Coventry asserted that "[s]uch deliberately one-sided reviews are unlikely to lead to an 'accurate, complete and truthful' account of overall payment accuracy…." Further, Coventry stated that "OIG's audit was unfairly skewed by its very design towards finding alleged overpayments."

According to Coventry, CMS sets the risk-adjusted payment rates to MA organizations using FFS data that inevitably contain errors (incorrect diagnosis codes). To this point, Coventry stated, "[i]n contrast to the unaudited diagnosis data from original Medicare providers, [OIG]. . . subjects MA data to strict and improper auditing standards." Specifically, Coventry stated that CMS's use of unaudited data to determine the risk adjustment rates followed by our use of "*audited* data to calculate extrapolated refunds (and ultimately determining payments to [MA organizations]) disrupts actuarial equivalence between original FFS Medicare and MA."

To demonstrate its position, Coventry provided a chronology of CMS's actions that eventually resulted in a final rule in 2023, "codifying that RADV audits will include extrapolation without an FFS adjuster." However, Coventry stated that it disagreed with that final rule and cited recent litigation to support its disagreement. Coventry further stated that it believes that CMS's final rule is contrary to law and that it "has no legal obligation to comply with OIG's recommendation to refund the [$7.2 million]."

Further, Coventry cited previous OIG audits and stated that "OIG may not depart from its longstanding policy [that declined to engage in contract-wide extrapolation absent a FFS adjustor] without providing good reasons for the change and without explaining why those reasons are sufficient to justify overriding [Coventry's] reasonable reliance interests." Coventry also "[highlighted] that OIG's audit of FFS data found that '[a]lmost all of the selected acute stroke diagnosis codes that physicians submitted to CMS under traditional Medicare . . . did not comply with Federal requirements."[27] To this point, Coventry stated that "OIG recommends audits only for [MA Organizations] knowing similar audits do not occur in FFS Medicare" and that OIG's recommendations violate "actuarial equivalence between MA and original Medicare and are arbitrary and capricious."

Further, according to Coventry, OIG may be "double counting" refund amounts because CMS already reduces the reimbursement MA organizations receive for diagnosis codes that CMS believes are susceptible to over-coding, including codes identified in this audit. In these respects, Coventry stated that "if CMS requires [Coventry] and other [MA organizations] to refund these inflated overpayment estimates, [MA organizations] will end up being systematically underpaid, further disrupting actuarial equivalence."

OIG Response

We agree with Coventry in that we designed our audit to review diagnosis codes that were at high risk for being miscoded. However, with respect to Coventry's statement that our audit violated the requirements of actuarial equivalence, we note that our audit methodology was designed and executed to accomplish our audit objective. This methodology included calculating any overpayments or underpayments in accordance with CMS's risk-adjustment payment requirements. To this point, CMS has not issued any requirements that compelled us to reduce our net overpayment calculation. Further, our approach to conduct this audit was reasonable; however, it did not mirror CMS's approach on its RADV audits in all aspects, nor did it have to.

Our audit methodology correctly applied MA program requirements to properly identify the overpayment amount associated with unsubstantiated HCCs for each sample item. Specifically, we used the results of the independent medical review contractor's review to determine which HCCs were not validated and, in some instances, to identify HCCs that should have been used (but were not used) in the associated enrollees' risk score calculations. We followed CMS's risk adjustment program requirements to determine the payment that CMS should have made for each enrollee and to estimate net overpayments made to Coventry for the high-risk groups included in the sampling frame. Accordingly, the fact that we made recommendations to Coventry based on errors identified in this audit while acknowledging that similar errors occurred in FFS Medicare does not render these recommendations as arbitrary and capricious.

[27] Incorrect Acute Stroke Diagnosis Codes Submitted by Traditional Medicare Providers Resulted in Millions of Dollars in Increased Payments to Medicare Advantage Organizations (A-07-17-01176) Sept. 16, 2020.

While we acknowledge that Federal requirements mandate that payments to MA organizations be based on the anticipated cost of providing Medicare benefits to a given enrollee,[28] we do not agree with Coventry's assertion that underreported and overreported diagnosis codes offset each other to achieve overall payment accuracy. Further, these requirements do not prohibit audits of specific diagnosis codes, especially for diagnoses that we have determined to be at high risk for being miscoded. Our estimation of net overpayments was limited to errors associated with these specific diagnosis codes and did not extend to the identification of all possible diagnosis codes that Coventry could have submitted on behalf of the sampled enrollee-years because this was beyond the scope of our audit.

Further, we do not agree with Coventry's assertion that we may be "double counting" the amounts that we recommend Coventry refund to the Federal Government. Reductions that CMS may have made to the reimbursement rates for HCCs associated with certain diagnosis codes, including those identified in our audit, do not have any bearing on the requirement that diagnosis codes submitted for use in CMS's risk adjustment program must be supported in medical records. We found that for 249 of the 300 sampled enrollee-years, either the medical records that Coventry provided did not support the diagnosis codes or Coventry could not locate the medical records to support the diagnosis codes. In these instances, Coventry should not have received the increased payment associated with these diagnosis codes, regardless of whether the reimbursement rate for the diagnosis codes had been reduced by CMS.

We also disagree with Coventry's assertion that our previous reports created a policy regarding extrapolation. In this regard and in the context of CMS's requirements and updated guidance, including the 2023 Final Rule, we continue to recognize that CMS— not OIG—is responsible for making operational and program payment determinations for the MA program. (See footnote 24.)

Thus, we believe that the steps that we followed in this audit provide a reasonable basis for our findings and conclusions, including our calculation of net overpayments.

Coventry Stated That OIG's Audit Process Was Unfair, Arbitrary and Capricious, and Contrary to Law

Coventry Comments

Coventry stated that OIG's audit process was unfair, arbitrary and capricious, and contrary to law. Coventry had concerns regarding our audit methodology and independent medical review contractor's review process, to which it made the following assertions:

- Coventry stated that "OIG's audit methodology and coding standards were not promulgated through notice-and-comment rulemaking as required by statute." Coventry stated that "[i]f CMS were to enforce OIG's recommended recoupment of

[28] The Act §§ 1853(a)(1)(c) and (a)(3); 42 CFR § 422.308(c).

$7.2 million, then OIG's underlying review standards would constitute requirements or policies establishing substantive legal standards governing the payment for services. But neither the ICD Coding Guidelines, nor the Manual, nor presumably any of the other unknown standards that OIG applied during its audit, have been promulgated by notice-and-comment rulemaking." Coventry stated that it would be contrary to law for this guidance to serve as substantive legal standards that govern payment for services.

- Coventry stated that "OIG's approach of treating disagreements between senior coders as ties to be resolved by a coding supervisor was arbitrary and capricious." Specifically, Coventry disagreed with our methodology to have a coding supervisor resolve disagreements between senior coders and instead maintained that we should have deferred to the code submitted by the treating physician.

OIG Response

We do not agree with Coventry's assertions that our audit process was unfair, arbitrary and capricious, and contrary to law.

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

  We also disagree with Coventry's assertion that our reliance on the ICD Coding Guidelines and the Manual was contrary to law because these sources have not been promulgated through notice-and-comment rulemaking. Federal regulations at 42 CFR § 422.310(d)(1) and 45 CFR §§ 162.1002(c)(2)-(3) require that diagnoses be coded according to the International Classification of Diseases, Clinical Modification, Official Guidelines for Coding and Reporting. Further, the Manual is legally binding on an MA organization based not only on regulation, but also on its contract with CMS. Federal regulations state that MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes and that such data must conform to all relevant national standards. In addition, MA organizations that contract with CMS must agree to follow CMS's instructions, including the provisions of the Manual.[29] Coventry has agreed to operate in compliance with the Manual under the terms of its contract with CMS and is bound by the requirements of that contract, including any applicable provisions of the Manual.

[29] 42 CFR §§ 422.504(a) and 422.310(b).

- We disagree with Coventry's statement that we should have deferred to the treating physician in the event that the first and second senior coders disagreed. We believe the use of the coding supervisor as the final decision maker, as stated in our methodology, reflects a reasonable method to determine whether the medical record adequately supported the submitted diagnosis codes and ensured accurate coding review results.

Coventry Did Not Agree With OIG's Use of the 90-Percent Confidence Interval in Estimating Overpayments

Coventry Comments

Coventry stated that "[i]n estimating an alleged contract-level overpayment, OIG used a less statistically sound confidence interval than CMS, without giving a reason for this choice." Coventry said that in using the lower limit of the two-sided 90-percent confidence interval, "OIG departs from the more statistically sound approach of using the lower limit of a 99% confidence interval that CMS follows in its RADV audits." Coventry further stated that "[i]t is arbitrary and capricious for OIG to use a less statistically sound method than CMS, without providing any reasoned explanation for doing so."

OIG Response

We disagree with Coventry's comment that our use of a lower confidence level, which is different from CMS's, is less statistically sound. OIG is an independent oversight agency; therefore, our estimation methodology does not need to mirror CMS's estimation methodology. Our policy recommends recovery at the lower limit of a two-sided 90-percent confidence interval. The lower limit of a two-sided 90-percent confidence interval provides a reasonably conservative estimate of the total amount overpaid to Coventry for the enrollee-years, high-risk groups, and time period covered in our sampling frame. This approach, which is routinely used by HHS for recovery calculations,[30] results in a lower limit (the estimated net overpayment amount) that is designed to be less than the actual overpayment total 95 percent of the time.

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

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

Coventry Comments

Coventry stated that aspects of our audit were slanted in favor of finding alleged overpayments. Specifically, according to Coventry:

- OIG's selection of "distant" audit years created a data validation problem because "[t]he loss of [medical] records [by some providers] prevented [Coventry] from retrieving medical record support for physician diagnosis coding that was undisputedly authentic."

- OIG "sought to identify only overpayments." In this respect, Coventry asserted that OIG instructed it "to flag only the page numbers and text of the medical records directed by OIG." Coventry also stated that "OIG declined to even review vast segments of the medical records containing factual support for diagnoses that treating physicians should have submitted and did not." According to Coventry, "[t]he result was to eliminate or reduce the offsetting of overreported codes with underreported codes and generate an alleged overpayment."

- OIG's instructions for Coventry to identify the specific page number and text on inpatient records "turned the process into a hunt for specific words in the inpatient records and impeded [Coventry's] efforts to show how the diagnoses were supported by the records as a whole." Coventry further stated that "OIG's prescriptive approach was arbitrary and capricious and further skewed the audit in favor of identifying alleged overpayments."

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

OIG Response

We do not agree with Coventry's statements that aspects of our audit were slanted in favor of finding alleged overpayments.

- We disagree with Coventry's comment that our selection of "distant years" for our audit period created a data validation problem. We audited payment years 2018 and 2019; thus, CMS allowed Coventry to submit or update claims for new diagnoses until January 31, 2019, and January 31, 2020, respectively. We started our audit in July 2022 and, in November 2022, requested supporting medical records from Coventry for the audited HCCs. We initially provided a reasonable period—5 months—for Coventry to

submit the medical records and worked with Coventry officials during our audit to extend the medical record collection timeframe to account for any collection difficulties. Coventry provided its medical records by June 2023.

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

- We disagree with Coventry's statement that we sought only to identify overpayments. We did consider underpayments as they related to our objective. In this regard, we considered instances in which our independent medical review contractor found a diagnosis that should have been submitted to CMS instead of the diagnosis code that was submitted. However, the identification of all possible diagnosis codes that Coventry could have submitted on behalf of the sampled enrollee-years was beyond the scope of our audit.

  Specifically, each of the sampled enrollee-years had one claim on CMS's systems with a diagnosis that was at high risk for being miscoded. We asked Coventry to provide the medical records for those claims. If our contractor identified a diagnosis code that should have been submitted to CMS instead of the diagnosis code that was submitted, we included the financial impact of the resulting HCC in our calculation of net overpayments. Specifically, for this audit, the net overpayment calculation included one underpayment that we identified within the Pressure Ulcer high-risk group.

  We also gave Coventry the option to provide up to four additional medical records as support for the audited HCC for each sampled enrollee-year. The claims associated with these medical records did not have a diagnosis code on CMS's systems that mapped to the audited HCC. Therefore, we asked Coventry to flag the page number of these medical records to identify the areas of the record that it believed supported the audited HCC. Our contractor reviewed the entire medical record—not just those pages identified by Coventry—to determine whether support existed for a diagnosis that mapped to audited HCCs. However, it was beyond the scope of our audit to determine if there was support for a diagnosis that mapped to another HCC.

- We disagree with Coventry's statement that our instructions to identify the specific page number and text on inpatient records "impeded [Coventry's] efforts to show how the diagnoses were supported by the records as a whole." Our methodology allowed Coventry the opportunity to highlight the areas of the inpatient medical record that it believed supported the audited HCC. Our independent medical review contractor began

its review of those records with the portions identified as pertinent by Coventry and then reviewed the remaining portions of the medical record to determine whether support existed for a diagnosis that mapped to audited HCCs. Thus, our contractor reviewed more than those pages identified by Coventry to make accurate coding decisions.

- We disagree with Coventry's statement that we overrode the treating physicians' diagnoses. As explained in our audit methodology (Appendix A), this coding review followed a specific process for which our contractor used both skilled senior coders and coding supervisors. Our contractor performed a coding review—not a clinical review—of each medical record that Coventry provided to us to determine whether diagnoses were coded in accordance with Federal requirements. This process was not arbitrary and capricious; rather, it was reasonable to accomplish our audit objective.

Coventry Stated That OIG Had No Statutory Authority to Extrapolate Overpayments

Coventry Comments

Coventry stated that it "does not concur with OIG's recommendation to refund $7.2 million in extrapolated alleged overpayments because that estimate is flawed, and OIG has no statutory authority to make that recommendation."

Coventry stated that "OIG also lacks authority to apply extrapolation in its audits of [MA organizations]." Coventry said that "[i]n a 2023 [F]inal [R]ule, HHS amended the RADV audit regulation … to provide for recovery from [MA organizations] of improper payments 'in accordance with the Secretary's payment error extrapolation and recovery methodologies,' specifying that 'CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years.'" Coventry stated that "[t]he preamble to the [F]inal [R]ule explained this change in position by asserting that the authority to use sampling and extrapolation in Medicare audits is 'grounded in [HHS's] statutory and regulatory authority to audit providers and recoup improper payments,' without identifying any specific statutory provisions…."

Coventry stated that the RADV audit regulation "does not delegate authority to OIG to apply extrapolation in the audits that it separately carries out." It also stated that "OIG's asserted authority to conduct RADV audit activity, the [Inspector General] Act, does not delegate to OIG the authority to use extrapolation in its audits." Furthermore, Coventry stated that "OIG's framing of its extrapolated alleged overpayment as a mere recommendation does nothing to mitigate the confusion of the public or reputational harm to [Coventry] from OIG's finding of an alleged overpayment…."

OIG Response

Coventry's assertion that we do not have statutory authority under the Inspector General Act to calculate extrapolated overpayments is inaccurate. Neither Federal statute nor any other

authority limits our ability to use sampling techniques with extrapolation to calculate overpayments or recommend a recovery based on extrapolation. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare.[31] Furthermore, the 2023 Final Rule does not specify a sampling or extrapolation methodology but requires a reasonable methodology for CMS or OIG audits. We properly executed our statistical sampling methodology in that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used our statistical sampling software to apply the correct formulas for the extrapolation. We believe this methodology provides a reasonable basis for our monetary recommendation.

COVENTRY DID NOT AGREE WITH OIG'S RECOMMEDATION TO IDENTIFY SIMILAR INSTANCES OF NONCOMPLIANCE FOR THE HIGH-RISK DIAGNOSES THAT OCCURRED AFTER THE AUDIT PERIOD

Coventry Comments

Coventry disagreed with our second recommendation—that it identify similar instances of noncompliance for the high-risk diagnoses that occurred after the audit period and to refund any overpayments—because, according to Coventry, we are making "new interpretations of . . . regulations with substantial financial and operational implications that should have gone through notice and comment rulemaking."

In this respect, Coventry stated that our recommendation would "impose additional and widespread auditing obligations on [MA organizations]" despite "longstanding guidance *effective during the time of the audit*." Coventry cited guidance from CMS that MA organizations "cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that {CMS}, the OIG, and DOJ believe is reasonable to enforce."[32] According to Coventry, "[MA organizations] were told they had 'broad discretion … to design their compliance plan structure.'" Coventry also cited related guidance that stated that MA organizations are encouraged to conduct only "sample audits and spot checks."[33]

Coventry also stated that – in a response to comments that Coventry's parent organization made in another audit – we "indicated that notice and comment rulemaking was not required because '[n]o new requirements were imposed.'" Coventry stated that this was "simply not

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

[32] 65 Fed. Reg. 40,170, 40,268 (Jun. 29, 2000).

[33] 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999).

true" and asked that we address how our prior guidance supports our recommendations for this report. To this question, Coventry stated that, although MA organizations must certify that its risk adjustment data is accurate based on "best knowledge, information, and belief," this requirement does not support OIG's recommendation that MA organizations should conduct the "widespread audits proposed."

Coventry asserted that if an MA organization conducts the "expansive audits" we recommend, the MA organization would be "double counting overpayment amounts because CMS has already accounted for the potential over-coding when setting the rates." To this point, Coventry stated "it would be arbitrary and capricious to issue a recommendation knowing duplicative adjustments are already being made."

OIG Response

We disagree with Coventry's assertion that our second recommendation results in a new interpretation of Federal requirements with substantial financial and operational implications that should have gone through notice-and-comment rulemaking. We found that for 249 of the 300 sampled enrollee-years, Coventry's submissions of the selected diagnosis codes did not comply with Federal requirements; accordingly, our recommendation for Coventry to identify and correct similar errors that occurred after our audit period is appropriate. Consistent with the previous report that Coventry referenced, we continue to maintain that no new requirements were imposed; thus, there was no need for notice-and-comment rulemaking.

We also do not agree with Coventry's interpretation of Federal requirements. We recognize that MA organizations have the latitude to design their own federally mandated compliance programs. We also recognize that the requirement that MA organizations certify the data they submit to CMS is based on "best knowledge, information, and belief." Further, as stated previously, we acknowledge that Federal requirements mandate that payments to MA organizations be based on the anticipated cost of providing Medicare benefits to a given enrollee. However, contrary to Coventry's assertions, we believe that our second recommendation conforms to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (see Appendix E).

With regard to Coventry's statement that it cannot reasonably be expected to know that every piece of data is correct, Federal regulations state that MA organizations must "implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS's program requirements." Further, the regulations specify that Coventry's compliance plan "must, at a minimum, include [certain] core requirements," such as "an effective system for routine monitoring and identification of compliance risks . . .[including] internal monitoring and audits and, as appropriate, external audits to evaluate . . . compliance with CMS requirements and the overall effectiveness of the compliance program." These regulations also require MA organizations to implement procedures and a system for investigating "potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for

recurrence." Thus, CMS has, through the issuance of these Federal regulations, assigned the responsibility for dealing with potential compliance issues to the MA organizations themselves.

In this regard, CMS has provided additional guidance in chapter 7 § 40 of the Manual, which states:

> If upon conducting an internal review of submitted diagnosis codes, the [MA organization] determines that any diagnosis codes that have been submitted do not meet risk adjustment submission requirements, the plan sponsor is responsible for deleting the submitted diagnosis codes as soon as possible…. Once CMS calculates the final risk scores for a payment year, [MA organizations] may request a recalculation of payment upon discovering the submission of inaccurate diagnosis codes that CMS used to calculate a final risk score for a previous payment year and that had an impact on the final payment. [MA organizations] must inform CMS immediately upon such a finding.

Further, we do not agree with Coventry's assertion that MA organizations would be "double counting" overpayment amounts if the MA organizations conduct the reviews we recommend. Our second recommendation is for Coventry to review high-risk diagnosis codes in years after our audit period. Reductions that CMS may have made to the reimbursement rates for HCCs associated with certain diagnosis codes do not have any bearing on the possibility that the diagnosis codes submitted by Coventry for use in CMS's risk adjustment program may not have been supported in medical records and thus may have resulted in further overpayments.

In conclusion, we believe that the error rates identified in this report demonstrate that Coventry has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope. Accordingly, we maintain that our second recommendation is valid.

COVENTRY DID NOT CONCUR WITH OIG'S RECOMMENDATION THAT COVENTRY ENHANCE ITS EXISTING COMPLIANCE PROCEDURES

Coventry Comments

Coventry stated that while it "does not concur with OIG's recommendation regarding its compliance program, it will nevertheless look for ways to evaluate and improve its MA compliance program." Coventry stated that it "engages in continuous process improvement across its MA operations, and its compliance program is no exception. The compliance program has evolved greatly in the 6 years since the audit period ended to take into account OIG's audit findings as well [as] other issues that have arisen in the industry." For these reasons, Coventry also stated that "it remains committed to continuous process improvement and will continue, where appropriate, to look for and implement improvements to its compliance program in the future."

OIG Response

We did not review the evolution of Coventry's compliance program. Rather, we limited our review to selected diagnoses that we determined to be at high risk for being miscoded for our audit period. Our audit revealed a substantial error rate for some of these high-risk areas. (See Appendix D.) We acknowledge that Coventry had compliance procedures in place to promote the accuracy of diagnosis codes submitted to CMS to calculate risk-adjusted payments, including procedures related to the high-risk diagnosis codes that are the subject of this audit. Federal regulations at 42 CFR § 422.503(b) require MA organizations like Coventry to establish and implement an effective system for routine monitoring and the identification of compliance risks. This regulation further explains that a compliance system should consider both internal monitoring and external audits.

We concluded that Coventry's compliance program could be improved. The continued improvement of procedures will assist Coventry in attaining better assurance with regard to the accuracy, completeness, and truthfulness of the risk adjustment data that it submits to CMS in the future. Accordingly, we maintain that our recommendation to examine Coventry's existing compliance procedures is valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid Coventry $3,535,798,499 to provide coverage to its enrollees for 2018 and 2019. We identified a sampling frame of 4,026 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2017 and 2018 service years; Coventry received $59,780,395 in payments from CMS for these enrollee-years for 2018 and 2019. We selected for audit 300 enrollee-years with payments totaling $5,344,690.

The 300 enrollee-years included 30 acute stroke diagnoses, 30 acute myocardial infarction diagnoses, 30 sepsis diagnoses, 30 embolism diagnoses, 30 pressure ulcer diagnoses, 30 lung cancer diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, 30 prostate cancer diagnoses, and 30 ovarian cancer diagnoses (Table 1). We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $1,152,808 for our sample.

Our audit objective did not require an understanding or assessment of Coventry's complete internal control structure, and we limited our review of internal controls to those directly related to our objective. Specifically, we reviewed Coventry's controls for preventing, detecting, and correcting noncompliance with Federal requirements for CMS's risk adjustment program.

We performed audit work from July 2022 through October 2024.

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:

    - 94 diagnosis codes for acute stroke,
    - 17 diagnosis codes for acute myocardial infarction,

- 63 diagnosis codes for embolism,
- 30 diagnosis codes for sepsis,
- 50 diagnosis codes for pressure ulcer,
- 17 diagnosis codes for lung cancer,
- 54 diagnosis codes for breast cancer,
- 10 diagnosis codes for colon cancer,
- 1 diagnosis code for prostate cancer, and
- 9 diagnosis codes for ovarian cancer.

- We developed our sampling frame using data from CMS systems. Our sampling frame consisted of enrollee-years on whose behalf providers documented the high-risk diagnosis codes. To create this frame, and as explained further in Appendix C, we used extracts from CMS's:

  - Risk Adjustment Processing System (RAPS)[34] and the Encounter Data System (EDS)[35] to identify enrollees who received high-risk diagnosis codes from a physician during the service years,

  - Risk Adjustment System (RAS)[36] to identify enrollees who received an HCC for the high-risk diagnosis codes,

  - Medicare Advantage Prescription Drug System (MARx)[37] to identify enrollees for whom CMS made monthly Medicare payments to Coventry, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C),

  - EDS[38] to identify enrollees who received specific procedures, and

  - Prescription Drug Event (PDE) file[39] to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.

- We interviewed Coventry officials to gain an understanding of: (1) the policies and procedures that Coventry followed to submit diagnosis codes to CMS for use in the risk

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

[35] CMS uses the EDS to collect encounter data, including diagnosis codes, from MA organizations.

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

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

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

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

adjustment program and (2) Coventry's monitoring of those diagnosis codes to detect and correct noncompliance with Federal requirements.

- We selected for audit a stratified random sample of 300 enrollee-years (Appendix C).

- We used an independent medical review contractor to perform a coding review for the 288 enrollee-years (footnote 14) to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.[40]

- 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(s), 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(s):

        - 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 the coding supervisor reviewed the medical record(s) to make the final determination.

    - If either the first or second senior coder asked the coding supervisor for assistance, the coding supervisor's decision became the final determination. Additionally, at any point in the review process, a senior coder or coding supervisor may have consulted a physician reviewer for additional clarification.

- We used the results of the independent medical review contractor, and CMS's systems, to calculate overpayments or underpayments (if any) for each enrollee-year. Specifically, we calculated:

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

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

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

- We estimated the total net overpayment made to Coventry for the high-risk groups included in the sampling frame for the audit period in accordance with CMS's regulations for the use of extrapolation in RADV audits for recovery purposes.[41]

- We discussed the results of our audit with Coventry officials.

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

[41] Federal regulations at 42 CFR § 422.311(a) state: "[T]he Secretary annually conducts RADV audits to ensure risk-adjusted payment integrity and accuracy. (1) Recovery of improper payments from MA organizations will be conducted in accordance with the Secretary's payment error extrapolation and recovery methodologies. (2) CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years" (88 Fed. Reg. 6643, 6655 (Feb. 1, 2023)).

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HealthAssurance, Pennsylvania, Inc. (Contract H5522) Submitted to CMS	A-05-22-00020	9/23/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Humana Health Plan, Inc. (Contract H2649) Submitted to CMS	A-02-22-01001	9/23/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Independent Health Association, Inc. (Contract H3362) Submitted to CMS	A-07-19-01194	6/26/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MediGold (Contract H3668) Submitted to CMS	A-07-20-01198	2/16/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That SelectCare of Texas, Inc. (Contract H4506), Submitted to CMS	A-06-19-05002	11/27/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Aetna, Inc. (Contract H5521) Submitted to CMS	A-01-18-00504	10/02/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS	A-07-20-01197	8/03/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS	A-07-20-01202	7/10/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. (Contract H3952) Submitted to CMS	A-03-20-00001	5/31/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS	A-05-19-00013	4/04/2023

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified Coventry enrollees who: (1) were continuously enrolled in Coventry throughout all of the 2017 or 2018 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 2017 or 2018 or in January of the following year, and (3) received certain high-risk diagnoses during 2017 or 2018 that caused an increased payment to Coventry for 2018 or 2019, respectively.

We presented the data for these enrollees to Coventry 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 Coventry. After we performed these steps, our finalized sampling frame consisted of 4,026 enrollee-years.

SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2018 or 2019.

SAMPLE DESIGN AND SAMPLE SIZE

The design for our statistical sample comprised 10 strata of enrollee-years. For the enrollee-years in each respective stratum, each enrollee received:

- an acute stroke diagnosis that mapped to the HCC for Ischemic or Unspecified Stroke on only one physician claim during the service year but did not have an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim (1,234 enrollee-years);

- an acute myocardial infarction diagnosis that mapped to the HCC for Acute Myocardial Infarction on only one physician or outpatient claim during the service year but did not have an acute myocardial infarction diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician or outpatient claim (516 enrollee-years);

- an embolism diagnosis that mapped to an Embolism HCC on only one claim during the service year but did not have an anticoagulant medication dispensed on his or her behalf (255 enrollee-years);

- a sepsis diagnosis that mapped to the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock on only one physician or outpatient claim during the service year but did not have a sepsis diagnosis on a corresponding inpatient hospital claim (295 enrollee-years);

- a pressure ulcer diagnosis that mapped to a Pressure Ulcer HCC on only one claim during the service year but did not have a pressure ulcer diagnosis on another claim during the prior and subsequent service years (52 enrollee-years);

- a lung cancer diagnosis that mapped to the HCC for Lung and Other Severe Cancers on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the lung cancer diagnosis administered within a 6-month period before or after the diagnosis (144 enrollee-years);

- a breast cancer diagnosis that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the breast cancer diagnosis administered within a 6-month period before or after the diagnosis (639 enrollee-years);

- a colon cancer diagnosis that mapped to the HCC for Colorectal, Bladder, and Other Cancers on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (241 enrollee-years);

- a prostate cancer diagnosis for an individual 74 years old or younger that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (606 enrollee-years); or

- an ovarian cancer diagnosis that mapped to an Ovarian Cancer HCC on only one claim during the service year but did not have surgical therapy or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (44 enrollee-years).

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

Table 3: Sample Design for Audited High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee-Years	CMS Payment for HCCs in Audited High-Risk Groups	Sample Size
1 – Acute stroke	1,234	$2,482,246	30
2 – Acute myocardial infarction	516	1,023,155	30
3 – Embolism	255	704,464	30
4 – Sepsis	295	1,021,945	30
5 – Pressure Ulcer	52	531,088	30
6 – Lung cancer	144	1,102,193	30
7 – Breast cancer	639	820,952	30
8 – Colon cancer	241	596,118	30
9 – Prostate cancer	606	747,507	30
10 – Ovarian cancer	44	232,645	30
Total	**4,026**	**$9,262,313**	**300**

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

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

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to estimate the total net overpayments made to Coventry for the high-risk groups included in the sampling frame at the lower limit of the two-sided 90-percent confidence interval (Appendix D, Table 5). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Details and Results

Audited High-Risk Groups	Frame Size	CMS Payments for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payments for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With HCCs That Were Not Validated	Net Overpayments for HCCs That Were Not Validated (for Sampled Enrollee-Years)
1 – Acute stroke	1,234	$2,482,246	30	$56,064	29	$53,823
2 – Acute myocardial infarction	516	1,023,155	30	62,846	28[42]	47,952
3 – Embolism	255	704,464	30	85,990	26	75,741
4 – Sepsis	295	1,021,945	30	88,269	14	44,245
5 – Pressure Ulcer	52	531,088	30	313,043	11	62,319
6 – Lung cancer	144	1,102,193	30	239,223	24	181,489
7 – Breast cancer	639	820,952	30	36,938	30	36,938
8 – Colon cancer	241	596,118	30	71,934	29	65,425
9 – Prostate cancer	606	747,507	30	36,609	29	35,433
10 – Ovarian cancer	44	232,645	30	161,892	29	149,222
Total	**4,026**	**$9,262,313**	**300**	**$1,152,808**	**249**	**$752,587**

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

Point Estimate	$7,343,703
Lower Limit	6,995,522
Upper Limit	7,691,885

[42] For 1 of these enrollee-years, there was no financial impact associated with the HCC that was not validated. (See footnote 19.)

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

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

> Any entity seeking to contract as an MA organization must . . . .
>
> (4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following . . . .
>
> (vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:
>
> (A) Written policies, procedures, and standards of conduct that—
>
> (1) Articulate the organization's commitment to comply with all applicable Federal and State standards;
>
> (2) Describe compliance expectations as embodied in the standards of conduct;
>
> (3) Implement the operation of the compliance program;
>
> (4) Provide guidance to employees and others on dealing with potential compliance issues;
>
> (5) Identify how to communicate compliance issues to appropriate compliance personnel;
>
> (6) Describe how potential compliance issues are investigated and resolved by the organization; and
>
> (7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials . . . .
>
> (F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The

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

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

(1) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

(2) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.

(3) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

APPENDIX F: COVENTRY COMMENTS



Jennifer Webb
Regional Inspector General for Audit Services
Office of Audit Services, Region II
26 Federal Plaza, Room 3900
New York, NY 10278

November 22, 2024

Re: Office of Inspector General's (OIG) Draft Report No. A-02-22-01020

Dear Ms. Webb,

CVS Health Corporation, on behalf of its subsidiaries offering Medicare Advantage ("MA") plans (collectively, "CVS Health"), writes to respond to the Office of Inspector General's ("OIG") Draft Report No. A-02-22-01020 concerning the audit of Contract H1608. We thank OIG for the opportunity to respond to OIG's Draft Report. With family and friends enrolled in Medicare and MA plans, we recognize the imperative goal of preserving Medicare Trust funds–it's personal for us. Still, we believe OIG's Draft Report departs from clear and contrary Medicare guidance–including from OIG itself–and contributes to the false impression that MA plans are gaming the system. As we discuss below, that perception is flawed and we ask OIG to consider and address our comments. We note for readers not familiar with these audits that OIG is explicitly not addressing requirements that would reduce the overpayment amount and that bear on compliance and auditing requirements.

MA Organizations ("MAOs") submit millions of risk adjustment submissions annually. Given the vast volume of data, the risk adjustment model is not intended to determine the actual costs or conditions for particular enrollees. Instead, reimbursement should be appropriate for the entire population–a necessity given the amount of data submitted. The model is a statistical regression that assumes a distribution across a spectrum, with providers over-coding some conditions while under-coding others.[1] But when aggregated, reimbursement will be appropriate as long as it is actuarially equivalent to reimbursement in Traditional Fee-For-Service ("FFS") Medicare. In fact, the Centers for Medicare & Medicaid Services ("CMS") already reduces MAO reimbursement for codes it believes are susceptible to over-coding, including codes identified in this audit.[2] OIG's approach falsely assumes that *every* code in the millions of submissions must be accurate. By even OIG's prior estimation, that is not feasible or required.

We highlight and ask OIG to specifically address prior government representations acknowledging this reality. As an example, CMS indicated that MAOs "cannot reasonably be expected to know

[1] *See generally* Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (Feb. 1, 2023) at p. 47-48 (available at https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf).
[2] *Id.*

that every piece of data is correct, nor is that the standard that [CMS], the OIG, and [the Department of Justice ("DOJ")] believe is reasonable to enforce."[3] MAOs indeed have "broad discretion … to design their compliance plan structure[.]"[4] Even OIG has said MAOs should conduct "sample audits and spot checks."[5] An MAO's obligation to sift through its risk adjustment data is limited to "the same type of limited error correction that is present throughout Medicare."[6] OIG's Draft Report, especially its recommendation that MAOs conduct widespread audits of their risk adjustment data, flies in the face of this guidance. Moreover, the widespread audits recommended were never part of the risk adjustment program prior to OIG's audits. Put simply, prior to the new standards set out by OIG in its recent risk adjustment audits, MAOs had no obligation to conduct widespread and material audits of their risk adjustment data to identify every so-called "high-risk diagnosis." Indeed, that was never the intent of the risk adjustment program. By definition, this recommendation is a new and material obligation thrust upon MAOs that must go through notice and comment rulemaking, even assuming it is consistent with MA guidance.

The issues identified in the Draft Report are not unique to CVS Health or even the MA industry. OIG found similar error rates in more than twenty OIG audits of other MAOs.[7] In fact, OIG found the same level of coding errors in FFS data[8]–an indication that OIG's audit reveals more about provider coding generally than allegedly inappropriate behavior by MAOs. Ultimately, almost all risk adjustment submissions are derived from provider coding. Providers are human and, at times,

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[3] *Medicare Program: Medicare+Choice Program*, 65 Fed. Reg. 40,170, 40,268 (June 29, 2000) (available at: https://www.govinfo.gov/content/pkg/FR-2000-06-29/pdf/00-15648.pdf).

[4] *Id.* at 40,265.

[5] Publication of the OIG's Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans, 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999) (MAOs "should ordinarily conduct sample audits and spot checks of this system to verify whether it is yielding accurate information") (available at: https://www.govinfo.gov/content/pkg/FR-1999-11-15/pdf/99-29632.pdf).

[6] *UnitedHealthcare Ins. Co. v. Azar et al.*, Final Brief for Appellants at p. 39 (2020 WL 4544757) (Apr. 2020).

[7] *See* OIG, Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS (Mar. 2023) (finding that for 224 of the 270 sampled enrollee-years, the medical records did not support the diagnosis codes submitted); OIG, Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS (July 2023) (finding that for 202 of the 210 sampled enrollee-years, the medical records did not support the diagnosis codes submitted); OIG, Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS (Aug. 2023) (finding that for 198 of the 211 sampled enrollee-years, the medical records did not support the diagnosis codes submitted).

[8] *See* OIG, Incorrect Acute Stroke Diagnosis Codes Submitted By Traditional Medicare Providers Resulted in Millions of Dollars in Increased Payments to Medicare Advantage Organizations, A-07-17-01176 at p. 3 (Sept. 2020) (available at https://oig.hhs.gov/documents/audit/8837/A-07-17-01176-Complete%20Report.pdf).

make coding mistakes (like accidentally coding an active heart attack rather than a history of a heart attack). OIG's Draft Report, and others like it, creates a false impression of the industry that is not consistent with MA regulations or the vast amount of data submitted.

Setting aside our concerns about OIG's Draft Report, we share OIG's fundamental goal of ensuring MA enrollees receive efficient and effective care. Recognizing the need to be good stewards of Medicare funds, we have invested tremendous resources and efforts to improving our compliance programs. In response to OIG audits, we have improved our auditing and analytical tools, revised our educational materials to providers, and held training sessions with providers on the issues identified by OIG. We have looked critically at our risk adjustment programs and provider contracts and will continue to do so. Yet despite all of this work, it will never be possible to ensure the thousands of providers servicing MA members will code the millions of submissions accurately every time. We disagree with OIG's audit approach and recommendations in the Draft Report as we set forth in Exhibit A to this letter.

Sincerely,



Patrick Jeswald
Vice President
Chief Compliance Officer, Medicare

Exhibit A

The MA program is an increasingly popular choice for seniors. More than half of all Medicare beneficiaries choose MA plans rather than FFS Medicare. The MA program has succeeded because it benefits both MA enrollees and CMS—enrollees obtain supplemental benefits that are not covered by original Medicare, while CMS shifts financial risk for the healthcare costs of the enrollees to MAOs like CVS Health.

Under the MA program, CMS makes fixed monthly payments to MAOs for each enrollee.[9] The Medicare statute requires CMS to implement a risk-adjustment scheme that adjusts these monthly payments to account for how various characteristics, such as health status, affect different enrollees' expected cost of coverage.[10] OIG's Draft Report never addresses the statutory mandate of actuarial equivalence, the overarching principle that guides risk adjustment. The Medicare statute expressly requires CMS to adjust payments to MAOs for risk factors, including health status, "so as to ensure actuarial equivalence" with FFS Medicare.[11] Simply put, CMS should pay MAOs the same amount for each enrollee that it would expect to pay to cover that enrollee in FFS Medicare. This requirement ensures that MA members receive the same—and often more—benefits than their FFS counterparts.

First, consider the drastic evolution of standards OIG has offered when interpreting auditing requirements for MAOs. As we set forth more fully below, CMS, DOJ, and OIG have indicated that perfection is not feasible or required, and that MAOs must perform "spot checks" that are similar to the auditing done for Traditional Medicare. Contrast this limited–and given the volume of risk adjustment data, more practical–standard with OIG's recent audit reports. No similar auditing occurs in Traditional Medicare, yet OIG now demands more for MAOs. In prior OIG responses, OIG suggests notice and comment rulemaking is not required because "no new requirements were imposed." Not so–we ask OIG to address how the recommendations in its Draft Report align with prior representations.

Even setting aside OIG's prior representations, its approach improperly adopts standards for MAOs that far outpace those for FFS Medicare. This violates Medicare guidance, including actuarial equivalence, and is arbitrary and capricious. Consider an MA member and a FFS member with the same conditions seeing the same doctor. If the doctor makes the same coding mistake for both members—for instance, inadvertently coding an active stroke when the doctor should have coded a history of stroke—OIG would reduce reimbursement to the MA Plan (and then extrapolate) while the FFS diagnosis remains unaudited. This one-sided reduction violates the actuarial equivalence mandate that MAOs should be reimbursed in a way that is actuarially equivalent to FFS reimbursement. Extrapolating these errors across an entire contract only compounds the actuarial equivalence issue. We ask OIG to address its authority to impose heightened standards on MA plans when compared to FFS Medicare, especially given guidance that the MAO auditing requirements should align with the limited auditing performed in FFS

[9] 42 U.S.C. § 1395w-23(a)(1)(A)-(B); 42 C.F.R. § 422.304(a).
[10] 42 U.S.C. § 1395w-23(a)(1)(C); 42 C.F.R. § 422.308(c)(1).
[11] 42 U.S.C. § 1395w-23(a)(1)(C)(i).

Medicare.

In this response, we first address how prior representations by CMS, OIG, and DOJ, directly contradict OIG's current recommendations. We ask that OIG explain how its Draft Report aligns with these representations. We then turn to the substantive MA regulations, most notably the requirement of actuarial equivalence and its necessary implications to OIG's Draft Report. While we understand OIG does not address how actuarial equivalence impacts its overpayment findings (and we continue to disagree with that approach), we emphasize that actuarial equivalence also necessarily impacts OIG's recommendations that CVS Health conduct widespread audits. This ultimately has nothing to do with CMS' financial recovery. It is arbitrary and capricious to ignore actuarial equivalence entirely, especially with relation to OIG's auditing recommendations.

I. OIG's stark departure from prior guidance on MAOs' auditing and compliance obligations are new standards that must be implemented through notice and comment rulemaking.

Given the vast volume of risk adjustment data submitted annually, MAOs cannot ensure the accuracy of every risk adjustment submission, and prior regulatory guidance aligns with this reality. Consider first the regulatory environment during the audit period in which MAOs like CVS Health submitted their bids to CMS.[12] At almost every turn, OIG, CMS, and DOJ emphasized the limited nature of an MAO's auditing obligations. As an example, OIG's Draft Report departs from longstanding CMS guidance recognizing the volume of data submitted, including confirmations from CMS that MA plans "cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the OIG, and DOJ believe is reasonable to enforce."[13] MAOs were told they had "broad discretion … to design their compliance plan structure[.]"[14] Even OIG indicated that MAOs should conduct "sample audits and spot checks."[15] In fact, even after the audit period the government recognized the limited nature of MAOs auditing obligation: the DOJ has indicated that an MAO's obligation to identify overpayments is "the same type of limited error correction that is present throughout Medicare."[16]

Despite this longstanding guidance *effective during the time of the audit*, OIG now seeks to impose additional and widespread auditing obligations on MAOs. In its Draft Report, OIG suggests that CVS Health conduct comprehensive audits–not limited in any way to particular contracts or time frames–to find similar coding errors before, during, and after the audit period. This widespread auditing is not present in FFS Medicare. OIG itself has found similar error rates

[12] We also address in Section II how MAOs relied on CMS' representations concerning the application of a FFS Adjuster when implementing the Risk Adjustment Data Validation ("RADV") audits when submitting their Medicare bids during the audit period.
[13] 65 Fed. Reg. 40,170 at 40,268.
[14] *Id.* at 40265.
[15] Publication of the OIG's Compliance Program Guidance for Medicare Choice Organizations Offering Coordinated Care Plans at 61,900.
[16] *UnitedHealthcare Ins. Co. v. Azar et al.*, Final Brief for Appellants at p. 39.

in FFS Medicare,[17] yet no widespread audits occur. Given DOJ's representations that MAOs need only adopt the limited error correction present in FFS Medicare, it is arbitrary and capricious for OIG to demand more for MAOs. We note that in response to prior plan comments, OIG has indicated that notice and comment rulemaking was not required because "[n]o new requirements were imposed."[18] That is simply not true, and we ask OIG to address how its prior guidance supports its current recommendations.

OIG may point to the annual risk adjustment attestation to support its position that the widespread audits it proposes are required, yet this requirement lacks any specificity to support OIG's recommendations. While it is true that MAOs must certify, based on best knowledge, information and belief, that its risk adjustment data is accurate, that regulation does not specify that MAOs should conduct the widespread audits proposed–especially years after the attestation was made. OIG makes a similar mistake when citing ICD coding guidance or provisions in the Medicare Managed Care Manual. While the Medicare Managed Care Manual suggests that "all" risk adjustment data should be accurate,[19] it is arbitrary and capricious to cite this provision yet ignore citations that directly contradict government representations on the MA program, including statements by OIG itself.

OIG's recommendations of wide spread audits are new interpretations of these regulations with substantial financial and operational implications that should have gone through notice and comment rulemaking.[20] Under an express provision of the Medicare statute, any rule or requirement that "establishes or changes a substantive legal standard governing … the payment for services" under Medicare must first go through a process "afford[ing] the public notice and a chance to comment."[21] OIG's after-the-fact interpretation of these regulations violates this statute. Because OIG's Draft Report violates these prior government representations and imposes new auditing obligations on MAOs, it is arbitrary and capricious.

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[17] OIG, Incorrect Acute Stroke Diagnosis Codes Submitted By Traditional Medicare Providers Resulted in Millions of Dollars in Increased Payments to Medicare Advantage Organizations at p. 3.

[18] OIG, Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HealthAssurance Pennsylvania, Inc. (Contract H5522) Submitted to CMS, A-05-22-0020 at p. 24 (Sept. 2024) (available at https://oig.hhs.gov/documents/audit/10006/A-05-22-00020.pdf).

[19] Medicare Managed Care Manual, Chapter 7 – Risk Adjustment, Section 40 (rev. Sept. 19, 2014) (available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c07.pdf).

[20] *See Azar v. Allina Health Serv.*, 139 U.S. 1804, 1808, 1814 (2019); *see also Georgetown Univ. Hosp. v. Bowen*, 821 F.2d 750, 757 (D.C. Cir. 1987) (noting that retroactive rulemaking is prohibited under the Administrative Procedures Act absent explicit Congressional authorization); *Medcenter One Health Sys. v. Leavitt*, 666 F. Supp. 2d 1043 (D.N.D. 2009), *rev'd on other grounds sub nom. Medcenter One Health Sys. v. Sebelius*, 635 F.3d 348 (8th Cir. 2011).

[21] 42 U.S.C. § 1395hh(a)(2); *Allina Health Serv.*, 139 U.S. at 1808 (2019); *see also* Memorandum from Kelly M. Cleary, Deputy General Counsel and CMS Chief Legal Officer, on the Impact of *Allina* on Medicare Payment Rules at p. 2 (Oct. 31, 2019).

II. Because it applies more strict standards for MAOs and recommends substantive audits not present in FFS Medicare, OIG's Draft Report violates key requirements of the MA program, including actuarial equivalence.

Even setting aside OIG's prior representations, its Draft Report is inconsistent with current law and, as a result, is arbitrary and capricious. Here, we focus on MA regulations and their impact on OIG's findings and recommendations. To implement health-status risk adjustment, CMS begins with a base payment rate that reflects the expected cost of care for an average beneficiary in FFS Medicare. CMS then uses a statistical model to convert data from claims forms submitted by providers under original Medicare from a previous year into expected costs of coverage for patients with various cost-predictive diagnoses.[22] To allow CMS to calculate the health-status adjustment for each MA beneficiary, MAOs are required to submit health characteristics data—specifically, the diagnosis codes recorded by providers—of their individual enrollees.[23] Based on this data submitted by MAOs, CMS calculates individual enrollees' risk scores, which determine what the monthly payment for each enrollee must be to achieve actuarial equivalence when compared to the base payment rate.[24]

The overarching purpose of the risk-adjustment scheme, including adjusting for individual enrollees' different health statuses, is to "ensure actuarial equivalence" with original Medicare.[25] As one federal court put it, the requirement to adjust payments to MAOs for the health status of the beneficiaries they enroll "is designed to blunt [MAOs'] incentives to enroll only the healthiest, and thus least expensive, beneficiaries while steering clear of the sickest and costliest—thereby rewarding [MAOs] to the extent that they achieve genuine efficiencies over traditional Medicare in addressing the same health conditions."[26]

To achieve actuarial equivalence, what matters is *overall* payment accuracy. This is reflected in CMS' prior RADV audit methodology, which contemplates that the overreporting of some diagnosis codes is offset by the underreporting of others.[27] Thus, in conducting a RADV audit of the diagnosis data submitted by an MAO, CMS compares a "representative sample[]" of diagnosis codes to the medical records of the relevant beneficiaries to verify whether the diagnosis

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[22] *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 874 (D.C. Cir. 2021); *see* 42 U.S.C. § 1395w-23(a)(1)(C); 42 C.F.R. § 422.308(c).

[23] 42 C.F.R. § 422.310(b).

[24] *UnitedHealthcare*, 16 F.4th at 873-874; *Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*, 79 Fed. Reg. 1918, 2001 (Proposed Rule) (Jan. 10, 2014) (available at: https://www.federalregister.gov/documents/2014/01/10/2013-31497/medicare-program-contract-year-2015-policy-and-technical-changes-to-the-medicare-advantage-and-the).

[25] 42 U.S.C. § 1395w-23(a)(1)(C)(i).

[26] *UnitedHealthcare*, 16 F.4th at 875.

[27] Wakely Consulting Group, *Medicare RADV: Review of CMS Sampling and Extrapolation Methodology* (July 2018) (noting that the "Fiscal Year (FY) 2016 Department of Health and Human Services (HHS) Agency Financial Report … implies that supported but not reported coding errors represent a material offset to reported but unsupported coding errors.").

codes are supported by the underlying medical records.[28]

OIG's audit of CVS Health used a fundamentally different methodology. OIG did not build a representative sample of enrollee diagnosis codes from across the full range of reported diagnoses. Rather, "[u]sing data mining techniques and considering discussions with medical professionals," OIG identified diagnosis codes that were at particularly high risk of being miscoded in one direction—miscoding that generates alleged *over*payments—and consolidated these into ten high-risk diagnosis groups.[29] As OIG described its own audit methodology, the audit looked at enrollees for whom CVS Health received increased risk-adjusted payments for payment years 2018 and 2019, and "limited [its] review" to payments "that were associated with [the identified] high-risk diagnosis codes."[30]

Such deliberately one-sided reviews are unlikely to lead to an "accurate, complete and truthful" account of overall payment accuracy, as the Ninth Circuit recognized in the context of False Claims Act litigation.[31] Because OIG's validation of diagnosis data against the underlying medical records was limited to diagnoses codes that, in OIG's view, are particularly likely to have been miscoded, OIG's audit was unfairly skewed by its very design towards finding alleged overpayments. The audit findings therefore present an incomplete and misleading picture of the overall accuracy of the diagnosis data submitted.

As previously explained, CMS sets the risk-adjusted payment rates to MAOs by calculating the expected cost of coverage associated with various diagnoses and health characteristics. To do this, CMS applies a regression analysis "to the mass of [beneficiaries'] data from traditional Medicare for a previous year"–specifically, diagnosis codes for particular beneficiaries, which healthcare providers under original FFS Medicare are required to report to CMS, along with the cost of covering the relevant beneficiaries.[32] These reported diagnosis codes from providers under FFS Medicare inevitably contain some errors–perfect coding is impossible across such a large mass of data.[33] Diagnosis reports for outpatient care under Medicare Part B are also especially unreliable, since providers are paid based on the services they provide, not on the diagnosis codes they submit.[34] In contrast to the unaudited diagnosis data from original Medicare providers, OIG's Draft Report subjects MA data to strict and improper auditing standards.

Put simply, using *unaudited* data to determine risk adjustment rates while then using *audited* data to calculate extrapolated refunds (and ultimately determining payments to MAOs) disrupts actuarial equivalence between original FFS Medicare and MA. Specifically, the

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[28] *See United States ex rel. Ormsby v. Sutter Health*, 444 F.Supp.3d 1010, 1069 (N.D. Cal. 2020); *UnitedHealthcare*, 16 F.4th at 877.
[29] Draft Report at p. 7.
[30] *Id.* at 21.
[31] *See United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1175 (9th Cir. 2016).
[32] *UnitedHealthcare*, 16 F.4th at 874.
[33] *See UnitedHealthcare Ins. Co. v. Azar*, 330 F.Supp.3d 173, 179 (D.D.C. 2018), *rev'd in part on other grounds sub nom UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867.
[34] *Id.*

discrepancy between using unaudited data to develop the risk adjustment rates while using audited data to apply them will tend to systematically underpay MAOs. CMS itself has previously acknowledged that this process would disrupt actuarial equivalence. After it first proposed in 2010 to conduct RADV audits where it would extrapolate a contract-level repayment from the error rate found in the audited samples,[35] it issued a notice in 2012 announcing that, in performing the contract-level payment error extrapolation calculation, it would apply a FFS "adjuster" to account for the fact that "the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims)."[36]

Six years later, however, CMS published a proposed rule in which it signaled that it would *not* use the FFS adjuster because it had conducted a study that purportedly showed that "errors in FFS claims data do not have any systematic effect on the risk scores calculated by the … risk adjustment model, and therefore do not have any systematic effect on the payments made to MA organizations."[37]

In fact, CMS' study was fundamentally flawed. As Aetna's comment on the proposed rule explained, the CMS study "fail[ed] to address the fundamental data inconsistency issue (use of unaudited FFS data), relie[d] on flawed analysis premised on inappropriate data and methodological errors, [was] inconsistent with CMS's prior findings, and depart[ed] from core actuarial principles."[38] That comment showed the impact of the data inconsistency issue by asking CMS to:

> Consider a simplified, hypothetical example where all FFS beneficiaries move to an MA plan, and this represents all MA enrollment. In theory, the average risk score across all MA plan members, applying risk factors developed using unaudited FFS data, should be the same as the average risk score across all FFS beneficiaries (i.e., a "1.0") to maintain actuarial equivalence. If unsubstantiated diagnoses were

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[35] CMS, *Medicare Advantage Risk Adjustment Data Validation (RADV) Notice of Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audit – Request for Comment* (Dec. 21, 2010) (available at: https://www.cms.gov/files/document/radvsamplingpaymenterrordescriptionpdf).

[36] CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* at p. 4-5 (Feb. 24, 2012) (available at: https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/recovery-audit-program-parts-c-and-d/other-content-types/radv-docs/radv-methodology.pdf).

[37] *Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for years 2020 and 2021*, 83 Fed. Reg. 54,982, 55,040 (Proposed Rule) (Nov. 1, 2018) (available at: https://www.govinfo.gov/content/pkg/FR-2018-11-01/pdf/2018-23599.pdf).

[38] CMS-2018-0133-0259 (Sept. 5, 2019) (available at: https://www.regulations.gov/comment/CMS-2018-0133-0259).

> removed from the MA payments as part of RADV audits, and the FFS Adjuster were zero, MA beneficiary risk scores would average something less than 1.0, and the MA plan would be paid commensurately less despite enrolling the same population as the FFS program—an impermissible result that destroys the actuarial equivalence required by law.[39]

For any extrapolation of a contract-level overpayment to comply with the statutory actuarial equivalence requirement, therefore, an FFS adjuster must be applied. In fact, OIG's focus on "high-risk codes" doubles down on the actuarial equivalence problem. OIG's audit findings are largely the result of innocuous provider coding errors. Providers are not making these mistakes just for their MA patients; instead, these errors occur in FFS data as well. As an example, it is entirely illogical to believe a provider is accidentally coding an active stroke rather than a history of stroke *just for their MA patients.* As we discuss above, OIG's audit focus of so-called "high-risk" codes sets MAOs up to fail and is inherently designed to find errors. Because these errors occur in FFS data as well, OIG's approach of recommending refunds for MAOs *only* violates actuarial equivalence, and the impact is magnified upon extrapolation.

Despite Aetna's and others' comments, CMS finalized a rule in 2023 codifying that RADV audits will include extrapolation without an FFS adjuster (2023 Final Rule).[40] Perhaps recognizing the serious flaws in the study it relied on in the proposed rule, CMS did not rely on the study in the final rule, instead rationalizing the application of extrapolation without a FFS adjuster on two legal grounds. First, citing the D.C. Circuit's decision in *UnitedHealthcare Insurance Co. v. Becerra* concerning the Overpayment Rule,[41] CMS posited that the statutory actuarial equivalence requirement does not "apply to the obligation to return improper payments for MAO diagnosis codes that are unsupported by medical records."[42] Second, CMS pointed to the coding pattern adjustment mandated by the Medicare statute.[43] The coding pattern adjustment implements a downward adjustment of MA payment rates to account for differences in coding intensity between original FFS Medicare and MA, given that MAOs have a greater incentive to report diagnoses.[44] CMS asserted that the statute's mandate of a coding pattern adjustment supported its rejection of a FFS adjuster, because "it would be unreasonable to interpret the [Medicare statute] as requiring a minimum reduction in payments in one provision (the coding pattern provision), while at the same time prohibiting CMS in an adjacent provision (the actuarial equivalence provision) from enforcing … documentation requirements (by requiring an offset to the recovery amount calculated for CMS audits)."[45]

Neither of the two legal reasons CMS cited support omitting a FFS adjuster when

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[39] *Id.*
[40] 88 Fed. Reg. 6,643, 6,664 (Final Rule) (Feb. 1, 2023) (available at: https://www.govinfo.gov/content/pkg/FR-2023-02-01/pdf/2023-01942.pdf).
[41] *UnitedHealthcare*, 16 F.4th at 891-892.
[42] 88 Fed. Reg. at 6,656.
[43] 42 U.S.C. § 1395w-23(a)(1)(C)(ii).
[44] *See* 88 Fed. Reg. at 6,657.
[45] *Id.* at 6,657.

extrapolating a contract-level overpayment estimate. First, as the 2023 Final Rule itself recognized, "the D.C. Circuit did not address the RADV audit context in its decision in *UnitedHealthcare*."[46] Indeed, the D.C. Circuit expressly observed that "[c]ontract-level RADV audits … are an error-correction mechanism that is materially distinct from the Overpayment Rule" that was at issue in *UnitedHealthcare*.[47]

Second, that Congress has separately mandated a downward adjustment to MA payments to reflect differences in coding patterns between MA plans and providers under original Medicare does not undermine the necessity of a FFS adjuster to the maintenance of actuarial equivalence where a contract-level overpayment is extrapolated. CMS has itself previously recognized that the coding pattern adjustment "is not intended to address unsupported or inaccurate codes reported by MAOs in particular instances but only the general practice, relative to Medicare FFS, of reporting codes with greater intensity, including codes that are *nonetheless accurate*."[48] The FFS adjuster, by contrast, serves to maintain actuarial equivalence between FFS Medicare and MA given the inevitable level of *erroneous* coding in the unaudited data submitted by original Medicare providers. There is nothing incongruous about implementing a coding pattern adjustment in MA payment rates, while also applying a FFS adjuster to any extrapolation of a contract-level overpayment from the miscoding found in an audited sample. Nor does the application of an FFS adjuster prohibit CMS from enforcing documentation requirements in MAO submissions, as CMS seems to suggest; rather, the FFS adjuster simply ensures—as the actuarial equivalence mandate requires—that the enforcement of documentation standards in submitted diagnosis codes through audit activity does not disrupt actuarial equivalence between original Medicare and MA.

The 2023 Final Rule that codifies extrapolation in RADV audits without applying an FFS adjuster is thus contrary to law. It is also contrary to law for CMS to require CVS Health to refund the $7,217,966 OIG has estimated without applying a FFS adjuster. For the same reason, CVS Health has no legal obligation to comply with OIG's recommendation to refund the $7,217,966.

What is more, OIG's longstanding prior policy declined to engage in contract-wide extrapolation absent a FFS adjuster.[49] MAOs like CVS Health have developed strong reliance interests in connection with OIG's prior policy. OIG may not depart from its longstanding policy without providing good reasons for the change and without explaining why those reasons are

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

[47] *UnitedHealthcare*, 16 F.4th at 892.

[48] 88 Fed. Reg. at 6,657 (emphasis added); *see also Azar*, 330 F.Supp.3d at p. 188 (explaining that the coding pattern adjustment is not intended to account for "improper coding").

[49] *See* OIG, *Risk Adjustment Data Validation of Payments Made to PacifiCare of California for Calendar Year 2007 (Contract Number H0543)* at ii-iii (2012); OIG, *Bravo Health Pennsylvania, Inc. (Contract H3949), Submitted Many Diagnoses to the Centers for Medicare & Medicaid Services That Did Not Comply With Federal Requirements for Calendar Year 2007* at ii-iii (2013); OIG, *Cigna Healthcare of Arizona, Inc. (Contract H0354), Submitted Many Diagnoses to the Centers for Medicare & Medicaid Services That Did Not Comply With Federal Requirements for Calendar Year 2007* at ii-iii (2013).

sufficient to justify overriding CVS Health's reasonable reliance interests.[50] OIG's failure to provide any explanation for its change in policy makes its refund recommendation arbitrary and capricious.

Because the risk adjustment model balances codes that may be overreported–like the codes identified by OIG–with those that may be underreported, extrapolation under a RADV audit should necessarily consider amounts OIG recommended in extrapolated refunds. We note that in response to prior Plan comments, OIG has disputed this assertion–it is wrong. As just one example, in the 2024 Advanced Notice setting MA reimbursement, CMS indicated that it was applying Principle 10 (an actuarial principle the risk adjustment model is based upon) to remove or reduce the weight of particular conditions that were subject to coding variation in the industry.[51] CMS explained that, because some codes appeared to be overreported, it was adjusting the relative reimbursement to account for coding variation:

> As there is variation in the coding of discretionary conditions – meaning that the coding of these conditions is likely not consistent across the industry – including them in the risk adjustment model can lead to distortion of the marginal costs estimated by the model, reducing the ability of the HCCs in the model to predict stable costs and accurately predict those costs in alignment with the severity of the condition.
>
> With a focus on principle 10, CMS identified a number of diagnoses and condition categories that we determined should be reclassified based on both relative coding in MA versus in FFS and based on clinical input regarding the degree of discretion to code each condition. Specifically, in consultation with clinician input regarding appropriate classification of identified conditions, this reclassification involved moving some discretionary diagnosis codes from condition categories included in the CMS-HCC model to condition categories not included in the model, removing from the model several condition categories that do not accurately predict the projected cost of a beneficiary, and constraining HCCs to be equal to each other so that they carry the same weight in the risk score.[52]

In other words, the risk adjustment is designed–and indeed recalibrated annually–to account for codes that may be overreported. Not only does this suggest OIG's focus on "high-risk codes" improperly tips the statistical scale for the risk adjustment model, *OIG may in fact be double counting* refund amounts where the model already adjusts the rates for overreported codes on the front end. We note, as an example, reimbursement for vascular disease was significantly curtailed in the 2024 Advanced Notice. If, as OIG recommends, a Plan conducts expansive audits for vascular disease, it will necessarily be double counting overpayment amounts because CMS has

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[50] *See DHS v. Regents of the Univ. of Cal.*, 140 U.S. 1891, 1913 (2020); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-516 (2009).

[51] Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies at p. 47-48 (Feb. 1, 2023) (available at: https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf).

[52] *Id.* at p. 48.

already accounted for potential over-coding when setting the rates.

OIG's skewed methodology toward finding alleged overpayments is made clear by the overwhelming tendency for OIG audits to determine that a large proportion of the audited diagnosis codes were unsupported. For example, in over twenty similar OIG audits, OIG found that for a majority of reviewed enrollee-years, the submitted diagnosis codes were not supported by the underlying medical records. Indeed, in many of these audits, OIG found that the vast majority of diagnosis codes it reviewed—more than 80% or even 90% in some audits—were unsupported.[53] OIG's apparent finding of the same high levels of miscoding of the same diagnosis codes in data submitted by multiple MAOs demonstrates that the design of OIG's audit methodology is flawed, not that there is rampant miscoding in the industry.

We highlight that OIG's audit of FFS data found that "[a]lmost all of the selected acute stroke diagnosis codes that physicians submitted to CMS under traditional Medicare—codes that CMS later used to make payments to MA organizations … on behalf of the 582 transferred enrollees—did not comply with Federal requirements."[54] Although even in OIG's estimation these errors occur in FFS Medicare, OIG recommends audits only for MAOs knowing similar audits do not occur in FFS Medicare. This violates actuarial equivalence and representations from the DOJ that MA error correction is limited only to "the same type of limited error correction that is present throughout Medicare."[55] As a result, OIG's recommendations regarding contract-level overpayment violates actuarial equivalence between MA and original Medicare and are arbitrary and capricious.

We ask OIG to explain how its recommendations that MAOs conduct comprehensive audits aligns with adjustments outlined in the rate notices setting up MA plans. This issue is entirely distinct from the actuarial equivalence argument OIG typically fails to address and it would be arbitrary and capricious to issue a recommendation knowing duplicative adjustments are already being made. Even assuming OIG's extrapolation recommendations are consistent with Medicare regulations, it is premature for CVS Health to take any action upon OIG's extrapolated refund recommendation.

In its Draft Report, OIG identified a total of $815,980 in alleged overpayments from what it determined were incorrectly submitted diagnosis codes among the sampled enrollee-years.[56] On

[53] *See* OIG, Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS (Mar. 2023) (finding that for 224 of the 270 sampled enrollee-years, the medical records did not support the diagnosis codes submitted); OIG, Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS (July 2023) (finding that for 202 of the 210 sampled enrollee-years, the medical records did not support the diagnosis codes submitted); OIG, Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS (Aug. 2023) (finding that for 198 of the 211 sampled enrollee-years, the medical records did not support the diagnosis codes submitted).

[54] Incorrect Acute Stroke Diagnosis Codes Submitted By Traditional Medicare Providers at p. 4.

[55] *UnitedHealthcare Ins. Co.*, 2020 WL 4544757 at * 39.

[56] Draft Report at 2.

the basis of these sample results, OIG used extrapolation to estimate that CVS Health received $7,217,966 in overall alleged overpayments during the audit period.[57] OIG recommended that CVS Health refund that amount to the federal government.[58] If CMS requires CVS Health and other MAOs to refund these inflated overpayment estimates, MAOs will end up being systematically underpaid, further disrupting actuarial equivalence. To make matters worse, OIG audits only a small portion of MA plans, placing audited MAOs and their enrollees at a disadvantage relative to unaudited plans.

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

CVS Health has submitted a list of enrollee-years for OIG to reconsider, as instructed by OIG at the exit conference. We summarize the clinical and coding issues in Exhibit B and ask OIG to reverse its findings concerning these enrollee-years.

IV. OIG's audit process was unfair, arbitrary and capricious, and contrary to law.

A. OIG's audit methodology and coding standards were not promulgated through notice-and-comment rulemaking as required by statute.

As we highlight above, any rule or requirement that "establishes or changes a substantive legal standard governing … the payment for services" under Medicare must first go through a process "afford[ing] the public notice and a chance to comment."[59] If CMS were to enforce OIG's recommended recoupment of $7.2 million, then OIG's underlying review standards would constitute requirements or policies establishing substantive legal standards governing the payment for services. But neither the ICD Coding Guidelines, nor the Manual, nor presumably any of the other unknown standards that OIG applied during its audit, have been promulgated by notice-and-comment rulemaking. Accordingly, it would be contrary to law for them to serve as substantive legal standards that govern payment for services.[60]

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[57] *Id.*

[58] *Id.*

[59] 42 U.S.C. § 1395hh(a)(2); *Allina Health Serv.*, 139 U.S. at 1808 (2019); *see also* Memorandum from Kelly M. Cleary, Deputy General Counsel and CMS Chief Legal Officer, on the Impact of *Allina* on Medicare Payment Rules at p. 2.

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

B. OIG's approach of treating disagreements between senior coders as ties to be resolved by a coding supervisor was arbitrary and capricious.

According to OIG's own description of the independent medical review contractor's coding review process, as set forth in Appendix A of its draft report, if the first senior coder did not find support for the diagnosis coded by the treating physicians in relevant medical records, a second senior coder would perform a separate review of the same medical records. If the second senior coder also did not find support, the diagnosis code was considered to be not validated. If instead the second senior coder found support, then the split between the two senior coders would be resolved by a coding supervisor, who would review the medical records at issue to make the final determination.[61] In other words, when the independent medical review contractor's coders split on the question of whether the diagnoses were supported, the split was treated as a tie that was resolved by using the coding supervisor's determination to break the tie. Instead of applying this tie-breaker rule, OIG should instead have followed a policy of deferring to the code submitted by the treating physician.

The lack of weight given to the diagnosis made and coded by the treating physician is arbitrary and capricious because the treating physician has more medical education and training than the reviewing coders and coding supervisors, and more importantly had a more direct interaction with the patient. Where the second coder agrees with the treating physician's coded diagnosis, the diagnosis code should be validated. OIG's tie-breaker rule fails to give appropriate deference to the judgment of the treating physician and is, for that reason, arbitrary and capricious.

C. In estimating an alleged contract-level overpayment, OIG used a less statistically sound confidence interval than CMS, without giving a reason for this choice.

In explaining the methodology it used to extrapolate an alleged estimated contract-level overpayment, OIG revealed that it placed the estimate at "the lower limit of the two-sided 90-percent confidence interval."[62] In using that lower limit, OIG departs from the more statistically sound approach of using the lower limit of a 99% confidence interval that CMS follows in its RADV audits.[63] It is arbitrary and capricious for OIG to use a less statistically sound method than CMS, without providing any reasoned explanation for doing so.

D. OIG selected audit years that created a data validation problem for CVS Health.

OIG audited payment years 2018 and 2019, which means that the audited service years began in 2017 (7 years ago) and ended in 2018 (6 years ago). CVS Health took all reasonable

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[61] Draft Report.

[62] Draft Report at 26.

[63] CMS, HHS Risk Adjustment Data Validation (HHS-RADV) White Paper at p. 6 (Dec. 6, 2019) (available at: https://www.cms.gov/files/document/2019-hhs-risk-adjustment-data-validation-hhs-radv-white-paper.pdf); Milliman, *Medicare Advantage RADV FFS Adjuster: White Paper* (Aug. 23, 2019) (available at: https://us.milliman.com/-/media/milliman/importedfiles/ektron/medicare_advantage_radv_ffs_adjuster_8-23-2019.ashx).

steps to ensure that records for the audit period were available for use by not only OIG but also CVS Health itself. For example, CVS Health complied with the requirement under 42 C.F.R. § 422.504(d)(2) that its provider contracts include a provision obligating the provider to retain "records" for a minimum timeframe of 10 years. CVS Health also exhausted all reasonable efforts to obtain records in the possession, custody, or control of its contracted providers. But CVS Health does not control all actions by its contracted providers. And in the past 6 years, some of those providers have ceased to exist, or failed to meet their contractual obligation to retain records, or encountered *force majeure* events that resulted in the loss of records. The loss of records prevented CVS Health from retrieving medical record support for physician diagnosis coding that was undisputedly authentic. Yet OIG did not give CVS Health the benefit of the doubt. The choice by OIG to audit distant years, coupled with circumstances outside the control of CVS Health, combined to further slant the audit towards finding alleged overpayments.

E. OIG barred CVS Health from reopening audit years and identifying underpayments.

The audit sought to identify only overpayments, and OIG went so far as to instruct CVS Health to flag only the page numbers and text of the medical records directed by OIG. OIG did not reopen the audit period to allow CVS Health to identify underpayments. Indeed, OIG declined to even review vast segments of the medical records containing factual support for diagnoses that treating physicians should have submitted and did not. The result was to eliminate or reduce the offsetting of overreported codes with underreported codes and generate an alleged overpayment.

F. OIG's audit process was narrowly prescriptive in ways that were arbitrary and capricious.

OIG directed CVS Health to support the diagnoses in the enrollee-years in the audit sample by providing the specific medical record support for the diagnosis code including the specific PDF page number and specific text for any supporting inpatient records. Outpatient records were not subject to the same instruction. The instruction turned the process into a hunt for specific words in the inpatient records and impeded CVS Health's efforts to show how the diagnoses were supported by the records as a whole.

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

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

The physicians who initially treat MA enrollees are the ones who diagnose MA enrollees by evaluating the available information about the enrollee and applying clinical judgment. Subsequent treating physicians may make different diagnoses at later points in time, when more information is available. Regardless of what an initial or subsequent treating physician

recommends for treatment, the enrollee is the one who ultimately decides whether to accept and act on the recommendation. The enrollee may reject his/her physician's recommendation for physical, mental, philosophical, or financial reasons that have nothing to do with the physician's underlying diagnosis. Alternatively, the enrollee may accept the recommendation, and choose to implement it through new and different providers or coverage or funding mechanisms for reasons that likewise have nothing to do with the physician's underlying diagnosis. Neither the decisions by the enrollee nor the conclusions drawn by any subsequent treating physicians render invalid the underlying diagnosis by the physician who recommended the treatment to the enrollee. OIG, however, relied on such facts—as well as OIG's own *post hoc* clinical preferences—to find that diagnoses by treating physicians in the sample were unsupported.

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

V. CVS Health does not concur with OIG's recommendation to refund $7.2 million in extrapolated alleged overpayments because that estimate is flawed, and OIG has no statutory authority to make that recommendation.

OIG also lacks authority to apply extrapolation in its audits of MAOs. In fact, CMS may also lack that authority—HHS previously conceded that CMS lacked such authority when it sought legislation that would give it that authority.[64] In a 2023 final rule,[65] HHS amended the RADV audit regulation—without any intervening legislation—to provide for recovery from MAOs of improper payments "in accordance with the Secretary's payment error extrapolation and recovery methodologies," specifying that "CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years."[66] The preamble to the final rule explained this change in position by asserting that the authority to use sampling and extrapolation in Medicare audits is "grounded in [HHS's] statutory and regulatory authority to audit providers and recoup improper payments," without identifying any specific statutory provisions that authorize the recoupment of estimated alleged overpayments based on the extrapolation of a contract-wide overpayment from the alleged overpayment rate found in a sample.[67]

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[64] *See Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations for 2011: Hearings Before the H.R. Comm. on Appropriations*, 111th Cong. pt. 7, at 14 (2010) (written statement of HHS Deputy Secretary William Corr); CMS, Fiscal Year 2011 Performance Budget, p. 177 (2010) (describing proposal that would "[c]larify in statute that CMS can extrapolate the error rate found in the [RADV] audits to the entire MA plan payment for a given year when recouping overpayments.") (available at: https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/downloads/cmsfy11cj.pdf).

[65] 88 Fed. Reg. at 6,665 (Feb. 1, 2023).

[66] 42 C.F.R. § 422.311(a)(1)-(2); *see also* 42 C.F.R. § 422.310(e).

[67] *Id.* at 6,648.

Even supposing that CMS has authority to apply extrapolation in RADV audits because it is so authorized by HHS regulations, and that HHS has been delegated rulemaking authority by Congress,[68] this does not authorize *OIG* to apply extrapolation in its payment audits of MAOs. First, the RADV audit regulation specifically provides that "*CMS* may apply extrapolation to audits"; it does not delegate authority to OIG to apply extrapolation in the audits that it separately carries out.[69] Second, OIG's asserted authority to conduct RADV audit activity, the IG Act,[70] does not delegate to OIG the authority to use extrapolation in its audits. While the IG Act does authorize the HHS OIG to "conduct and supervise audits and investigations relating to the programs and operations" of HHS,[71] it does not delegate the specific authority to use extrapolation in its payment audits of MAOs. Given Congress's silence on OIG's authority to extrapolate from its audit findings, OIG may not do so because an agency "may only take action that Congress has *authorized*," not merely any action that "Congress has not *prohibited*."[72]

OIG's lack of lawful authority to extrapolate a contract-level overpayment from its audit sample findings is not cured simply by framing its determination of a contract-level alleged overpayment as a "recommendation" addressed to CMS. In its Draft Report, OIG emphasizes that its "audit recommendations do not represent final determinations"; rather, CMS "will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures."[73] But the substance of OIG's recommendation remains that CVS Health should refund a contract-level alleged overpayment arrived at by extrapolating from the findings of its audit. OIG had no authority to extrapolate from its audit findings in the first place. And while OIG suggests that CMS will apply its own policies and procedures in determining how much it will recoup from CVS Health, OIG presumably does not expect that CMS will conduct its own, duplicative, RADV audit. OIG must expect CMS to largely ratify its extrapolated alleged overpayment finding even though OIG – and arguably CMS – lacks the authority to do so. Finally, OIG's framing of its extrapolated alleged overpayment as a mere recommendation does nothing

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[68] *See* 42 U.S.C. § 1302(a); 42 U.S.C. § 1395hh(a)(1).
[69] 42 C.F.R. § 422.311(a)(2).
[70] HHS has itself stated that OIG's statutory authority to conduct payment audits of MAOs is the IG Act. *See Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*, 79 Fed. Reg. 29,844, 29,934 (May 23, 2014) (available at: https://www.federalregister.gov/documents/2014/05/23/2014-11734/medicare-program-contract-year-2015-policy-and-technical-changes-to-the-medicare-advantage-and-the).
[71] 5 U.S.C. § 402(b)(1); *see also* 5 U.S.C. § 404(a)(1).
[72] *Bais Yaakov of Spring Valley v. FCC*, 852 F.3d 1078, 1082 (D.C. Cir. 2017).
[73] Draft Report at 20. Similarly, in previous audit reports, OIG has insisted that it is not itself collecting any refund of overpayments but simply making a recommendation to CMS, asserting that "action officials at CMS – not OIG – will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures." OIG, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Aetna, Inc. (Contract H5521) Submitted to CMS*, A-01-18-00504 (Oct. 2023) (available at: https://oig.hhs.gov/documents/audit/5851/A-01-18-00504-Complete%20Report.pdf).

to mitigate the confusion of the public or the reputational harm to CVS Health from OIG's finding of an alleged overpayment of more than $7.2 Million.

VI. While CVS Health does not concur with OIG's recommendation regarding its compliance program, it will nevertheless look for ways to evaluate and improve its MA compliance program.

CVS Health has invested tremendous time, effort, and resources into advancing its compliance program. These compliance procedures include provider attestation protocols, provider education, a chart review program, corrective action plans for providers that continue to submit inaccurate coding, and a Special Investigations Unit designed to detect and investigate a wide range of fraud, waste, and abuse. Notwithstanding CVS Health's robust efforts, OIG concluded that CVS Health's compliance procedures during the audit period "could be improved."[74]

CVS Health engages in continuous process improvement across its MA operations, and its compliance program is no exception. The compliance program has evolved greatly in the 6 years since the audit period ended to take into account OIG's audit findings as well other issues that have arisen in the industry. OIG's conclusion that CVS Health's compliance program "could be improved" was also based on its finding that there was an elevated level of error in the audited sample.[75] But, as CVS Health has already explained, OIG's audit methodology was, by design, skewed to finding alleged overpayments. OIG's stated reason for concluding that CVS Health's compliance program requires improvement is thus untenable.

While, for the reasons stated, CVS Health does not concur with OIG's recommendation to take further steps to enhance its compliance program, it remains committed to continuous process improvement and will continue, where appropriate, to look for and implement improvements to its compliance program in the future. We thank OIG for the opportunity to respond to its Draft Report.

[74] *Id.* at 16.
[75] *Id.*

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