

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE COMPLIANCE
AUDIT OF SPECIFIC DIAGNOSIS CODES
THAT MEDI GOLD (CONTRACT H3668)
SUBMITTED TO CMS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



Amy J. Frontz
Deputy Inspector General
for Audit Services

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Report in Brief

Date: February 2024

Report No. A-07-20-01198

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



Why OIG Did This Audit

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

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

For this audit, we reviewed one MA organization, MediGold, and focused on seven groups of high-risk diagnosis codes. Our objective was to determine whether selected diagnosis codes that MediGold 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 210 unique enrollee-years with the high-risk diagnosis codes for which MediGold received higher payments for 2017 through 2018. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$567,570.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MediGold (Contract H3668) Submitted to CMS

What OIG Found

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that MediGold submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, for 189 of the 210 sampled enrollee-years, the medical records that MediGold provided did not support the diagnosis codes and resulted in \$469,907 in net overpayments. As demonstrated by the errors found in our sample, MediGold's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements could be improved. On the basis of our sample results, we estimated that MediGold received at least \$3.7 million of net overpayments for 2017 and 2018. Because of Federal regulations that limit the use of extrapolation in Risk Adjustment Data Validation audits for recovery purposes to payment years 2018 and forward, we are reporting the overall estimated overpayment amount but are recommending a refund of \$2.2 million in net overpayments (\$224,001 for the sampled enrollee-years from 2017 and an estimated \$2 million for 2018).

What OIG Recommends and MediGold Comments

We recommend that MediGold: (1) refund to the Federal Government the \$2.2 million of estimated net overpayments; (2) identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before and 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 and take the necessary steps to enhance those procedures.

MediGold disagreed with some of our findings and requested that we withdraw all of our recommendations. Specifically, MediGold did not agree with our findings for 30 of the 194 enrollee-years in error identified in our draft report and provided additional information for our consideration. MediGold did not directly agree or disagree with our findings for the remaining 164 enrollee-years. MediGold did not agree with our audit methodology, use of extrapolation, standards for data accuracy, and medical record review process. After reviewing MediGold's comments and the additional information MediGold 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.

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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 65 breast cancer diagnoses into 1 group.) This audit covered MediGold for contract number H3668 and focused on seven groups of high-risk diagnosis codes for payment years 2017 and 2018.³

OBJECTIVE

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

BACKGROUND

Medicare Advantage Program

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

¹ The providers code diagnoses using the International Classification of Diseases (ICD), Clinical Modification, *Official Guidelines for Coding and Reporting* (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 All subsequent references to "MediGold" in this report refer solely to contract number H3668.

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 2021, CMS paid MA organizations \$349.9 billion, which represented 42 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
- *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

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.

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

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

⁸ During our audit period CMS calculated risk scores based on the Version 22 CMS-HCC model.

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.

records do not support the diagnosis codes that an MA organization submitted to CMS, the HCCs are unvalidated, which causes overstated enrollee risk scores and overpayments from CMS.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 seven 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 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 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

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 "unsupported" to denote whether or not the reviewed diagnoses were evidenced in the medical records. If our audit determines that the diagnoses are supported or unsupported, we accordingly use the terms "validated" or "unvalidated" with respect to the associated HCC.

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.

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

MediGold

MediGold is an MA organization based in Columbus, Ohio. As of December 2018, MediGold provided coverage under contract number H3668 to 46,555 enrollees. For the 2017 and 2018 payment years (audit period), CMS paid MediGold approximately \$1.1 billion to provide coverage to its enrollees.^{11, 12}

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of the seven high-risk groups during the 2016 and 2017 service years, for which MediGold received increased risk-adjusted payments for payment years 2017 and 2018,

¹¹ The 2017 and 2018 payment year data were the most recent data available at the start of the audit.

¹² All of the payment amounts that CMS made to MediGold and the net overpayment amounts that we identified in this report reflect the budget sequestration reduction.

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 2,220 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$4,490,016).¹³ We selected for audit a stratified random sample of 210 enrollee-years as shown in Table 1.

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

High-Risk Group	Number of Sampled Enrollee-Years		
	Payment Year 2017	Payment Year 2018	Total
1. Acute stroke	12	18	30
2. Acute myocardial infarction	16	14	30
3. Embolism	13	17	30
4. Lung cancer	15	15	30
5. Breast cancer	16	14	30
6. Colon cancer	12	18	30
7. Prostate cancer	21	9	30
Total for All High-Risk Groups	105	105	210

MediGold provided medical records as support for the selected diagnosis codes associated with the 210 sampled enrollee-years.¹⁴ We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. For the HCCs that were not validated, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or if we identified another diagnosis code (on CMS’s systems) that mapped to an HCC in the related-disease group, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

We conducted this performance audit in accordance with generally accepted government auditing standards (GAGAS). 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.

¹³ The 2,220 unique enrollee-years and associated payments that we reviewed consisted of 1,083 enrollee-years (\$2,100,911) for payment year 2017 and 1,137 enrollee-years (\$2,389,105) for payment year 2018.

¹⁴ Along with its written comments on our draft report, MediGold submitted medical record documentation that it had located for the 2 enrollee-years that it previously could not locate (both in the Acute Stroke high-risk group).

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

FINDINGS

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that MediGold submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 21 of the 210 sampled enrollee-years, the medical records validated the reviewed HCCs.¹⁵ For the remaining 189 enrollee-years, however, the medical records that MediGold provided did not support the diagnosis codes and the associated HCCs were therefore not validated, which resulted in \$469,907 in net overpayments.

As demonstrated by the errors found in our sample, MediGold'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 MediGold received at least \$3,753,525 of net overpayments for 2017 and 2018.¹⁶ Because of Federal regulations that limit the use of extrapolation in Risk Adjustment Data Validation (RADV) audits for recovery purposes to payment years 2018 and forward, we are reporting the overall estimated overpayment amount but are recommending a refund of \$2,183,514 in net overpayments (\$224,001 for the sampled enrollee-years from 2017 and an estimated \$1,959,513 for 2018).¹⁷

¹⁵ For 1 of the 21 enrollee-years, our independent medical review contractor validated the reviewed HCC and also found a diagnosis related to the reviewed diagnosis that should have been submitted but was not. This related diagnosis mapped to an HCC for a more severe manifestation of the related-disease group. Thus, even though the reviewed HCC was validated, MediGold should not have received a lesser payment for the lung cancer diagnosis (that it submitted) but should have received an increased payment for the identified metastatic cancer diagnosis (that it did not submit). This resulted in an underpayment. We discuss this enrollee-year in "Incorrectly Submitted Diagnosis Codes for Lung Cancer" later in this report.

¹⁶ To be conservative, we estimate net overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

¹⁷ After we had reviewed the sampled enrollee-years, CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643 (Feb. 1, 2023)). Therefore, for sampled enrollee-years from payment year 2017, we limited our calculation of overpayments to the financial impact associated with these enrollee-years. For sampled enrollee-years from payment year 2018, we used the financial impact associated with the enrollee-years to estimate the total amount of net overpayments for that year. See also footnotes 26 and 40 later in this report.

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) (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 (ICD), Clinical Modification, *Official Guidelines for Coding and Reporting* (ICD Coding Guidelines) (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).

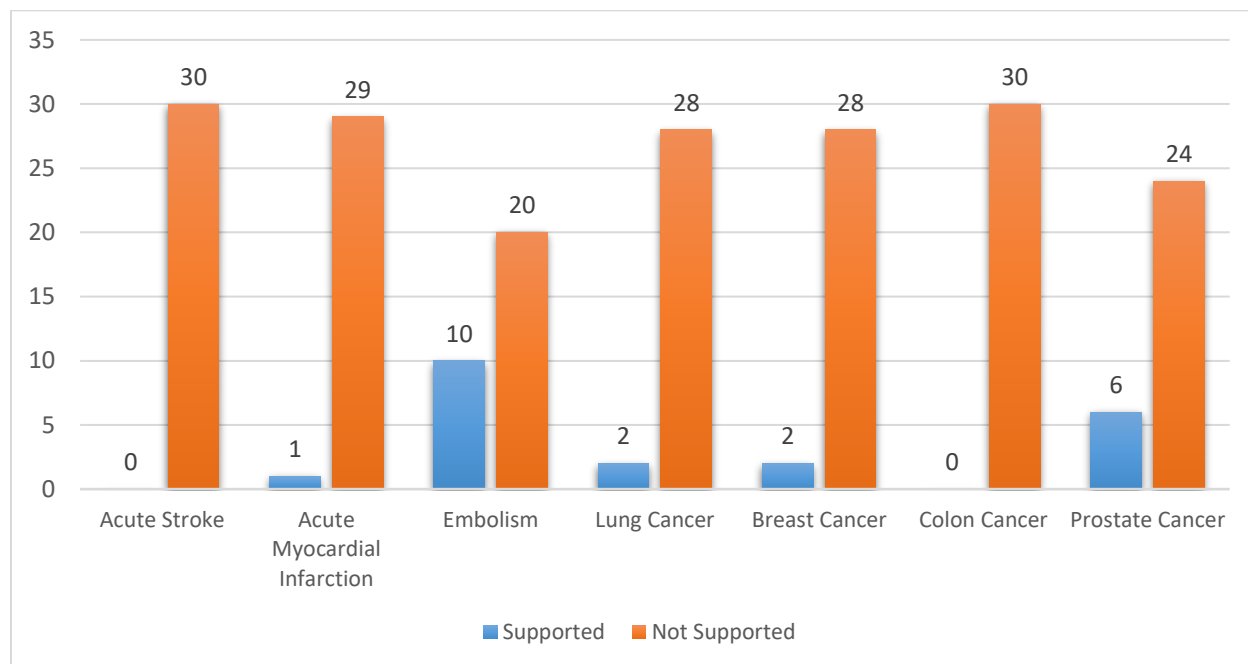
Federal regulations state that MA organizations must monitor the data that they receive from providers and submit to CMS. Federal regulations also state that MA organizations must "adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements . . ." Further, MA 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 MEDIGOLD SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Most of the selected high-risk diagnosis codes that MediGold submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, as shown in the figure on the following page, the medical records for 189 of the 210 sampled

enrollee-years did not support the diagnosis codes. In these instances, MediGold should not have submitted the diagnosis codes to CMS and received the resulting net overpayments.

Figure: Analysis of High-Risk Groups



Incorrectly Submitted Diagnosis Codes for Acute Stroke

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

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

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC or a related HCC. There is documentation of a history of a stroke [diagnosis] but no description of residuals or sequelae that should be coded.”¹⁸ The history of stroke diagnosis code does not map to an HCC.

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

¹⁸ Residuals or sequelae are the late effects of an injury that can occur only after the acute phase of the injury or illness has passed.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Ischemic or Unspecified Stroke].”

- For 1 enrollee-year, MediGold submitted an acute stroke diagnosis code (which was not supported in the medical record) instead of a diagnosis code for hemiplegia (which was supported in the medical record).¹⁹ The independent medical review contractor stated that “there is no evidence of an acute stroke, however the patient has paralysis affecting [the] left non dominant side from an old stroke . . . and would result in the assignment of [the] HCC [for Hemiplegia/Hemiparesis] which should have been assigned instead of the . . . HCC [for Ischemic or Unspecified Stroke].” Accordingly, MediGold should not have received an increased payment for the acute stroke diagnosis but instead should have received a lesser increased payment for the hemiplegia diagnosis.

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and MediGold received \$55,524 in overpayments (\$20,925 for 2017 and \$34,599 for 2018) for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Myocardial Infarction

MediGold incorrectly submitted diagnosis codes for acute myocardial infarction for 29 of 30 sampled enrollee-years. Specifically:

- For 17 enrollee-years, the medical records indicated in each case that the individual had an old myocardial infarction diagnosis, but the records did not justify an acute myocardial infarction diagnosis at the time of the physician’s service.²⁰

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 a past medical history of myocardial infarction [diagnosis] that does not result in an HCC.”

- For 4 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 manifestation of the related-disease group. Accordingly, MediGold should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the other diagnosis identified.

¹⁹ Hemiplegia is defined as complete paralysis or loss of function of one-half of the body, including one leg and arm, because of injury or disease in the motor centers of the brain.

²⁰ An “old myocardial infarction” is a distinct diagnosis that represents a myocardial infarction that occurred more than 4 weeks previously, has no current symptoms directly associated with that myocardial infarction, and requires no current care.

- For the remaining 8 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 elevated troponin [diagnosis] that does not result in an HCC.”²¹

As a result of these errors, the HCC for Acute Myocardial Infarction was not validated, and MediGold received \$50,539 (\$25,294 for 2017 and \$25,245 for 2018) in overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

MediGold incorrectly submitted diagnosis codes for embolism for 20 of 30 sampled enrollee-years. Specifically:

- For 13 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 will result 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.”²²

- For 6 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 will result in the assignment of [the] HCC [for Vascular Disease with Complications]. There is documentation of deep vein thrombosis prophylaxis that does not result in an HCC and during this inpatient admission the patient was ruled out for having a pulmonary embolism.”^{23, 24}

²¹ Troponin is a type of protein found in the muscles of the heart. When heart muscles become damaged, troponin is sent into the bloodstream. As heart damage increases, greater amounts of troponin are released in the blood.

²² Deep vein thrombosis occurs when a blood clot forms in one or more of the deep veins of the body, usually in the legs.

²³ Prophylaxis is a preventative measure taken to maintain health and deter disease or another unwanted consequence.

²⁴ Pulmonary embolism is a blockage in one of the pulmonary arteries in the lungs. In most cases, pulmonary embolism is caused by blood clots that travel to the lungs from deep veins in the legs.

- For the remaining 1 enrollee-year, the medical record did not support an embolism diagnosis. However, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. The independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Vascular Disease with Complications]. There is documentation of stenosis of the proximal left subclavian artery that results in [the] HCC [for Vascular Disease].”²⁵ Accordingly, MediGold should not have received an increased payment for the submitted embolism diagnosis but should have received a lesser increased payment for the other diagnosis identified.

As a result of these errors, the Embolism HCCs were not validated, and MediGold received \$51,321 in overpayments (\$25,378 for 2017 and \$25,943 for 2018) for these 20 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

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

- For 19 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 will result 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 8 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 that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, MediGold should not have received an increased payment for the submitted lung cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

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 Lung and Other Severe Cancers].” However, there was documentation that supports the HCC for Lymphoma and Other Cancers, which was a less severe manifestation of the related-disease group.

²⁵ Subclavian artery stenosis is a form of peripheral arterial disease. It causes symptomatic ischemic problems that affect the upper extremities, brain, and heart.

- For the remaining 1 enrollee-year, the medical record did not support a lung cancer diagnosis. The independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Lung and Other Severe Cancers]. Lung cancer is listed in the documentation however there is no support to code this as active or historical.”

In addition to the 28 enrollee-years discussed above, for 1 other enrollee-year, MediGold correctly submitted a diagnosis code for lung cancer (footnote 15). However, we also identified support for another diagnosis that our independent medical review contractor stated was related to the reviewed diagnosis. MediGold did not submit, but should have submitted, this other related diagnosis to CMS. This related diagnosis mapped to an HCC for a more severe manifestation of the related-disease group. The independent medical review contractor stated that “there is evidence of a diagnosis of right lung cancer . . . the documentation also substantiated a diagnosis of metastatic cancer . . . that would result in assignment of [the] HCC [for Metastatic Cancer and Acute Leukemia].” Accordingly, MediGold should not have received a lesser payment for the lung cancer diagnosis (that it submitted) but should have received an increased payment for the metastatic cancer diagnosis identified (that it did not submit). This error caused an underpayment for payment year 2018.

As a result of these errors, either the HCC for Lung and Other Severe Cancers was not validated (28 sampled enrollee-years) or the HCC for Metastatic Cancer and Acute Leukemia was validated by a diagnosis code that MediGold should have submitted but did not (1 sampled enrollee-year). MediGold received \$169,417 in net overpayments (\$90,263 for 2017 and \$79,154 for 2018) for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

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

- For 25 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, 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 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.”

- 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 will result 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 MediGold received \$38,833 in overpayments (\$15,092 for 2017 and \$23,741 for 2018) for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

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

- For 22 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 will result 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 3 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 will result in the assignment of [the] HCC [for Colorectal, Bladder, and Other Cancers].”

- For the remaining 5 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 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, MediGold should not have received an increased payment for the submitted colon cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and MediGold received \$76,113 in overpayments (\$26,065 for 2017 and \$50,048 for 2018) for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

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

- For 22 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 will result 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 the remaining 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 will result 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 MediGold received \$28,160 in overpayments (\$20,984 for 2017 and \$7,176 for 2018) for these 24 sampled enrollee-years.

Summary of Incorrectly Submitted Diagnosis Codes

In summary and with respect to the seven high-risk groups covered by our audit, MediGold received \$469,907 in net overpayments for the 189 (of 210) sampled enrollee-years (\$224,001 for 2017 and \$245,906 for 2018).

THE POLICIES AND PROCEDURES THAT MEDIGOLD 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 MediGold 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.

During our audit period, MediGold had compliance procedures in place that were designed to prevent the submission of incorrect diagnosis codes. These procedures included providing published ICD Coding Guidelines (footnote 1) to its providers to help ensure that medical records were coded consistently and accurately. MediGold’s compliance procedures also included detection and correction measures that were designed to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. For

example, MediGold performed various diagnosis coding audits to evaluate the accuracy of the diagnosis codes. If the coding audits identified any coding errors, MediGold's policies and procedures provided guidance on how to submit the corrections to CMS.

When asked about the errors identified in this audit, MediGold officials told us that since our audit period, MediGold has placed greater emphasis on the prevention and detection of incorrect high-risk diagnosis codes. For instance, MediGold has implemented an enhanced provider outreach program that includes coding training and education; this enhanced program aimed to improve the ability of MediGold's contracted providers to deliver appropriate care and correctly document enrollee conditions. Furthermore, MediGold officials stated that MediGold has added steps to improve its coding audit process. MediGold has also implemented service-level agreements with its coding vendors that require at least a 95 percent accuracy rate for medical record reviews and code submissions. Thus, according to MediGold officials, MediGold has taken steps to ensure that it submits accurate diagnoses to CMS.

Based on our assessment of the policies and procedures that were in place for our audit period, our discussions with MediGold officials, and the fact that the diagnosis codes for 189 of the 210 sampled enrollee-years were not supported by the medical records, we believe that MediGold's compliance procedures to prevent, detect, and correct incorrect high-risk diagnoses could be improved.

MEDIGOLD RECEIVED NET OVERPAYMENTS

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that MediGold received at least \$3,753,525 in net overpayments for our audit period.

Because of Federal regulations that limit the use of extrapolation in RADV audits for recovery purposes to payment years 2018 and forward,²⁶ we are reporting the estimated overpayment amount but are recommending a refund of \$2,183,514 in net overpayments (\$224,001 for the sampled enrollee-years from 2017 and an estimated \$1,959,513 for 2018). (See footnote 17 and Appendix D for sample results and estimates.)

²⁶ After we had reviewed the sampled enrollee-years, CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643 (Feb. 1, 2023)). RADV audits are conducted to verify that diagnoses submitted by MA organizations for risk-adjusted payment are supported by medical record documentation.

RECOMMENDATIONS

We recommend that MediGold:

- refund to the Federal Government the \$2,183,514 of estimated net overpayments;²⁷
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before and 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.

MEDIGOLD COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, MediGold disagreed with some of our findings and all of our recommendations and also requested that we withdraw our recommendations. Specifically, MediGold did not agree with our findings for 30 of the 194 enrollee-years in error identified in our draft report and provided additional information for our consideration.²⁸ MediGold did not directly agree or disagree with our findings for the remaining 164 enrollee-years.

MediGold also stated that our audit methodology was inconsistent with the fundamentals of payment under the MA program. Additionally, MediGold stated that CMS does not require MA organizations to identify similar instances of noncompliance and that its "compliance program meets all legal and regulatory requirements." MediGold also requested that we clarify language in our draft report regarding its coding and education practices.

After reviewing MediGold's comments and the additional information MediGold provided, we reduced the number of enrollee-years in error from 194 to 189 and adjusted our calculation of

²⁷ 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 CMS's 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.

²⁸ In its written comments, MediGold stated that it gave us additional information for 35 of the 194 enrollee-years that our draft report had identified as having diagnosis codes that were submitted in error. However, MediGold provided information for only 34 enrollee-years. Further, the information for 4 of those enrollee-years was the same information that MediGold had previously submitted to us and that had already been reviewed by our independent medical review contractor. Therefore, MediGold was actually providing additional information for 30, not 35, enrollee-years that our draft report had identified as having diagnosis codes that were submitted in error.

net overpayments. Accordingly, we reduced our first recommendation from \$2,224,283 to \$2,183,514 for this final report. We also, as requested by MediGold, revised our language regarding MediGold’s coding and education practices for this final report. We maintain that our second and third recommendations remain valid.

A summary of MediGold’s comments and our responses follows. MediGold’s comments, from which we have removed an attachment that contained personally identifiable information, appear as Appendix F. We are separately providing MediGold’s comments in their entirety to CMS.

MEDIGOLD DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL’S RECOMMENDATION THAT IT REFUND OVERPAYMENTS

MediGold Did Not Agree With the Office of Inspector General’s Findings for 30 Sampled Enrollee-Years

MediGold Comments

MediGold did not agree with our findings for 30 sampled enrollee-years (as shown in Table 2) and provided additional information supporting its belief that the HCCs in question were validated.

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

High-Risk Group			
	Payment Year 2017	Payment Year 2018	Total
Acute stroke	2	0	2
Acute myocardial infarction	2	2	4
Embolism	4	6	10
Lung cancer	1	2	3
Breast cancer	3	5	8
Colon cancer	0	1	1
Prostate cancer	1	1	2
Total for All High-Risk Groups	13	17	30

Office of Inspector General Response

Our independent medical review contractor reviewed the additional information that MediGold provided for the 30 enrollee-years.

- For 25 of the 30 enrollee-years, our independent medical review contractor reaffirmed that the audited HCCs were not validated.

For example, for 1 enrollee-year from the prostate cancer high-risk group, our contractor upheld its original decision upon reconsideration and noted, “The new medical record documents a past medical history of [a] prostate cancer [diagnosis] which does not result in any HCC. There is no documented active treatment, and the patient will be screened yearly.”

- For the remaining 5 enrollee-years (from the embolism and breast cancer high-risk groups), our contractor found support for the audited HCCs and therefore reversed its original decision and validated the HCCs.

Accordingly, we reduced the number of enrollee-years in error from 194 (as reported in our draft report) to 189. We also revised our findings and reduced the associated monetary recommendation.

MediGold Stated That the Office of Inspector General’s Audit Methodology Did Not Ensure Payment Accuracy and Departed From Established CMS Standards for Evaluating Proper Payments to Medicare Advantage Organizations

MediGold Comments

MediGold stated that our audit methodology “was not designed to ensure risk adjustment payment integrity and accuracy” and that we “did not follow CMS’s program regulations, guidance and requirements for conducting a risk adjustment coding audit.” Specifically, MediGold made the following points:

- MediGold stated our audit “looked only for overpayments and not underpayments” and “targeted” only HCCs that we determined were more likely to be erroneous. Therefore, according to MediGold, our sampling frame was “not representative of MediGold’s enrolled population which is a prerequisite to extrapolation.” Furthermore, MediGold stated that our audit did not ensure payment accuracy because we did not:
 - include enrollee-years for which MediGold was most likely underpaid (i.e., enrollee-years with no or few submitted HCCs), or
 - allow MediGold “to demonstrate support for and receive credit for diagnosis codes that had not previously been submitted to CMS for the audited [enrollee-years] that were unrelated to the targeted diagnosis codes.”

Additionally, MediGold stated that when we identified support for another diagnosis that mapped to an HCC for a more or less severe manifestation of the related-disease group, it was “not clear” how we factored the impact into our net overpayment amount.

Therefore, according to MediGold, “it is highly likely” that our net overpayment amount is incorrect.

- MediGold stated that there are “inconsistencies” in the methodology we used from one audit to another and that our methodology differed from the audit methodology CMS used in its RADV audits. Specifically:
 - MediGold’s comments included a table that listed the differing number of high-risk groups that we reviewed in several Office of Inspector General (OIG) audits. MediGold also noted that it had “high payment accuracy rate findings” on its recently completed CMS contract-level RADV audit; however, it (and other MA organizations) scored “much lower” on OIG audits because of our “flawed audit methodology.”
 - MediGold also referred to our use of a physician in what it referred to as “a three-level review process” in instances when two coding reviewers disagree. MediGold stated that “CMS uses a two-level review process with certified coders only.” MediGold stated it had concerns with our use of a physician reviewer because “the physician is unlikely to be a certified coder” and “it suggests that the review process may be taking into consideration whether the clinical diagnosis was appropriate.” According to MediGold, “CMS has indicated clinical discretion is not to play any role in determining the appropriateness of a diagnosis code.”
 - MediGold stated that CMS “publicizes and follows a single, consistent RADV audit approach, promulgated in a formal manner pursuant to notice and comment rulemaking” and that our audit was “retroactive, variable in scope and methodology, and unaccompanied by any notice and comment rulemaking.” MediGold stated that any audit conducted on a MA organization should follow CMS’s approach and “adhere to the rulemaking process” with a methodology that was “set forth in detail well in advance in generally available publications.”
- MediGold stated that our audit period made payment accuracy “unachievable as a practical matter” because it covered dates of service in 2016 and 2017. According to MediGold, the “gap” between the audit period and the audit itself created “a significant data validation issue.” MediGold described various “significant data validation issues” that result from gaps in time of this nature, including unlocatable providers, lost paper records, upgraded or replaced electronic health record systems, and uncooperative facilities and practices. MediGold stated these examples (and other “practical realities”) “ma[d]e it impossible for OIG to assess payment accuracy.” Furthermore, MediGold said that “[t]he payment years subject to this audit were closed multiple years ago” and therefore, MediGold cannot add diagnoses that were not previously reported.

Office of Inspector General Response

We disagree with MediGold’s statement that our audit was not designed to ensure payment integrity and accuracy, and we also acknowledge that our audit methodology is different from that of the CMS RADV audit methodology. Specifically:

- We designed our audit to determine whether selected high-risk diagnosis codes that MediGold submitted to CMS for use in CMS’s risk adjustment program complied with Federal requirements. For the creation of our sampling frame, it was beyond the scope of our audit to identify: (1) enrollees for whom MediGold did not submit any risk-adjusted diagnosis codes and (2) all possible diagnosis codes that MediGold could have submitted (but did not) on behalf of the sampled enrollee-years.

Additionally, and contrary to MediGold’s suggestions that we “looked only for overpayments and not underpayments,” we did consider underpayments as they related to our objective. For the HCCs that were not validated, if the independent medical review 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 provided details on these calculations to MediGold officials for each of the 210 sampled enrollee-years.

A valid estimate of overpayments, given the objective of our audit, does not need to take into consideration all potential HCCs or underpayments within the audit period; this estimate addressed only the accuracy of the portion of payments related to the reviewed HCCs and did not extend to HCCs that were beyond the scope of this audit.

- The methodology and approaches that we have used to identify high-risk diagnosis codes and calculate overpayments for our series of audits of MA organizations have evolved over time. As a result, the methodology used in this audit did not mirror the methodology used in earlier audits—nor did it have to. Further, we agree with MediGold that our audit methodology is different from that of the CMS RADV audit methodology. Although our approach was generally consistent with the methodology used by CMS in its RADV audits, it did not mirror CMS’s approach in all aspects, nor did it have to. We make the following additional points in response to MediGold’s statements on our differing methodologies:
 - We disagree with MediGold’s comments that MA organizations are scoring “much lower” on our audits because of a “flawed audit methodology” on our part. For each of our audits, MA organizations have the opportunity to submit multiple medical records supporting the diagnosis codes that they submitted to CMS. The results of these audits are solely driven by whether these medical records support the diagnosis codes.

- We do not agree with MediGold’s comment regarding our independent medical review coding review process. The independent medical review contractor used both skilled coders and physicians (when necessary) to review medical record documentation in accordance with the relevant CMS guidance,²⁹ which states, “**reviewers** should evaluate all listed conditions . . . for consistency within the full provider documentation” (emphasis added). The coders and physicians did not, as MediGold suggested, make clinical judgments, but rather, they applied coding rules to accurately assign applicable ICD codes that translated to HCCs. Physician input was not an assessment of clinical support; rather, it constituted an assessment of documented evidence in support of the assignment of diagnosis codes. We believe that the use of a physician to serve as the final decision maker (i.e., tiebreaker), was a reasonable method for determining whether the medical records adequately supported the submitted diagnosis codes.
- We also do not agree with MediGold’s comments regarding the need for notice-and-comment rulemaking to establish the methodology we used in this audit. We did not apply any new regulatory requirements that would be subject to notice-and-comment rulemaking, and in that sense our audit does not make major changes to a CMS-administered program. Our audits are intended to provide an independent assessment of Department of Health and Human Services (HHS) programs and operations in accordance with the Inspector General Act of 1978, 5 U.S.C. Ch. 4.
- In regard to MediGold’s comment that our audit period made payment accuracy “unachievable,” as well as its comment about the inability to reopen payment years, we reiterate, as we point out in footnote 11, that at the start of our audit, the 2017 and 2018 payment year data were the most recent data available. Additionally, during our audit, we worked with MediGold officials to extend the medical record collection timeframe to account for any collection difficulties that MediGold may have encountered. Moreover, we followed CMS’s guidance for medical records that are unavailable because of “extraordinary circumstances” (Contract-Level Risk Adjustment Data Validation CMS Submission Instructions). Based on our assessment of CMS’s guidance, none of the examples provided by MediGold would be considered an extraordinary circumstance that would prevent MediGold from locating the medical records for the enrollee-years in question.

Accordingly, given the points presented above, we believe that we designed our audit methodology in accordance with GAGAS and that it provides a reasonable basis for our findings and conclusions based on our audit objective.

²⁹ CMS, Contract-Level Risk Adjustment Data Validation, Medical Record Reviewer Guidance, in effect as of 3/20/2019. Available online at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/Medical-Record-Reviewer-Guidance.pdf>. Accessed on Dec. 7, 2023.

MediGold Stated That Any Extrapolated Repayment Amount Must Be Adjusted To Ensure Actuarial Equivalence to the Fee-for-Service Medicare Program as Required by Law

MediGold Comments

MediGold stated that our audit methodology did not account for a payment principle known as “actuarial equivalence,” because we did not apply an adjustment called a Fee-for-Service (FFS) Adjuster. MediGold stated that the “actuarial equivalence requirement which was effective during the audit period extends to OIG’s estimation and extrapolation of a potential ‘overpayment’ amount in this audit.” Furthermore, MediGold stated that “[t]he lack of [an] FFS Adjuster violates important principles of administrative law, in particular the requirement for prospective notice and comment rulemaking.” MediGold added that “while recent rulemaking by CMS has effectively removed the FFS adjuster from the MA payment calculation, its removal is prospective and cannot be retroactively applied by OIG. As a result, OIG’s estimated and extrapolated repayment amount is both legally and actuarially unsound.”

Additionally, MediGold stated that because we did not apply an FFS Adjuster, we departed from past practices. MediGold cited prior OIG contract-level RADV audits and stated that “OIG acknowledged that the actuarial equivalence requirement made it inappropriate to estimate an extrapolated audit liability in the absence of a[n] FFS Adjuster.”

Office of Inspector General Response

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, both in our prior contract-level RADV audits and in this audit, to determine the payment that CMS should have made for each enrollee and to estimate overpayments.

Regarding MediGold’s statement that CMS’s final rule³⁰ for the removal of the FFS Adjuster was prospective and cannot be retroactively applied by OIG, we note that before issuance of this final rule, CMS had not issued any requirements that compelled us to reduce our net overpayment calculations. In the context of CMS’s requirements, both before and after the final rule was finalized, we recognize that CMS—not OIG—was responsible in 2007 (the year that we audited in our prior contract-level RADV audits), 2017, and 2018, and is responsible now, for making operational and program payment determinations for the MA program.

³⁰ 88 Fed. Reg. 6643 (Feb. 1, 2023).

MediGold Stated That the Office of Inspector General’s Use of a 90-Percent Confidence Interval To Calculate Repayment Amounts Departed From CMS Methodology

MediGold Comments

MediGold did not agree with our use—which MediGold described as a “conservative position”—of the lower limit of a two-sided 90-percent confidence interval to calculate the extrapolated repayment amount. MediGold stated that CMS “uses the lower-bound of a 99% confidence interval when calculating extrapolated repayment amounts for its RADV audits” and that we should “align with the CMS 99% confidence interval established for use in its RADV audits of [MA organizations].”

Office of Inspector General Response

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. We believe that the lower limit of a two-sided 90-percent confidence interval provides a reasonably conservative estimate of the total amount overpaid to MediGold 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.

MEDIGOLD DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL’S RECOMMENDATION TO PERFORM ADDITIONAL REVIEWS BEFORE AND AFTER THE AUDIT PERIOD

MediGold Comments

MediGold disagreed with our second recommendation—that MediGold perform additional reviews to determine whether similar instances of high-risk diagnoses occurred before and after the audit period and to refund any resulting overpayments—because, according to MediGold, “MA regulations do not require [it] to conduct the type of audit OIG conducted here nor do MA regulations require [MA organizations] to ensure data perfection.” Moreover, MediGold stated that “even if [it] were to identify unsubstantiated diagnosis codes, instances of individual unsubstantiated diagnosis codes would not necessarily equate to . . . ‘overpayments.’”

³¹ For example, HHS has used the two-sided 90-percent confidence interval when calculating recoveries in both the Administration for Child and Families and Medicaid programs. See e.g., *New York State Department of Social Services*, HHS Departmental Appeals Board (DAB) No. 1358, 13 (1992); *Arizona Health Care Cost Containment System*, DAB No. 2981, 4-5 (2019). In addition, HHS contractors rely on the one-sided 90-percent confidence interval, which is less conservative than the two-sided interval, for recoveries arising from Medicare fee-for-service (FFS) overpayments. See e.g., *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff’d*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 17-18 (E.D.N.Y. 2012).

MediGold also stated that our recommendation “does not align with the requirements of an MA compliance program because the MA program does not compel MediGold . . . to conduct audits of specific ‘high-risk diagnoses.’” To elaborate on this point, MediGold stated that “CMS has not implemented any regulations or guidance” in this context and added that we did not identify any “statutory or regulatory authority” that would require MediGold to perform these additional reviews. MediGold also said that to the extent that our recommendation “conflicts with CMS’s regulations and guidance, it would arbitrarily and capriciously subject MediGold to two contradictory regulatory regimes from the same agency.”

To amplify its comments regarding “data perfection,” MediGold cited to CMS regulations at 42 CFR § 422.504(l), which require MA organizations to “take reasonable steps to ensure the ‘accuracy, completeness, and truthfulness’ of the risk adjustment data they submit based on ‘best knowledge, information, and belief,’ but do not impose a requirement of 100 percent accuracy” (emphasis in original). Moreover, MediGold stated that CMS has recognized that MA organizations receive risk adjustment data from many different sources, which presents “‘significant verification challenges,’” and quoted a CMS comment that MA organizations “‘cannot reasonably be expected to know that every piece of data is correct.’”³²

With these considerations in mind, MediGold stated that implementation of our second recommendation would require it to “review every single claim submitted to CMS for risk adjustment purposes” MediGold added that the administrative costs needed to review every claim “would inhibit the ability of MediGold to provide the extensive supplemental benefits afforded by our plan and [that] are appreciated by our [enrollees]” and said that this requirement would also “increase the administrative burden that providers consistently argue inhibit the health care” rendered to enrollees.

Office of Inspector General Response

We do not agree with MediGold’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 MediGold’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 non-compliance with CMS’ program requirements.” Furthermore, these regulations specify that MediGold’s compliance plan “must, at a minimum, include [certain] core requirements,” which include “an effective system for routine monitoring and identification of compliance risks . . . [including] internal monitoring and audits and, as appropriate, external audits to evaluate . . . compliance with CMS requirements and the overall effectiveness of the compliance program.”

³² The CMS comment that MediGold quoted appears at 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999).

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” (42 CFR § 422.503(b)(4)(vi)(G)). Thus, CMS has, through the issuance of these Federal regulations, assigned the responsibility for dealing with potential compliance issues to the MA organizations.

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.

When an MA organization identifies overpayments, the Overpayment Rule (42 U.S.C. §§ 1301-1320d-8, 1395-1395hhh) requires that, if the MA organization learns that a diagnosis it submitted to CMS for payment lacks support in the associated individual’s medical record, the MA organization must refund that payment within 60 days.

Furthermore, MediGold’s comments implied that we opined on its responsibilities to ensure 100-percent accuracy on 100 percent of the data it submitted to CMS. That was not our intention or our focus for this audit. We limited our audit and recommendations to certain diagnosis codes that we had determined to be at high risk for being miscoded. We believe that the error rate identified in our audit (189 of 210 enrollee-years (see Appendix D)) demonstrates that MediGold has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope.

Accordingly, we maintain the validity of our second recommendation that MediGold identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period.

MEDIGOLD DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL’S RECOMMENDATION THAT IT CONTINUE TO EXAMINE ITS EXISTING COMPLIANCE PROCEDURES AND TAKE NECESSARY STEPS TO ENHANCE THEM

MediGold Comments

MediGold disagreed with our third recommendation—that it continue to examine its existing compliance procedures for diagnoses that are at high risk for being miscoded and enhance those procedures as necessary. Specifically, MediGold stated that it “believes that its current RADV compliance program is strong and sufficient to meet its current obligations prescribed under MA regulations.” MediGold also stated that it “has made significant changes to its RADV compliance program” since our audit period and described a number of steps it has taken in recent years “to enhance its risk adjustment oversight” and make improvements that were “consistent with CMS requirements and expectations.”

Furthermore, MediGold stated that these implemented changes have “effectively mitigated the risk of non-compliance associated with [the] submission of unsupported (erroneous) HCC codes.” MediGold also stated it would continue to provide oversight and education to its contracted providers.

Office of Inspector General Response

MediGold’s comments implied that we opined on the effectiveness of its entire compliance program. That was not our intention or our focus for this audit. Rather, we limited our audit to selected diagnoses that we determined to be at high risk for being miscoded. Our audit revealed a significant error rate for these high-risk groups. Thus, we continue to believe that MediGold should continue to examine and enhance its compliance procedures with respect to these high-risk groups of diagnoses.

Moreover, we acknowledge (as we stated in our draft report) that MediGold had compliance procedures in place to promote the accuracy of diagnosis codes submitted to CMS to calculate risk-adjusted payments during our audit period, and we acknowledge that MediGold has enhanced its compliance program subsequent to our audit period. The continued improvement of MediGold’s existing procedures (based on the results of this audit) will assist MediGold in attaining better assurance with regard to the “accuracy, completeness and truthfulness” of the risk adjustment data that it submits in the future. Accordingly, we maintain that our third recommendation remains valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid MediGold \$1,051,437,440 to provide coverage to its enrollees for 2017 and 2018. We identified a sampling frame of 2,220 unique enrollee-years (footnote 13) on whose behalf providers documented high-risk diagnosis codes during the 2016 and 2017 service years; MediGold received \$32,388,682 in payments from CMS for these enrollee-years for 2017 and 2018. We selected for audit 210 enrollee-years with payments totaling \$3,267,214.

The 210 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, and 30 prostate cancer diagnoses (Table 1). We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$567,570 for our sample.

Our audit objective did not require an understanding or assessment of MediGold'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 February 2020 through April 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:
 - 74 diagnosis codes for acute stroke,
 - 38 diagnosis codes for acute myocardial infarction,
 - 85 diagnosis codes for embolism,
 - 24 diagnosis codes for lung cancer,
 - 65 diagnosis codes for breast cancer
 - 20 diagnosis codes for colon cancer, and

- 2 diagnosis codes for prostate cancer.
- 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 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 MediGold, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C),
 - EDS³⁷ to identify enrollees who received specific procedures, and
 - Prescription Drug Event (PDE) file³⁸ to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.
- We interviewed MediGold officials to gain an understanding of: (1) the policies and procedures that MediGold followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) MediGold’s monitoring of those diagnosis codes to detect and correct noncompliance with Federal requirements.
- We selected for audit a stratified random sample of 210 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 210 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, the HCC was considered validated.
 - If the first senior coder did not find support on the medical record, a second senior coder performed a separate review of the same medical record:
 - If the second senior coder also did not find support, the HCC was considered to be not validated.
 - If the second senior coder found support, then a physician independently reviewed the medical record to make the final determination.
 - If either the first or second senior coder asked a physician for assistance, the physician’s decision became the final determination.
- We used the results of the independent medical review contractor, 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 net overpayment made to MediGold for 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 Specifically, we calculated the recommended recovery amount as the sum of the overpayments identified for the sampled enrollee-years from payment year 2017 and the estimate of total net overpayments made to MediGold for the enrollee-years from payment year 2018.
- We discussed the results of our audit with MediGold officials.

We conducted this performance audit in accordance with GAGAS. 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: “the Secretary annually conducts RADV audits to ensure risk adjusted payment integrity and accuracy.” Recovery of improper payments from MA organizations will be conducted in accordance with the Secretary’s payment error extrapolation and recovery methodologies. CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years. 88 Fed. Reg. 6643, 6655 (Feb. 1, 2023).

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That SelectCare of Texas, Inc. (Contract H4506) Submitted to CMS</i>	<u>A-06-19-05002</u>	11/27/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Aetna, Inc. (Contract H5521) Submitted to CMS</i>	<u>A-01-18-00504</u>	10/2/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS</i>	<u>A-07-20-01197</u>	8/3/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS</i>	<u>A-07-20-01202</u>	7/10/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. (H3952) Submitted to CMS</i>	<u>A-03-20-00001</u>	5/31/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS</i>	<u>A-05-19-00013</u>	4/4/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring Life & Health Insurance Company, Inc. (Contract H4513) Submitted to CMS</i>	<u>A-07-19-01192</u>	3/28/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS</i>	<u>A-02-20-01008</u>	3/24/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS</i>	<u>A-09-21-03011</u>	3/16/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Cigna-HealthSpring of Tennessee, Inc. (Contract H4454) Submitted to CMS</i>	<u>A-07-19-01193</u>	12/22/2022

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified MediGold enrollees who: (1) were continuously enrolled in MediGold throughout all of the 2016 or 2017 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 2016 or 2017 or in January of the following year, and (3) received a high-risk diagnosis during 2016 or 2017 that caused an increased payment to MediGold for 2017 or 2018, respectively.

We presented the data for these enrollees to MediGold 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 MediGold. After we performed these steps, our finalized sampling frame consisted of 2,220 enrollee-years (footnote 13).

SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2017 or 2018.

SAMPLE DESIGN AND SAMPLE SIZE

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

- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on only one physician claim during the service year but did not have an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim (844 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 (353 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 (187 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 (78 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 (368 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 (156 enrollee-years); or
- 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 (234 enrollee-years).

The specific strata are shown in Table 3.

Table 3: Sample Design for Audited High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee-Years	CMS Payment for HCCs in Audited High-Risk Groups	Sample Size
1 – Acute stroke	844	\$1,671,796	30
2 – Acute myocardial infarction	353	652,633	30
3 – Embolism	187	500,474	30
4 – Lung cancer	78	555,932	30
5 – Breast cancer	368	450,954	30
6 – Colon cancer	156	384,980	30
7 – Prostate cancer	234	273,247	30
Total	2,220	\$4,490,016	210

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We sorted the items in each stratum by an enrollee’s unique identification number and payment year and then consecutively numbered the items in each stratum in the stratified

sampling frame. After generating 210 random numbers according to our sample design, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

Estimated Net Overpayments

We used the OIG, OAS, statistical software to estimate the total net overpayments made to MediGold for payment years 2017 and 2018 at the lower limit of the two-sided 90-percent confidence interval (Appendix D, Table 7). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

Estimated Net Overpayments for Recommended Recovery

After we had reviewed the sampled enrollee-years, CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (footnote 40). Therefore, we calculated the recommended recovery amount in accordance with CMS's regulations. Specifically, we calculated the recommended recovery amount as the sum of the overpayments identified for the sampled enrollee-years from payment year 2017 and the estimate of total net overpayments made to MediGold for the enrollee-years from payment year 2018.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

**Table 4: Sample Details and Results
(Payment Years 2017 and 2018 Combined)**

Audited High-Risk Groups	Frame Size	CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With Unvalidated HCCs	Net Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)*
1 – Acute stroke	844	\$1,671,796	30	\$56,767	30	\$55,524
2 – Acute myocardial infarction	353	652,633	30	56,647	29	50,539
3 – Embolism	187	500,474	30	80,099	20	51,321
4 – Lung cancer	78	555,932	30	216,369	28	169,417
5 – Breast cancer	368	450,954	30	41,107	28	38,833
6 – Colon cancer	156	384,980	30	81,781	30	76,113
7 – Prostate cancer	234	273,247	30	34,800	24	28,160
Total	2,220	\$4,490,016	210	\$567,570	189	\$469,907

* The \$169,417 in the lung cancer high-risk group includes the 1 sampled enrollee-year (for payment year 2018) for which we validated the reviewed HCC and also identified support for another diagnosis that MediGold did not submit but should have submitted to CMS.

Table 5: Sample Details and Results for Payment Year 2017

Audited High-Risk Groups	Frame Size	CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With Unvalidated HCCs	Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)
1 – Acute stroke	388	\$746,890	12	\$20,925	12	\$20,925
2 – Acute myocardial infarction	182	326,280	16	28,994	15	25,294
3 – Embolism	83	219,035	13	33,331	11	25,378
4 – Lung cancer	35	248,141	15	105,643	15	90,263
5 – Breast cancer	195	232,520	16	17,366	14	15,092
6 – Colon cancer	77	185,833	12	29,470	12	26,065
7 – Prostate cancer	123	142,212	21	24,050	18	20,984
Total	1,083	\$2,100,911	105	\$259,779	97	\$224,001

Table 6: Sample Details and Results for Payment Year 2018

Audited High-Risk Groups	Frame Size	CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With Unvalidated HCCs	Net Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)*
1 – Acute stroke	456	\$924,906	18	\$35,842	18	\$34,599
2 – Acute myocardial infarction	171	326,353	14	27,653	14	25,245
3 – Embolism	104	281,439	17	46,768	9	25,943
4 – Lung cancer	43	307,791	15	110,726	13	79,154
5 – Breast cancer	173	218,434	14	23,741	14	23,741
6 – Colon cancer	79	199,147	18	52,311	18	50,048
7 – Prostate cancer	111	131,035	9	10,750	6	7,176
Total	1,137	\$2,389,105	105	\$307,791	92	\$245,906

* The \$79,154 in the lung cancer high-risk group includes the 1 sampled enrollee-year for which we validated the reviewed HCC and also identified support for another diagnosis that MediGold did not submit but should have submitted to CMS.

**Table 7: Estimated Net Overpayments in the Sampling Frame
(Payment Years 2017 and 2018 Combined)
(Limits Calculated for a 90-Percent Confidence Interval)**

Point Estimate	\$4,008,925
Lower Limit	\$3,753,525
Upper Limit	\$4,264,324

**Table 8: Total Estimated Net Overpayments in the Sampling Frame
for Recommended Recovery
(Limits Calculated for a 90-Percent Confidence Interval)**

	Overpayment for Sampled Enrollee- Years for 2017	Estimated Net Overpayment for Statistical Sample for 2018	Total Net Estimated Overpayments
Point Estimate	\$224,001	\$2,172,012	\$2,396,013
Lower Limit	224,001	1,959,513	2,183,514
Upper Limit	224,001	2,384,511	2,608,512

**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.

May 10, 2023

Maureen Seufert
 Assistant Regional Inspector General for Audit Services
 Department of Health and Human Services
 Office of the Inspector General
 Office of Audit Services, Region VII
 Maureen.Seufert@oig.hhs.gov

RE: MediGold Response to OIG's Draft Report for Audit A-07-20-01198

Dear Ms. Seufert:

Mount Carmel Health Plan, Inc. dba MediGold ("MediGold") welcomes the opportunity to respond to the Draft Report provided by the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") in connection with the Medicare Advantage Compliance Audit of Specific Diagnosis Codes that MediGold (Contract H3668) Submitted to CMS¹. MediGold respectfully requests that the OIG revise its Draft Report and withdraw each of its recommendations. Our request is based on the following, as further described below: (1) additional medical records relevant to the audit that validate certain diagnoses coded in various samples have been submitted following OIG's issuance of the Draft Report; (2) OIG's audit framework significantly deviates from the statutory and regulatory requirements of the Medicare Advantage program and CMS's Risk Adjustment Data Validation ("RADV") processes; (3) MA Organizations ("MAOs") are not required to conduct the specific types of audits OIG had recommended; and (4) MediGold's compliance program meets all legal and regulatory requirements.

I. OIG'S AUDIT METHODOLOGY IS INCONSISTENT WITH THE FUNDAMENTALS OF MEDICARE ADVANTAGE PAYMENT

A. OIG's Audit Methodology Does Not Ensure Payment Accuracy and Departs from Established CMS Standards for Evaluating Proper Payments to MA Organizations

MA regulations at 42 C.F.R. §§ 422.2 and 422.311(a) establish that a payment audit of a Medicare Advantage Organization ("MAO") conducted by the Secretary of HHS ensures the integrity and accuracy of risk adjustment payment data. Over the last fifteen years, CMS has developed and proposed multiple audit and sampling methodologies and has undertaken multiple rounds of industry engagement, thereby attempting to establish a sampling methodology that ensures payment integrity and accuracy. OIG did not follow CMS's program regulations, guidance and requirements for conducting a risk adjustment coding audit.

OIG's audit was not designed to ensure risk adjustment payment integrity and accuracy. OIG's audit methodology was so targeted that it could not equally identify overpayments and underpayments. In particular, the sample framework targeted seven specific diagnosis categories that OIG hypothesized, prior to conducting the audit, are likely to be at high risk for noncompliance based on medical claims data and prescription drug claims data, and therefore likely to have resulted in an "overpayment." This biased targeting resulted in findings that do not ensure accuracy because the audit was not designed to look at MAO payment accuracy, which would include both overpayments and underpayments. OIG neither (1)

¹ OIG, DRAFT REPORT– Medicare Advantage Compliance Audit of Specific Diagnosis Codes that MediGold (Contract H3668) Submitted to CMS, A-07-20-01198 (April 2023) ("Draft Report").

simultaneously conducted an audit of members for which MediGold was most likely underpaid (i.e., members with no or few submitted Hierarchical Condition Categories (“HCCs”), nor (2) allowed MediGold to demonstrate support for and receive credit for diagnosis codes that had not previously been submitted to CMS for the audited members that were unrelated to the targeted diagnosis codes.

The flaws in OIG’s targeted audit methodology are evidenced by the fact that no MAO has performed well during any of the audits targeting high-risk diagnoses. It is also worth noting the inconsistencies in OIG’s audit methodology amongst OIG’s targeted audits of MAOs that commenced in 2019 as reflected in the table below².

Plan	What the Audit Targeted	Errors Found (thousands)	Extrapolated Amounts (millions)	Payment Years
Humana Choice (H6609)	7 categories	\$480	\$27.4	2015, 2016
Cigna-HealthSpring (H4513)	9 categories	\$468	\$6.2	2016, 2017
MCS Advantage (H5577)	9 categories	\$221	\$6.2	2016, 2017
Geisinger (H3954)	9 categories	\$566	\$6.5	2016, 2017
Cigna-HealthSpring TN (H4454)	10 categories	\$409	\$6.0	2016, 2017
BCBS RI (H4152)	9 categories	\$543	\$4.9	2016, 2017
California Physicians' (H0504)	7 categories	\$320	\$2.0	2015, 2016
Humana Choice (R5826)	9 categories	\$574	\$34.4	2016, 2017
Highmark (H3916)	6 categories	\$556	\$6.2	2015, 2016
BCBS TN (H7917)	9 categories	\$491	\$7.8	2016, 2017
Inter Valley (H0545)	3 categories	\$152	\$5.3	2015
Regence BCBS OR (H3817)	7 categories	\$249	\$1.9	2015, 2016
Wellcare FL (H1031)	7 categories	\$410	\$3.5	2015, 2016
Cariten (H4461)	9 categories	\$557	\$9.2	2016, 2017
Peoples (H1961)	7 categories	\$413	\$3.3	2015, 2016
Tufts (H2256)	7 categories	\$536	\$3.8	2015, 2016
SCAN (H5425)	200 enrollees	\$237	\$54.3	2015
Healthfirst (H3359)	7 categories	\$517	\$5.2	2015, 2016
UPMC (H3907)	10 categories	\$681	\$6.4	2015, 2016
Coventry (H2663)	6 categories	\$549	None	2013, 2014, 2015
Anthem Community (H3655)	7 categories	\$354	\$3.5	2015, 2016
Humana (H1036)	200 enrollees	\$249	\$197.7	2015

² OIG’s audits differ not only from one audit to the next, but also from CMS’s approach. Most obviously, CMS’s RADV audits use a more representative sample of diagnosis codes rather than targeting just codes with a high risk of error. Additionally, as noted above, when extrapolating, CMS uses a lower bound of 99% confidence interval instead of the two-sided 90% confidence interval utilized by the OIG. Further, in the coding review, CMS uses a two-level review process with certified coders only, whereas OIG utilizes a three-level review process in which a physician makes the determination if the second level reviewer disagrees with the first level reviewer. This raises concerns not only because it differs from CMS’s approach but also because the physician is unlikely to be a certified coder and because it suggests that the review process may be taking into consideration whether the clinical diagnosis was appropriate. And CMS has indicated clinical discretion is not to play any role in determining the appropriateness of a diagnosis code. See CMS, ICD-10CM Official Guidelines for Coding and Reporting.

BCBS MI (H9572)	7 categories	\$668	\$14.4	2015, 2016
Essence	2 categories	\$159	None	2013, 2014, 2015

Even MAOs like MediGold, which recently completed a contract-level RADV audit of H3668 that resulted in high payment accuracy rate findings, are scoring much lower because of the flawed audit methodology. Further, this discrepancy indicates that if OIG’s targeted audit was designed for payment accuracy, as required by 42 C.F.R. § 422.311(a), then the findings would be different and would be a much more accurate reflection of the MAO’s risk adjustment data validation.

Unlike CMS, which publicizes and follows a single, consistent RADV audit approach, promulgated in a formal manner pursuant to notice and comment rulemaking and advance written notice and manuals, these OIG audits are retroactive, variable in scope and methodology, and unaccompanied by any notice and comment rulemaking. In the interest of fairness, audits conducted on MAOs that recommend repayments should utilize a consistent prospective approach with clear parameters and methods that adhere to the rulemaking process, and that are set forth in detail well in advance in generally available publications.

It is also worth noting the timing of the OIG’s audit also makes payment accuracy unachievable as a practical matter. This audit covered dates of service in 2016 and 2017. The five- and six-year gap between the encounters at issue and the audit creates a significant data validation issue for MediGold. Providers may have moved, left our network, retired, or passed away. Paper records may have been lost. Electronic health record (EHR) systems may have been upgraded or replaced, making older electronic records harder or impossible to access. Facilities and other practices may not cooperate with requests seeking records from that far in the past (and they face no realistic sanction for deciding they cannot or do not wish to cooperate). These and similar practical realities make it impossible for OIG to assess payment accuracy via a RADV-styled audit of targeted high-risk diagnoses.

These issues indicate that OIG’s audit methodology is not appropriately designed to identify underpayments, and, as a consequence, does not appear to be able to reliably generate a statistically valid “net” overpayment figure for the audit sample. This reinforces our disagreement with OIG’s first recommendation as the proposed overpayment figure for payment year 2018 used by OIG cannot be an adequate basis for a valid extrapolation.

B. OIG’s Audit Was Not Designed to Fairly Determine Whether Overall Payments to MediGold Were Appropriate and In Accordance with CMS Requirements.

MediGold is concerned that OIG’s audit was not designed to consider the entirety of MediGold’s coding and risk adjustment submissions to CMS. OIG’s audit design targeted only HCC deemed by OIG most likely to be prone to errors rendering its results inherently unreliable. The audit did not assess the overall accuracy of payments by CMS to MediGold, including both “overpayments” and “underpayments.” In other words: the OIG audit looked only for overpayments and not underpayments. As such, OIG’s sample frame is not representative of MediGold’s enrolled population which is a prerequisite to extrapolation.

Based on OIG’s instructions, MediGold’s medical record submissions consisted of far less than all records available for the sampled enrollee-years. Thus, OIG’s review could not and does not account for all HCCs that are substantiated but not submitted to the OIG for the sampled enrollee years- just as OIG found certain “underpayments” in the records actually subject to review as described further below.

A net overpayment³ could only be calculated pursuant to a methodology that accounts for diagnosis coding errors in the traditional Medicare program (e.g., a FFSA) in order to ensure consistency with the actuarial requirements of the Social Security Act (“SSA”). OIG ignored the fact that for each identified member, there may be supported diagnoses not previously submitted to CMS (i.e., “underpayments”) (due to system limitations and MA program instructions), creating additional bias toward identifying “overpayments.” As OIG is aware, an MAO cannot reopen payment years to add diagnoses that it determines were not previously reported. The payment years subject to this audit were closed multiple years ago. By OIG limiting its review to only instances of potential “overpayments,” OIG knew that MediGold would be unable, on its own, to demonstrate that it was not in fact “overpaid” because MediGold is not able to submit diagnoses identified in 2023 as support for dates of services in 2016 and 2017. The only way for MediGold to be credited for such previously unreported codes, and for this audit to ensure payment accuracy, is for OIG to take such diagnoses into account.

C. OIG Should Recognize That MAOs Are Not Required to Have Perfect Data

MediGold, like all MAOs, relies on medical providers to produce large amounts of risk adjustment data based on the providers' clinical discretion and the providers' implementation of a complex diagnosis coding system. CMS regulations state that MAOs should take *reasonable steps* to ensure the "accuracy, completeness, and truthfulness" of the risk adjustment data they submit based on "best knowledge, information, and belief," but do not impose a requirement of 100 percent accuracy.⁴ CMS implemented the current regulatory regime after acknowledging industry concerns about reporting of widespread healthcare provider "mistakes" and "incomplete or inaccurate" provider-generated data.⁵ Commenters at the time explained that "it would be unfair and unrealistic to hold [MA] organizations to a '100 percent accuracy' certification standard."⁶ In response, CMS explicitly recognized that risk adjustment data are submitted to MAOs from many different sources, including healthcare providers, thereby presenting "significant verification challenges."⁷ As CMS explained, MAOs "cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the OIG, and [the U.S. Department of Justice] believe is reasonable to enforce."⁸

D. Any Extrapolated Repayment Amount Must Be Adjusted to Ensure Actuarial Equivalence to the Fee-for-Service Medicare Program As Required by Law

A perfection standard is also at odds with the “actuarial equivalence” requirement at 42 U.S.C. § 1395w-23(a)(1)(C)(i). Statute and regulation requires CMS to pay MAOs an amount that is “actuarially equivalent” to the expected cost that CMS would have otherwise incurred had it provided required Medicare benefits directly to the MAO’s enrollees.⁹ CMS does this by making risk-adjusted payments to MAOs that are based on actuarially sound calculations of the expected cost of providing traditional Medicare benefits to enrollees with differing health statuses.¹⁰

Actuarial Standard of Practice 45, section 3.2 requires that the “type of input data that is used in the application of risk adjustment should be reasonably consistent with the type of data used to develop

³ Overpayment is defined as any [funds](#) that an [MAO](#) has received or retained under title XVIII of the [Act](#) to which the [MA organization](#), after applicable reconciliation, is not entitled under such title. See 42 CFR 422.326(a).

⁴ 42 C.F.R. § 422.504(l). CMS reiterated this standard in its April 15, 2022 Memo to MAOs. See *Reminder of Existing Obligation to Submit Accurate Risk Adjustment Data*, CMS (Apr. 15, 2022).

⁵ Medicare Program: Medicare+Choice Program, 65 Fed. Reg. 40,169, 40,250, 40,268 (June 29, 2000).

⁶ *Id.* at 40,268.

⁷ *Id.*

⁸ 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999).

⁹ 42 U.S.C. § 1395w-24(a)(5)(A), (a)(6)(A)(i)-(iii).

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

the model.”¹¹ In 2011, the American Academy of Actuaries wrote that the inconsistency between the unaudited data to create the HCC model and extrapolation in RADV audits “not only creates uncertainty, it also may create systematic underpayment, undermining the purpose of the risk-adjustment system and potentially in payment inequities.”¹² More recently, most qualified statisticians and actuaries to consider the question concluded that a significant FFS adjuster was essential to meeting the statutory requirement of actuarial equivalence.¹³

The actuarial equivalence requirement which was effective during the audit period extends to OIG’s estimation and extrapolation of a potential “overpayment” amount in this audit. OIG did not apply a FFS Adjuster to account for errors in the data used to create the risk adjustment payment model. The lack of FFS Adjuster violates important principles of administrative law, in particular the requirement for prospective notice and comment rulemaking. It also would mark a departure from OIG’s past audit practices. In prior contract-level RADV audits, OIG acknowledged that the actuarial equivalence requirement made it inappropriate to estimate an extrapolated audit liability in the absence of a FFS Adjuster:

Although an analysis to determine the potential impact of error rates inherent in FFS data on MA payments was beyond the scope of our audit, we acknowledge that CMS is studying this issue and its potential impact on audits of [MAOs]. Therefore, because of the potential impact of these error rates on the CMS model that we used to recalculate MA payments for the beneficiaries in our sample, we (1) modified one recommendation to have [the MAO] refund only the overpayments identified for the sampled beneficiaries rather than refund the estimated overpayments and (2) added a recommendation that [the MAO] work with CMS to determine the correct contract-level adjustments for the estimated overpayments.¹⁴

¹¹ CMS is required to follow actuarial standards. See HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, Part II: HHS Agency Responsibilities and Guidelines, E. Centers for Medicare & Medicaid Services, V. Agency Quality Assurance Policies, Standards and Processes (Oct. 1, 2002)

¹² Letter from Thomas F. Wildsmith, American Academy of Actuaries, to Cheri Rice, Acting Director, Medicare Plan Payment Group, Re: Comment on RADV Sampling and Error Calculation Methodology, 2 (Jan 21, 2011).

¹³ See, e.g., Avalere Health, Eliminating the FFS Adjuster from the RADV Methodology May Affect Plan Payment (Mar. 2019); Avalere Health, Impact of Eliminating the FFS Adjuster May Vary Based on Plan Enrollee Characteristics (Aug. 21, 2019); Sean Creighton, The FFS Adjuster matters for accurate Medicare Advantage payment: An examination of the methodology and evidence behind a regulatory proposal to eliminate the adjuster, RISE Health (Dec. 11, 2019); Rob Pipich, Milliman, Medicare Advantage RADV FFS adjuster: White paper (Aug. 23, 2019); Matthew G. Mercurio, Response to CMS “Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits” Announcement (Aug. 27, 2019); Bo Martin, Ankura Consulting Group, Comment Regarding CMS’s Proposals Not to Implement a “Fee-for-Service Adjuster” For RADV Audits and To Implement a Sub-Cohort Audit Method (Aug. 27, 2019); Ross Winkelman, Wakely Consulting Group, Actuarial Report on CMS’ November 1, 2018 Proposed Rule (Aug. 27, 2019); Julia Lambert, Wakely Consulting Group, Actuarial Report on Medicare Advantage FFS Adjuster (Aug 28, 2019); Stefan Boedeker, Comment on The Centers for Medicare and Medicaid Services Proposed Rule (Aug. 28, 2019).

¹⁴ 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, A-03-09-00003, 7 (Sept. 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, A-0710-01082, iii (May 2013).

Additionally, audits of OIG deemed “high-risk” codes perfectly exemplify the importance of addressing the Data Inconsistency Issue in an actuarially sound manner: such codes are likely to be equally unsubstantiated in the FFS context. For example, OIG found that “almost all of the selected acute stroke diagnosis codes that physicians submitted to CMS under traditional Medicare ... did not comply with Federal requirements.”¹⁵ Further exacerbating this issue is the fact that CMS has not implemented policies or procedures to evaluate whether supposedly “high-risk” codes, like acute stroke and other diagnosis codes examined in OIG’s Draft Report, are always supported by underlying medical record documentation in the MA or the FFS program.¹⁶

Considering this history, it is not possible for OIG to determine whether MediGold received an overpayment without establishing an actuarially sound methodology that takes into account diagnosis coding errors in the FFS data. And while recent rulemaking by CMS has effectively removed the FFS adjuster from the MA payment calculation, its removal is prospective and cannot be retroactively applied by OIG. As a result, OIG’s estimated and extrapolated repayment amount is both legally and actuarially unsound.

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

OIG acknowledged it was taking a conservative position by using the lower limit of a two-sided 90-percent confidence interval to calculate the extrapolated repayment amount.¹⁷ While OIG has defended its use of the 90% confidence interval in other reports¹⁸, CMS announced that it uses the lower-bound of a 99% confidence interval when calculating extrapolated repayment amounts for its RADV audits and MediGold relied on that announcement in submitting its bid. OIG, in recalculating the extrapolated “overpayment” amount based on MediGold’s comments, should use the 99% confidence interval to align with the CMS 99% confidence interval established for use in its RADV audits of MAOs.

II. MEDIGOLD STATEMENTS OF CONCURRENCE/NONCONCURRENCE WITH OIG’S RECOMMENDATIONS

A. MediGold Disagrees with OIG’s Recommendation to Refund to the Federal Government the \$2,224,283 of Estimated Net Overpayments.

OIG recommends that MediGold refund to the Federal Government the \$2,224,283 of estimated net overpayments. In addition to the issues MediGold takes with the OIG’s audit methodology described above, prior to the issuance of the Draft Report, MediGold identified additional medical records that it sought to provide as a means of validating HCCs that OIG found to be submitted in error. At the time of submission of this letter, MediGold will have submitted medical records that may validate approximately 35 enrollee samples. MediGold is confident that some of those records will result in validation. And as a result, the “overpayment” amounts associated with the sample enrollee years for payment years 2017 and 2018 will be reduced.¹⁹

¹⁵ See HHS OIG, Audit Report No. A-07-17-01176, *Incorrect Acute Stroke Diagnosis Codes Submitted by Traditional Medicare Providers Resulted in Millions of Dollars in Increased Payments to Medicare Advantage Organizations* (Sept. 2020) at 8, available at <https://www.oig.hhs.gov/oas/reports/region7/7170117.pdf> (“Acute Stroke Audit Report”).

¹⁶ See *Id.* at page 8.

¹⁷ OIG Draft Report at page 7, note 16.

¹⁸ HumanaChoice Report at 28-29; HealthFirst Report at 24-25; and Cariten Report at 24-25.

¹⁹ See Draft Report at pages 27-28. OIG determined that 2017 sampled-enrollee years “overpayment” equals \$228,825 and for 2018 sampled-enrollee years “overpayment equals \$251,708.

With regards to the extrapolated amount of \$1,743,750 for payment year 2018, the sampling frame was inappropriately defined and therefore does not support extrapolation. According to the Draft Report²⁰, the sampling frame used by the OIG, which is inconsistent with the CMS RADV audit methodology described above, was limited to MediGold enrollees who:

- were (1) were continuously enrolled in MediGold throughout all of the 2016 or 2017 service year and January of the following year,
- were not classified as being enrolled in hospice or as having end-stage renal disease status at any time during 2016 or 2017 or in January of the following year, and
- received a high-risk diagnosis during 2016 or 2017 that caused an increased payment to MediGold for 2017 or 2018, respectively.

Limiting the sampling frame to members who had at least one HCC in their 2017 and 2018 payment risk scores fails to consider the members for whom MediGold did not report a qualifying diagnosis but who had a condition documented in the medical record.²¹ While OIG indicates MediGold received a credit for an HCC within the Lung Cancer HCC grouping that provides for lesser reimbursement, it is not clear how such lesser-coded related HCC impacted the net overpayment amount.²² Moreover, there is no indication that any of the 18 remaining lesser HCCs that relate to an HCC grouping were credited to MediGold. Thus, it is highly likely the net “overpayment” amount for 2018 that was used as the basis for extrapolation is erroneous.

By excluding members who MediGold did not report to have an HCC in both payment year 2017 and 2018, the OIG’s sampling methodology excluded members for whom MediGold was most likely underpaid. This limitation in the audited sample is inconsistent with the importance of potential underpayments in calculating the error rates in the OIG’s analysis. In addition to the members included in the audited sample, potential underpayments also existed among MediGold’s enrolled population, and are the only type of diagnosis code payment error for those members for whom no HCCs were reported.

OIG audit did not consider all the risk adjustment submissions to CMS and did not evaluate the overall accuracy of payments made to MediGold. Considering that the overall accuracy of the payments to MediGold were not evaluated, the OIG’s actual and extrapolated repayment calculations are higher than what would be evident from a statistically valid sampling methodology. Thus, MediGold disagrees with any refund amount that is not supported by a valid sampling methodology.

B. MediGold Disagrees with OIG’s Recommendations that MediGold Identify, for the High-Risk Diagnoses Included in the Draft Report, Similar Instances of Noncompliance that Occurred Before and After the Audit Period and Refund Any Resulting Overpayments to the Federal Government.

OIG recommends that MediGold “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

²⁰ See Draft Report at page 23.

²¹ The likelihood of this occurrence is confirmed by the Draft Report, which identified HCCs among the audited sample for which the medical records supported diagnosis codes that MediGold could have submitted to CMS for risk adjustment payment purposes, but did not submit. Specifically, OIG specified 1 instance of this with Acute Stroke (Hemiplegia should have been coded); 4 with Myocardial Infarction (lesser HCC not specified); 1 for Embolism (Vascular Disease should have been coded); 8 for Lung Cancer (Lymphoma and Other Cancers should have been coded); and 5 for Colon Cancer (Breast, Prostate and Other Cancers/Tumors) should have been coded.

²² See Draft Report at page 28 which provides an asterisk containing the following: The \$79,154 in the lung cancer high-risk group includes the 1 sampled enrollee-year for which we validated the reviewed HCC and also identified support for another diagnosis that MediGold did not submit but should have submitted to CMS.

overpayments to the Federal Government”²³. In recommending these additional audits, OIG is essentially expecting data perfection from MediGold. And as described above, the same is not required by CMS. In fact, the Becerra court notes that “nothing in the Overpayment Rule obligates insurers to audit their reported data,” a fact the court notes that CMS did not dispute. *Becerra* at 884.

OIG’s recommendation does not align with the requirements of an MA compliance program because the MA program does not compel MediGold or any other MAO to conduct audits of specific “high-risk diagnoses.” Despite CMS’s awareness of “several diagnosis codes that are at high risk for inaccurate payments” throughout the MA industry, CMS has not implemented any regulations or guidance to address such issues or require additional compliance measures. Nor does OIG identify any statutory or regulatory authority that would allow it to unilaterally impose new substantive requirements on MediGold, rather than merely identifying non-compliance with duly promulgated regulations. And, as explained, to the extent OIG’s recommendation conflicts with CMS’s regulations and guidance, it would arbitrarily and capriciously subject MediGold to two contradictory regulatory regimes from the same agency. To the extent HHS intends to impose new regulatory requirements on MediGold, it must do so through notice-and-comment, under both the Administrative Procedure Act and the SSA.²⁴

MediGold uses the majority of its revenue to provide services to enrolled beneficiaries. In order to carry out OIG’s recommendation, MediGold would need to review every single claim submitted to CMS for risk adjustment purposes to identify both underpayments and overpayments. The administrative costs that would need to be devoted to review every claim submitted for risk adjustment would inhibit the ability of MediGold to provide the extensive supplemental benefits afforded by our plan and are appreciated by our enrolled beneficiaries. Providers spend most of their time providing health services to beneficiaries. To require providers to submit to MediGold medical records on every claim would increase the administrative burden that providers consistently argue inhibit the health care provided to beneficiaries.

Accordingly, MediGold disagrees with this recommendation because (1) MA regulations do not require MediGold to conduct the type of audit OIG conducted here nor do MA regulations require MAOs to ensure data perfection and (2) even if MediGold were to identify unsubstantiated diagnosis codes, instances of individual unsubstantiated codes would not necessarily equate to an “overpayments”.

C. MediGold Disagrees with OIG’s Recommendation to 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 and Take the Necessary Steps to Enhance Those Procedures.

OIG recommends that MediGold 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 procedures²⁵. As OIG acknowledges, MediGold has made significant changes to its RADV compliance program since the close of OIG’s audit period. While MediGold regularly evaluates its compliance programs in order to both respond to regulatory changes and to identify opportunities for improvement, MediGold believes that its current RADV compliance program is strong and sufficient to meet its current obligations prescribed under MA regulations. Accordingly, MediGold requests that OIG withdraw its recommendation that MediGold make changes to its existing RADV compliance program.

²³ Draft Report at page 17.

²⁴ See 5 U.S.C. § 553; 42 U.S.C. § 1395hh(a)(2).

²⁵ Draft Report at page 17.

Generally speaking, MediGold does agree that an effective compliance program should be subject to periodic reviews for appropriate enhancements. As such, it is MediGold's regular practice to evaluate its compliance program policies and procedures to identify appropriate improvement opportunities consistent with CMS requirements and expectations. Over the past several years, MediGold has taken several steps to enhance its risk adjustment oversight. Such steps include the following:

- Contracted with a reputable and well-regarded independent consultant with substantial experience in MA risk adjustment;
- Built a risk Adjustment Department which carries out several responsibilities that are aimed at ensuring the submission of accurate claim data and condition data, including regular monitoring and audits. The Department includes a Director, Manager, two Coding Auditors, two Medical Data Analysts, two Encounter Resolution Specialists, and a Project Coordinator;
- Developed and implemented several risk adjustment policies which are subject to annual review including:
 - Risk Adjustment Overview
 - Contract and National Improper Payment Measure (aka RADV)
 - HCC Internal Audits
 - Vendor Coding Audits
 - In-Home Assessments Initiatives
 - Provider Engagement Initiatives
 - Retrospective Medical Record Reviews
 - Encounter Data Submission & Error Resolution
- Timely corrections, including additions and deletions of under and over-coded claims, as identified through internal and vendor coding audits utilizing CMS prescribed processes.
- Developed MediGold internal coding guidelines which take into consideration various guidance released by CMS and also account for any changes to ICD-10;
- Requiring compliance with MediGold internal coding guidelines by third-party risk adjustment vendors;
- Annual review of MediGold internal coding guidelines and communication of these guidelines with third-party risk adjustment vendors;
- Modified contractual agreements with all third-party risk adjustment vendors to include service level agreements (“SLAs”) that require a 95% accuracy rate for medical record review and in-office and in-home assessment code submissions;
- Administration of these SLAs by conducting vendor audits and developing corrective action plans (“CAP”) for noncompliance, assessment of contractual SLA penalties and confirming CAPs have been fully implemented and issue(s) have been resolved;
- Provision of coding education to MediGold contracted providers at various meetings and through various provider communications. Such coding education is aimed at ensuring MediGold contracted providers deliver appropriate care for and maintain appropriate documentation of MediGold members' conditions;
- Obtaining independent assessments of the effectiveness of the MediGold's compliance program
- Ongoing participation and attendance by MediGold Risk Adjustment Department members in CMS hosted events and monitoring of CMS published materials concerning risk adjustment program requirements; and
- Regular reporting of compliance activities (i.e., internal/external audits, issuance of CAPs and status, etc.) associated with the various risk adjustment initiatives to the MediGold Board of Directors and the MediGold Compliance Committee.

MediGold firmly believes that its risk adjustment department and the changes described above and within its risk adjustment policies and procedures have effectively mitigated the risk of non-compliance associated with submission of unsupported (erroneous) HCC codes. MediGold will continue

its oversight and auditing mechanisms described above and provide provider-specific education and general coding education to its contracted providers.

III. REQUEST TO CLARIFY MEDIGOLD CODING EDUCATION PRACTICES

MediGold respectfully requests the OIG to clarify in its Final Report that MediGold provides its proprietary coding guidelines to its internal staff and third-party vendors that assist with risk adjustment medical record reviews and coding audits. With respect to coding initiatives involving its contracted providers, MediGold routinely provides coding education to its contracted providers at various meetings and through various provider communications. Such coding education is aimed at ensuring MediGold contracted providers deliver appropriate care of and documentation of MediGold members' conditions. MediGold does not provide its internal coding guidelines to its contracted providers.

Conclusion

For the reasons described, we believe that the overall intent and design of OIG's audit is contrary to MA regulations and the goal of payment accuracy audits. MediGold respectfully requests OIG withdraw its recommendations and update its Draft Report to account for the inherent bias in such a targeted audit. MediGold further requests that OIG revise its Draft Report and withdraw its recommendations that MediGold (a) refund to the Federal Government \$2,224,283 of estimated overpayments, (b) identify similar instances of noncompliance outside of the audit period and refund any resulting overpayments, and (c) examine existing compliance procedures to identify where improvements can be made to ensure diagnosis codes that are at high risk for being miscoded comply with Federal requirements.

As was done over the course of the Audit, we are willing to work collaboratively with OIG, CMS, and other stakeholders to discuss our response together in an open, cooperative, and transparent way. We would appreciate the opportunity to meet prior to OIG's issuance of the Final Report to discuss our feedback and how it might be incorporated therein. We respectfully request that MediGold's concerns, and comments be shared with CMS and the public in connection with OIG's transmittal of its report and findings.

Sincerely,

Jack Randolph /s/

Jack Randolph
President & CEO

cc: Patricia Suffern, Medicare Compliance Officer, MediGold
Trisha Whetstone, Associate Counsel, Trinity Health Corporation
Dawn Geisert, SVP, Chief Compliance & Integrity Officer, Trinity Health Corporation