Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE ADVANTAGE COMPLIANCE AUDIT OF SPECIFIC DIAGNOSIS CODES THAT HEALTHASSURANCE PENNSYLVANIA, INC. (CONTRACT H5522) SUBMITTED TO CMS

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

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HealthAssurance Pennsylvania, Inc. (Contract H5522) Submitted to CMS

Why OIG Did This Audit

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations according to a system of risk adjustment that depends on the health status of each enrollee. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources than to healthier enrollees who would 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 diagnosis codes are at higher risk for being miscoded, which may result in overpayments from CMS.

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

How OIG Did This Audit

We selected a stratified random sample of 269 unique enrollee-years with the high-risk diagnosis codes for which HealthAssurance (administered by Aetna, a CVS Health company) received higher payments for 2018 and 2019. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $966,561.

What OIG Found

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that HealthAssurance submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 222 of the 269 sampled enrollee-years, the medical records that HealthAssurance provided did not support the diagnosis codes and resulted in $657,744 in overpayments.

As demonstrated by the errors found in our sample, HealthAssurance'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 HealthAssurance received at least $4.2 million in overpayments for 2018 and 2019.

What OIG Recommends and HealthAssurance Comments

We recommend that CVS Health: (1) refund to the Federal Government the $4.2 million in overpayments; (2) identify, for the high-risk diagnoses included in the report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and (3) continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for us in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

HealthAssurance, through CVS Health, disagreed with some of our findings, did not concur with our recommendations, and provided additional explanations for certain sampled enrollee-years. HealthAssurance disagreed with our audit methodology and our overpayment estimation methodology. HealthAssurance also stated that our recommendation to identify similar instances of noncompliance does not align with Federal requirements and that its compliance program satisfies all legal and regulatory requirements.

After reviewing HealthAssurance's comments and the explanations it provided, we reduced the number of enrollee-years in error and revised the amount in our first recommendation. We maintain that our second and third recommendations remain valid.

The full report can be found on the OIG website.

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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 HealthAssurance Pennsylvania, Inc. (HealthAssurance), for contract number H5522 and focused on nine groups of high-risk diagnosis codes for payment years 2018 and 2019.[3]

OBJECTIVE

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

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

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

[3] HealthAssurance is a Medicare Advantage plan administered by Aetna, a CVS Health company. All subsequent references to "HealthAssurance" in this report refer solely to contract number H5522. We are addressing our recommendations to CVS Health.

BACKGROUND

Medicare Advantage Program

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

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

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

Risk Adjustment Program

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

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

- *Base rate*: Before the start of each year, each MA organization submits bids to CMS that reflect the MA organization's estimate of the monthly revenue required to cover an enrollee with an average risk profile.[6] CMS compares each bid to a specific benchmark amount for each geographic area to determine the base rate that an MA organization is paid for each of its enrollees.[7]

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

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

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

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

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

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

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

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

The risk adjustment program is prospective. Specifically, CMS uses the diagnosis codes that the enrollee received for one 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.

[8] During our audit period CMS calculated risk scores based on the Version 22 CMS-HCC model for payment year 2018 and Version 23 CMS-HCC model for payment year 2019.

CMS multiplies the risk scores by the base rates to calculate the total monthly Medicare payment that an MA organization receives for each enrollee before applying the budget sequestration reduction.[9] Thus, if the factors used to determine an enrollee's risk score are incorrect, CMS will make an improper payment to an MA organization. Specifically, if medical records do not support the diagnosis codes that an MA organization submitted to CMS, the HCCs are not validated, which causes overstated enrollee risk scores and overpayments from CMS.[10] Conversely, if medical records support the diagnosis codes that an MA organization did not submit to CMS, validated HCCs may not have been included in enrollees' risk scores, which may cause those risk scores to be understated and may result in underpayments.

High-Risk Groups of Diagnoses

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

- *Acute stroke*: An enrollee received one acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on 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 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 a myocardial infarction (which does not map to an HCC) typically should have been used.

- *Embolism*: An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease With Complications (Embolism HCCs) 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

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

[10] 42 CFR § 422.310(e) requires MA organizations (when undergoing an audit conducted by the Secretary) to submit "medical records for the validation of risk adjustment data." For purposes of this report, we use the terms "supported" or "not supported" to denote whether 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.

indication that the provider is evaluating a prior acute embolism diagnosis, which does not map to an HCC) typically should have been used.

- *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.

- *Sepsis:* An enrollee received one sepsis diagnosis (that mapped to the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock) on 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[11] that either mapped to the HCC for Pressure Ulcer of Skin with Full Thickness Skin Loss or the HCC for Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone (Pressure

[11] Pressure ulcer diagnoses are categorized into five groups according to severity: stages 1, 2, 3, 4, and unstageable. For this audit, we only audited the most severe types of pressure ulcers: stages 3, 4, and unstageable.

Ulcer HCCs) on only one claim during the service year but did not have a pressure ulcer diagnosis on another inpatient, outpatient, or physician claim for either the calendar year before or the calendar year after the service year. Individuals diagnosed with the most severe types of pressure ulcers generally receive treatment on multiple occasions.

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

HealthAssurance

HealthAssurance is an MA Preferred Provider Organization based in Harrisburg, Pennsylvania. As of December 2019, HealthAssurance provided coverage under contract number H5522 to 72,153 enrollees. For the 2018 and 2019 payment years (audit period), CMS paid HealthAssurance approximately $1.45 billion to provide coverage to its enrollees.[12, 13]

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of the nine high-risk groups during the 2017 and 2018 service years, for which HealthAssurance 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 2,411 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes ($5,575,916). We selected for audit a stratified random sample of 269 enrollee-years as shown in Table 1 on the next page.

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

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

Table 1: Sampled Enrollee-Years

High-Risk Group	Number of Sampled Enrollee-Years
(1) Acute stroke	30
(2) Acute myocardial infarction	30
(3) Embolism	30
(4) Lung cancer	30
(5) Breast cancer	30
(6) Colon cancer	30
(7) Prostate cancer	30
(8) Sepsis	30
(9) Pressure ulcer	29
Total for All High-Risk Groups	**269**

HealthAssurance provided medical records as support for the selected diagnosis codes associated with the 269 sampled enrollee-years. We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. For the HCCs that were not validated, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or if we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

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

FINDINGS

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that HealthAssurance submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 47 of the 269 sampled enrollee-years, the medical records validated the reviewed HCCs. However, for the remaining 222 enrollee-years, the diagnosis codes were not supported in the medical records and resulted in $657,744 in overpayments.

As demonstrated by the errors found in our sample, HealthAssurance'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 HealthAssurance received at least $4.2 million in overpayments for 2018 and 2019.[14]

FEDERAL REQUIREMENTS

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

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

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

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).

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

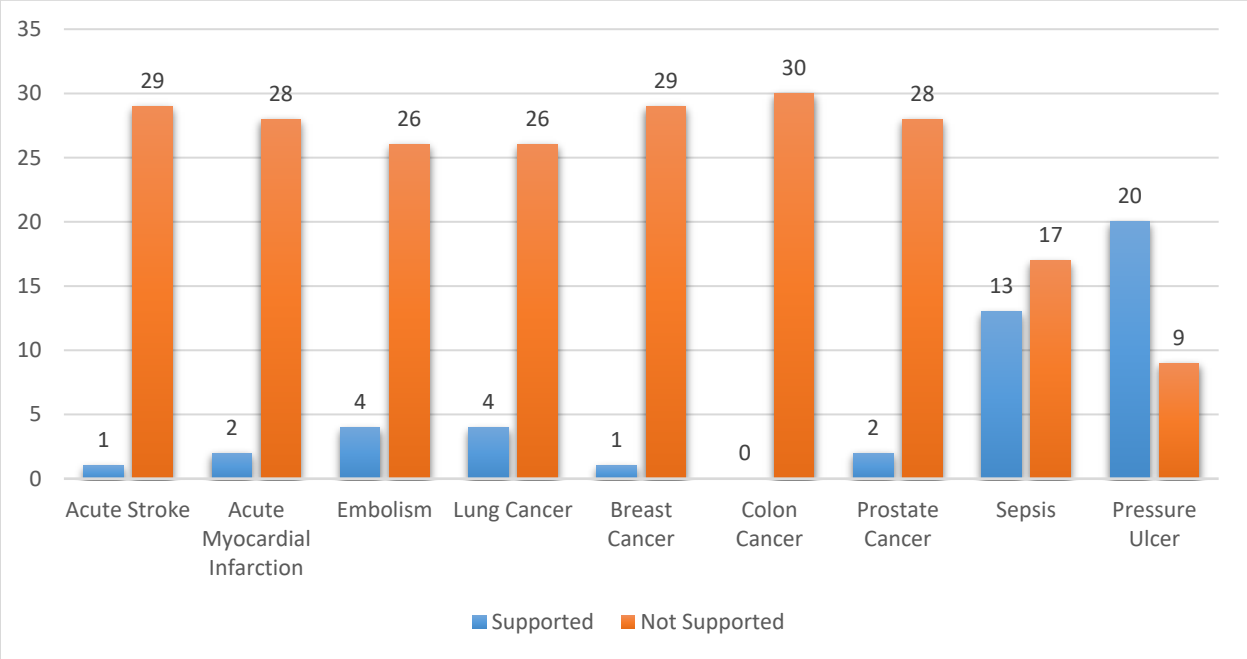
[14] To be conservative, we estimate overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

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

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

Most of the selected high-risk diagnosis codes that HealthAssurance submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, as shown in the figure below, the medical records for 222 of the 269 sampled enrollee-years did not support the diagnosis codes. In these instances, HealthAssurance should not have submitted the diagnosis codes to CMS and received the resulting overpayments.

Figure: Analysis of High-Risk Groups



Incorrectly Submitted Diagnosis Codes for Acute Stroke

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

- For 22 enrollee-years, the medical records indicated in each case that the individual had previously had a stroke, but the records did not justify an acute stroke diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no 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."[15]

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

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of an acute cerebrovascular accident that results in the assignment of the HCC [for Ischemic or Unspecified Stroke]. There is documentation of a transient ischemic attack (TIA) [diagnosis] which does not result in an HCC."[16]

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and HealthAssurance received $46,312 in overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Myocardial Infarction

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

- For 13 enrollee-years, the medical records indicated in each case that the individual had previously had an acute myocardial infarction, but the records did not justify an acute myocardial infarction 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 Acute Myocardial Infarction]. There is documentation of a past medical history of myocardial infarction [diagnosis] that does not result in an HCC."

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

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

- For the remaining 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 for another diagnosis that mapped to an HCC for a less severe

[15] Cerebrovascular accident is the medical term for a stroke. A stroke is when blood flow to a part of the brain is stopped either by a blockage or the rupture of a blood vessel.

[16] A transient ischemic attack is a temporary period of symptoms similar to those of a stroke.

manifestation of the related-disease group. Accordingly, HealthAssurance 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.

As a result of these errors, the HCC for Acute Myocardial Infarction was not validated, and HealthAssurance received $52,064 in overpayments for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

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

- For 14 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not justify a diagnosis that mapped to an Embolism HCC at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Vascular Disease]. There is documentation of a past medical history of deep vein thrombosis [diagnosis] that does not result in an HCC."[17]

- For the remaining 12 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Embolism HCC.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC [for Vascular Disease]. [The] provider has documented that the enrollee does not have a prior history of pulmonary embolism. No current condition either was documented."[18]

As a result of these errors, the Embolism HCCs were not validated, and HealthAssurance received $73,985 in overpayments for these 26 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

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

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

[18] A pulmonary embolism is a blood clot that blocks and stops blood flow to an artery in the lung.

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

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that 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] that does not result in an HCC."

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

  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 lung mass (diagnosis) which does not result in an HCC. There was also documentation of 'likely' terminal carcinoma that cannot be coded as confirmed based on coding guidelines."[19]

- For the remaining 4 enrollee-years, the medical records in each case did not support a lung cancer diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis on CMS's systems that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, HealthAssurance 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 HealthAssurance received $197,559 in overpayments for these 26 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

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

- For 26 enrollee-years, the medical records indicated in each case that the individual had previously had breast cancer, but the records did not justify a breast cancer diagnosis at the time of the physician's service.

  For example, 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] that does not result in an HCC."

[19] A lung mass is an abnormal growth or area in the lungs that is more than 3 centimeters in diameter.

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

  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]."

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and HealthAssurance received $41,787 in overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

HealthAssurance incorrectly submitted diagnosis codes for colon cancer for all 30 of the sampled enrollee-years. Specifically:

- For 24 enrollee-years, the medical records indicated in each case that the individual had previously had colon cancer, but the records did not justify a colon cancer diagnosis at the time of the physician's service.

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

- For 4 enrollee-years, the medical records in each case did not support the submitted colon cancer diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis on CMS's systems 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, HealthAssurance should not have received an increased payment for the submitted colon cancer diagnoses. Rather, it should have received a lesser increased payment for the other diagnosis identified.

- For the remaining 2 enrollee-years, the medical records in each case did not support a colon cancer diagnosis.

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

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and HealthAssurance received $71,794 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

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

- For 26 enrollee-years, the medical records indicated in each case that the individual had previously had prostate cancer, but the records did not justify a prostate cancer diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that 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] that does not result in an HCC."

- For 2 enrollee-years, the medical records in each case did not support a prostate cancer diagnosis.

  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]."

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and HealthAssurance received $41,079 in overpayments for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Sepsis

HealthAssurance incorrectly submitted diagnosis codes for sepsis for 17 of 30 sampled enrollee-years. Specifically:

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

  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 documentation of a concern for sepsis [diagnosis] with patient treatment for pneumonia, [however the] inpatient record never establishes the patient as septic." HealthAssurance did not include a sepsis diagnosis on an inpatient claim that it submitted to CMS.

- For 3 enrollee-years, the medical records indicated in each case that the individual had previously had sepsis, but the records did not justify 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 documentation of a past medical history of sepsis [diagnosis] that does not result in an HCC."

As a result of these errors, the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock was not validated, and HealthAssurance received $58,283 in overpayments for these 17 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Pressure Ulcer

HealthAssurance incorrectly submitted diagnosis codes for pressure ulcer for 9 of 29 sampled enrollee-years. Specifically:

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

  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 Pressure Ulcer of Skin with Full Thickness Skin Loss]. There is documentation of pressure ulcer of left hallux, Stage II (diagnosis) which does not result in an HCC."

- For 3 enrollee-years, the medical records in each case did not support the submitted pressure ulcer diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to the HCC for a less severe manifestation of the related-disease group. Accordingly, HealthAssurance should not have received an increased payment for the submitted pressure ulcer diagnoses. Rather, it should have received a lesser increased payment for the other diagnosis identified.

As a result of these errors, the Pressure Ulcer HCCs were not validated, and HealthAssurance received $74,883 in overpayments for these 9 sampled enrollee-years.

Summary of Incorrectly Submitted Diagnosis Codes

In summary and with respect to the nine high-risk groups covered by our audit, HealthAssurance received $657,744[20] in overpayments for 222 of the 269 sampled enrollee-years.

[20] The high-risk group overpayments do not sum to the total overpayments due to rounding.

THE POLICIES AND PROCEDURES THAT HEALTHASSURANCE 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 HealthAssurance 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.

As part of its preventative measures, HealthAssurance requires that its providers attest to the risk adjustment data that they submit. As a part of this process, HealthAssurance requires that its providers submit accurate, complete, and truthful risk adjustment data; correct any inaccurate risk adjustment data; and provide prompt notification to HealthAssurance of any inaccurate risk adjustment data. HealthAssurance also requires that its providers participate in its training and coding education and complete an annual Medicare compliance training that, according to HealthAssurance, complies with CMS guidance.

As part of its detection and correction measures, HealthAssurance has implemented a chart review program in which it flags claims for diagnosis codes that may not comply with Federal requirements, including some of the "high-risk" diagnosis codes that we identified in this report. HealthAssurance compares the diagnosis codes on the claims to the associated medical records and, if necessary, submits deletions (for the diagnoses) to CMS in accordance with CMS requirements. HealthAssurance's legal and compliance team also analyzes these coding reviews and provides appropriate education and training to its providers. Further, HealthAssurance said that it implements corrective action plans for providers that continue to submit inaccurate coding, and it may terminate the provider's contract if issues persist. HealthAssurance also has a Special Investigations Unit designed to detect and investigate a wide range of fraud, waste, and abuse. As a result of these audits, HealthAssurance stated that it has conducted onsite meetings with providers to discuss their coding; in one case, a provider was terminated.

We acknowledge that HealthAssurance has compliance procedures that include measures designed to ensure that diagnosis codes, including some of the diagnoses that we classified as high risk for being miscoded, comply with Federal requirements. However, because we found that 232 of the 269 sampled enrollee-years were not supported by medical records, we believe that these procedures, as they relate to diagnoses that are at high risk for being miscoded, could be improved.

HEALTHASSURANCE RECEIVED OVERPAYMENTS

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that HealthAssurance received at least $4,256,568 in overpayments for our audit period.

RECOMMENDATIONS

We recommend that CVS Health:

- refund to the Federal Government the $4,256,568 of estimated overpayments;[21]

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

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

HEALTHASSURANCE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, HealthAssurance, through CVS Health, did not agree with some of our findings and did not concur with our recommendations. Specifically, HealthAssurance did not agree with our findings for 15 of the 232 enrollee-years in error in our draft report. For these 15 enrollee-years, HealthAssurance explained why the medical records it originally provided to us validated the reviewed HCCs.[22] HealthAssurance did not state whether it agreed or disagreed with our findings for the HCCs related to the remaining 217 enrollee-years.

HealthAssurance stated that it did not concur with our recommendations "because they arise from an audit process that was flawed and at odds with Congress's directives regarding the MA risk-adjustment scheme." HealthAssurance stated that we used a one-sided audit methodology that was skewed to find alleged overpayments and that it did not agree with our overpayment estimation methodology. Additionally, HealthAssurance stated that our recommendation to identify similar instances of noncompliance does not align with Federal requirements. Lastly, HealthAssurance did not concur with our recommendation regarding its compliance program but stated that it will look for ways to evaluate and improve its MA program.

[21] 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 RADV appeals process.

[22] These explanations were included in an attachment to its comments. We excluded that attachment from this report because it contained personally identifiable information. We are separately providing HealthAssurance's comments and attachments in their entirety to CMS.

After considering HealthAssurance's comments, we reduced the number of enrollee-years in error from 232 to 222 and adjusted our calculation of estimated overpayments. Accordingly, we reduced the recommended refund in our first recommendation from $4,429,546 to $4,256,568 for this final report. We made no changes to our second and third recommendations.

A summary of HealthAssurance's comments and our responses follows. HealthAssurance's comments are included as Appendix F.

HEALTHASSURANCE DID NOT CONCUR WITH OIG'S RECOMMENDATION THAT HEALTHASSURANCE REFUND ESTIMATED OVERPAYMENTS

HealthAssurance Did Not Agree With OIG's Findings for 15 Sampled Enrollee-Years

HealthAssurance Comments

HealthAssurance did not agree with our draft report findings for 15 sampled enrollee-years (as shown in Table 2) and explained that the medical records it provided to us validated the reviewed HCCs.[23]

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

High-Risk Group	Number of Sampled Enrollee-Years
(1) Acute stroke	1
(2) Acute myocardial infarction	2
(3) Prostate cancer	1
(4) Lung cancer	2
(5) Sepsis	6
(6) Pressure ulcer	3
Total for All High-Risk Groups	**15**

For the 15 sampled enrollee-years, HealthAssurance maintained that the diagnosis codes were supported based on the providers' clinical documentation and coding.

OIG Response

Our independent medical review contractor reviewed the explanations that HealthAssurance provided for these 15 enrollee-years.

[23] HealthAssurance also provided explanations as to why it believed an HCC that was for a less severe manifestation of disease should be included in the enrollee's risk score; however, that HCC was not within the scope of our audit.

- For 5 of the 15 enrollee-years, our contractor reaffirmed that the audited HCCs were not validated.
- For the remaining 10 enrollee-years, our contractor found support for the audited HCCs and therefore validated the HCCs. These validations included:
    - 1 enrollee-year from the acute myocardial infarction high-risk group. For this enrollee-year, our contractor stated "[t]here is documentation of non-ST elevation myocardial infarction (NSTEMI) [diagnosis] for which the patient underwent tests, resulting in HCC [Acute Myocardial Infarction]."
    - 1 enrollee-year from the Prostate Cancer high-risk group. For this enrollee-year, our contractor stated "[t]here is documentation of a diagnosis of prostate cancer which results in HCC [Breast, Prostate, and Other Cancers and Tumors]."
    - 2 enrollee-years from the Lung Cancer high-risk group. For both of these enrollee-years, our contractor stated '[t]here is documentation of a diagnosis of lung cancer which results in HCC [Lung and Other Severe Cancers]."
    - 4 enrollee-years from the Sepsis high-risk group. Our contractor stated that, for 3 of the enrollee-years "[t]here is documentation of a diagnosis of Sepsis which results in HCC [Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock]." For the remaining enrollee-year, our contractor stated "[t]here is documentation of septic shock due to pneumonia which results in HCC [Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock]."
    - 2 enrollee-years from the Pressure Ulcer high-risk group. For 1 of the enrollee-years, our contractor stated "[t]here is documentation of a stage 3 pressure ulcer of other site which results in HCC [Pressure Ulcer of Skin with Full Thickness Skin Loss]." For the other enrollee-year, our contractor stated "[t]here is documentation of a diagnosis of pressure ulcer of the toe, stage 3, which results in HCC [Pressure Ulcer of Skin with Full Thickness Skin Loss]."

Accordingly, we reduced the number of enrollee-years in error from 232 (in our draft report) to 222 for this final report. We also revised our findings and reduced the associated monetary recommendation. Our independent medical review contractor confirmed that HealthAssurance's written comments and additional explanations had no impact on the decisions that it made for other sampled enrollee-years and stated that there were no "systemic issues identified" in its reviews.

HealthAssurance Stated That OIG's Audit Methodology Is Inconsistent With the Medicare Statute's Requirement To Ensure Actuarial Equivalence Between Fee-for-Service Medicare and the Medicare Advantage Program

HealthAssurance Comments

HealthAssurance said OIG's "one-sided" audit methodology of limiting our review to payments that were associated with high-risk diagnosis codes is skewed to finding alleged overpayments. HealthAssurance 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 HealthAssurance, actuarial equivalence means that "CMS must reimburse an [MA organization] the same amount for each enrollee that it would expect to pay to cover that enrollee in [fee-for-service] FFS Medicare." HealthAssurance said, "[t]o achieve this goal of actuarial equivalence, what matters is *overall* payment accuracy," where "the overreporting of some diagnosis codes is offset by the underreporting of others."

In this respect, HealthAssurance 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 it believes were at particularly high risk of being miscoded in one direction," generating alleged overpayments. To these points, HealthAssurance also stated "OIG's failure to account for actuarial equivalence results in a systematic underpayment to [MA organizations] … [that] will undermine the overall goals of the risk-adjustment scheme, disrupting actuarial equivalence between MA and original Medicare…."

OIG Response

We agree with HealthAssurance in that we designed our audit to review diagnosis codes that were at high risk for being miscoded. However, and with respect to HealthAssurance's statement that our audit methodology failed to account for actuarial equivalence, we note that our audit methodology was designed and executed to accomplish our audit objective. This methodology included calculating any overpayments in accordance with CMS's risk-adjustment payment requirements. To this point, CMS has not issued any requirements that compelled us to reduce our 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.

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,[24] we do not agree with HealthAssurance's assertion that underreported and overreported diagnosis codes offset each other to achieve overall payment accuracy. Further, these requirements do

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

not prohibit audits of specific diagnosis codes, especially for diagnoses that we have determined to be at high risk for being miscoded.

HealthAssurance Stated That OIG's Extrapolation of a Contract-Level Overpayment Destroys Actuarial Equivalence Between Medicare Advantage and Original Medicare

HealthAssurance Comments

HealthAssurance said that "OIG's audit and recommendations go against the Medicare statute's express mandate to 'ensure actuarial equivalence'." According to HealthAssurance, CMS sets the risk-adjusted payment rates to MA organizations using FFS data that inevitably contain errors (incorrect diagnosis codes). To this point, HealthAssurance stated, "[i]n contrast to the unaudited diagnosis data from original Medicare providers, [OIG]. . . subjects MA data to strict and improper auditing standards." Specifically, HealthAssurance 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." In this respect, HealthAssurance stated that "if CMS requires [HealthAssurance] and other [MA organizations] to refund these inflated overpayment estimates, [MA organizations] will end up being systematically underpaid, further disrupting actuarial equivalence."

To demonstrate its position, HealthAssurance provided a chronology of CMS's actions that eventually resulted in a final rule in 2023, "codifying in regulation that RADV audits will include extrapolation without an FFS adjuster." However, HealthAssurance stated that it disagreed with that final rule and cited recent litigation to support its disagreement. HealthAssurance further stated that it believes that CMS's final rule is contrary to law and it "has no legal obligation to comply with OIG's recommendation to refund the [$4.4 million]."

Finally, HealthAssurance stated that "CMS has not provided any guidance on how it may extrapolate RADV and OIG audits to avoid duplication."

OIG Response

Regarding HealthAssurance's statement that we did not ensure actuarial equivalence in our overpayment calculations, our audit methodology correctly applied CMS requirements to properly identify the overpayment amount associated with the unvalidated HCCs for each sampled enrollee-year. Specifically, we used the results of the independent medical review contractor's review to determine which HCCs were not validated and, in some instances, to identify HCCs that should have been used but were not used in the associated enrollees' risk score calculations. We followed CMS's risk adjustment program requirements to determine the payment that CMS should have made for each enrollee and to estimate overpayments. 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 overpayments.[25] In the context of CMS's requirements and updated guidance, including the 2023 Final Rule, we recognize that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program.

In regard to the possibility of duplication between RADV and OIG audits, OIG has a process to send the sampling frame to CMS to ensure that OIG and CMS do not select the same enrollees for our audits.

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

HealthAssurance Comments

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

- HealthAssurance stated that "OIG failed to disclose information critical for [HealthAssurance] to evaluate the determinations made by the medical record review contractor." HealthAssurance requested that OIG identify the independent medical review contractor and disclose the assessments made by the contractor's coders at initial levels of review.

  HealthAssurance also said that OIG did not disclose the coding standards used in its audit. HealthAssurance stated that it lacks sufficient information to assess OIG's audit determinations and requested information on how the independent medical review contractor applied the ICD Coding Guidelines, including whether the contractor augmented those guidelines with additional coding resources.

- HealthAssurance 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, HealthAssurance 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.

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

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

of $4.4 million, then OIG's underlying medical records review standards would constitute requirements or polices 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." HealthAssurance stated that it would be contrary to law for this guidance to serve as substantive legal standards that govern payment for services.

OIG Response

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

- It is not our practice to name our independent medical review contractor. Identifying our contractor by name would not provide information about our contractor's qualifications beyond what we state in this audit report. Furthermore, during the course of the audit, we informed HealthAssurance that our medical reviews were performed by professional coders credentialed by the American Health Information Management Associations (AHIMA) and the American Academy of Professional Coders (AAPC).[26] These coders were experienced in coding ICD-10 diagnosis codes for hospital inpatient, outpatient, and physician medical records.

  With regard to HealthAssurance's assertion that we did not disclose our coding standards (specifically, medical record review standards), we provided HealthAssurance with a document explaining our medical review process. Our independent medical review contractor reviewed each medical record that HealthAssurance provided in conformance with CMS's risk-adjustment program to determine whether support existed for a diagnosis code that mapped to the audited HCC. Experienced senior coders performed these reviews and in doing so used the following coding and documentation standards: (1) CMS's *Contract-Level Risk Adjustment Data Validation*

[26] Our independent medical review contractor used senior coders all of whom possessed on or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS, Certified Coding Specialist – Physician Based (CCS-P), Certified Professional Coder (CPC), CPC-Instructor, and Certified Risk Adjustment Coder (CRC0. RHITs have completed a 2-year degree program and have passed an AHIMA certification exam. AHIMA also credentials individuals with CCS and CCS-P certifications, and the AAPC credentials both CPCs and CRCs. This information also appears in a footnote in Appendix A of both our draft and final reports.

Medical Record Reviewer Guidance,[27] (2) *ICD-10-CM Official Guidelines for Coding and Reporting*,[28] and the AHA Coding Clinic for ICD-10-CM and ICD-10-PCS.[29]

- We disagree with HealthAssurance'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 HealthAssurance provided does not constitute creation of a new payment rule. Rather, we designed our audit to determine whether HealthAssurance 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 HealthAssurance'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.[30] HealthAssurance 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.

- We disagree with HealthAssurance'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.

[27] CMS, Contract-Level Risk Adjustment Validation Medical Record Reviewer Guidance As of 9/27/17. Accessed on May 1, 2024.

[28] ICD-10-CM Official Guidelines for Coding and Reporting.

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

[30] 42 CFR §§ 422.504(a) and 422.310(b).

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

HealthAssurance Comments

HealthAssurance stated that "[i]n estimating an alleged contract-level overpayment, OIG uses a less statistically sound confidence interval than CMS, without giving a reason for this choice." HealthAssurance 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." HealthAssurance 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 HealthAssurance's comment that our use of a lower confidence interval, 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 HealthAssurance for the enrollee-years and time period covered in our sampling frame. This approach, which is routinely used by HHS for recovery calculations,[31] results in a lower limit (the estimated overpayment amount) that is designed to be less than the actual overpayment total 95 percent of the time.

HealthAssurance Stated That It Could Not Adequately Assess OIG's Sampling and Extrapolation Methodology

HealthAssurance Comments

HealthAssurance stated that "OIG failed to disclose information that is critical for [HealthAssurance] to be able to evaluate OIG's sampling and extrapolation methodology." In addition, it also stated that "OIG failed to disclose a breakdown of the data exclusions applied as well as the selection process of the nine 'high-risk' groups." HealthAssurance further stated that OIG "failed to explain how many unique [enrollees] compose each [stratum], why the

[31] 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).

sample for each stratum was limited to 30, and what statistical assumptions were made to support these choices."

OIG Response

We disagree that we did not provide HealthAssurance with sufficient information and data to assess our sampling and extrapolation methodology.

To ensure the accuracy of the data, at our request, HealthAssurance validated the sampling frame. We asked HealthAssurance to ensure that the individuals were enrolled during all 12 months of the relevant service year and at least January of the relevant payment year. We also asked HealthAssurance to validate whether the enrollees had an HCC in their risk scores for the relevant high-risk groups. After HealthAssurance performed its validation, both HealthAssurance and our additional analyses identified enrollees who did not meet our sampling frame definitions. We removed those enrollees, finalized our sampling frame, and selected our sample of enrollee-years. Subsequent to receiving HealthAssurance's comments on our draft report, we sent copies of all of our sampling information to them.

We chose the audited nine high-risk groups because the HCCs were relevant to the audit objective and to the services provided by HealthAssurance during the audit period. In addition, we did not review unique enrollees in each stratum. As explained in the "How We Conducted This Audit" section of this report, because enrollees could be classified in more than one high-risk group or 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."

Regarding HealthAssurance's question, "why the sample for each stratum was limited to 30," we note that the estimate of overpayments ($4,256,568) was based upon the overall sample size of 269, and we chose a stratum size of 30 because it was a reasonable number to accomplish our objective. Small sample sizes, e.g., smaller than 100, have routinely been upheld by the Departmental Appeals Board and Federal courts. Additionally, the legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.[32] As detailed in Appendix C, we properly executed a statistically valid 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.

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

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

HealthAssurance Comments

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

- OIG's selection of "distant" audit years created a data validation problem because the "loss of [medical] records [by some providers] prevented [HealthAssurance] from retrieving medical record support for physician diagnosis coding that was undisputedly authentic."

- OIG instructed it "to flag only the page numbers and text of the medical records [as] directed by [the] OIG." HealthAssurance 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." In addition, OIG's instructions for HealthAssurance 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 [HealthAssurance's] efforts to show how the diagnoses were supported by the records as a whole." HealthAssurance further stated that "OIG's prescriptive approach was arbitrary and capricious and further skewed the audit in favor of identifying alleged overpayments."

- OIG used pharmacy data to "populate" its sample but "would not permit [HealthAssurance] to use any pharmacy data to show that diagnos[i]s codes were supported."

- OIG "acted arbitrarily and capriciously by overriding physician diagnoses based on subsequent treatments, patient choices, and OIG's clinical preferences." Specifically, HealthAssurance 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 HealthAssurance's statements that aspects of our audit were slanted in favor of finding alleged overpayments.

- We disagree with HealthAssurance'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 HealthAssurance to submit or update claims for new diagnoses until January 31, 2020. We started our audit in 2022. We initially provided a reasonable period—5 months—for HealthAssurance to submit medical records for the

audited HCCs and worked with HealthAssurance officials during our audit to extend the medical record collection timeframe to account for any collection difficulties. HealthAssurance provided the bulk of its medical records in 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, HealthAssurance did not convey to us that it had confronted any extraordinary circumstances for which it was not able to provide us medical records.

- We believe that our methodology of identifying which portions of the medical records to review was reasonable to accomplish our audit objective. We did not ask our independent medical review contractor to review the pages of the medical records outside of those flagged. Each of the sampled enrollee-years had one claim with a diagnosis that was at high risk for being miscoded. We asked HealthAssurance to provide the medical records for those claims and, at its option, up to four other medical records as support for the audited HCC for each enrollee-year. Because the claims associated with these additional medical records—when HealthAssurance initially submitted them to CMS—did not have a diagnosis code that mapped to the audited HCC, we asked HealthAssurance to flag the page number of the medical record for which it believed support existed for the relevant diagnosis.

- We agree with HealthAssurance that we used pharmacy data, specifically prescription drug event data, as a means to identify enrollee-years for our sampling frame with diagnoses that were at high risk for being miscoded. However, to determine whether the associated HCC was validated, we only reviewed the medical records that conformed to CMS's requirements (inpatient, outpatient, or physician records) as support for the audited HCC.

- Our independent medical review contractor did not override the treating physicians' diagnoses. Instead, our contractor separately reviewed each medical record that HealthAssurance provided to us to determine whether support existed for a diagnosis that mapped to audited HCCs. As explained in our audit methodology (Appendix A), this coding review followed a specific process for which our contractor used both skilled senior coders and coding supervisors. For the HCCs that were not validated, if our contractor identified a diagnosis code that should have been submitted to CMS instead of the diagnosis code that was submitted, or if we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related disease group, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments. This process was not arbitrary and capricious; rather, it was reasonable to accomplish our audit objective.

HealthAssurance Stated That OIG Had No Statutory Authority To Extrapolate Overpayments

HealthAssurance Comments

HealthAssurance stated that it "does not concur with OIG's recommendation to refund $4.4 million in extrapolated alleged overpayments because that estimate is flawed, and OIG has no statutory authority to make that recommendation."

HealthAssurance stated that "OIG also lacks authority to apply extrapolation in its audits of [MA organizations]." HealthAssurance said that "In 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.'" HealthAssurance 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…."

HealthAssurance 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 IG Act, does not delegate to OIG the authority to use extrapolation in its audits." Furthermore, HealthAssurance 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 [HealthAssurance] from OIG's finding of an alleged overpayment …."

Additionally, HealthAssurance stated that OIG failed to show that it accounted for the "lesser increased payments" for diagnoses that mapped to HCCs for less severe manifestations of the related disease groups, "either in its statement of the alleged overpayments for sampled enrollee years, or the extrapolated alleged overpayment estimate."

OIG Response

HealthAssurance'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. As stated previously, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare. 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.

Regarding HealthAssurance's comment that we did not account for "lesser increased payments," we used the results of our independent medical review contractor's review to determine which HCCs were not validated and, in some instances, to identify HCCs that should have been used but were not used in the associated enrollee's risk score calculations. If our contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC in our calculation of overpayments and the resulting estimate. We followed CMS's risk adjustment program requirements to determine the payment that CMS should have made for each enrollee and to estimate overpayments.

HEALTHASSURANCE DID NOT CONCUR WITH OIG'S RECOMMEDATION TO PERFORM ADDITIONAL REVIEWS OF HIGH-RISK DIAGNOSIS CODES FOR THE YEARS BEFORE AND AFTER THE AUDIT PERIOD

HealthAssurance Comments

HealthAssurance stated that it "does not concur with OIG's recommendation to perform what amounts to a self-audit of high-risk diagnosis codes for the years before and after the audit period." HealthAssurance said that OIG cited Federal requirements and regulations that require MA organizations: (1) to certify the accuracy, completeness, and truthfulness of the risk-adjustment data they submit (42 CFR § 422.504(l)) and (2) to set up "an effective compliance program" to "prevent, detect, and correct non-compliance with CMS' program requirements" (42 CFR § 422.503(b)(4)(vi). HealthAssurance said that "while [HealthAssurance] remains committed to an effective compliance program, 42 CFR § 422.503(b)(4)(vi) does not establish any legal obligation for [HealthAssurance] to comply with OIG's recommendation to engage in extensive self-auditing of the diagnosis codes designated as high risk by OIG."

OIG Response

We do not agree with HealthAssurance'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." However, contrary to HealthAssurance'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)).

These Federal regulations state that MA organizations must "implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS's program requirements." Further, the regulations specify that HealthAssurance'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.

We believe that the error rates identified in this report demonstrate that HealthAssurance 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.

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

HealthAssurance Comments

HealthAssurance 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 program." HealthAssurance said that it was pleased that we acknowledged that, during the audit period, it had in place "compliance procedures that include measures designed to ensure that diagnosis codes, including some of the diagnoses that [OIG] classified as high risk for being miscoded, comply with Federal requirements." HealthAssurance also 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, HealthAssurance also stated that while it "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."

OIG Response

We did not review the evolution of HealthAssurance's compliance program. We limited our review to selected diagnoses that we determined to be at high risk for being miscoded for our audit period. Our audit revealed a significant error rate (222 of 269 enrollee-years). (See Appendix D.) We acknowledge that HealthAssurance 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 HealthAssurance 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 HealthAssurance's compliance program could be improved. The continued improvement of procedures will assist HealthAssurance in attaining better assurance with regard to the accuracy, completeness, and truthfulness of the risk adjustment data that it submits in the future. Accordingly, we maintain that our recommendation to examine HealthAssurance's existing compliance procedures is valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid HealthAssurance $1,449,071,237 to provide coverage to its enrollees for 2018 and 2019. We identified a sampling frame of 2,411 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2017 and 2018 service years. HealthAssurance received $37,209,200 in payments from CMS for these enrollee-years for 2018 and 2019. We selected for audit 269 enrollee-years with payments totaling $4,547,456.

The 269 enrollee-years included 30 acute stroke diagnoses, 30 acute myocardial infarction diagnoses, 30 embolism diagnoses, 30 lung cancer diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, 30 prostate cancer diagnoses, 30 sepsis diagnoses, and 29 pressure ulcer diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $966,561 for our sample.

Our audit objective did not require an understanding or assessment of HealthAssurance's complete internal control structure, and we limited our review of internal controls to those directly related to our objective.

We performed audit work from June 2022 through December 2023.

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,
    - 17 diagnosis codes for lung cancer,
    - 54 diagnosis codes for breast cancer,

- 10 diagnosis codes for colon cancer,
- 1 diagnosis code for prostate cancer,
- 30 diagnosis codes for sepsis, and
- 50 diagnosis codes for pressure ulcer.

- We used CMS's systems to identify the enrollee-years on whose behalf providers documented the high-risk diagnosis codes. Specifically, we used extracts from CMS's:

  - Risk Adjustment Processing System (RAPS)[33] and the Encounter Data System (EDS)[34] to identify enrollees who received high-risk diagnosis codes from a physician during the service years,

  - Risk Adjustment System (RAS)[35] to identify enrollees who received an HCC for the high-risk diagnosis codes,

  - Medicare Advantage Prescription Drug System (MARx)[36] to identify enrollees for whom CMS made monthly Medicare payments to HealthAssurance before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C),

  - EDS[37] to identify enrollees who received specific procedures, and

  - Prescription Drug Event (PDE) file[38] to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.

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

- We selected for audit a stratified random sample of 269 enrollee-years (Appendix C).

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

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

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

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

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

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

- We used an independent medical review contractor to perform a coding review for the 269 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.[39]

- 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(s), 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.

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

[39] 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 calculated the recommended recovery amount in accordance with CMS's regulations that limit the use of extrapolation in RADV audits for recovery purposes.[40]

- We discussed the results of our audit with HealthAssurance officials on December 11, 2023.

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.

[40] Federal regulations at 42 CFR § 422.311(a) state: "[T]he Secretary conducts RADV audits to ensure risk-adjusted payment integrity and accuracy. (1) Recovery of improper payments from MA organizations is 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"

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
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	10/2/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS	A-07-20-01197	8/3/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS	A-07-20-01202	7/10/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. (Contract H3952) Submitted to CMS	A-03-20-00001	5/31/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS	A-05-19-00013	4/4/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring Life & Health Insurance Company, Inc. (Contract H4513) Submitted to CMS	A-07-19-01192	3/28/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS	A-02-20-01008	3/24/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS	A-09-21-03011	3/16/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Cigna-HealthSpring of Tennessee, Inc. (Contract H4454) Submitted to CMS	A-07-19-01193	12/22/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BCBS of Rhode Island (Contract H4152) Submitted to CMS	A-01-20-00500	11/16/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That California Physician's Service, Inc. (Contract H0504) Submitted to CMS	A-09-19-03001	11/10/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract R5826) Submitted to CMS	A-05-19-00039	9/30/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (H3916) Submitted to CMS	A-03-19-00001	9/29/2022

Report Title	Report Number	Date Issued
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS	A-07-19-01195	9/29/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS	A-09-20-03009	9/13/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc., (Contract H1032) Submitted to CMS	A-04-19-07084	8/29/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS	A-02-20-01009	7/18/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health Network (Contract H1961) Submitted to CMS	A-06-18-05002	5/25/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS	A-01-19-00500	2/14/2022

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified HealthAssurance enrollees who: (1) were continuously enrolled in HealthAssurance 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 a high-risk diagnosis during 2017 or 2018 that caused an increased payment to HealthAssurance for 2018 or 2019, respectively.

We presented the data for these enrollees to HealthAssurance 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 HealthAssurance. After we performed these steps, our finalized sampling frame consisted of 2,411 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 of nine strata of enrollee-years. For the enrollee-years in each respective stratum, each individual received:

- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on only one physician claim during the service year but did not have an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim (747 enrollee-years);

- a 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 (387 enrollee-years);

- a diagnosis (that mapped to an Embolism HCC) on only one claim during the service year but did not have an anticoagulant medication dispensed on his or her behalf (157 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 (100 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 (388 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 (145 enrollee-years);

- a prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors), for an individual 74 years old or younger, on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (305 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 (153 enrollee years); or

- a pressure ulcer diagnosis that mapped to a Pressure Ulcer HCC (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) on only one claim during the service year but did not have a pressure ulcer diagnosis on another inpatient, outpatient, or physician claim for either the calendar year before or the calendar year after the service year (29 enrollee-years).

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

Table 3: Sample Design for Audited High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee-Years	CMS Payment for HCCs in Audited High-Risk Groups	Sample Size
1 – Acute stroke	747	$1,517,058	30
2 – Acute myocardial infarction	387	765,233	30
3 – Embolism	157	437,732	30
4 – Lung cancer	100	768,887	30
5 – Breast cancer	388	504,094	30
6 – Colon cancer	145	368,743	30
7 – Prostate cancer	305	397,043	30
8 – Sepsis	153	531,008	30
9 – Pressure ulcer	29	286,118	29
Total	**2,411**	**$5,575,916**	**269**

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 the enrollee-year (a combination of the enrollee identifier and the year being reviewed), 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 amount of overpayments to HealthAssurance at the lower limit of the two-sided 90-percent confidence interval (Appendix D). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Details and Results

Audited High-Risk Groups	Frame Size	CMS 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	Overpayments for HCCs That Were Not Validated (for Sampled Enrollee-Years)
1 – Acute stroke	747	$1,517,058	30	$48,495	29	$46,312
2 – Acute myocardial infarction	387	765,233	30	62,803	28	52,064
3 – Embolism	157	437,732	30	85,524	26	73,985
4 – Lung cancer	100	768,887	30	222,133	26	197,559
5 – Breast cancer	388	504,094	30	43,360	29	41,787
6 – Colon cancer	145	368,743	30	75,786	30	71,794
7 – Prostate cancer	305	397,043	30	43,645	28	41,079
8 – Sepsis	153	531,008	30	98,697	17	58,283
9 – Pressure Ulcer	29	286,118	29	286,118	9	74,883
Total	**2,411**	**$5,575,916**	**269**	**$966,561**	**222**	**$657,744**[41]

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

Point estimate	$4,547,712
Lower limit	4,256,568
Upper limit	4,838,856

[41] The stratum amounts do not sum to the total amount due to rounding.

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: HEALTHASSURANCE COMMENTS

CVSHealth.

Sheri L. Fulcher
Regional Inspector General for Audit Services
Office of Audit Services, Region V
233 North Michigan, Suite 802
Chicago, Illinois, 60601

April 12, 2024

Re: Office of Inspector General's (OIG) Draft Report No. A-05-22-00020

Dear Ms. Fulcher:

CVS Health Corporation, on behalf of its several subsidiaries offering Medicare Advantage plans (collectively, "CVS Health"), writes to respond to the Office of Inspector General's Draft Report No. A-05-22-00020 concerning the audit of Contract H5522. We thank OIG for its collaboration throughout the audit process and for recognizing the tremendous work CVS Health puts into its compliance efforts. Still, we believe OIG's Draft Report reflects a skewed and improper approach to the risk adjustment program, and we respectfully ask OIG to revise its Draft Report as set forth below.

OIG's Draft Report ignores the realities of the risk program. Medicare Advantage Organizations (MAOs) submit tens of millions of encounter data submissions annually. OIG's Draft Report departs from longstanding CMS guidance recognizing the volume of data submitted, including confirmations from CMS that Medicare Advantage 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."[1] We note that OIG found similar error rates in each of the 20 OIG audits of other MAOs highlighted in its Draft Report–an indication that OIG's audit reveals more about the Medicare Advantage risk adjustment system than CVS Health's compliance and auditing programs.

Acknowledging that perfect coding is not feasible or required, the risk adjustment model is not designed to predict actual costs or conditions for particular enrollees. Instead, the model assumes that some codes will be overreported while others will be underreported. The model balances these competing effects to ensure that reimbursement will be appropriate *overall*. OIG's findings and extrapolation on codes it views as "high risk" for miscoding defeats the balancing that the risk adjustment model is intended to achieve and ignores the statistical modelling built into the program. Ultimately, this approach violates actuarial equivalence—a statutory requirement for the risk adjustment program.

In short, Medicare regulations require that CMS reimburse MAOs in a manner that ensures actuarial equivalence with Fee-for-Service (FFS) Medicare. Put simply, CMS must reimburse an MAO the same amount for each enrollee that it would expect to pay to cover that enrollee in FFS

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

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CVSHealth.

Medicare. OIG's Draft Report never addresses this key requirement of the risk adjustment program. This flaw runs through each of OIG's recommendations, from its alleged overpayment findings based on strict documentation standards not found in FFS Medicare to its recommendation that CVS Health conduct comprehensive audits that are neither feasible nor required.

Setting aside our concerns about OIG's Draft Report, we share OIG's fundamental goal of ensuring MA enrollees receive efficient and effective care. We recognize the need to be good stewards of Medicare funds, and we have invested tremendous efforts into improving our compliance and auditing programs. We offer providers education and training on OIG's targeted conditions and proactively identify providers in need of training. We have also incorporated OIG's analytics into our own auditing protocols, and we will continue to critically evaluate our program in response to OIG's findings. Nonetheless, we disagree with OIG's audit approach and recommendations in the Draft Report as we set forth in Attachment A to this letter.

Sincerely,

Patrick Jeswald
Vice President
Chief Compliance Officer, Medicare

CVSHealth.

Exhibit A

CVS Health, through its subsidiaries, offers Medicare Advantage (MA) plans under Contract H5522 with the Centers for Medicare & Medicaid Services (CMS), the agency within the U.S. Department of Health and Human Services (HHS) charged with administering the MA program. The HHS Office of Inspector General (OIG) audited selected diagnosis codes from service years 2017 and 2018 that CVS Health submitted to CMS for use in determining risk adjustment payments for beneficiaries of CVS Health's MA plans in payment years 2018 and 2019.

CVS Health does not concur with OIG's recommendations because they arise from an audit process that was flawed and at odds with Congress's directives regarding the MA risk-adjustment scheme. To appreciate how far afield OIG's recommendations would take the MA program, some context is helpful. The MA program is an increasingly popular choice for seniors. More than half of all Medicare beneficiaries choose MA plans rather than Fee-for-Service (FFS) Medicare. The MA program has succeeded because it helps 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 Medicare Advantage Organizations (MAOs) like CVS Health.

Under the MA program, CMS makes fixed monthly payments to MAOs for each enrollee.[2] 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.[3] 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.[4] 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 OIG's documentation standards: while FFS Medicare claims are largely unaudited, OIG's Draft Report subjects MA data to far higher standards, second guessing physicians in a manner that CMS does not do for FFS claims. As an example, 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 history of stroke—OIG would reduce reimbursement to the MA Plan while the FFS diagnosis remains unaudited. Extrapolating these errors across an entire contract only compounds the actuarial equivalence issue.

Second, we ask OIG to consider the role of MA plans in the risk adjustment program. MA plans submit tens of millions of risk adjustment submissions annually. Ultimately, the vast

[2] 42 U.S.C. § 1395w-23(a)(1)(A), (A)(1)(B); 42 C.F.R. § 422.304(a).
[3] 42 U.S.C. § 1395w-23(a)(1)(C); 42 C.F.R. § 422.308(c)(1).
[4] 42 U.S.C. § 1395w-23(a)(1)(C)(i).

majority of risk adjustment submissions are driven by provider coding—not coding by the MA plan. Providers are human and, at times, make mistakes. It is not feasible or required that MA plans review every provider submission to ensure accuracy. This has been emphasized repeatedly by CMS, OIG, and DOJ. As an example, CMS has indicated 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."[5]

The disconnect between OIG's Draft Report and this guidance is highlighted by OIG's approach for claims from the emergency department (ED). Although ED physicians often operate with limited information and must guard against potential complications, for at least 4 samples, OIG ruled that a valid diagnosis submitted by an ED physician was unsupported simply because a *later* inpatient admission ruled out the condition. Obviously, the ED physician may not have had the benefit of tests or symptoms noted after the member left the ED. Still, OIG's expectation is that MAOs request and review inpatient claims for all ED visits to determine whether appropriately billed emergency room diagnoses were invalidated by later inpatient stays. That approach is not feasible or required by CMS regulations.

At its core, the risk adjustment model was not intended to predict the actual health status or expenses for individual enrollees. The model assumes that, while some codes may be overreported, others will be underreported. Actuarial equivalence requires that reimbursement to MAOs will be accurate *overall*. OIG's focus on highly specific coding ignores the balancing the risk adjustment model is intended to achieve. To monitor whether risk-adjustment data is consistent with this overall accuracy standard, CMS has long conducted risk adjustment data validation (RADV) audits where CMS reviews a representative sample of diagnosis codes against the underlying medical records.[6] OIG's audit methodology was strikingly different from the approach used in CMS's RADV audits, however. Instead of auditing a representative sample of diagnosis codes submitted by CVS Health during the audit period, OIG focused its review exclusively on specific coding scenarios that it deemed high risk, thus skewing its audit to finding alleged overpayments. This impact is even more pronounced given OIG's recommendation that CVS Health refund an *extrapolated* amount. An audit designed to produce errors by definition is not a representative sample appropriate for statistical extrapolation.

I. OIG's audit methodology is inconsistent with the Medicare statute's requirement to ensure actuarial equivalence between FFS Medicare and the MA program.

A. While CMS performs RADV audits to check for overall payment accuracy, OIG's one-sided audit methodology is skewed to finding alleged overpayments.

CMS makes monthly payments to MAOs for providing covered benefits to enrollees. Under the Medicare statute, these monthly payments must be adjusted for each enrollee to account for "such risk factors as … health status."[7] To implement health-status risk adjustment, CMS

[5] *Medicare Program: Medicare+Choice Program*, 65 Fed. Reg. 40,170, 40,268 (June 29, 2000).
[6] 42 C.F.R. § 422.311(a).
[7] 42 U.S.C. § 1395w-23(a)(1)(A)-(C).

begins with a base payment rate that reflects the expected cost of care for an average beneficiary in FFS Medicare. Then CMS 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.[8] 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.[9] 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.[10]

The overarching purpose of the risk-adjustment scheme, including adjusting for individual enrollees' different health statuses, is to "ensure actuarial equivalence" with original Medicare.[11] 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."[12]

To achieve this goal of actuarial equivalence, what matters is *overall* payment accuracy. This is reflected in CMS' RADV audit methodology, which contemplates that the overreporting of some diagnosis codes is offset by the underreporting of others.[13] 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 codes are supported by the underlying medical records.[14]

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 it believes were at particularly high risk of being miscoded in one direction—miscoding that generates alleged *over*payments—and

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[8] *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).
[9] 42 C.F.R. § 422.310(b).
[10] *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 (Jan. 10, 2014).
[11] 42 U.S.C. § 1395w-23(a)(1)(C)(i).
[12] *UnitedHealthcare*, 16 F.4th at 875
[13] Wakely Consulting Group, *Medicare RADV: Review of CMS Sampling and Extrapolation Methodology* (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 unsupported coding errors.").
[14] *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.

consolidated these into nine high-risk diagnosis groups.[15] 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."[16]

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.[17] 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 to CMS by CVS Health.

That OIG's methodology is skewed toward finding alleged overpayments is demonstrated by the overwhelming tendency for OIG audits to determine that a large proportion of the audited diagnosis codes were unsupported. For example, in *every* one of the 20 OIG audits listed in Appendix B of the draft report, OIG found that for a majority of reviewed enrollee-years, the submitted diagnosis codes were not supported by the underlying medical records.[18] 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.[19] 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.

OIG's failure to account for actuarial equivalence results in a systematic underpayment to MAOs. This systematic underpayment will undermine the overall goals of the risk-adjustment scheme, disrupting actuarial equivalence between MA and original Medicare and creating incentives to avoid enrolling sicker beneficiaries.

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[15] Draft Report, at 1, 4, 9, 18.
[16] *Id.* at 6; *see also id.* at 18.
[17] *See United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1175 (9th Cir. 2016).
[18] *See* Draft Report, at 22-23.
[19] *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).

B. OIG's extrapolation of a contract-level overpayment destroys actuarial equivalence between MA and original Medicare.

OIG's audit and recommendations go against the Medicare statute's express mandate to "ensure actuarial equivalence" between payments under original FFS Medicare and MA in another way.[20] In its Draft Report, OIG identified a total of $701,500 in alleged overpayments from what it determined were incorrectly submitted diagnosis codes among the sampled enrollee-years.[21] On the basis of these sample results, OIG used extrapolation to estimate that CVS Health received $4,429,546 in overall alleged overpayments during the audit period.[22] OIG recommended that CVS Health refund that amount to the federal government.[23] 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.

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.[24] These reported diagnosis codes from providers under FFS Medicare inevitably contain some errors–perfect coding is impossible across such a large mass of data.[25] Diagnosis reports for outpatient care under Medicare Part B are also especially unreliable, since providers are paid based on the procedures they perform, not on the diagnosis codes they submit.[26] 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 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

[20] 42 U.S.C. § 1395w-23(a)(1)(C).
[21] Draft Report, at 15, 27.
[22] *Id.* at 16, 20-21, 27.
[23] Draft Report, at 17.
[24] *UnitedHealthcare*, 16 F.4th at 874.
[25] *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.
[26] *Id.*

found in the audited samples,[27] it issued a notice in 2012 announcing that, in performing the contract-level payment error extrapolation calculation, it would apply a "Fee-for-Service Adjuster" (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)."[28]

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 score calculated by the … risk adjustment model, and therefore do not have any systematic effect on the payments made to MA organizations."[29]

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." 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 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.

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

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[27] CMS, *Medicare Advantage Risk Adjustment Data Validation (RADV) Notice of Payment Error Calculation Methodology for Part C Organizations Selected for RADV Audit – Request for Comment* (Dec. 21, 2010).

[28] CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* 4-5 (Feb. 24, 2012).

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

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 in regulation that RADV audits will include extrapolation without an FFS adjuster (2023 Final Rule).[30] 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 an FFS adjuster on two legal grounds. First, citing the D.C. Circuit's decision in *UnitedHealthcare Insurance Co. v. Becerra* concerning the Overpayment Rule,[31] 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."[32] Second, CMS pointed to the coding pattern adjustment mandated by the Medicare statute.[33] 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.[34] CMS asserted that the statute's mandate of a coding pattern adjustment supported its rejection of an FFS adjuster, since "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)."[35]

Neither of the two legal reasons CMS cited support omitting an FFS adjuster when 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*."[36] 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*.[37]

Second, that Congress has separately mandated a downward adjustment to MA payments to reflect differences in coding patterns between Medicare Advantage 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

[30] 88 Fed. Reg. at 6,664.
[31] *UnitedHealthcare*, 16 F.4th at 891-892.
[32] 88 Fed. Reg. at 6,656.
[33] 42 U.S.C. § 1395w-23(a)(1)(C)(ii).
[34] *See* 88 Fed. Reg. at 6,657.
[35] *Id.* at 6,657.
[36] *Id.* at 6,656.
[37] *UnitedHealthcare*, 16 F.4th at 892.

to Medicare FFS, of reporting codes with greater intensity, including codes that are *nonetheless accurate*."[38] 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 an FFS adjuster to any extrapolation of a contract-level overpayment from the miscoding found in an audited sample. Nor does the application of a 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 $4,429,546 OIG has estimated without applying an FFS adjuster. For the same reason, CVS Health has no legal obligation to comply with OIG's recommendation to refund the $4,429,546.

What is more, OIG's longstanding prior policy declined to engage in contract-wide extrapolation absent an FFS adjuster.[39] 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 sufficient to justify overriding CVS Health's reasonable reliance interests.[40] OIG's failure to provide any explanation for its change in policy makes its refund recommendation arbitrary and capricious.

CMS has not provided any guidance on how it may extrapolate RADV and OIG audits to avoid duplication. 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. As a result, 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.

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[38] 88 Fed. Reg. at 6,657 (emphasis added); *see also Azar*, 330 F. Supp. 3d at 188 (explaining that the coding pattern adjustment is not intended to account for "improper coding").

[39] *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).

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

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II. 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.

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

A. OIG failed to disclose information critical for CVS Health to evaluate the determinations made by the medical record review contractor.

OIG has not shared with CVS Health information that it needs to independently evaluate the determinations made by OIG's medical record review contractor.

First, OIG only transmitted to CVS Health the final determination by the contractor on each claim. CVS Health therefore has no way of evaluating the contractor's decision-making process as a whole, including the assessments made by the contractor at the initial levels of review. Nor does CVS Health have any way of evaluating whether the coders who performed the review were qualified, beyond OIG's generic and uninformative indication that the 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)."[41]

CVS Health requests that OIG identify the independent medical record review contractor and disclose the assessments made by the contractor's coders at initial levels of review, pursuant to the Data Quality Act and generally accepted government auditing standards.[42] In the event that CMS acts to implement OIG's recommendations, the requested information will bear on CVS Health's administrative appeal rights under 42 C.F.R. § 422.311.

Second, OIG did not disclose the coding standards used in its audit. In explaining OIG's audit methodology, the draft report states that OIG "reviewed applicable Federal laws, regulations, and guidance" and "discussed with CMS program officials the Federal requirements that MA organizations should follow" in submitting diagnosis codes.[43] The Draft Report further explains that the audit sought to determine whether the high-risk diagnosis codes CVS Health submitted to CMS for the sampled enrollee-years "complied with Federal requirements."[44] These requirements include CMS's instructions as set out in the *Medicare Managed Care Manual* (Manual), the Draft

[41] OIG, Draft Report: *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That CVS Health Pennsylvania, Inc. (H5522) Submitted to CMS* 20 n.27 (Feb. 2024) (Draft Report).
[42] Data Quality Act, Pub. L. 106-554, § 515, 114 Stat. 2763, 2763A-153 to 2763A-154 (2001); U.S. Gov't Accountability Off., *Government Auditing Standards 2018 Revision: Technical Update April 2021*.
[43] Draft Report, at 18.
[44] *Id.* at 20.

Report explains, because MAOs must contract with CMS and agree to follow CMS's instructions, which include those in the Manual.[45] The Draft Report also observes that, under the MA program, "providers code diagnoses using the International Classification of Diseases (ICD), Clinical Modification (CM), *Official Guidelines for Coding and Reporting* (ICD Coding Guidelines)."[46] Beyond these generic statements, OIG provided no notice regarding the coding standards that the medical review contractor used in conducting its review.

CVS Health therefore lacks sufficient information to assess OIG's audit determinations. In particular, the ICD Coding Guidelines do not specify the full information needed for providers and MAOs to make coding judgments.[47] Even CMS has tacitly recognized the limits of the ICD Coding Guidelines by referring MAOs and providers to supplemental resources, including those published by the American Health Information Management Association (AHIMA), the American Medical Association (AMA), the American Hospital Association (AHA), and the American Academy of Professional Coders.[48] Even these supplementary resources have their limits[49] and are sometimes inconsistent.[50]

For these reasons, it was important for OIG to do more than identify the ICD Coding Guidelines as a standard for the medical record review process. At a minimum, CVS Health requests information on how the independent medical review contractor applied the ICD Coding Guidelines, including whether the contractor augmented those guidelines with additional coding

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[45] *Id.* at 8.

[46] *Id.* at 1 n.1.

[47] ICD-10-CM, *Official Guidelines for Coding and Reporting* 16 (2022) (describing how coders should proceed in the absence of guidance); CMS, *Medical Record Reviewer Guidance* 16 (2019) ("It is critical to understand all guidance pertaining to these documentation issues will be considered on a case-by-case basis. The guidance and examples are not exhaustive in content. … [M]edical records can be unique … .").

[48] ICD-10-CM, *Official Guidelines for Coding and Reporting* (2022) (noting that the guidelines have been approved by the AHA, AHIMA, CMS, and NCHS); *see also* CMS, *RADV Medical Record Reviewer Guidance* 56 (2019) ("[c]ode assignment may be based on other physician [documentation] … This information is consistent with the [AHIMA] documentation guidelines."); CMS, *Regional Technical Assistance Risk Adjustment*, at 6-2 (2008) ("ICD-9-CM diagnosis codes are 3- to 5-digit codes used to describe the clinical reason for a patient's treatment. They do not describe the service performed, just the patient's medical condition. For any classification system to be reliable, the application of the codes must be consistent across users. Therefore, CMS, the [AHA], the [AHIMA], and the National Center for Health Statistics (NCHS) together have developed coding guidelines.").

[49] CMS, *Medical Record Reviewer Guidance* 7 (2019).

[50] OIG, *CMS Did Not Adequately Address Discrepancies in the Coding Classification for Kwashiorkor* 1 (2017), ("[w]e reviewed the medical records for 2,145 inpatient claims at 25 providers and found that all but 1 claim incorrectly included the diagnosis code for Kwashiorkor . . . [t]he ICD-CM coding classification contained a discrepancy between the tabular list and the alpha index on the use of diagnosis code 260 … CMS did not have adequate policies and procedures in place to address this discrepancy.").

resources.

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

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."[51] If CMS were to enforce OIG's recommended recoupment of $4.4 million, then OIG's underlying medical records 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.[52]

C. 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.[53] 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

[51] 42 U.S.C. § 1395hh(a)(2); *Azar v. Allina Health Serv.*, 139 S. Ct. 1804, 1808, 1814 (2019); *see also* Memorandum from CMS Chief Legal Officer Kelly M. Cleary on Impact of *Allina* on Medicare Payment Rules 2 (Oct. 31, 2019).

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

[53] Draft Report, Appendix A.

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. CVS Health submits that the appropriate policy where the second coder agrees with the treating physician's coded diagnosis is to deem the diagnosis code 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.

D. In estimating an alleged contract-level overpayment, OIG uses 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."[54] 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.[55] OIG does not explain its reasons for choosing the 90% confidence interval instead of the 99% confidence interval that CMS would otherwise apply in a RADV audit. It is arbitrary and capricious for OIG to use a less statistically sound method than CMS, without providing any reasoned explanation for doing so.

E. OIG did not provide CVS Health with sufficient information to adequately assess its extrapolation methodology.

OIG failed to disclose information that is critical in order for CVS Health to be able to evaluate OIG's sampling and extrapolation methodology. OIG failed to disclose a breakdown of the data exclusions applied as well as the selection process of the nine "high risk" groups. Among other reasons, this information is required in order to assure the validity of the final sampling frame and to rule out the potential for a biased sample. OIG further failed to explain how many unique patients compose each strata, why the sample for each stratum was limited to 30, and what statistical assumptions were made to support these choices. We ask OIG to clarify these questions.

F. 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 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

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[54] Draft Report, at 26.

[55] CMS, HHS Risk Adjustment Data Validation (HHS-RADV) White Paper, at 6 (Dec. 6, 2019); Milliman, *Medicare Advantage RADV FFS Adjuster: White Paper* (Aug. 23, 2019), http://assets.-milliman.com/ektron/Medicare_Advantage_RADV_FFS_adjuster_8-23-2019.pdf.

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.

G. 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.

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

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

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

OIG directed CVS Health to support the diagnoses in the 269 enrollee-years in the audit sample by providing "the specific medical record support for the diagnosis code for the one specific date of service identified," including the "specific PDF page no. and specific text" for any supporting inpatient records. Outpatient records were not subject to the same instruction. The instruction turned the process into a hunt for specific words in the inpatient records and impeded 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 for one specific date of service chosen by CMS. Furthermore, MAOs receive additional opportunities to identify medical record support. CVS Health informed OIG about the differences between the RADV and OIG processes, and OIG declined to align the two. OIG's prescriptive approach was arbitrary and capricious and further skewed the audit in favor of identifying alleged overpayments.

J. 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.

IV. CVS Health does not concur with OIG's recommendation to refund $4.4 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.[56] In a 2023 final rule,[57] 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."[58] 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

[56] *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 177 (2010) (describing proposal that would "[c]larify in statute that CMS can extrapolate the error rate found in the risk adjustment validation (RADV) audits to the entire MA plan payment for a given year when recouping overpayments.").

[57] *Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021*, 88 Fed. Reg. 6,643, 6,665 (Feb. 1, 2023).

[58] 42 C.F.R. § 422.311(a)(1)-(2); *see also* 42 C.F.R. § 422.310(e).

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.[59]

Even supposing that 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,[60] 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.[61] Second, OIG's asserted authority to conduct RADV audit activity, the IG Act,[62] 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,[63] 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*."[64]

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."[65] 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 to CMS to largely ratify its extrapolated alleged

[59] *Id.* at 6,648.
[60] *See* 42 U.S.C.A. § 1302(a); 42 U.S.C. § 1395hh(a)(1).
[61] 42 C.F.R. § 422.311(a)(2).
[62] 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).
[63] 5 U.S.C. § 402(b)(1); *see also* 5 U.S.C. § 404(a)(1).
[64] *Bais Yaakov of Spring Valley v. FCC*, 852 F.3d 1078, 1082 (D.C. Cir. 2017).
[65] Draft Report, at 17. 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* 27 (2023).

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 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 $4.4 Million.

As set forth above, CVS Health has submitted a list of enrollee-years for which it disagrees with OIG's conclusion in Exhibit B. Additionally, OIG itself notes that for several enrollee years, its contracted coders did not find support for the targeted diagnosis, but identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related disease group. OIG states that in these instances, CVS Health should not have received an increased payment for the targeted diagnosis, but should have received a lesser increased payment for the other diagnosis identified.[66] OIG then fails to show that it accounted for what it, according to its review, identified as these "lesser increased payments" either in its statement of the alleged overpayments for sampled enrollee years, or the extrapolated alleged overpayment estimate.[67] Properly accounting for these enrollee-years would impact OIG's statement of the alleged overpayments for sampled enrollee years, and consequently, the extrapolated alleged overpayment estimate.

V. CVS Health does not concur with OIG's recommendation to perform what amounts to a self-audit of high-risk diagnosis codes for the years before and after the audit period.

OIG recommends that CVS Health seek to identify, in data submitted for the years before and after the audit period, unsupported diagnosis codes among those diagnoses designated high risk in its report, and to refund any resulting overpayments found.[68] But CVS Health has no legal obligation to perform a self-audit and does not concur in this recommendation.

In the draft report, OIG does not specifically cite its authority for this self-audit recommendation. However, the draft report does lay out a number of "federal requirements," compliance with which OIG's audit seeks to determine.[69] These cited federal requirements included federal regulations requiring MAOs (1) to certify the risk-adjustment data they submit; and (2) to set up compliance programs.[70] To the extent that OIG is suggesting that these regulations provide its authority to recommend that MAOs perform self-audits, CVS Health disagrees.

One "federal requirement" OIG relies on is 42 C.F.R. § 422.504(*l*), which provides that, as a condition for receiving monthly payments, MAOs must agree to certify the "accuracy, completeness, and truthfulness" of the risk-adjustment data that they submit to CMS. Because the regulation makes MAOs responsible for the accuracy of the diagnosis codes they submit to CMS

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[66] Draft Report at P. 10-15.
[67] Draft Report at P. 10-15; 27.
[68] Draft Report, at 17.
[69] *Id.* at 8-9.
[70] 42 C.F.R. § 422.504(*l*); 42 CFR § 422.503(b)(4)(vi).

only to the extent of their "best knowledge, information, and belief,"[71] it does not require MAOs to engage in self-audits, nor does it provide authority to the government to require such self-audits. As the D.C. Circuit has explained in connection with interpreting provisions in the Affordable Care Act (ACA) obligating MAOs to report and return any *known* overpayment that they receive from CMS,[72] since the ACA only requires MAOs to refund monthly payment amounts "they *know* were overpayments, *i.e.*, payments they *are aware* lack support in a beneficiary's medical records," the regulation "does not impose a self-auditing mandate."[73] Given that the regulation similarly requires certification of risk-adjustment data only to MAOs' "best knowledge, information, and belief," it likewise does not establish a self-auditing mandate.

CMS has previously acknowledged this, observing that MAOs "cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the OIG, and DOJ believe is reasonable to enforce."[74] Indeed, OIG itself has similarly acknowledged that the regulatory requirement for MAOs to certify the accuracy, completeness and truthfulness of risk adjustment data, based on best knowledge, information and belief, "does not constitute an absolute guarantee of accuracy" but simply "creates a duty on the [MAO] to put in place an information collection and reporting system reasonably designed to yield accurate information."[75] Accordingly, 42 C.F.R. § 422.504(*l*) does not impose any legal obligation on CVS Health to conduct a self-audit of the time periods before and after the 2017 and 2018 service years in the wake of OIG's audit report.

Another "federal requirement" OIG relies on is 42 CFR § 422.503(b)(4)(vi). This regulation provides that MAOs "must" have "administrative and management arrangements satisfactory to CMS," including "at least" putting in place "an effective compliance program" to "prevent, detect, and correct non-compliance with CMS' program requirements," and to "prevent, detect, and correct fraud, waste, and abuse."[76] This compliance program "must" include, as a "core requirement[]," an "effective system for routine monitoring and identification of compliance risks"[77] This monitoring system "*should* include internal monitoring and audits and, as appropriate, external audits" to evaluate the MAO's "compliance with CMS requirements."[78]

The regulation frames its directives in a careful mix of mandatory and precatory—that is, advisory—language. Where "must" is used, a directive is mandatory.[79] Thus, the regulation

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[71] *Id.*
[72] *See* 42 U.S.C. § 1320a-7k(d)(1),(2).
[73] *UnitedHealthcare v. Becerra*, 16 F.4th at 880-881, 884; see also *UnitedHealthcare v. Azar*, 330 F. Supp. 3d at 190-191.
[74] *Medicare Program: Medicare+Choice Program*, 65 Fed. Reg. 40,170, 40,268 (June 29, 2000).
[75] *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).
[76] 42 C.F.R. § 422.503(b)(4)(vi).
[77] 42 C.F.R. § 422.503(b)(4)(vi)(F).
[78] *Id.* (emphasis added).
[79] *See Bankers Ins. Co. v. Fla. Residential Prop. & Cas. Joint Underwriting Ass'n*, 137 F.3d 1293, 1298 (11th Cir. 1998).

mandates that MAOs like CVS Health set up effective compliance programs, and further mandates that MAOs establish effective routine monitoring systems. Where "should" is used in a legal provision, by contrast, the provision is precatory.[80] That is, while the regulation *advises* MAOs to conduct internal and external audits, it does not require them to do so. Accordingly, while CVS Health remains committed to an effective compliance program, 42 CFR § 422.503(b)(4)(vi) does not establish any legal obligation for CVS Health to comply with OIG's recommendation to engage in extensive self-auditing of the diagnosis codes designated as high risk by OIG.

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 program.

CVS Health has invested tremendous time, effort, and resources into advancing its compliance program. CVS Health is therefore pleased that OIG "acknowledge[d] that CVS Health [had during the audit period] compliance procedures that include measures designed to ensure that diagnosis codes, including some of the diagnoses that [OIG] classified as high risk for being miscoded, comply with Federal requirements."[81] 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.[82] Notwithstanding CVS Health's robust efforts, OIG concluded that CVS Health's compliance procedures during the audit period "could be improved,"[83] and recommended that CVS Health "continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures."[84]

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.[85] 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

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[80] *See, e.g., Monahan v. Dorchester Counseling Ctr., Inc.*, 961 F.2d 987, 993 (1st Cir. 1992) (interpreting the use of the term "should" to indicate that a statutory provision "is merely precatory"); *Union Elec. Co. v. Consolidation Coal Co.*, 188 F.3d 998, 1001 (8th Cir. 1999) (interpreting "should" in a contract term as "purely precatory language").

[81] Draft Report, at 16.

[82] *Id.*

[83] *Id.*

[84] *Id.* at 17.

[85] *Id.* at 16.

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.