Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE ADVANTAGE COMPLIANCE AUDIT OF SPECIFIC DIAGNOSIS CODES THAT INDEPENDENT HEALTH ASSOCIATION, INC. (CONTRACT H3362) 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
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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Independent Health Association, Inc. (Contract H3362) Submitted to CMS

Why OIG Did This Audit

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations according to a system of risk adjustment that depends on the health status of each enrollee. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources than to healthier enrollees, who would 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, Independent Health Association, Inc. (IHA), and focused on eight groups of high-risk diagnosis codes. Our objective was to determine whether selected diagnosis codes that IHA submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

How OIG Did This Audit

We sampled 247 unique enrollee-years with the high-risk diagnosis codes for which IHA received higher payments for 2016 through 2017. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $744,772.

What OIG Found

With respect to the eight high-risk groups covered by our audit, most of the selected diagnosis codes that IHA submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, for 230 of the 247 sampled enrollee-years, the medical records that IHA provided did not support the diagnosis codes and resulted in $646,217 in overpayments. As demonstrated by the errors found in our sample, IHA'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 IHA received at least $7.0 million in overpayments for 2016 and 2017. 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 only the overpayments for the sampled enrollee-years.

What OIG Recommends and IHA Comments

We recommend that IHA: (1) refund to the Federal Government the $646,217 of 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 (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

IHA disagreed with some of our findings and our first and second recommendations and requested that we withdraw all of our recommendations. Specifically, IHA did not agree with our findings for 17 of the 232 enrollee-years in error identified in our draft report and provided additional information for our consideration. IHA did not directly agree or disagree with our findings for the remaining 215 enrollee-years. IHA did not agree with our audit methodology, use of extrapolation, and standards for data accuracy. After reviewing IHA's comments and the additional information IHA provided, we reduced the number of enrollee-years in error and revised the amount in our first recommendation. We maintain that our second and third recommendations remain valid.

The full report can be found on the OIG website.

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INTRODUCTION

WHY WE DID THIS AUDIT

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

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS.[2] Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 65 breast cancer diagnoses into 1 group.) This audit covered Independent Health Association, Inc. (IHA), for contract number H3362 and focused on eight groups of high-risk diagnosis codes for payment years 2016 and 2017.[3]

OBJECTIVE

Our objective was to determine whether selected diagnosis codes that IHA 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 (CM), *Official Guidelines for Coding and Reporting* (ICD Coding Guidelines). The ICD is a coding system that is used by physicians and other health care providers to classify and code all diagnoses, symptoms, and procedures. Effective October 1, 2015, CMS transitioned from the ninth revision of the ICD Coding Guidelines (ICD-9-CM) to the tenth revision (ICD-10-CM). Each revision includes different diagnosis code sets.

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

[3] All subsequent references to "IHA" in this report refer solely to contract number H3362.

traditional fee-for-service (FFS) program.[4] Individuals who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

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

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

Risk Adjustment Program

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

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

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

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

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

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[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 not validated, which causes overstated enrollee risk scores and overpayments from CMS.[10] Conversely, if medical records support the diagnosis codes that an MA organization did not submit to CMS, validated HCCs may not have been included in enrollees' risk scores, which may cause those risk scores to be understated and may result in underpayments.

High-Risk Groups of Diagnoses

Using data mining techniques and discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. For this audit, we focused on eight 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 heart attack*: An enrollee received one diagnosis (that mapped to either the HCC for Acute Myocardial Infarction or to the HCC for Unstable Angina and Other Acute Ischemic Heart Disease (Acute Heart Attack HCCs)) on only one physician or outpatient claim during the service year but did not have an acute heart attack diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician or outpatient claim). In these instances, a diagnosis indicating a history of a myocardial infarction (which does not map to an HCC) typically should have been used.

- *Embolism*: An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease With Complications (Embolism HCCs) on only one claim during the service year but did not have an anticoagulant medication dispensed on his or her behalf. An anticoagulant medication is typically used to treat an embolism. In these instances, a diagnosis of history of embolism (an 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 "not supported" to denote whether or not the reviewed diagnoses were evidenced in the medical records. If our audit determines that the diagnoses are supported or not supported, we accordingly use the terms "validated" or "not validated" with respect to the associated HCC.

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.

- *Potentially mis-keyed diagnosis codes*: An enrollee received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition (which mapped to a possibly unvalidated HCC). For example, ICD diagnosis code 250.00 (which maps to the HCC for Diabetes Without Complication) could be transposed as diagnosis code 205.00 (which maps to the HCC for Metastatic Cancer and Acute Leukemia and in this example would be unvalidated). Using an analytical tool that we developed, we identified 3,135 scenarios in which diagnosis codes could have been mis-keyed because numbers were transposed, or other data-entry errors occurred that could have resulted in the assignment of an unvalidated HCC.

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

Independent Health Association, Inc.

IHA is an MA organization based in Buffalo, New York. As of December 2017, IHA provided coverage under contract number H3362 to 67,879 enrollees. For the 2016 and 2017 payment

years (audit period), CMS paid IHA approximately $1.6 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 eight high-risk groups during the 2015 and 2016 service years, for which IHA received increased risk-adjusted payments for payment years 2016 and 2017, 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 3,854 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes ($7,642,573). We selected for audit a sample of 247 enrollee-years, which comprised: (1) a stratified random sample of 210 (out of 3,817) enrollee-years for the first 7 high-risk groups and (2) a nonstatistical sample of 37 enrollee-years for the remaining high-risk group.

Table 1 details the number of sampled enrollee-years (of the 247) for each of the 8 high-risk groups.

Table 1: Sampled Enrollee-Years

High-Risk Group	Number of Sampled Enrollee-Years
1. Acute stroke	30
2. Acute heart attack	30
3. Embolism	30
4. Lung cancer	30
5. Breast cancer	30
6. Colon cancer	30
7. Prostate cancer	30
Total for Stratified Random Sample	210
8. Potentially mis-keyed diagnosis codes	37
Total for All High-Risk Groups	247

[11] The 2016 and 2017 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 IHA and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

IHA provided medical records as support for the selected diagnosis codes associated with 244 of the 247 sampled enrollee-years.[13] 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.

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 eight high-risk groups covered by our audit, most of the selected diagnosis codes that IHA submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 17 of the 247 sampled enrollee-years, the medical records validated the reviewed HCCs. For the remaining 230 enrollee-years, however, either the medical records that IHA provided did not support the diagnosis codes or IHA could not locate the medical records to support the diagnosis codes and the associated HCCs were therefore not validated. As a result, IHA received $646,217 in overpayments.

As demonstrated by the errors found in our sample, IHA'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 IHA received at least $7.0 million in overpayments for 2016 and 2017.[14] 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

[13] IHA could not locate medical records for the remaining 3 sampled enrollee-years.

[14] Specifically, we estimated that IHA received at least $7,000,225 in overpayments ($6,885,297 for the statistically sampled groups plus $114,928 for the group of potentially mis-keyed diagnosis codes). To be conservative, we estimate overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

estimated overpayment amount but are recommending a refund of $646,217 in overpayments for the sampled enrollee-years.[15]

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 (CM), *Official Guidelines for Coding and Reporting* (42 CFR § 422.310(d)(1) and 45 CFR §§ 162.1002(b)(1) and (c)(2)-(3)). Further, MA organizations must implement procedures to ensure that diagnoses come only from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities, and physicians (the Manual, chap. 7, § 40).

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

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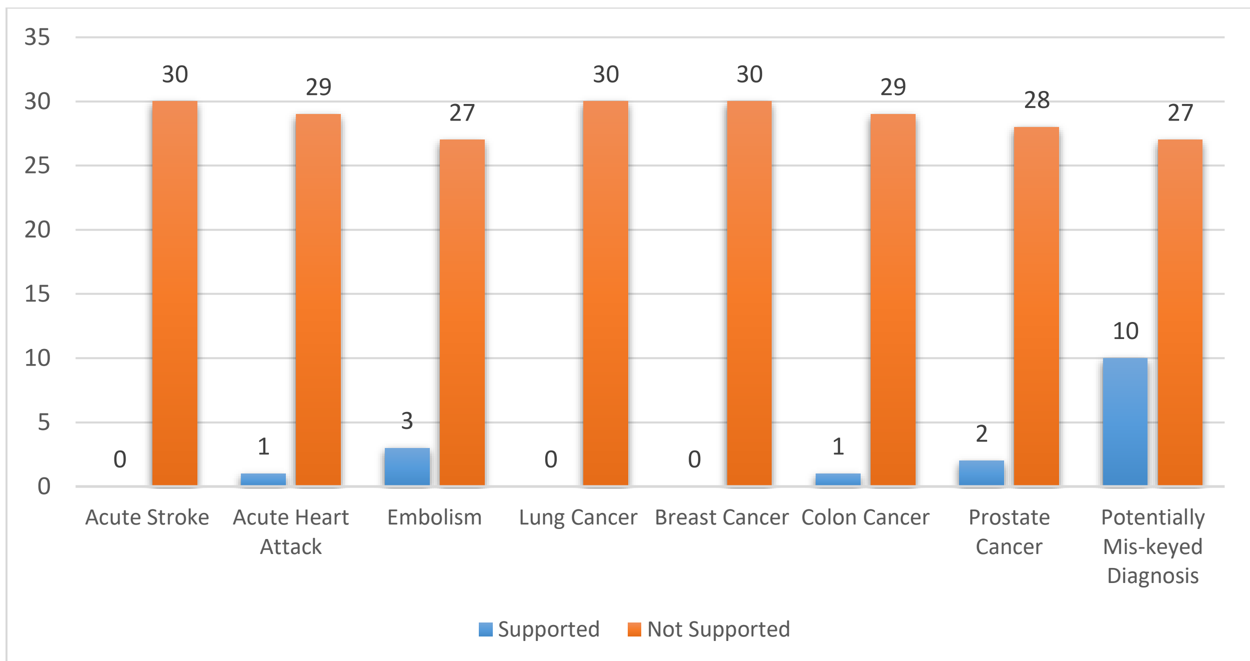
[15] After we had reviewed the sampled enrollee-years, CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643 (Feb. 1, 2023)).

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

Most of the selected high-risk diagnosis codes that IHA submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, as shown in the figure, the medical records for 230 of the 247 sampled enrollee-years did not support the diagnosis codes (footnote 13). In these instances, IHA should not have submitted the diagnosis codes to CMS and received the resulting overpayments.

Figure: Analysis of High-Risk Groups



Incorrectly Submitted Diagnosis Codes for Acute Stroke

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

- For 17 enrollee-years, the medical records indicated in each case that the individual had previously had a stroke, but the records did not 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."[16] The history of stroke diagnosis code does not map to an HCC.

- For the remaining 13 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.

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

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and IHA received $62,159 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Heart Attack

IHA incorrectly submitted diagnosis codes for acute heart attack for 29 of 30 sampled enrollee-years. Specifically:

- For 16 enrollee-years, the medical records indicated in each case that the individual had an old myocardial infarction diagnosis, but the records did not justify one of the diagnoses that mapped to an Acute Heart Attack HCC at the time of the physician's service.[17]

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that 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 11 enrollee-years, the medical records in each case did not support the submitted diagnosis that mapped to an Acute Heart Attack 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 Unstable Angina and Other Acute Ischemic Heart Disease]."

- For the remaining 2 enrollee-years, the medical records in each case did not support the submitted diagnosis that mapped to an Acute Heart Attack HCC. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to the

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[16] 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.

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

HCC for Unstable Angina and Other Acute Ischemic Heart Disease, which is a less severe manifestation of the related-disease group. Accordingly, IHA should not have received an increased payment for the acute myocardial infarction diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

As a result of these errors, the Acute Heart Attack HCCs were not validated, and IHA received $53,046 in overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

IHA incorrectly submitted diagnosis codes for embolism for 27 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 with Complications]. There is documentation of history of pulmonary embolism that does not result in an HCC."[18]

- For 13 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]."

- For the remaining 1 enrollee-year, IHA could not locate a medical record to support a diagnosis that mapped to an Embolism HCC; therefore, an Embolism HCC was not validated.

As a result of these errors, the Embolism HCCs were not validated, and IHA received $74,086 in overpayments for these 27 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

IHA incorrectly submitted diagnosis codes for lung cancer for all 30 sampled enrollee-years. Specifically:

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[18] 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 17 enrollee-years, the medical records indicated in each case that the individual had previously had lung cancer, but the records did not justify a lung cancer diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that 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, IHA 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.

  Table 2 identifies the HCCs for the less severe manifestations of the related-disease groups that were supported for the 8 enrollee-years.

Table 2: Hierarchical Condition Categories (HCCs) for a Less Severe Manifestation of the Related-Disease Group That Were Supported (Instead of the HCC for Lung and Other Severe Cancers)

Count of Enrollee-Years	Less Severe Hierarchical Condition Category
6	Breast, Prostate, and Other Cancers and Tumors
2	Colorectal, Bladder, and Other Cancers

- For 4 enrollee-years, the medical records in each case did not support a lung cancer diagnosis.[19]

  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]."

- For the remaining 1 enrollee-year, IHA could not locate a medical record to support the lung cancer diagnosis; therefore, the HCC for Lung and Other Severe Cancers was not validated.

[19] For 1 of these enrollee-years, the medical record that IHA provided to support the reviewed HCC was a radiology report signed and credentialed by a radiologist. This record was not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3)); the Manual, chap. 7, §§ 40 and 120.1)).

As a result of these errors, the HCC for Lung and Other Severe Cancers was not validated, and IHA received $207,261 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

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

- For 27 enrollee-years, the medical records indicated in each case that the individual had previously had breast cancer, but the records did not 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 a condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors]. Although the diagnosis of breast cancer [diagnosis] was listed, the medical record does not include support that the condition is current . . . ."

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and IHA received $34,480 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

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

- For 25 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 2 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, IHA should not have received an increased payment for the submitted colon cancer diagnoses, but it should have received a lesser increased payment for the other diagnosis identified.

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

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

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and IHA received $66,811 in overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

IHA incorrectly submitted diagnosis codes for prostate cancer for 28 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 5 enrollee-years, the medical records in each case did not support a prostate cancer diagnosis.[20]

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of a condition that would result in the assignment of the submitted HCC [for Breast, Prostate, and Other Cancers and Tumors]. Although the

[20] The 5 enrollee-years included 1 enrollee-year that the independent medical review contractor classified as an illegible record. We asked IHA to provide additional information associated with this enrollee-year but did not receive any. As stated in 42 CFR § 482.24(c)(1), all patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided.

diagnosis of prostate cancer [diagnosis] was listed, the medical record does not include additional support that the condition exists."

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

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and IHA received $33,446 in overpayments for these 28 sampled enrollee-years.

Potentially Mis-keyed Diagnosis Codes

IHA submitted potentially mis-keyed diagnosis codes for 27 of 37 sampled enrollee-years. In each of these cases, the individuals associated with the enrollee-years received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition. Specifically:

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

  For example, for 1 enrollee-year, IHA submitted three diagnosis codes for acute myeloid leukemia[21] (200.50) and one diagnosis code for diabetes mellitus[22] (250.00). The independent medical review contractor limited its review to the diabetes mellitus diagnosis, for which it did not find support. The independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Diabetes Without Complications]."

- For 6 enrollee-years, the medical records did not support the diagnosis for the unrelated condition. However, we identified support for another diagnosis code that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, IHA should not have received an increased payment for the submitted diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

  For example, for 1 enrollee-year, the medical records did not support a diagnosis that mapped to the HCC for Vascular Disease With Complications. The independent medical review contractor stated: "There is documentation of abdominal aortic aneurysm that results in [the] HCC [for Vascular Disease], which should have been assigned instead of

[21] Acute myeloid leukemia is a type of cancer that starts in the blood-forming cells of the bone marrow.

[22] Diabetes mellitus is a chronic disease associated with abnormally high levels of the sugar glucose in the blood.

the submitted HCC."[23] Accordingly, IHA should not have received an increased payment for the HCC for Vascular Disease With Complications, but it should have received a lesser increased payment for the HCC for Vascular Disease.

Appendix F contains the HCCs that were not validated for the 27 enrollee-years (Table 7) and the HCCs for the less severe manifestations of the related-disease groups that were supported for the 6 enrollee-years (Table 8).

As a result of these errors, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated, and IHA received $114,928 of overpayments for these 27 sampled enrollee-years.

Summary of Incorrectly Submitted Diagnosis Codes

In summary and with respect to the eight high-risk groups covered by our audit, IHA received $646,217 in overpayments for the 230 sampled enrollee-years in error.

THE POLICIES AND PROCEDURES THAT INDEPENDENT HEALTH ASSOCIATION 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 IHA 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, IHA had compliance procedures in place that were designed to prevent the submission of incorrect diagnosis codes. These procedures included a variety of provider-specific outreach efforts to train and educate its providers on medical record documentation, including how to: (1) accurately document diagnosis codes that are at high risk for being miscoded (including some that we also identified for this audit) and (2) distinguish between active and historical medical conditions.

IHA's compliance procedures also included detection and correction measures designed to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. For example, IHA performed various diagnosis coding audits for which it selected previously submitted claims, through either a random sample or a focused selection, to verify that submitted diagnosis codes were supported by medical record documentation. However, these diagnosis coding audits did not specifically focus on the high-risk diagnosis codes that we identified in our audit.

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[23] An abdominal aortic aneurysm is a weakened area that causes a bulge or swell in the main artery that supplies blood to the lower body. If it is not treated early enough, aortic aneurysms can rupture, leading to life-threatening internal bleeding.

When asked about the errors identified in this audit, IHA officials told us that since our audit period, IHA has placed greater emphasis on the prevention and detection of incorrect high-risk diagnosis codes. For instance, IHA officials stated that IHA has improved its provider education program and enhanced its random sample and focused coding audits to identify and review diagnosis codes that are at a higher risk of being miscoded. IHA officials added that IHA has implemented coding audits for diagnosis codes submitted by its vendors.

Based on our assessment of the policies and procedures that IHA had in place during our audit period, our discussions with IHA officials, and the fact that the diagnosis codes for 230 of the 247 sampled enrollee-years were not supported by medical records, we believe that IHA's compliance procedures to prevent, detect, and correct incorrect high-risk diagnoses could be improved.

INDEPENDENT HEALTH ASSOCIATION RECEIVED OVERPAYMENTS

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that IHA received at least $7,000,225 in overpayments for 2016 and 2017. (See Appendix D for sample results and estimates).

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 estimated overpayment amount but are recommending a refund of only the $646,217 in overpayments that IHA received for the sampled enrollee-years.[24]

RECOMMENDATIONS

We recommend that Independent Health Association, Inc.:

- refund to the Federal Government the $646,217 of overpayments;[25]

- 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

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[24] 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.

[25] 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.

- 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.

INDEPENDENT HEALTH ASSOCIATION COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, IHA disagreed with some of our findings and our first and second recommendations and requested that we withdraw all of our recommendations. Specifically, IHA did not agree with our findings for 17 of the 232 enrollee-years in error identified in our draft report and provided additional information for our consideration. IHA did not directly agree or disagree with our findings for the remaining 215 enrollee-years.

IHA stated that we based our overpayment calculations and estimated overpayment amount on risk factors that it described as "incorrect" and "biased" and said that our audit methodology "arbitrarily and capriciously" either aligned, or did not align, with published CMS RADV methodology to the "disadvantage of IHA." Furthermore, IHA stated that "[t]he general inconsistency and lack of timeliness" of our audits "pose a direct problem" in IHA's ability to set "meaningful and accurate" bid amounts.[26]

IHA also stated that CMS does not require MA organizations "to perform audits to the standard that OIG [Office of Inspector General] recommends . . ." and that IHA "has a robust compliance program in place that adheres to MA compliance program requirements . . . ."

After reviewing IHA's comments and the additional information IHA provided, we reduced the number of enrollee-years in error from 232 (in our draft report) to 230 and adjusted our calculation of overpayments. Accordingly, we reduced the recommended refund in our first recommendation from $653,953 to $646,217 for this final report. We maintain that our second and third recommendations remain valid.

A summary of IHA's comments and our responses follows. IHA's comments appear as Appendix G. We are separately providing IHA's comments along with the additional information it gave us to CMS.

[26] IHA generally used the term "bid rates" in its written comments. This term may be regarded as synonymous with "bid amounts," which we introduced and explained in "Risk Adjustment Program" earlier in this report, and which we continue to use throughout this final report.

INDEPENDENT HEALTH ASSOCIATION DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S RECOMMENDATION THAT IT REFUND OVERPAYMENTS

Independent Health Association Did Not Agree With the Office of Inspector General's Findings for 17 Sampled Enrollee-Years

Independent Health Association Comments

IHA did not agree with our findings for 17 sampled enrollee-years (as shown in Table 3) and provided additional information supporting its belief that the HCCs in question were validated.

Table 3: Summary of Enrollee-Years for Which Independent Health Association, Inc., Disagreed With Our Findings

High-Risk Group	Number of Sampled Enrollee-Years
1. Acute heart attack	1
2. Embolism	3
3. Lung cancer	2
4. Breast cancer	1
5. Colon cancer	1
6. Prostate cancer	7
7. Potentially mis-keyed diagnosis codes	2
Total for all High-Risk Groups	17

Office of Inspector General Response

Our independent medical review contractor reviewed the additional information that IHA provided for these 17 enrollee-years.

- For 15 of the 17 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 stated that "there is no documentation of any condition that results in the assignment of the HCC under review. There is documentation of a past medical history of [a] prostate cancer [diagnosis] which does not result in any HCC."

- For the remaining 2 enrollee-years (from the embolism high-risk group), our contractor found support for the audited HCCs and therefore validated the HCCs.

Accordingly, we reduced the number of enrollee-years in error from 232 (as reported in our draft report) to 230. We also revised our findings and reduced the associated monetary recommendation.

Independent Health Association Stated That the Office of Inspector General Based Both Its Sample Refund Recommendation and Its Extrapolated Estimate of Net Overpayments on Incorrect and Biased Risk Factors

Independent Health Association Comments

IHA disagreed with, and requested that we withdraw, our first recommendation to refund overpayments. Specifically, IHA stated that we based both the recommended refund amount and the extrapolated estimated overpayment amount on risk factors that it described as “incorrect” and “biased.” IHA also stated that the CMS-HCC model is calibrated using data from FFS claims and that FFS data is “not validated by medical record documentation.” IHA added that for that reason, “there can be and are unsupported diagnoses reported in the FFS data.” Therefore, according to IHA, the “individual risk factors” we used to calculate overpayments and our extrapolated estimated overpayment are “biased” as these risk factors are “different than what would have been achieved” had the FFS data not included “unsupported diagnoses.”

Furthermore, IHA stated that our audit implied a “perfection standard for IHA” because we reviewed only selected high-risk diagnosis codes. IHA stated that we made “no attempt to calculate what the appropriate relative risk factors would be had this same perfection standard been applied to the FFS diagnosis data.”

Office of Inspector General Response

We disagree with IHA that our overpayment calculations and estimated overpayment amount are based on “incorrect and biased” risk factors. Our audit did not require that we analyze the development of CMS’s payment models. We used CMS’s systems and the appropriate CMS-HCC models for our audit period and calculated the overpayment amount associated with the unvalidated HCCs for each sampled enrollee-year in accordance with CMS requirements.

Furthermore, our audit did not imply a perfection standard for the diagnoses that we evaluated for this audit. We identified certain diagnosis codes that, when combined with other conditions, were at high risk for being miscoded. The determination as to whether an overpayment exists for the associated HCCs was solely made—as mandated by the Federal requirements cited in this report—according to whether the medical records supported the diagnoses.

Independent Health Association Stated That the Office of Inspector General Arbitrarily and Capriciously Aligned, or Did Not Align, Its Audit Methodology With CMS's Risk Adjustment Data Validation Methodology to the Disadvantage of Independent Health Association

Independent Health Association Comments

IHA stated that our audit methodology "arbitrarily and capriciously" either aligned, or did not align, with published CMS RADV methodology to the "disadvantage of IHA" and that it "joins other [MA organizations] . . . that have objected to [our] audit methodology . . . ." Specifically, IHA stated that we recognized CMS's RADV requirements "when doing otherwise would benefit" IHA and departed from CMS's RADV methodology "when it disadvantage[d]" IHA. IHA supported this statement by citing the responses we included in other OIG reports issued to MA organizations in which, at certain points, we recognized CMS's operational and program authority and, at other points, stated that we are an independent oversight agency and are not required to mirror CMS's RADV approaches or methodologies. Thus, according to IHA, we have demonstrated our "willingness" to either recognize, or depart, from CMS methodologies—to IHA's disadvantage. IHA also cited the following examples:

- IHA stated (quoting from another OIG report) that we aligned our methodology to recalculate overpayments "with CMS's current approach to RADV audits," in that we "'did not apply an FFS adjuster or other mechanism to account for errors in the [FFS] data' . . . nor did OIG 'consider actuarial equivalence in [its] overpayment calculations.'" According to IHA, if we had applied an FFS adjuster, it would have reduced the overpayment amount we calculated. IHA said that therefore, our decision not to include an FFS adjuster was to the disadvantage of IHA.

- IHA also stated that we elected not to align our methodology with CMS in "several other ways, all of which also lead to the disadvantage of IHA." Specifically:

    - IHA said that although CMS conducts single payment year audits, our audit covered multiple payment years.

    - IHA stated: "CMS RADV guidance has traditionally estimated extrapolated overpayments using the lower bound of a 99% confidence interval. OIG instead elects to use the lower bound of a 90% confidence interval." According to IHA, "using 90% instead of 99% raises the associated lower bound estimate and thus yields a larger extrapolated overpayment estimate . . . ."

    - IHA added that our audit targeted "certain diagnosis codes for [enrollees] without considering all potentially unreported conditions for those same [enrollees]." Thus, according to IHA, our audit "did not consider potential underpayments" and was therefore "biased towards identifying overpayments."

Furthermore, IHA stated that we varied the “number and types of conditions” that we included in the high-risk groups associated with the MA organizations that we have audited. As an example, IHA said that we “replaced” the Major Depressive Disorder (MDD) high-risk group that we have evaluated in other audits in this series with, for this audit, four cancer-related groups of high-risk diagnosis codes. According to IHA, the MDD group “validates at a higher rate” whereas the four cancer-related groups “typically have a much lower validation rate.” IHA also stated that because we “did not adjust the sample size” of the high-risk groups we evaluated, IHA was “arbitrarily penalize[d]” when compared to other audited MA organizations that included the MDD high-risk group but excluded the cancer-related high-risk groups.

Office of Inspector General Response

We disagree with IHA’s comments as we did not design an audit methodology that would “arbitrarily and capriciously” align, or not align, with CMS requirements with the intent of placing MA organizations, including IHA, at a “disadvantage.” Our methodology did, however, identify diagnoses that we determined to be at a higher risk for being miscoded and therefore at a higher risk of resulting in an overpayment. In this regard, the OIG responses in the different reports that IHA cited are still applicable and are not, in fact, contradictory. OIG is an independent oversight agency and our audits are intended to provide an independent assessment of HHS programs and operations in accordance with the Inspector General Act of 1978, 5 U.S.C. ch. 4. Accordingly, we did not mirror CMS’s methodology in all aspects, nor did we have to. Thus, 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. Furthermore, we provide these responses to the examples IHA cited of what it described as our “arbitrary” audit methodology:

- With respect to IHA’s statement that we aligned with CMS to the disadvantage of IHA because we did not apply an FFS adjuster or consider “actuarial equivalence” in our overpayment calculations, we note that CMS has not issued any requirements that compelled us to reduce our overpayment calculations. In the context of CMS’s requirements, CMS stated that it “will not apply an adjustment factor (known as an FFS Adjuster) in RADV audits.”[27] IHA is thus accurate in pointing out that we recognize that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program.

- With respect to IHA’s statement that we did not align with CMS—again to the disadvantage of IHA, we make the following points:

    - As mentioned above, we designed our audit methodology in accordance with GAGAS, under which it is an entirely acceptable practice for us to audit multiple payment years instead of a single payment year.

[27] 88 Fed. Reg. 6643 (Feb. 1, 2023).

- Regarding our extrapolation of overpayments, longstanding OIG policy is to recommend 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 IHA for the enrollee-years and time period covered in our sampling frame. This approach, which is routinely used by HHS for recovery calculations,[28] 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.

- Additionally, and contrary to IHA's suggestions that our audit "is biased towards identifying overpayments," we did consider underpayments as they related to our objective.[29] 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.

  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.

Furthermore, regarding IHA's statement that we varied the "numbers and types of conditions" that we included in the high-risk groups we have audited, we note that we selected the high-risk groups in this audit based on factors that were relevant to IHA, not on factors that were relevant to the other audited MA organizations. Additionally, 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, we have updated the criteria used to identify the high-risk diagnosis codes included in some of our high-risk groups, and we have developed additional high-risk groups that are appropriate areas for audit.

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[28] 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).

[29] Section IV of IHA's comments (in Appendix G of this report) acknowledged in passing what IHA described as "a few instances" in which we considered potential underpayments.

Independent Health Association Stated That Medicare Advantage Organizations Cannot Effectively Submit Appropriate Bid Amounts Because of the Variability and Timeliness of Office of Inspector General Audits

Independent Health Association Comments

IHA stated that "[t]he general inconsistency and lack of timeliness" of our audits "pose a direct problem" in an MA organization's ability to set "meaningful and accurate" bid amounts in order for it "to adequately cover healthcare services" for its enrollees. IHA elaborated on its concerns with two related points:

- IHA referred to certain variations in the publicly available reports on the MA organizations we have selected for audit. Specifically, IHA stated that we have included a varying number of high-risk groups in several of our audits of high-risk diagnosis codes. IHA noted that one audit included two high-risk groups and other audits had as many as nine high-risk groups. IHA also stated that the number of audited diagnosis codes within these groups "can vary considerably" from one OIG audit to another.

- IHA stated that our audits are conducted "substantially after payment years are deemed 'settled.'" IHA added that demanding that it "comply with recommended refunds from a settled payment year renders ineffective any bid [amount] calculation which relied upon the settled year information." Furthermore, IHA stated that "looking forward, the implication that 'settled years' are not in actuality settled can inject further imprecision into bid [amount] estimation" and inject "needless uncertainty into future year bid [amount] calculations."

Office of Inspector General Response

IHA's argument that our audits "pose a direct problem" with an MA organization's ability to set bid amounts in order "to adequately cover healthcare services" is outside the scope of our audit. For this audit, our objective was to determine whether IHA submitted diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. OIG audit findings and recommendations do not represent final determinations by CMS. CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures (footnote 25).

INDEPENDENT HEALTH ASSOCIATION DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S RECOMMENDATION TO CONDUCT SIMILAR REVIEWS FOR OTHER PAYMENT YEARS

Independent Health Association Comments

IHA disagreed with, and requested that we withdraw, with our second recommendation—that IHA 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—because, according to IHA, CMS regulations "do not require IHA or any [MA organization] to perform audits to the standard that OIG recommends, and no such obligation is documented in IHA's contract with CMS."

Additionally, IHA stated that "CMS has explicitly stated that [MA organizations] are not held to a perfection standard as they, 'cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the OIG, and [Department of Justice] believe is reasonable to enforce.'" IHA added that "[t]he OIG itself has also explicitly stated the same in commenting, '[t]he requirement that the [MA organization officials] certify as to the accuracy, completeness and truthfulness of data, based on best knowledge, information and belief, does not constitute an absolute guarantee of accuracy.'" [30]

Furthermore, IHA stated that because our "sampling and extrapolation methodologies are significantly flawed . . . any such audit performed in the same manner undertaken by IHA would thus be flawed along the same lines and would not result in 'risk adjustment payment integrity and accuracy.'" In addition, IHA said that its ability to conduct such an audit would be hampered because we had not "provided sufficient information to fully replicate" our own audit. IHA also added that any audit "would not result in payment accuracy since IHA would not be able to submit diagnosis codes that it found were supported but not reported in payment years that are closed for submissions."

Office of Inspector General Response

We do not agree with IHA's interpretation of Federal requirements. We recognize that MA organizations have the latitude to design their own federally mandated compliance programs. We also acknowledge the requirement that MA organizations certify that the data they submit to CMS are based on "best knowledge, information, and belief." However, contrary to IHA's statements, we believe that our second recommendation conforms to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (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 IHA's compliance plan "must, at a minimum, include [certain] core requirements:" which include "an effective system for routine monitoring and identification of compliance risks . . . [including] internal monitoring and audits and, as appropriate, external audits, to evaluate . . . compliance with CMS requirements and the overall effectiveness of the compliance program." These regulations also require MA organizations to 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

[30] The language that IHA quotes in this paragraph may be found in 64 Fed. Reg. 61893, 61900 (Nov. 15, 1999).

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.

Additionally, IHA'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 (230 of 247 enrollee-years (see Appendix D)) demonstrates that IHA has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope.

Furthermore, we disagree with IHA's comments that we did not provide IHA with sufficient information to identify, for the high-risk diagnoses included in this report, similar instances of noncompliance. We communicated the objective, scope, and methodology of the audit multiple times throughout the engagement. We did not recommend that IHA "fully replicate" our entire audit.

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

INDEPENDENT HEALTH ASSOCIATION REQUESTED THAT WE WITHDRAW THE OFFICE OF INSPECTOR GENERAL'S RECOMMENDATION THAT IT CONTINUE TO EXAMINE ITS EXISTING COMPLIANCE PROCEDURES AND TAKE NECESSARY STEPS TO ENHANCE THEM

Independent Health Association Comments

IHA requested that we withdraw 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, IHA stated that it "has an established compliance program that is regularly evaluated both internally and externally." IHA also stated that it "received a perfect score in its most recent CMS Program Audit, with no non-compliance conditions issued . . . ." To bolster its comments regarding its compliance procedures, IHA cited our draft report in which we acknowledged that IHA had compliance procedures in place during our audit period and that enhancements had been made to its policies and procedures since our audit period.

Furthermore, IHA stated that our recommendation was "based on the review of data that [are] now many years old and OIG does not offer specific recommendations for improvement or account for current policies and procedures." Moreover, IHA stated that it "monitors the effectiveness of not only its compliance program, but also its underlying policies and procedures" and added that it "has routinely made a number of enhancements" to those policies and procedures, including its coding auditing programs and provider education initiatives, consistent with MA program requirements and OIG guidance."

Office of Inspector General Response

We do not fully agree with IHA's statements. Although we commend IHA for its stated improvements to its policies and procedures, our audit revealed a significant error rate for all eight of the audited high-risk groups. Thus, we continue to believe that IHA 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 IHA had compliance procedures in place to promote the accuracy of diagnosis codes submitted to CMS to calculate risk-adjusted payments during our audit period. The continued improvement of IHA's existing procedures (based on the results of this audit) will assist IHA 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 IHA $1,554,672,262 to provide coverage to its enrollees for 2016 and 2017. We identified a sampling frame of 3,854 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2015 and 2016 service years. IHA received $50,226,834 in payments from CMS for these enrollee-years for 2016 and 2017. We selected for audit 247 enrollee-years with payments totaling $7,642,573.

The 247 enrollee-years included 30 acute stroke diagnoses, 30 acute heart attack diagnoses, 30 embolism diagnoses, 30 lung cancer diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, 30 prostate cancer diagnoses, and 37 potentially mis-keyed diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $744,772 for our sample.

Our audit objective did not require an understanding or assessment of IHA'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 September 2019 through June 2024.

METHODOLOGY

To accomplish our objective, we performed the following steps:

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

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

- We identified, through data mining and discussions with medical professionals at a Medicare administrative contractor, diagnosis codes and HCCs that were at high risk for noncompliance. We also identified the diagnosis codes that potentially should have been used for cases in which the high-risk diagnoses were miscoded.

- We consolidated the high-risk diagnosis codes into specific groups, which included:

  - 74 diagnosis codes for acute stroke,
  - 38 diagnosis codes for acute heart attack,
  - 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 developed an analytical tool that identified 3,135 scenarios in which either ICD-9-CM or ICD-10-CM diagnosis codes (footnote 1), when mis-keyed into an electronic claim because of a data transposition or other data entry error, could result in the assignment of an incorrect HCC to an enrollee's risk score. For each of the 3,135 occurrences, the tool identified a potentially mis-keyed diagnosis code and the likely correct diagnosis code. Accordingly, we considered the potentially mis-keyed diagnosis codes to be high risk.

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

  - Risk Adjustment Processing System (RAPS)[31] and Encounter Data System (EDS)[32] to identify enrollees who received high-risk diagnosis codes from a physician during the service years,

  - Risk Adjustment System (RAS)[33] to identify enrollees who received an HCC for the high-risk diagnosis codes,

  - Medicare Advantage Prescription Drug System (MARx)[34] to identify enrollees for whom CMS made monthly Medicare payments to IHA, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C),

  - Encounter Data System (EDS)[35] to identify enrollees who received specific procedures, and

  - Prescription Drug Event (PDE) file[36] to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.

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

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

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

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

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

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

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

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

- We selected for audit a sample of 247 enrollee-years, which consisted of: (1) a stratified random sample of 210 (out of 3,817) enrollee-years and (2) a nonstatistical sample of the remaining 37 enrollee-years as identified by our analytical tool.

- We used an independent medical review contractor to perform a coding review for the 244 enrollee-years (footnote 13) to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.[37]

- 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 records, the HCC was considered validated.

  - If the first senior coder did not find support on the medical records, a second senior coder performed a separate review of the same medical records:

    - If the second senior coder also did not find support, the HCC was considered to be not validated.

    - If the second senior coder found support, then the coding supervisor independently reviewed the medical record to make the final determination.

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

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

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

[37] 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.

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

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

- We calculated the recommended recovery amount in accordance with CMS's regulations that limit the use of extrapolation in RADV audits for recovery purposes to the sampled enrollee-years.[38]

- We discussed the results of our audit with IHA 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.

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

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MediGold (Contract H3668) Submitted to CMS	A-07-20-01198	2/16/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That SelectCare of Texas, Inc. (Contract H4506) Submitted to CMS	A-06-19-05002	11/27/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Aetna, Inc. (Contract H5521) Submitted to CMS	A-01-18-00504	10/2/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS	A-07-20-01197	8/3/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS	A-07-20-01202	7/10/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. (H3952) Submitted to CMS	A-03-20-00001	5/31/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS	A-05-19-00013	4/4/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring Life & Health Insurance Company, Inc. (Contract H4513) Submitted to CMS	A-07-19-01192	3/28/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS	A-02-20-01008	3/24/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS	A-09-21-03011	3/16/2023

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified IHA enrollees who: (1) were continuously enrolled in IHA throughout all of the 2015 or 2016 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 2015 or 2016 or in January of the following year, and (3) received a high-risk diagnosis during 2015 or 2016 that caused an increased payment to IHA for 2016 or 2017, respectively.

We presented the data for these enrollees to IHA 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 IHA. After we performed these steps, our finalized sampling frame consisted of 3,854 enrollee-years.

SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2016 or 2017.

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 (1,070 enrollee-years);

- an acute heart attack diagnosis (that mapped to an Acute Heart Attack HCC) on only one physician or outpatient claim during the service year but did not have an acute heart attack diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician or outpatient claim (408 enrollee-years);

- an embolism diagnosis (that mapped to an Embolism HCC) on only one claim during the service year but did not have an anticoagulant medication dispensed on his or her behalf (285 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 (146 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 (1,108 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 (267 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 (533 enrollee-years).

The specific strata are shown in Table 4.

Table 4: Sample Design for Audited High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee-Years	CMS Payment for HCCs in Audited High-Risk Groups	Sample Size
1 – Acute stroke	1,070	$2,236,904	30
2 – Acute heart attack	408	802,656	30
3 – Embolism	285	749,184	30
4 – Lung cancer	146	1,046,554	30
5 – Breast cancer	1,108	1,353,702	30
6 – Colon cancer	267	642,151	30
7 – Prostate cancer	533	640,553	30
Total – First Seven Strata	**3,817**	**$7,471,704**	**210**

After we selected the 210 enrollee-years, we identified an additional group of 37 enrollee-years that represented individuals who received 1 of the 3,135 potentially mis-keyed diagnosis codes (each of which mapped to a potentially unvalidated HCC) and multiple instances of diagnosis codes that were likely keyed correctly. Thus, we selected for audit a total of 247 enrollee-years.

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We sorted the items in each stratum by the enrollee year (a combination of the enrollee identifier and the year being reviewed) and then consecutively numbered the items in each stratum in the stratified sampling frame. After generating random numbers according to our sample design, we selected the corresponding frame items for review. We also selected all 37 nonstatistical sample items from the potentially mis-keyed group.

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to estimate the total amount of overpayments made to IHA at the lower limit of the two-sided 90-percent confidence interval (Appendix D). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time. We also identified the overpayments from the nonstatistical sample of 37 items for the potentially mis-keyed diagnosis codes and added that amount to the estimate for the statistical sample to obtain the total amount of overpayments.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 5: Sample Details and Results

Audited High-Risk Groups	Frame Size	CMS Payments for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payments for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With HCCs That Were Not Validated	Overpayments for HCCs That Were Not Validated (for Sampled Enrollee-Years)
1 – Acute stroke	1,070	$2,236,904	30	$62,159	30	$62,159
2 – Acute heart attack	408	802,656	30	57,175	29	53,046
3 – Embolism	285	749,184	30	83,933	27	74,086
4 – Lung cancer	146	1,046,554	30	229,013	30	207,261
5 – Breast cancer	1,108	1,353,702	30	34,480	30	34,480
6 – Colon cancer	267	642,151	30	71,527	29	66,811
7 – Prostate cancer	533	640,553	30	35,616	28	33,446
Totals for Statistical Sample	**3,817**	**$7,471,704**	**210**	**$573,903**	**203**	**$531,289**
8 – Potentially mis-keyed diagnoses	37	$170,869	37	$170,869	27	$114,928
Totals - All	**3,854**	**$7,642,573**	**247**	**$744,772**	**230**	**$646,217**

Table 6: Estimated Overpayments in the Sampling Frame
(*Limits Calculated at the 90-Percent Confidence Level)*

	Estimated Overpayments for Statistically Sampled High-Risk Groups	Overpayments for High-Risk Group With Potentially Mis-keyed Diagnosis Codes	Total Estimated Overpayments
Point Estimate	$7,113,229	$114,928	$7,228,157
Lower Limit	6,885,297	114,928	7,000,225
Upper Limit	7,341,161	114,928	7,456,089

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

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

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

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

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

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

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

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

(3) Implement the operation of the compliance program;

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

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

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

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

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

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

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

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

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

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

APPENDIX F: DETAILS OF POTENTIALLY MIS-KEYED DIAGNOSIS CODES

Table 7: Potentially Mis-keyed Diagnosis Codes and Associated Overpayments

Number of Sampled Enrollee-years	One Diagnosis for a Condition (Determined To Be Incorrect)		Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment
	Diagnosis Code	Diagnosis Code Description	Diagnosis Code	Diagnosis Code Description	
4	714.9	Unspecified inflammatory polyarthropathy	174.9	Malignant neoplasm of breast (Female), unspecified	$10,771
3	433.01	Occlusion and stenosis of basilar artery with cerebral infarction	433.10	Occlusion and stenosis of carotid artery without mention of cerebral infarction	7,637
3	444.1	Embolism and thrombosis of thoracic aorta	441.4	Abdominal aneurysm without mention of rupture	2,509
2	441.01	Dissection of aorta, thoracic	414.01	Coronary atherosclerosis of native coronary artery	1,610
2	250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled	205.00	Acute myeloid leukemia, without mention of having achieved remission	1,047
2	441.00	Dissection of aorta, unspecified Site	414.00	Coronary atherosclerosis of unspecified type of vessel, native or graft	3,714
1	205.00	Acute myeloblastic leukemia, not having achieved remission	250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled	17,539

Number of Sampled Enrollee-years	One Diagnosis for a Condition (Determined To Be Incorrect)		Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment
	Diagnosis Code	Diagnosis Code Description	Diagnosis Code	Diagnosis Code Description	
1	227.4	Benign neoplasm of pineal gland	272.4	Other and unspecified hyperlipidemia	1,311
1	205.01	Acute myeloid leukemia, in remission	250.01	Diabetes mellitus without mention of complication, type 1, not stated as uncontrolled	19,253
1	200.02	Reticulosarcoma, intrathoracic lymph nodes	250.02	Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled	2,430
1	200.62	Anaplastic large cell lymphoma, intrathoracic lymph nodes	250.62	Diabetes with neurological manifestations, type II or unspecified type, uncontrolled	4,382
1	205.02	Acute myeloid leukemia, in relapse	250.02	Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled	18,065
1	250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled	205.10	Chronic myeloid leukemia, without mention of having achieved remission	2,838
1	254.9	Unspecified disease of thymus gland	245.9	Thyroiditis, unspecified	1,333
1	402.01	Malignant hypertensive heart disease with heart failure	402.10	Benign hypertensive heart disease without heart failure	2,658
1	518.81	Acute respiratory failure	581.81	Nephrotic syndrome in diseases classified elsewhere	2,134

Number of Sampled Enrollee-years	One Diagnosis for a Condition (Determined To Be Incorrect)		Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment
	Diagnosis Code	**Diagnosis Code Description**	**Diagnosis Code**	**Diagnosis Code Description**	
1	C78.5	Secondary malignant neoplasm of large intestine and rectum	E78.5	Hyperlipidemia, unspecified	15,697
27					**$114,928**

Table 8: Hierarchical Condition Categories That Were Not Validated, but We Found Support for an HCC for a Less Severe Manifestation of the Related-Disease Group

Count of Enrollee-Years	More Severe Hierarchical Condition Category That Was Not Validated	Less Severe Hierarchical Condition Category That Was Supported
5	Vascular Disease With Complications	Vascular Disease
1	Metastatic Cancer and Acute Leukemia	Colorectal, Bladder, and Other Cancers

511 Farber Lakes Drive, Buffalo, New York 14221 716.631.3001 www.independenthealth.com

August 11, 2023

Via E-mail

Re: **Response to OIG Draft Audit Report Number: A-07-19-01194 of Independent Health Association, Inc. (Contract H3362)**

James I. Korn, Regional Inspector General for Audit Services
Maureen Seufert, Assistant Regional Inspector General for Audit Services
Office of Audit Services, Region VII
601 East 12th Street, Room 0429
Kansas City, MO 64106

Dear Mr. Korn:

Independent Health Association, Inc ("IHA") writes to respond to the United States Department of Health and Human Services ("HHS") Office of Inspector General's ("OIG") Draft Report for Audit No. A-07-19-01194 titled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Independent Health Association, Inc. (Contract H3362) Submitted to CMS* ("OIG Draft Report").

IHA disagrees with OIG's recommendation that IHA, "refund to the Federal Government the $653,953 of overpayments" and respectfully requests that OIG withdraw:

(1) its recommendation that IHA refund to the Federal Government $653,953 in purported net overpayments related to payment years 2016 and 2017, and

(2) its stated estimation that IHA received at least $7,076,584 in net overpayments for 2016 and 2017.

Further, OIG recommended that IHA, "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." IHA also disagrees with this recommendation for several reasons detailed below and respectfully requests that OIG withdraw its recommendation.

Finally, OIG recommended that IHA, "continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that

Independent Health's Affiliated Companies: Independent Health Association, Inc.; Independent Health Corporation; Independent Health Benefits Corporation; Independent Health Foundation; Individual Practice Association of Western New York; Nova Healthcare Administrators, Inc.; Independent Health's Pharmacy Benefit Dimensions, LLC; Specialty Pharmacy Management, LLC

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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." As described in more detail below, IHA routinely reviews and assesses its existing compliance procedures to identify areas for continued improvement and believes that the current procedures are robust, effective, and compliant with Medicare Advantage ("MA") program requirements and OIG guidelines. IHA respectfully requests the OIG also withdraw this recommendation.

I. IHA Has Identified Medical Record Documentation That Was Not Reviewed By OIG Which Validates Hierarchical Condition Categories ("HCCs") that OIG Purportedly Concluded Were Not Validated

In its preliminary findings, OIG indicated to IHA that records were not received for a subset of HCC samples. As part of its response to the OIG Draft Report, IHA will submit 17 additional records and respectfully requests that OIG recalculate its estimated repayment and extrapolation amounts in light of any validating records submitted by IHA.

II. OIG Bases Both Its Sample Refund Recommendation and its Extrapolated Estimate of Net Overpayments on Incorrect and Biased Risk Factors

As noted in the OIG Draft Report:

> *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.*[1]

The risk-score component of risk-adjusted payment calculation for an enrollee is "based on an enrollee's health status…and demographic characteristics…"[2]

To determine the health status component of an enrollee's risk score:

> *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). Each HCC has a [relative risk] factor (which is a numerical value) assigned to it for use in each enrollee's risk score.*[3]

[1] OIG Draft Report, p. 2.
[2] OIG Draft Report, p. 3.
[3] OIG Draft Report, p. 3.

Given that an enrollee's risk score is dependent on the relative risk factors associated with its demographic and HCC characteristics, OIG acknowledges that:

> *[I]f the factors used to determine an enrollee's risk score are incorrect, CMS will make an improper payment to an MA organization.*[4]

The relative risk factors associated with each risk adjusting demographic and HCC characteristic are determined through the calibration of the "CMS-HCC model" described by CMS in general as:

> *The CMS-HCC risk adjustment model is prospective—it uses a profile of major medical conditions in the base year, along with demographic information (age, sex, Medicaid dual eligibility, disability status), to predict Medicare expenditures in the next year. It is calibrated on a population of [Fee-for-Service ("FFS")] beneficiaries entitled to Part A and enrolled in Part B because CMS has complete Medicare expenditure and diagnoses data for this population.*[5]

CMS describes the model econometrically as:

> *The [CMS-HCC] model uses costs and disease diagnoses from FFS claims in an Ordinary Least Squares (OLS) regression framework to associate the diagnoses reported for beneficiaries in one year with FFS costs incurred in the following year. In general, each coefficient estimated by the CMS-HCC model represents the allocation of the FFS costs for an average beneficiary to either a disease or demographic attribute.*[6]

These coefficients, which are in dollar terms and estimated through the model calibration, are then converted to the relative risk factors above described.

The FFS data on which the CMS-HCC model is calibrated is not validated by medical record documentation.[7] Accordingly, there can be and are unsupported diagnoses reported in the FFS data.[8] Econometrically, the reporting of these unsupported diagnoses is equivalent to "measurement error" in the explanatory variables in a regression analysis.

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[4] OIG Draft Report, p. 3.
[5] CMS Report to Congress: Risk Adjustment in Medicare Advantage, December 2021, p. 14, *available at: https://www.cms.gov/files/document/report-congress-risk-adjustment-medicare-advantage-december-2021.pdf.*
[6] CMS: Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits, October 26, 2018, p. 1, *available at: https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-risk-adjustment-data-validation-program/other-content-types/radv-docs/ffs-adjuster-excecutive-summary.pdf.*
[7] *Ibid.*
[8] *Ibid, p. 2.*

It is well established in econometric literature that measurement error of the type occurring in the CMS-HCC model leads to measurement error bias in the explanatory variable coefficients.[9] In other words, the presence of unsupported diagnoses in the FFS data used to calibrate the CMS-HCC model leads to biased individual risk factors relative to what would have been estimated had the FFS data been free of measurement error.[10]

The implication of this well-established econometric result is that the individual risk factors which OIG uses to calculate the "net overpayment estimates" associated with each high-risk diagnosis in its audit are biased. These biased risk factors are different than what would have been achieved had the FFS data been free from measurement error.

Accordingly, even if OIG's findings that certain diagnoses in its audit sample are unsupported, the net overpayment amounts it recommends IHA repay associated with these purported unsubstantiated submissions are inaccurate.

The concept of hypothesizing a refund that might be owed based on the sample diagnoses is different than recommending a specific refund amount. A specific refund amount is one calculated based upon specific risk factor estimates. In this instance, these estimates were derived under a very specific econometric setting where measurement error was present in the FFS data used to generate the estimates. Any use of those estimates, as OIG does in calculating its sample refund recommendation, presumes a world in which measurement error is thus allowed.

In contrast to the FFS diagnosis data, the OIG audit implies a perfection standard for IHA, at minimum among the diagnoses studied in the audit. This audit makes no attempt to calculate what the appropriate relative risk factors would be had this same perfection standard been applied to the FFS diagnosis data. As such, OIG is using relative risk factors calculated under an assumption that does not apply in its own audit framework. Simply put, by applying a perfection standard to IHA without the same standard applied to the relative risk factors, OIG is attempting to price apples using the cost of oranges and makes no effort to understand how the prices relate.

III. OIG's Extrapolated Overpayment Estimate of Over $7 Million Associated with the Studied Diagnosis Codes for Payment Years 2016 and 2017 Is Based on an Invalid Extrapolation – and therefore an Invalid Sampling Exercise

Not only is the sample refund recommendation of $653,953 based upon biased risk factors and therefore incorrect, so too is the methodology which yields the extrapolated estimate of over $7

[9] *See* for example Aigner, Dennis J. "Regression with a binary independent variable subject to errors of observation." *Journal of Econometrics* 1.1 (1973): 49-59.
[10] Referring to the same econometric literature, this finding extends even in the presence of *additional* measurement error of the type where supported, but *unreported* diagnoses are omitted from the FFS data.

million net overpayments for the plan associated with the studied high-risk diagnoses for payment years 2016 and 2017. The extrapolated point estimate and associated lower bound by default are incorrect given the overpayment calculated for the sample is inaccurate due to the biased risk factors discussed above. In that regard, the sampling methodology – which includes the sample estimate calculation and the extrapolation calculation – is invalid.

IHA disputes that a sampling methodology that uses incorrect relative risk factors would constitute a valid sampling and extrapolation exercise.

IV. OIG Arbitrarily and Capriciously Aligns Its RADV Audit, Sampling, and Extrapolation Methodology with CMS' RADV Methodology and Recommendations to the Disadvantage of IHA

IHA joins other MAOs subject to OIG "high-risk diagnosis" audits that have objected to OIG's audit methodology, but IHA also does so for a more global reason than any individual audit design choice made by OIG.

CMS issued requirements for its RADV audit sampling design, including payment error extrapolation calculations, in February 2012.[11] Additionally, CMS has provided updated guidance for RADV audits included in the 2018 Final Rule.[12]

OIG's "high-risk diagnosis" audit of IHA, including its sampling and extrapolation methodology, arbitrarily and capriciously aligns or does not align with published CMS methodology for conducting RADV audits of Medicare Advantage Organizations ("MAOs") to the disadvantage of IHA.

For example, as noted in the preceding section, OIG elects to calculate its sample refund recommendation based upon risk factors determined by CMS. Responding to related criticisms in other audits that OIG "did not apply an FFS adjuster or other mechanism to account for errors in the [FFS] data when conducting this audit,"[13] nor did OIG "consider actuarial equivalence in [its] overpayment calculations,"[14] OIG stated:

> *To this point, we recognize that CMS is responsible for making operational and program payment determinations for the MA program and note that CMS has*

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

[12] CMS: Medicare Advantage Risk Adjustment Data Validation Final Rule (CMS-4185-F2) Fact Sheet, January 30, 2023, *available at: https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-risk-adjustment-data-validation-final-rule-cms-4185-f2-fact-sheet*

[13] HHS-OIG: Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS, p. 24, *available at: https://oig.hhs.gov/oas/reports/region2/22001008.pdf.*

[14] *Ibid.*

not issued any requirements that compel us to further reduce our net overpayment calculations. Moreover, CMS stated … that it 'will not apply an adjustment factor (known as an FFS Adjuster) in RADV audits.'[15]

In this instance, OIG aligns its repayment calculation methodology with CMS's current approach to RADV audits. An FFS Adjuster of the sort referenced in the preceding quote, would be expected to *reduce* the amount owed by any MAO. Thus, electing not to include one disadvantages MAOs in general and concerning this audit, IHA in particular.

In contrast, OIG elects *not* to align its methodology with that of CMS in several other ways, all of which also lead to the disadvantage of IHA.

For example, CMS typically conducts its audits concerning single payment years, whereas this audit concerns multiple payment years (i.e., 2016 and 2017).

As another example, CMS RADV guidance has traditionally estimated extrapolated overpayments using the lower bound of a 99% confidence interval. OIG instead elects to use the lower bound of a 90% confidence interval. All else equal, using 90% instead of 99% raises the associated lower bound estimate and thus yields a larger extrapolated overpayment estimate, again disadvantaging IHA.

A final example concerns OIG's use of audits targeting certain diagnosis codes for beneficiaries without considering all potentially unreported conditions for those same beneficiaries. OIG made no effort to collect and review medical records for the selected beneficiaries that may have contained documented support for conditions that were not reported to CMS. As a result, except for a few instances for which OIG found support for another condition in the same hierarchy as the high-risk diagnoses being audited or support for another condition resulting from a mis-keyed diagnosis, OIG's sample did not consider potential underpayments. Therefore, the audit is biased towards identifying overpayments.[16]

In response to criticisms that OIG has departed from CMS' audit methodology, OIG has stated its independence from CMS in multiple ways:

With regard to MCS's comment that we deviated from CMS's RADV audit standards, we note that our approach was generally consistent with the

[15] *Ibid.*

[16] CMS RADV audits are performed at the beneficiary level and fully consider all conditions that are supported by medical record documentation submitted by MAO for the sampled beneficiaries, regardless of whether the diagnosis codes were submitted to CMS. However, CMS excludes from consideration any beneficiaries who have no HCCs submitted in the year, which creates a different kind of overpayment bias.

methodology that CMS uses in its RADV audits; however, it did not mirror CMS's approach in all aspects, nor did it have to.[17]

and

OIG is an independent oversight agency; therefore, we do not need to mirror CMS's estimation methodology.[18]

OIG thus states its independence and willingness to use a methodology which departs from CMS' requirements (e.g., the use of the lower bound of a 90% confidence interval) when it disadvantages the audited MAO, but recognizes CMS' responsibility for making operational and program determinations for the MA program when doing otherwise would benefit the MAO (*see Table 1*).

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[17] HHS-OIG: Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS, p. 22, *available at: https://oig.hhs.gov/oas/reports/region2/22001008.pdf.*
[18] *Ibid, p. 24.*

Table 1: OIG's Methodological Choices Disadvantage IHA

Methodological Choice	OIG Elects to Follow CMS RADV Guidance	OIG Elects Not to Follow CMS Guidance	OIG's Methodological Choice Relative to Making the Other Choice
Selection of Multiple Years of Submissions for Review		√	Disadvantages IHA
Apply CMS' Good Faith Attestation Standard for MA Organizations Certifying the Large Volume of Data Submitted to CMS for Use in the Risk Adjustment Program[19]		√	Disadvantages IHA
Considers All Unreported HCCs (and Associated Diagnoses) at the Beneficiary Level		√	Disadvantages IHA
Stratum Level Sample Size		√	Disadvantages IHA
Biased to Identify Overpayments	√		Disadvantages IHA
Identification of the Overpayment Amount Derived from Unvalidated HCCs in the FFS data	√		Disadvantages IHA
OIG's Method of Estimating an Extrapolated Amount Owed (Use of Lower Bound of 90% Confidence Interval Rather than 99% Lower Bound)		√	Disadvantages IHA

Further, OIG varies the number and types of conditions that are included in the high-risk diagnosis audits. Since the associated sample and extrapolated overpayments are derived from the underlying conditions audited, the overpayment amount can vary between MAOs even if they had the same underlying coding and patient populations if OIG selects different conditions for audit. This arbitrary selection of conditions can favorably or unfavorably affect the overpayment calculations from MAO to MAO. In this audit, OIG replaced Major Depressive Disorder ("MDD"), a diagnosis group frequently in other high-risk audits and one that typically validates at a higher rate, with four cancer HCCs, all of which typically have a much lower validation rate. However, OIG did not adjust the sample size per condition (i.e., 30 sampled

[19] *Ibid, p. 25.*

enrollees), which arbitrarily penalizes IHA compared to other MAOs that have undergone high-risk diagnosis audits that included MDD but excluded cancer HCCs.

V. MAOs Cannot Effectively Submit Appropriate Bid Rates

As part of the risk adjustment process each year, MAOs submit bid rates to estimate the costs required from CMS to treat the average enrollee in its respective plan. These bid rates are primarily determined through analysis of historical costs incurred by the MAOs to treat an average risk beneficiary. The general inconsistency and lack of timeliness of OIG audits pose a direct problem in bid rate setting which render ineffective efforts by MAOs to set meaningful and accurate rates to adequately cover healthcare services for their members.

A. Given the Variability of Potential Exposure Depending on If a Contract is Selected for OIG High-Risk Diagnosis Audit

As mentioned above, across its high-risk diagnosis audits, OIG has selected different sets of high-risk diagnoses for review. Publicly available high-risk audits have included as few as 2 high-risk diagnosis groups under audit to as many as 9 high-risk diagnosis groups.[20,21] Within these groups, the number of diagnoses can vary considerably. For example, the present audit of IHA concerned 65 diagnoses codes associated with breast cancer, whereas the high-risk audit of MCS concerned only 5 diagnosis codes associated with breast cancer.[22]

Given that high-risk audits tend to draw samples of up to 30 enrollee-years per audited diagnosis group, the size of the sample audit can vary considerably based upon the number of targeted diagnosis groups. All else equal, this variation also corresponds to considerable variation in the possible repayment recommendations and extrapolated estimated net overpayment amount.

Even if an MAO assumes that it will undergo an OIG high-risk diagnosis audit, the breadth, required effort to comply and respond, and ultimate exposure can vary considerably depending on the composition of the audit OIG happens to select for that particular MAO.

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[20] HHS-OIG: Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply with Federal Requirements, p. 3, *available at: https://oig.hhs.gov/oas/reports/region7/71701170.pdf.*
[21] HHS-OIG: Medicare Advantage Compliance Audit of Specific Diagnosis Codes that MCS Advantage, Inc. (Contract H5577) submitted to CMS, p. 7, *available at: https://oig.hhs.gov/oas/reports/region2/22001008.pdf.*
[22] OIG Draft Report, p. 19 and Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS, p. 29, *available at: https://oig.hhs.gov/oas/reports/region2/22001008.pdf.*

B. Given that the Recommended Refund Pertains to Payment Years Which Have Been Settled

As noted, as with this audit, OIG high-risk diagnosis audits can occur substantially after payment years are deemed "settled." Moreover, OIG high-risk diagnosis audits can span multiple settled payment years. The costs incurred and revenue required to care for beneficiaries associated with settled payment years directly inform the benefit packages and bid rates submitted by MAOs on a yearly basis. Demanding an MAO comply with recommended refunds from a settled payment year renders ineffective any bid rate calculation which relied upon the settled year information which is now itself inaccurate. Further, looking forward, the implication that "settled years" are not in actuality settled can inject further imprecision into bid rate estimation.

The combination of re-opening settled years and the variation of the scope of OIG high-risk audits, also injects needless uncertainty into future year bid rate calculations. Bid rate estimation models and thus the ability of MAOs to effectively set bid rates would only improve from greater consistency in the nature of potential audits and the certainty which accompanies that a settled year is actually settled.

VI. IHA Does Not Agree with OIG's Recommendation that It Conduct Similar Audits for Other Payment Years

OIG recommends that IHA, "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." IHA disagrees with this recommendation and respectfully requests that OIG withdraw it for the following reasons.

A. IHA Is Under No Obligation to Conduct Audits Similar to OIG's Audit and Cannot Be Held to a Perfection Standard

CMS regulations require that MAOs adopt and implement an effective compliance program that includes routine auditing and monitoring, but they do not require IHA or any MAO to perform audits to the standard that OIG recommends, and no such obligation is documented in IHA's contract with CMS.[23] OIG's suggested audit impermissibly expands the MA compliance program requirements. As detailed below, IHA has a robust compliance program in place that adheres to MA compliance program requirements and includes coding **auditing program**s **and provider education initiatives aimed at ensuring the accuracy of IHA's risk adjustment data.**

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[23] 42 C.F.R. § 422.503(b)(4)(vi).

Further, CMS has explicitly stated that MAOs are not held to a perfection standard as they, "cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the OIG, and DOJ believe is reasonable to enforce."[24] The OIG itself has also explicitly stated the same in commenting, "The requirement that the CEO or CFO [of an MAO] certify as to the accuracy, completeness and truthfulness of data, based on best knowledge, information and belief, does not constitute an absolute guarantee of accuracy. Rather, it creates a duty on the [MAO] to put in place an information collection and reporting system reasonably designed to yield accurate information."[25] This understanding is also implicit in the risk adjustment data accuracy certification requirements for MAO's that are based on, "best knowledge, information and belief."[26]

B. Even if IHA Were to Conduct Audits Similar to OIG's Audit, Any Such Audit Would Be Subject to the Same Flaws as the OIG's Audit, Would Not Result in Payment Accuracy, and Would Be Penal to Audited MAOs

As detailed above in Sections I through V, OIG's sampling and extrapolation methodologies are significantly flawed and any such audit performed in the same manner undertaken by IHA would thus be flawed along the same lines and would not result in "risk adjustment payment integrity and accuracy." Additionally, as noted above under Section IV, OIG's audit is biased to identify overpayments by targeting potentially unsupported diagnoses without considering diagnoses that are supported but were not reported during the plan year. Even if IHA were to conduct an audit of high-risk diagnosis codes, for which OIG has not provided sufficient information to fully replicate, any corrections would not result in payment accuracy since IHA would not be able to submit diagnosis codes that it found were supported but not reported in payment years that are closed for submissions.

For OIG to recommend that each MAO that has been subjected to an OIG high-risk audit undertake a similar audit over multiple other years also unfairly penalizes MAOs that were selected for a high-risk audit versus those that were not audited.

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[24] Medicare Program; Medicare+Choice Program, 65 Fed. Reg. 40268 (June 29, 2000).
[25] Publication of the OIG's Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans, 64 Fed. Reg. 61900 (November 15, 1999).
[26] 42 C.F.R. § 422.504(l)(2).

VII. IHA's Risk Adjustment Compliance Program is Robust

CMS provides MAOs broad discretion "to design their compliance plan structure to meet the unique aspects of each organization."[27] IHA has an established compliance program that is regularly evaluated both internally and externally. In fact, IHA received a perfect score in its most recent CMS Program Audit, with no non-compliance conditions issued by CMS for IHA's compliance program effectiveness or in any of the operational areas CMS reviewed.[28]

In its own Draft Report, OIG acknowledges that, "IHA had compliance procedures in place that were designed to prevent the submission of incorrect diagnosis codes…" and "IHA's compliance procedures also included detection and correction measures designed to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct." Further, OIG acknowledges that during the audit, IHA officials discussed enhancements made to IHA's policies and procedures over time.[29] Nonetheless, OIG indicates that IHA's compliance policies and procedures "could be improved."[30] This finding is based on the review of data that is now many years old and OIG does not offer specific recommendations for improvement or account for current policies and procedures. IHA monitors the effectiveness of not only its compliance program, but also its underlying policies and procedures. Subsequently, IHA has routinely made a number of enhancements to its risk adjustment policies and procedures, including its coding auditing programs and provider education initiatives, consistent with MA program requirements and OIG guidance.

OIG recommends that IHA, "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." IHA respectfully requests the withdrawal of this recommendation as IHA has made, and will continue to make, good faith efforts to implement and enhance internal policies and procedures to ensure the accuracy and completeness of the data submitted to CMS as part of its routine compliance monitoring.

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[27] Medicare Program; Medicare+Choice Program, 65 Fed. Reg. 40268 (June 29, 2000).
[28] CMS: 2021 Part C and Part D Program Audit and Enforcement Report, June 7, 2022, *available at https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html*
[29] *Ibid.*
[30] OIG Draft Report, p. 17.

VIII. Conclusion

For the reasons stated above, IHA requests that OIG withdraw its recommendations to: (1) refund to the Federal Government the $653,953 of overpayments, along with its stated estimation that IHA received at least $7,076,584 in net overpayments for payment years 2016 and 2017; (2) identify, for the high-risk diagnoses include 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 (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

Sincerely,

/s/ Nicole Britton

Nicole Britton
Chief Compliance Officer, Independent Health Association, Inc.

cc: Michael W. Cropp, President and CEO, Independent Health Association, Inc.
Kenneth J. Sodaro, General Counsel, Independent Health Association, Inc.
James A. Dunlop, Chief Financial Officer, Independent Health Association, Inc.
Robert Tracy, SVP Government Programs, Independent Health Association, Inc.