Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE ADVANTAGE COMPLIANCE AUDIT OF DIAGNOSIS CODES THAT INTER VALLEY HEALTH PLAN, INC. (CONTRACT H0545), SUBMITTED TO CMS

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Office of Inspector General

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Report in Brief
Date: September 2022
Report No. A-05-18-00020

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

Why OIG Did This Audit

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

To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS. CMS then maps certain diagnosis codes, on the basis of similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs). Thus, CMS makes higher payments for enrollees who receive diagnoses that map to HCCs.

For this audit, we reviewed the contract that Inter Valley Health Plan, Inc., has with CMS with respect to the diagnosis codes that Inter Valley submitted to CMS. Our objective was to determine whether Inter Valley submitted diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements.

How OIG Did This Audit

We selected a sample of 200 enrollees with at least 1 diagnosis code that mapped to an HCC for 2015. Inter Valley provided medical records as support for 1,553 HCCs associated with the 200 enrollees. We used an independent medical review contractor to determine whether the diagnosis codes complied with Federal requirements.

Medicare Advantage Compliance Audit of Diagnosis Codes That Inter Valley Health Plan, Inc. (Contract H0545), Submitted to CMS

What OIG Found

Inter Valley did not submit some diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. First, although most of the diagnosis codes that Inter Valley Health Plan submitted were supported in the medical records and therefore validated 1,411 of the 1,553 sampled enrollees' HCCs, the remaining 142 HCCs were not validated and resulted in overpayments. These 142 unvalidated HCCs included 23 HCCs for which we identified 23 other, replacement HCCs for more and less severe manifestations of the diseases. Second, there were an additional 12 HCCs for which the medical records supported diagnosis codes that Inter Valley should have submitted to CMS but did not.

Thus, the risk scores for the 200 sampled enrollees should not have been based on the 1,553 HCCs. Rather, the risk scores should have been based on 1,446 HCCs (1,411 validated HCCs + 23 other HCCs + 12 additional HCCs). As a result, we estimated that Inter Valley received at least $5.3 million in net overpayments for 2015. These errors occurred because Inter Valley's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved.

What OIG Recommends and Inter Valley's Comments

We recommend that Inter Valley refund to the Federal Government the $5.3 million of estimated net overpayments and continue to enhance its policies and procedures to prevent, detect, and correct noncompliance with Federal requirements for diagnosis codes that are used to calculate risk-adjusted payments.

Inter Valley did not concur with our findings and recommendations and provided additional medical record documentation that it believed validated specific HCCs. Inter Valley asked that we limit our first recommendation "to only the erroneous payments for [sampled] member-HCCs that were not validated" and requested that we withdraw our second recommendation. After reviewing Inter Valley's comments and the additional information that it provided, we revised our findings and the associated monetary recommendation from $5.9 million (in our draft report) to $5.3 million but made no change to our second recommendation.

The full report can be found at https://oig.hhs.gov/oas/reports/region5/51800020.asp.

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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[1] from their providers and submit these codes to CMS.

Incorrect diagnosis codes can lead to improper payments. An improper payment is any payment that should not have been made or that was made in an incorrect amount (either an overpayment or an underpayment). An estimated 7.87 percent of payments to MA organizations for calendar year 2017 were improper, mainly due to MA organizations submitting unsupported diagnosis codes to CMS.[2] Our previous audits have shown that MA organizations submitted diagnosis codes that did not comply with Federal requirements.

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.[3] We reviewed one MA organization, Inter Valley Health Plan, Inc. (Inter Valley), with respect to the diagnosis codes that Inter Valley submitted to CMS for contract number H0545.

OBJECTIVE

Our objective was to determine whether Inter Valley submitted diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements.

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

[2] The Department of Health and Human Services' (HHS's) *FY [Federal fiscal year] 2019 Agency Financial Report* estimated that 7.87 percent of the payments for the MA program were improper. This figure includes errors for both overpayments and underpayments. The error rate is determined in accordance with the Improper Payments Elimination and Recovery Improvement Act of 2012, P.L. No. 112-248 (Jan. 10, 2013), which requires Federal Agencies to: (1) review their programs and activities to identify programs that may be susceptible to significant improper payments, (2) test for improper payments in high-risk programs, and (3) develop and implement corrective action plans for high-risk programs.

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

BACKGROUND

Medicare Advantage Program

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

Under the MA program, CMS makes advance payments each month to MA organizations for the expected costs of providing health care coverage to enrollees. These payments are not adjusted to reflect the actual costs that the organizations incurred for providing benefits and services. Thus, MA organizations will generally 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 2020, CMS paid MA organizations $317 billion, which represented 34 percent of all Medicare payments for that year.

Risk Adjustment Program

Federal requirements mandate that payments to MA organizations be based on the anticipated cost of providing Medicare benefits to a given enrollee and, in doing so, also account for variations in the demographic characteristics and health status of each enrollee.[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 the MA organization is paid for each of its enrollees.[7]

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[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.

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

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

To determine an enrollee's health status for purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from acceptable data sources, including certain physicians and hospitals.[8] 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 factor (which is a numerical value) assigned to it for use in each enrollee's risk score.

CMS transitioned from one HCC payment model to another during our audit period. As part of this transition, for 2015, CMS calculated risk scores based on both payment models. CMS refers to these models as the Version 12 model and the Version 22 model, each of which has unique HCCs. Accordingly, a diagnosis code can map to either a Version 12 model HCC, a Version 22 model HCC, or to both models. For example, the diagnosis code for "Acute kidney failure, unspecified" maps to the Version 12 model HCC for Renal Failure and the Version 22 model HCC for Acute Renal Failure.

CMS blended the risk scores from both models into a single risk score for each enrollee. Thus, the total number of HCCs associated with an enrollee's risk score is based on the HCCs from both payment models.

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.[9]

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[8] CMS required face-to-face encounters during our audit period. However, in April 2020, CMS issued a memorandum to MA organizations stating that diagnoses resulting from telehealth services can meet the face-to-face requirement when the services are provided using an interactive audio and video telecommunications system that permits real-time interactive communication. This memorandum is available online at https://www.cms.gov/files/document/applicability-diagnoses-telehealth-services-risk-adjustment-4102020.pdf (accessed Aug. 26, 2020).

[9] In some instances, CMS has assigned the same factors for certain HCCs in a related-disease group. For example, the factor for the HCC for Drug/Alcohol Psychosis is the same as the factor for the HCC for Drug/Alcohol Dependence. These two HCCs (Version 12) are in the same related-disease group.

The risk adjustment program is prospective; 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 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 for providing coverage to enrollees who are 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.[10]

CMS uses diagnosis codes that it receives from MA organizations to determine which HCCs should be used in calculating enrollee risk scores. If medical records do not support these diagnosis codes, the HCCs are not validated. Unvalidated HCCs cause enrollee risk scores to be overstated. This results in improper payments (overpayments) from CMS to MA organizations. Conversely, if medical records support diagnosis codes that MA organizations do not submit to CMS, enrollee risk scores may be understated. This also may result in improper payments (underpayments).[11]

CMS designed its contract-level Risk Adjustment Data Validation (RADV) audits to be its primary corrective action on improper payments, which were estimated at 7.87 percent of payments to MA organizations for 2017. These CMS RADV audits verify that diagnoses submitted by MA organizations for risk-adjusted payment are supported by medical record documentation.

Inter Valley Health Plan, Inc.

Inter Valley, an MA organization located in Pomona, California, has a Medicare Part C contract with CMS. As of December 31, 2015, Inter Valley provided coverage under contract number H0545 to approximately 24,000 enrollees, most of whom reside in counties in Southern

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

[11] Enrollee risk scores are understated when unsubmitted diagnosis codes are related to HCCs in the payment model. This results in underpayments. However, when unsubmitted diagnosis codes are not related to HCCs in the payment model, there is no effect on enrollee risk scores or payments.

California. For our audit period (the 2015 payment year), CMS paid Inter Valley approximately $263 million to provide this coverage.[12]

HOW WE CONDUCTED THIS AUDIT

Our audit focused on enrollees on whose behalf Inter Valley submitted to CMS, for the 2014 service year, at least one diagnosis code that mapped to an HCC used in the enrollees' risk scores for the 2015 payment year. We identified a sampling frame of 14,806 enrollees from which we selected a stratified random sample of 200 enrollees on whose behalf CMS made payments totaling $3,084,557 to Inter Valley. Inter Valley provided medical records as support for 1,553 HCCs (total of both HCC payment models) associated with the 200 enrollees.

We used an independent medical review contractor to review the medical records to determine whether the diagnosis codes validated the 1,553 HCCs. The contractor reviewed these same records to determine whether any additional HCCs were validated by diagnosis codes that Inter Valley did not submit but should have submitted.

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

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

FINDINGS

Inter Valley did not submit some diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements.

First, 1,411 of the 1,553 sampled enrollees' HCCs were validated; however, the medical records did not validate the remaining 142 HCCs, which resulted in overpayments. These 142 unvalidated HCCs included 23 HCCs for which we identified 23 other HCCs for more and less severe manifestations of the diseases. These 23 other HCCs should have been included in the

[12] All of the payment amounts that CMS made to Inter Valley and the adjustment amounts that we identified in this report reflect the budget sequestration reduction.

enrollees' risk scores (instead of the 23 unvalidated HCCs), which would have reduced the overpayments associated with the 142 unvalidated HCCs in our sample.[13]

Second, in reviewing the medical record documentation for the diagnosis codes associated with the 1,553 sampled enrollee HCCs, we identified support for diagnosis codes that Inter Valley should have submitted to CMS but did not submit. If Inter Valley had submitted these diagnosis codes, an additional 12 HCCs would have been included in the enrollees' risk scores. These risk scores would have increased, and CMS's payments to Inter Valley would have been higher.

In summary, the risk scores for the 200 sampled enrollees should not have been based on the 1,553 HCCs. Rather, the risk scores should have been based on 1,446 HCCs (1,411 validated HCCs + 23 other HCCs associated with more and less severe manifestations of diseases + 12 additional validated HCCs that Inter Valley did not submit to CMS). On the basis of our sample results, we estimated that Inter Valley received at least $5,372,998 in net overpayments for 2015.

These errors occurred because Inter Valley's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved.

FEDERAL REQUIREMENTS

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

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

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

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

[13] The less severe manifestations of the diseases associated with 20 of the 23 other HCCs led to reduced overpayments for 20 HCCs. The more severe manifestations associated with 3 of the 23 other HCCs led to underpayments.

must be coded according to the International Classification of Diseases (ICD), Clinical Modification, *Official Guidelines for Coding and Reporting* (ICD Coding Guidelines) (42 CFR § 422.310(d)(1) and 45 CFR §§ 162.1002(b)(1) and (c)(2)-(3)). Further, the MA organizations must implement procedures to ensure that diagnoses come only from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities, and physicians (the Manual, ch. 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'[s] 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)).

INTER VALLEY DID NOT SUBMIT SOME DIAGNOSIS CODES IN ACCORDANCE WITH FEDERAL REQUIREMENTS

When submitting diagnosis codes to CMS for use in the risk adjustment program, Inter Valley did not always comply with Federal requirements. Specifically, Inter Valley either submitted some diagnosis codes that were not supported in the medical records or did not submit all of the correct diagnosis codes; both types of errors caused CMS to calculate incorrect risk scores for 67 of the 200 sampled enrollees.[14]

Some of the Diagnosis Codes That Inter Valley Submitted to CMS Were Not Supported in the Medical Records

The diagnosis codes that Inter Valley submitted to CMS were not supported in the medical records for 142 of the 1,553 sampled enrollees' HCCs. The 142 HCCs were not validated and should not have been used in the enrollees' risk scores. These 142 unvalidated HCCs, which also included more and less severe manifestations of the diseases, caused net overpayments from CMS to Inter Valley for 63 sampled enrollees.

Medical Records Did Not Support Submitted Diagnosis Codes or Any Other Diagnosis Codes

For 113 of the 142 unvalidated HCCs (50 sampled enrollees), the medical records did not support either the diagnosis code that Inter Valley submitted or any other diagnosis code that would have validated the HCC. These errors caused overpayments.

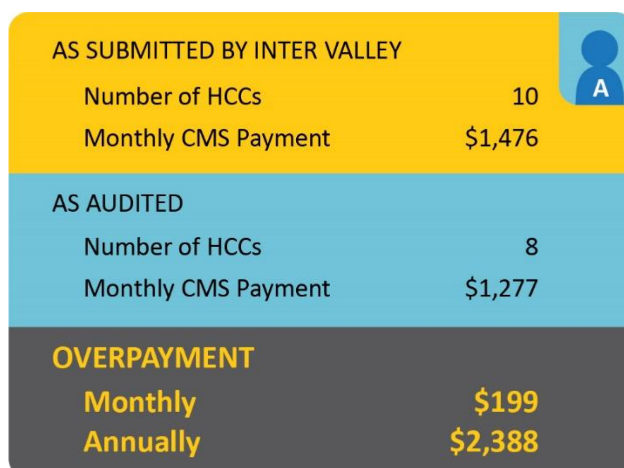
For example, for Enrollee A, Inter Valley submitted a diagnosis code for "major depressive affective disorder," which maps to both the Version 12 model HCC for Major Depressive, Bipolar, and Paranoid Disorders and the Version 22 model HCC for Major Depressive, Bipolar, and Paranoid Disorders. However, that diagnosis was not supported in the submitted medical

[14] There was more than one type of error for some enrollees.

records. Our independent medical review contractor stated that, based on review of the medical records submitted for the Version 12 model HCC and the Version 22 model HCC, there was no documentation of any condition that would result in assignment of a diagnosis code that translates to the assignment of these HCCs. One of the medical records stated that the patient had a diagnosis of depression, which does not result in an HCC.

As shown in Figure 1, the diagnosis codes that Inter Valley submitted to CMS on behalf of Enrollee A mapped to 10 HCCs, which CMS used to calculate a $1,476 monthly payment that it made to Inter Valley. Because the Version 12 model HCC and Version 22 model HCC for Major Depressive, Bipolar, and Paranoid Disorders were not validated, the CMS payment should have been based on eight HCCs, which would have resulted in a monthly payment of $1,277. This error caused a $2,388 overpayment for the year.

Figure 1: Overpayment Calculation for Enrollee A, Who Had HCCs That Were Not Validated



Medical Records Did Not Support Submitted Diagnosis Codes, but We Identified Other Hierarchical Condition Categories That Were Supported by Other Diagnosis Codes

For 23 of the 142 unvalidated HCCs (14 sampled enrollees), the medical records did not support the diagnosis codes that Inter Valley submitted (footnote 14). However, we identified 23 other HCCs (that were supported by other diagnosis codes) for more and less severe manifestations of the diseases. These 23 other HCCs should have been included in the enrollees' risk scores (instead of the 23 unvalidated HCCs). Including the 23 other HCCs would have reduced the overpayments associated with the 142 unvalidated HCCs in our sample (footnote 13).

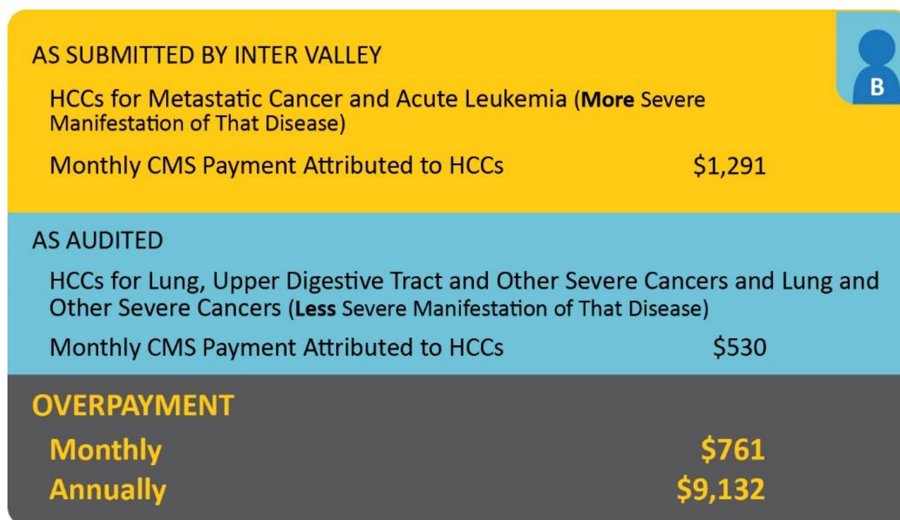
For 20 of the 23 unvalidated HCCs that were supported by other diagnosis codes (13 sampled enrollees), the diagnosis codes that Inter Valley submitted mapped to a more severe manifestation of the HCCs in the related-disease group but were not supported in the medical records. However, there were other diagnosis codes, which mapped to 20 other HCCs for less

severe manifestations, that should have been used in the enrollees' risk scores. These errors led to reduced overpayments for all of the 20 other HCCs.

For example, for Enrollee B, Inter Valley submitted a diagnosis for "Acute myeloid leukemia, without mention of having achieved remission." This diagnosis code maps to both the Version 12 model HCC for Metastatic Cancer and Acute Leukemia and the Version 22 model HCC for Metastatic Cancer and Acute Leukemia, both of which are more severe manifestations of the HCCs in those related-disease groups. That diagnosis was not supported in the submitted medical records. However, there was support for the diagnosis "Chronic myeloid leukemia, without mention of having achieved remission," which maps to HCCs that were both less severe manifestations of the HCCs in those related-disease groups (Lung, Upper Digestive Tract and Other Severe Cancers for the Version 12 model HCC and Lung and Other Severe Cancers for the Version 22 model HCC). Accordingly, Enrollee B's risk score should have been based on the HCCs with the less severe manifestation instead of the HCCs with the more severe manifestation.

As shown in Figure 2, this error caused a $9,132 overpayment for the year.

Figure 2: Overpayment Calculation for Enrollee B, Who Had HCCs for a Less Severe Manifestation of a Disease That Should Have Been Used Instead of HCCs for a More Severe Manifestation of That Disease



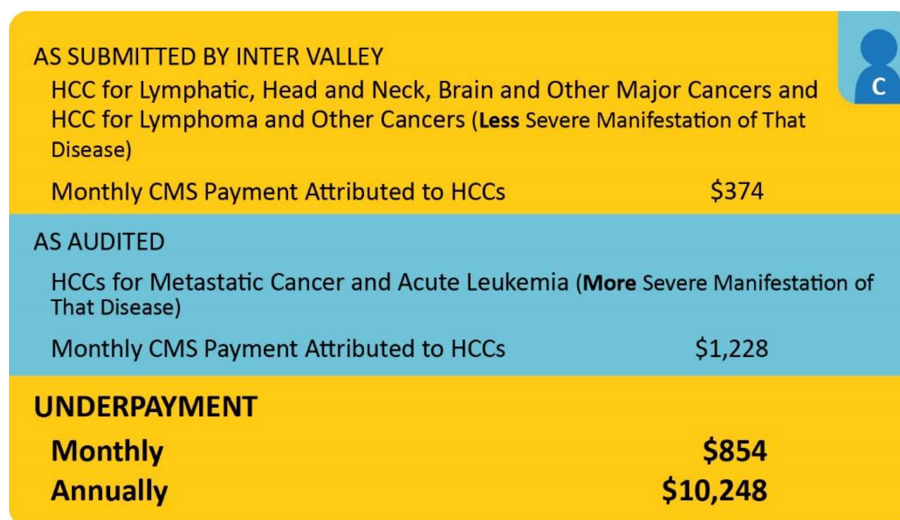
Note – For presentation purposes, we eliminated other HCCs that were either validated or not validated.

For 3 of the 23 unvalidated HCCs that were supported by other diagnosis codes (2 sampled enrollees), Inter Valley did not submit diagnosis codes that mapped to the most severe manifestation of the HCCs in the related-disease groups. Instead, Inter Valley submitted only the diagnosis codes that mapped to the less severe manifestations. If Inter Valley had submitted the correct diagnosis codes, the more severe HCCs would have been used instead of the less severe HCCs in the risk scores. These errors led to underpayments.

For example, for Enrollee C, Inter Valley submitted a diagnosis for “Malignant neoplasm of connective and soft tissue of head, face and neck.” This diagnosis code maps to both the Version 12 model HCC for Lymphatic, Head and Neck, Brain, and Other Major Cancers and the Version 22 model HCC for Lymphoma and Other Cancers, both of which are less severe manifestations of the HCCs in those related-disease groups. That diagnosis was not supported in the submitted medical records. However, our independent medical review contractor found support for the diagnosis “Secondary and unspecified malignant neoplasm of lymph nodes of head, face, and neck,” which maps to HCCs that were both more severe manifestations of the HCCs in those related-disease groups (Metastatic Cancer and Acute Leukemia for both the Version 12 and 22 model HCCs). Accordingly, Enrollee C’s risk score should have been based on the HCCs with the more severe manifestation instead of the HCCs with the less severe manifestation.

As shown in Figure 3, this error caused a $10,248 underpayment for the year.

Figure 3: Underpayment Calculation for Enrollee C, Who Had HCCs for a More Severe Manifestation of a Disease That Should Have Been Used Instead of HCCs for a Less Severe Manifestation of That Disease



Note – For presentation purposes, we eliminated other HCCs that were either validated or not validated.

Inter Valley Could Not Locate Certain Medical Records

Of the 142 unvalidated HCCs (3 sampled enrollees), 6 were not validated because Inter Valley could not locate the records. These errors caused overpayments.

Diagnosis Codes That Inter Valley Should Have Submitted but Did Not Submit to CMS

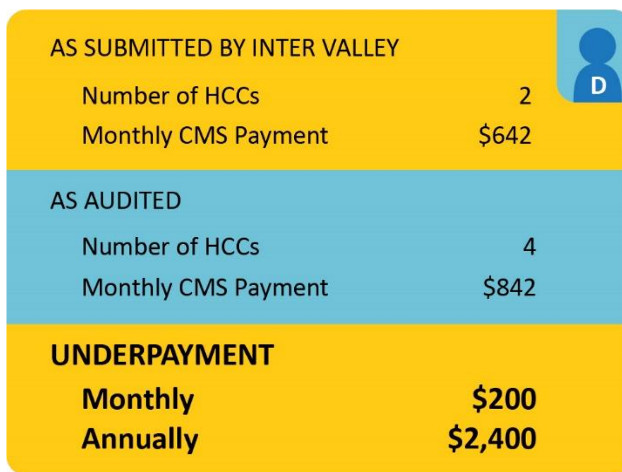
Inter Valley did not submit all of the correct diagnosis codes. Specifically, there were an additional 12 HCCs (9 sampled enrollees) for which the medical records supported diagnosis codes that Inter Valley should have submitted but did not submit to CMS and that should have

been used in the enrollees' risk scores. These errors caused underpayments from CMS to Inter Valley.

For example, for Enrollee D, Inter Valley did not submit a diagnosis code for "Diabetes with peripheral circulatory disorders, type II or unspecified type, not stated as uncontrolled." However, our independent medical review contractor, as part of its review of a different HCC, found support for this diagnosis documented in a medical record. This diagnosis code, which Inter Valley should have submitted but did not submit to CMS, maps to and validates two HCCs: the Version 12 model HCC for Diabetes with Renal or Peripheral Circulatory Manifestation and the Version 22 model HCC for Diabetes with Chronic Complications.

As shown in Figure 4, this error caused a $2,400 underpayment.

Figure 4: Underpayment Calculation for Enrollee D, Who Had HCCs That Were Validated From a Diagnosis Code That Inter Valley Should Have Submitted but Did Not Submit to CMS



Summary of Diagnosis Codes Not Submitted in Accordance With Federal Requirements

Because Inter Valley did not submit some diagnosis codes in accordance with Federal requirements for the 200 sampled enrollees, their risk scores should not have been based on the 1,553 HCCs. Rather, their risk scores should have been based on the 1,446 validated HCCs. Figure 5 on the following page summarizes these differences.

Figure 5: Number of HCCs Used in Risk Scores Contrasted With Number of HCCs That Should Have Been Used in Risk Scores for the 200 Sampled Enrollees

BASED ON DIAGNOSIS CODES THAT INTER VALLEY SUBMITTED	
Total Number of HCCs	1,553
AS AUDITED	
HCCs That Were Validated	1,411
HCCs Validated by Other Diagnosis Codes	23
Additional HCCs That Were Validated	+ 12
NUMBER OF HCCS THAT SHOULD HAVE BEEN USED	**1,446**

THE POLICIES AND PROCEDURES THAT INTER VALLEY USED 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 Inter Valley had to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations at 42 CFR § 422.503(b)(4)(vi), could be improved.

Inter Valley stated that it designed its compliance program to ensure that it submitted accurate diagnosis codes for use in CMS's risk adjustment program. To prevent the submission of incorrect diagnosis codes to CMS, Inter Valley had procedures by which it educated providers on the correct usage of diagnosis codes. Inter Valley also had procedures that were designed to detect and correct inaccurate diagnosis codes that were already submitted to CMS. In some cases, Inter Valley identified specific claims for which it accessed medical records, either through electronic medical record information or onsite visits, to determine whether the diagnosis codes on the claim were supported in the medical records.

Inter Valley officials told us that Inter Valley reviewed the effectiveness of its compliance program on an annual basis and maintained a process to identify and return overpayments to CMS. As an example, Inter Valley provided documentation to us demonstrating that it had identified several thousand incorrect diagnosis codes that it had submitted to CMS but should not have. Inter Valley also provided documentation supporting that it notified CMS of its corrective action.

However, because the risk scores for the 200 sampled enrollees should have been based on 1,446 HCCs instead of 1,553 HCCs, we believe that Inter Valley's policies and procedures associated with its compliance program could be improved.

INTER VALLEY RECEIVED NET OVERPAYMENTS

Inter Valley received $152,503 of net overpayments (consisting of $177,585 of overpayments and $25,082 of underpayments) for the 200 sampled enrollees (Appendix D). On the basis of our sample results, we estimated that Inter Valley received at least $5,372,998 of net overpayments for 2015.

RECOMMENDATIONS

We recommend that Inter Valley Health Plan, Inc.:

- refund to the Federal Government the $5,372,998 of estimated net overpayments and

- continue to enhance its policies and procedures to prevent, detect, and correct noncompliance with Federal requirements for diagnosis codes that are used to calculate risk-adjusted payments.

INTER VALLEY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Inter Valley did not concur with our findings and with both of our recommendations. Specifically, Inter Valley stated that it did not concur with our findings for some of the HCCs and gave us "statements outlining [its] reasons for non-concurrence" and requested that we perform additional reviews. In addition, Inter Valley requested that we limit our first recommendation "to only the erroneous payments for [sampled] member-HCCs that were not validated" because, among other things, Inter Valley did not agree with our sampling and extrapolation methodologies. Inter Valley also stated that it had an effective and comprehensive compliance program and it requested that we withdraw our second recommendation.

After reviewing Inter Valley's comments and the additional information that it provided, we revised our findings and the associated monetary recommendation (from $5,905,626 to $5,372,998) for this final report. We made no change to our second recommendation.

A summary of Inter Valley's comments and our responses follows. Inter Valley's comments appear as Appendix F. We excluded an attachment (which Inter Valley identified as Attachment A in its comments) that contained personally identifiable information. We are separately providing Inter Valley's comments and attachment in their entirety to CMS.

Inter Valley Did Not Agree With All Hierarchical Condition Category Determinations

Inter Valley Comments

Inter Valley, in the additional information that it provided, identified 14 HCCs that it believed we should reconsider for 9 sampled enrollees. The additional information included 4 previously unsubmitted medical records that Inter Valley believed validated the 14 HCCs.

Office of Inspector General Response

Our independent medical review contractor reviewed all of the additional information that Inter Valley provided and, as a result, validated 6 of the 14 HCCs. For one of the remaining eight HCCs, our independent medical review contractor maintained that the audited HCC was unvalidated but found support for a diagnosis code that mapped to a more severe manifestation of the HCC in the related-disease group (instead of a less severe manifestation of the HCC originally found in our draft report). This error led to an underpayment. Consequently, the number of unvalidated HCCs in our draft report decreased from 148 to 142 for this final report. Accordingly, we revised our findings and reduced the associated monetary recommendation from $5,905,626 to $5,372,998.

Inter Valley Did Not Agree With OIG's Use of the Two-Sided 90-Percent Confidence Interval in Estimating Overpayments

Inter Valley Comments

Inter Valley disagreed with how we calculated the estimated net overpayments. Specifically, Inter Valley stated that our use of the lower bound of a two-sided 90-percent confidence interval in estimating overpayments is inconsistent with both CMS' Medicare Program Integrity Manual (MPIM) and CMS' practice for RADV audits.

Inter Valley said that the MPIM "recommends using the lower bound of a one-sided [90-percent] confidence interval." In addition, Inter Valley stated that CMS, in 2012, published a final methodology that included the use of the lower bound of a two-sided 99-percent confidence interval for estimating payment errors on risk adjustment data validation contract-level audits. To these points, Inter Valley stated that it "believes it is more reasonable for OIG to use the lower bound of a [99-percent] two-sided confidence interval, consistent with CMS's RADV audit methodology."

Office of Inspector General Response

We do not agree with Inter Valley's assertion that we should have calculated the estimated net overpayments with the lower bound of a 99-percent two-sided confidence interval.

In accordance with the Inspector General Act of 1978, 5 U.S.C. App., our audits are intended to provide an independent assessment of HHS programs and operations. Accordingly, our estimation methodology does not need to mirror CMS' estimation methodology or CMS' MPIM. Our policy is to recommend recovery at the lower limit of a two-sided 90-percent confidence interval. The lower limit of a two-sided 90-percent confidence interval provided a reasonably conservative estimate of the total amount overpaid to Inter Valley for the enrollee-years and time period covered in our sampling frame. Further, we note that this approach, which HHS routinely uses for recovery calculations,[15] results in a lower limit (the estimated overpayment amount to refund) that is less than the actual overpayment amount 95 percent of the time.

Additionally, the legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.[16] As detailed in Appendix C, we properly executed a statistically valid sampling methodology in that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

Inter Valley Stated That OIG Provided No Rationale as to How It Determined Sample Sizes

Inter Valley Comments

Inter Valley made several statements regarding the number of sampled enrollees that we included in our three strata. Specifically, Inter Valley stated that we did not provide the rationale for why: (1) the stratum level sample sizes consisted of 50, 50, and 100 enrollees; (2) the sample size for the third stratum was twice as large as that of the other two (100 enrollees vs. 50 enrollees); and (3) the overall sample size consisted of 200 enrollees.

Inter Valley made a general statement that "[s]ample size arguments must be accompanied with further technical arguments, as overly simple criticisms of sample sizes have been rejected in many settings as a basis to invalidate the sample results. Additionally, the increase in burden to all parties should be considered if the overall sample size were to be increased as a response."

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

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

Therefore, Inter Valley provided further sample size criticism, stating that "relatively small strata and overall sample sizes should be addressed directly in terms of types of members present in the population but missing from the sample . . . . Statistical bias can be introduced when samples are missing important, but relatively rare, members/conditions."

To address the statistical bias, Inter Valley believes that a certainty stratum should be used stating that "[w]ithout a certainty stratum, the risk exists that one of these rare members with disproportionately large exposure risk could be selected in the random sample. As a result, the sample results could be non-representatively skewed upwards and then extrapolated over the population of members in the third stratum. Using a certainty stratum would allow OIG to derive more precise results with only minimal changes in overall sample size, while simultaneously avoiding this distortionary risk."

Office of Inspector General Response

Our audit was planned and performed in accordance with generally accepted government auditing standards so as to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions. Accordingly, we designed our audit to determine whether the diagnosis codes that Inter Valley submitted to CMS for use in the risk adjustment program were adequately supported in the medical records—and thus complied with Federal requirements.

Small sample sizes, e.g., smaller than 100, have routinely been upheld by the Departmental Appeals Board and Federal courts.[17] The legal standard for a sample size is that it must be sufficient to be statistically valid, not that it be the most precise methodology.[18] Because absolute precision is not required, any imprecision in the sample may be remedied by recommending recovery at the lower limit, which was done in this audit.[19] This approach results in an estimate that is lower than the actual overpayment amount 95 percent of the time, and thus it generally favors the provider.[20]

The method of stratification and strata sizes are design choices made by the audit team (such as whether we use a certainty stratum), and those we made for this audit were statistically valid. Further, our sample was representative of the sampling frame in that we selected the items from each stratum using a simple random sample in which each item within each stratum had an equal probability of being selected.

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[17] *See Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012) (upholding a sample size of 95 claims); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 (S.D. Tex. 2012) (upholding a sample size of 30 claims).

[18] *See John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at *34-35 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012).

[19] *See Pruchniewski v. Leavitt*, 2006 U.S. Dist. LEXIS 101218 at *51-52 (M.D. Fla. 2006).

[20] *See Puerto Rico Dep't of Health*, DAB No. 2385, at 10-11 (2011); *Oklahoma Dep't of Human Servs.*, DAB No. 1436, at 8 (1993) (stating that the calculation of the disallowance using the lower limit of the confidence interval gave the State the "benefit of any doubt" raised by use of a smaller sample size).

- Stratified random sampling designs result in an unbiased estimate of net overpayments, regardless of the number of items selected from each stratum.

- Although the third stratum accounted for the majority of the payments, our estimate of net overpayments accounted for the weighting of each stratum.

As detailed in Appendix C, we properly executed a statistically valid sampling methodology in that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

Inter Valley Did Not Agree That OIG's Sampling Frame Was Representative of Inter Valley's Enrollment, Creating an Overpayment Bias Concern

Inter Valley Comments

Inter Valley stated that we excluded from the sampling frame all enrollees without any diagnoses mapping to an HCC in the payment year. Therefore, Inter Valley believes our "sample design is not representative of the population and specifically in a way that is biased to overemphasize overpayments."

Office of Inspector General Response

Our objective was to determine whether Inter Valley submitted diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. In this regard, the inclusion in our sampling frame of enrollees for whom Inter Valley did not submit a qualifying diagnosis code to CMS was beyond the scope of our audit.

A valid estimate of net overpayments does not need to cover all enrollees or diagnosis codes within the audit period. Accordingly, our estimate of net overpayments does not extend to the diagnosis codes that were beyond the scope of review. In accordance with our objective, we properly executed our statistical sampling methodology in that we defined our sampling frame (Inter Valley enrollees with at least one HCC) and sample unit, randomly selected our sample, applied relevant criteria to evaluate the sample, and used statistical sampling software to apply the correct formulas to estimate the net overpayments in the sampling frame made to Inter Valley.

Inter Valley Did Not Agree With OIG's Assessment of Its Compliance Program

Inter Valley Comments

Inter Valley did not agree with our conclusion that the policies and procedures that Inter Valley had to prevent, detect, and correct noncompliance with CMS's program requirements could be improved. In this regard, Inter Valley stated that a validation rate (that is, the percentage of

sampled HCCs that were supported in the medical records) above 92 percent "is indicative of effective policies and procedures to detect potential coding errors."

Inter Valley stated that it "has a strong record of an effective and comprehensive compliance program," which includes provider education "designed to ensure that contracted providers update medical records accurately and according to industry standard coding guidelines." In addition, Inter Valley stated that its oversight efforts include "ongoing compliance chart reviews to ensure linkage between medical record documentation and encounter data [that it] received." To this point, Inter Valley stated that its compliance program identified and resolved diagnosis code issues for dates of service in 2014.

Inter Valley further stated that our second recommendation to improve its policies and procedures "implies that the OIG requires a 100[percent] validation rate, which equates to a perfection standard." In this regard, Inter Valley stated that "[t]he 100[percent] validation standard also suggests that [an MA organization] should review each and every medical record associated with a diagnosis code submission." Inter Valley said that CMS does not specify (in the Medicare Managed Care Manual) that an MA organization should substantiate "the validity of each diagnosis code against the medical record." Inter Valley stated that the Medicare Managed Care Manual lists certain core requirements to be included in compliance plans and that its "compliance program is designed to meet all of the core requirements."

Inter Valley said that our extrapolation methodology implies a perfection standard across the contract and that it "strongly disagrees with a perfection standard being applied to extrapolated overpayments." Inter Valley also said that "the perfection standard imposed on [MA organizations] in the audit is not maintained by the OIG in the current audit methodology." Specifically, Inter Valley said that our estimation methodology "implies that 5[percent] of the time OIG would be calculating an error rate that is higher than the true error rate . . . but . . . no error rate is acceptable to the OIG regarding payments to [MA organizations]."

Inter Valley requested that we withdraw our second recommendation.

Office of Inspector General Response

We acknowledge that Inter Valley had compliance procedures in place to promote the accuracy of diagnosis codes submitted to CMS to calculate risk-adjusted payments. However, based on the materiality of our findings – estimated net overpayments of approximately $5.3 million – we do not agree with Inter Valley that our second recommendation should be withdrawn.

Federal regulations (42 CFR § 422.503(b)) require MA organizations like Inter Valley to establish and implement an effective system for routine monitoring and identification of compliance risks. This regulation further explains that a compliance system should consider both internal monitoring and external audits. In this regard, we note that Inter Valley identified steps that it took to ensure accuracy of its risk adjustment submissions to CMS. We also concluded that Inter Valley should continue to make improvements. Specifically, the percentage of HCCs for the

sampled enrollees in error (142 of 1,553 or 9 percent) and the number of sampled enrollees with at least 1 incorrect HCC included in their risk score (67 of 200 or 33.5 percent (Appendix D)) demonstrates that Inter Valley's compliance program could be improved.

We also do not agree with Inter Valley's statement that our recommendation imposes a "perfection standard" on Inter Valley. Our description of Inter Valley's policies and procedures as "could be improved" to ensure compliance with CMS's program requirements serves to point directly to our second recommendation to *continue* to enhance these policies and procedures. The *continued* improvement of those policies and procedures, based on the results of this audit as well as the results of Inter Valley's routine chart reviews, will assist Inter Valley in attaining better assurance with regard to the accuracy and completeness of the risk adjustment data that it submits in the future.

Accordingly, we maintain that our second recommendation is valid.

Inter Valley Stated That OIG's Audit Focused on a Payment Year That Has Already Been "Settled" by CMS

Inter Valley Comments

Inter Valley stated that, "[our] audit was focused on dates of service in 2014 for payment year 2015, which has already been 'settled' with CMS" and our audit methodology "undermines the actuarial models used to determine the appropriate bid rates." Inter Valley further stated that had it "known when projecting the risk scores in its payment year 2015 bid calculations that millions of dollars in extrapolated premiums would be retracted at some point in the future, Inter Valley Health Plan would have increased its bid rates in an actuarially sound manner."

Office of Inspector General Response

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. App. For this audit, our objective was to determine whether Inter Valley submitted diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. Any 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. Similarly, any impact CMS's potential recoupment might have on bid rate calculations is outside the scope of the audit.

Inter Valley Stated That OIG's Extrapolation Methodology Did Not Apply Certain CMS Requirements

Inter Valley Comments

Inter Valley stated that our extrapolation methodology (to calculate estimated net overpayments) and our ensuing recommendation violated a payment principle known as "actuarial equivalence."

In this regard, Inter Valley stated that the Act requires that "payment amounts made in Medicare Advantage should be the same as the payments made under traditional Medicare FFS for an equivalent population of beneficiaries." To this point, Inter Valley stated that the risk scores for MA enrollees relied upon FFS diagnosis data that likely had "instances of errors or unsupported codes." According to Inter Valley, because our recommended repayment amount did not contemplate these diagnosis errors (through the application of a fee-for-service adjuster), we thereby violated actuarial equivalence.

Inter Valley also referenced a study that CMS released in 2018 in which, according to Inter Valley, CMS concluded that the underlying errors in the FFS data did not create an underpayment bias for MA organizations. However, Inter Valley said that many industry experts criticized the methodology and assumptions utilized in the 2018 study.

Office of Inspector General Response

Our audit methodology correctly applied CMS requirements to properly identify the overpayment amount associated with unsubstantiated HCCs for each sample item. Specifically, we used the results of the independent medical review contractor's review to determine which HCCs were not substantiated and, in some instances, to identify HCCs that should have been used but were not used in the associated enrollees' risk score calculations. We followed CMS's risk adjustment program requirements to determine the payment that CMS should have made for each enrollee and used the overpayments or underpayments to estimate net overpayments.

Regarding Inter Valley's statement that we did not consider "actuarial equivalence" in our overpayment calculations, we recognize that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program, including the application of any FFS Adjuster. Moreover, CMS has not issued any requirements that compel us to reduce our estimate of net overpayments.[21] If CMS deems it appropriate to apply an FFS Adjuster, it will adjust our overpayment finding by whatever amount it determines necessary. Thus, we maintain

[21] In 2018, CMS proposed "not to include an FFS Adjuster in any final RADV payment error methodology" (Proposed Rule at 83 Fed. Reg. 54982, 55041.)

that our audit methodology provides a reasonable basis for our findings and recommendations, including our estimation of net overpayments.[22]

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

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid Inter Valley $262,897,329 to provide coverage to 24,092 enrollees, most of whom resided in counties in Southern California for the 2015 payment year.[23] We identified a sampling frame of 14,806 enrollees who had at least 1 HCC in their risk scores; Inter Valley received $200,744,983 in payments from CMS for these enrollees for 2015. We selected for audit a stratified random sample of 200 enrollees on whose behalf CMS made payments totaling $3,084,557 to Inter Valley.

We reviewed Inter Valley's internal controls for ensuring that diagnosis codes it submitted to CMS for use in the risk adjustment program were in accordance with Federal requirements.

We performed audit work from June 2018 to December 2021.

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

- We reviewed Inter Valley's policies and procedures to understand how Inter Valley submitted diagnosis codes to CMS.

- We developed our sampling frame using data from CMS systems. Our sampling frame consisted of enrollees who had at least one HCC in their risk scores. To create this frame, and as explained further in Appendix C, we used data from the CMS:

    - Risk Adjustment Processing System, which MA organizations use to submit diagnosis codes to CMS;

    - Risk Adjustment System, which identifies the HCCs that CMS factors into each enrollee's risk score calculation; and

[23] Payment year 2015 data was the most current data available when we started our audit in 2018.

- Medicare Advantage Prescription Drug System, which identifies the Medicare payments, before applying the budget sequestration reduction, made to MA organizations.

- We presented the data for the enrollees in our sampling frame to Inter Valley for verification, performed an analysis of the data included on CMS's systems to ensure that the enrollees met the criteria for our sampling frame, and selected a stratified random sample of 200 enrollees from the sampling frame (Appendix C).

- We obtained 546 medical records from Inter Valley as support for the 1,553 HCCs associated with the 200 sampled enrollees.

- We used an independent medical review contractor to determine whether the diagnosis codes in the medical records validated the 1,553 HCCs.

- The independent medical review contractor's coding review of the 546 medical records followed a specific process to determine whether there was support for a diagnosis code and associated HCC. Under the process:

  - If the first senior coder found support for the diagnosis code on the medical record, the HCC was considered validated.

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

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

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

  - If either the first or second senior coder asked a physician for assistance, the physician's decision became the final determination.

  - For any diagnosis code that had not been previously submitted, the HCC was considered validated as an additional HCC if either: (1) both senior coders found support in the medical record or (2) one senior coder plus a physician did so.

- We reviewed available data from CMS's systems for the sampled enrollees to determine whether CMS's payments had been canceled or adjusted.

- We used the results of the independent medical review to calculate overpayments or underpayments (if any) for each enrollee. Specifically, we calculated:

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

   - the Medicare payment, before applying the budget sequestration reduction, that CMS should have made for each enrollee.

- We used the overpayments and underpayments identified for each enrollee to estimate net overpayments.

- We provided the results of our audit to Inter Valley officials on June 2, 2021 and provided updated results on September 9, 2022.

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

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS	A-03-18-00002	8/19/2022
Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS	A-07-17-01169	2/3/2022
Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS	A-07-16-01165	4/19/2021

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

Our sampling frame consisted of 14,806 enrollees who: (1) were continuously enrolled under contract number H0545 throughout all of the 2014 service year and January 2015 and (2) had at least one HCC in their 2015 payment year risk scores. Because CMS adjusts its risk-adjusted payments in the calendar year subsequent to when a beneficiary is diagnosed, we restricted our population to individuals who were enrolled—and thus diagnosed—at Inter Valley during the 2014 service year.

Our sampling frame included enrollees who were:

- not classified as having hospice or end-stage renal disease (ESRD) status at any time during the 2014 service year through January 2015 and

- continuously enrolled in Medicare Part B coverage during the 2014 service year.

SAMPLE UNIT

The sample unit was one enrollee.

SAMPLE DESIGN

We used a stratified random sample. To identify the strata, we used a two-step process in which we first calculated a value we refer to as the monthly-weighted-health risk score. We computed the monthly-weighted-health risk score using the following formula:

[health-related portion of the enrollee's risk score]
x
[number of monthly 2015 capitation payments affected by the enrollee's risk score][24]

We classified the enrollees according to the magnitude of the risk-adjusted payments made on their behalf. A higher monthly-weighted-health risk score signified a higher amount of risk-adjusted payments on behalf of that enrollee for the year. We then ranked the 14,806 enrollees according to their monthly-weighted-health risk score from lowest to highest and separated them into 3 strata. The specific strata are shown in Table 1.

[24] We excluded from this calculation months in 2015 for which enrollees were classified as having hospice or ESRD status.

Table 1: Strata Based on Monthly-Weighted-Health Risk Scores

Stratum	Sample Size	Number of Enrollees	Monthly-Weighted-Health Risk Score Range	Sampling Frame Dollar Total
1	50	4,942	0.114 – 6.972	$37,237,705
2	50	4,934	6.979 – 15.348	58,042,189
3	100	4,930	15.360 – 137.412	105,465,089
Total	**200**	**14,806**		**$200,744,983**

SOURCE OF THE RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the sample units within each stratum. After generating the random numbers, we selected the corresponding sample units in each stratum.

ESTIMATION METHODOLOGY

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

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 2: Sample Results

Stratum	Frame Size	CMS Payment (for Enrollees in Frame)	Sample Size	CMS Payment (for Sampled Enrollees)	Number of Sampled Enrollees With Incorrect Diagnosis Codes	Net Medicare Over/Under payments for Unvalidated HCCs (for Sampled Enrollees)
1	4,942	$37,237,705	50	$378,724	7	($1,777)
2	4,934	58,042,189	50	562,400	14	20,161
3	4,930	105,465,089	100	2,143,433	46	134,119
Total	**14,806**	**$200,744,983**	**200**	**$3,084,557**	**67**	**$152,503**

Table 3: Estimated Value of Net Medicare Overpayments in the Sampling Frame
(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	$8,425,898
Lower limit	5,372,998
Upper limit	11,478,798

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: INTER VALLEY COMMENTS

April 8, 2022

Ms. Sheri L Fulcher
Regional Inspector General for Audit Services
Office of Audit Services
Region V
233 N Michigan, Suite 1360
Chicago, IL 60601

Re: Report Number A-05-18-00020

Dear Ms. Fulcher:

Inter Valley Health Plan writes in response to the United States Department of Health and Human Services (HHS) Office of Inspector General's (OIG) Draft Report for Audit No A-05-18-00020 (Draft Report). For the reasons described below, Inter Valley Health Plan respectfully requests that the OIG withdraw its recommendations that Inter Valley Health Plan repay an extrapolated amount of $5,905,626, and instead limit repayment recommendations to only the erroneous payments for member-HCCs that were not validated at the conclusion of the OIG's audit. Inter Valley Health Plan also requests that the OIG withdraw its recommendation that the plan, "continue to enhance its policies and procedures to prevent, detect, and correct noncompliance with Federal requirements for diagnosis codes that are used to calculate risk-adjusted payments." Inter Valley Health Plan does not-concur with the OIG's recommendations for the reasons outlined below:

1. Appeal Effect Sensitivity
2. Confidence Interval Sensitivity
3. Stratum 3 Oversampling Sensitivity
4. Stratum Size Criticism
5. Overpayment Bias Criticism
6. Perfection Standard Criticism
7. Bid Rate Implication Argument
8. Actuarial Equivalence Argument

Appeal Effect Sensitivity

Inter Valley Health Plan does not concur with the OIG's draft findings for 9 member-HCCs. Inter Valley Health Plan has prepared statements outlining our reasons for non-concurrence for these members and requests additional review by the OIG (*see*

Attachment A).[1] To the extent that after additional review the OIG finds these member-HCCs to be supported by the corresponding medical records, the extrapolated overpayment amount will be impacted. Table 1 below provides an approximated update to the payment error estimate under the assumption that these 9 member-HCCs are validated by the OIG after additional review and removed from the extrapolation calculation (the "Appeal Effect").

Table 1: Comparison of Estimated Potential Exposure by Appeal Outcome[2]

		Estimated Extrapolated Overpayment	
Audit Scenario	**Sample Payment Error**	**Lower Bound 90% CI**	**Point Estimate**
OIG Audit File	$ 161,514	$ 5,905,626	$ 8,979,423
Appeal Effect	$ 154,098	$ 5,240,929	$ 8,247,187

Scenario Key:
OIG Audit = Payment Error per OIG's audit validation results
Appeal Effect = Assuming all appeals are successfully accepted

Confidence Interval Sensitivity

In certain payment audit settings, the Centers for Medicare & Medicaid Services ("CMS") recommends or requires employing the *lower bound* of the confidence interval as the amount to be demanded for recovery. For example, the Medicare Program Integrity Manual recommends using the lower bound of a one-sided 90% confidence interval:[3]

> *In most situations, the lower limit of a one-sided 90 percent confidence interval should be used as the amount of overpayment to be demanded for recovery from the provider/supplier. This procedure, which through confidence interval estimation, incorporates the uncertainty inherent in the sample design, is a conservative method that works to the financial*

[1] Additional medical record documentation supporting four of the nine member-HCCs will be separately transmitted to the OIG via OIG's secure document sharing platform.
[2] Exposure amounts are derived by applying a similar extrapolation methodology described in CMS's RADV Methodology Memo "Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits." Extrapolated figures do not consider any Fee-for-Service Adjuster in any scenario. *See* CMS, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits (Feb. 24, 2012), *available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf.*
[3] CMS, Medicare Program Integrity Manual, Chapter 8 – Administrative Actions and Sanctions and Statistical Sampling for Overpayment Estimation, Section 8.4.5.1 – The Point Estimate, (Rev. 906; Issued: 09-26-19; Effective: 01-02-19; Implementation: 01-02-19), *available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c08.pdf.*

advantage of the provider/supplier. That is, it yields a demand amount for recovery that is very likely less than the true amount of overpayment, and it allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for the point estimate. However, the contractor is not precluded from demanding the point estimate where high precision has been achieved, and when there are statistically sound reasons for the demand.

Similarly and most relevant to this audit, CMS published a final methodology on Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audit payment error estimations in February 2012. In this methodology, the lower bound of a two-sided 99% confidence interval is employed as a "preliminary payment recovery amount," prior to any Fee-for-Service Adjuster adjustment.[4]

To understand the impact of using the concept of a lower bound instead of the point estimate, we calculated the lower bounds associated with 90%, 95%, and 99% two-sided confidence intervals and compared those estimates to the point estimate. By definition, the lower bound of the confidence intervals will produce lower exposure amounts than the point estimate, with the amount decreasing as the confidence level increases. Table 2 below provides the estimated updated lower bound and point estimate exposure amounts using lower bounds associated with 90%, 95%, and 99% two-sided confidence intervals.

Table 2: Comparison of Estimated Potential Exposure by Confidence Interval Lower Bound and Point Estimate[5]

		Estimated Extrapolated Overpayment			
Audit Scenario	**Sample Payment Error**	**Lower Bound 99% CI**	**Lower Bound 95% CI**	**Lower Bound 90% CI**	**Point Estimate**
OIG Audit File	$ 161,514	$ 4,165,878	$ 5,316,768	$ 5,905,626	$ 8,979,423

Scenario Key:
OIG Audit = Payment Error per OIG's audit validation results
Appeal Effect = Assuming all appeals are successfully accepted

[4] CMS, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits (Feb. 24, 2012), *available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf.*
[5] Exposure amounts are derived by applying a similar extrapolation methodology described in CMS's RADV Methodology Memo "Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits." Extrapolated figures do not consider any Fee-for-Service Adjuster in any scenario. *Ibid.*

As noted in the preceding section, assuming that all or some portion of the 9 member-HCC appeals are validated by the OIG, as a general rule these estimates will be lowered. Table 3 below provides the estimated updated lower bound and point estimate exposure amounts assuming all 9 member-HCCs challenged by Inter Valley Health Plan are validated by the OIG.

Table 3: Comparison of Estimated Potential Exposure by Confidence Interval Lower Bound, Point Estimate, and by Appeal Outcome[6]

		Estimated Extrapolated Overpayment			
Audit Scenario	**Sample Payment Error**	**Lower Bound 99% CI**	**Lower Bound 95% CI**	**Lower Bound 90% CI**	**Point Estimate**
OIG Audit File	$ 161,514	$ 4,165,878	$ 5,316,768	$ 5,905,626	$ 8,979,423
Appeal Effect	$ 154,098	$ 3,539,408	$ 4,665,010	$ 5,240,929	$ 8,247,187

Scenario Key:
OIG Audit = Payment Error per OIG's audit validation results
Appeal Effect = Assuming all appeals are successfully accepted

As illustrated in Table 3, the OIG's decision to use the lower bound of a 90% two-sided confidence interval has meaningful impact of approximately $1.7 million on the extrapolated overpayment amount when compared to a 99% two-sided confidence interval. Inter Valley Health Plan disagrees that the 90% two-sided interval is the correct interval. Instead, Inter Valley Health Plan believes it is more reasonable for OIG to use the lower bound of a 99% two-sided confidence interval, consistent with CMS's RADV audit methodology.

Stratum 3 Oversampling Sensitivity

The current OIG methodology stratifies the member population eligible for audit into three strata and samples 50 members from the first two member strata (lowest and middle third of members ranked by the health-related portion of their risk score weighted by months enrolled), and 100 members from the third member stratum (the third of members with the highest weighted health-related risk scores). OIG has provided no rationale as to how it determined these sample sizes (as will be discussed in the following section). Further, OIG has provided no rationale as to why the sample size for the third stratum is twice as large as that of the other two (100 vs. 50).

Generally, increasing the sample size of any individual stratum, by statistical theory, increases the precision of the resulting estimate. Assuming no other statistical

[6] Exposure amounts are derived by applying a similar extrapolation methodology described in CMS's RADV Methodology Memo "Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits." Extrapolated figures do not consider any Fee-for-Service Adjuster in any scenario. *Ibid.*

concerns, sample sizes of 50 and 100 are generally considered to be large enough to provide unbiased estimates of the figure being estimated. OIG may argue that more members were sampled from the group with potentially larger exposure (i.e., the members with the highest weighted health-related risk scores) in order to increase the precision of what will likely be the stratum with the largest exposure amount and largest variation from sample to sample.

In practical terms, given the known ordering of the 100 members selected from the third stratum, one can calculate what the impact to the overall exposure estimate would be of using just the first 50 randomly selected members. Table 4 below includes the estimated updated lower bound and point estimate exposure amounts when limiting stratum 3 to the first 50 randomly selected members.

Table 4: Comparison of Estimated Potential Exposure Only Considering First 50 Members From Stratum 3[7]

				Estimated Extrapolated Overpayment			
Audit Scenario	**Sample Payment Error**	**Members in Sample**	**Sample Payment Error per Member**	**Lower Bound 99% CI**	**Lower Bound 95% CI**	**Lower Bound 90% CI**	**Point Estimate**
OIG Audit File	$ 161,514	200	$ 808	$ 4,165,878	$ 5,316,768	$ 5,905,626	$ 8,979,423
Appeal Effect	$ 154,098	200	$ 770	$ 3,539,408	$ 4,665,010	$ 5,240,929	$ 8,247,187
Cap Stratum 3	$ 58,789	150	$ 392	$ 1,607,757	$ 2,609,514	$ 3,122,068	$ 5,797,562

Scenario Key:
OIG Audit = Payment Error per OIG's audit validation results
Appeal Effect = Assuming all appeals are successfully accepted
Cap Stratum 3 = Only included the first 50 members from stratum 3 and assuming all appeals are successfully accepted

It is important to emphasize that although the sample payment error and point estimate derived by reviewing the first 50 randomly selected members from the third stratum is considerably lower than the OIG's estimate, this is entirely due to the random composition of the members drawn from the third stratum. If the sample were to be drawn repeatedly, we would expect the point estimates derived from both 50 and 100 member stratum 3 samples to cluster around a single point.

However, one would expect fluctuations in all stratum-level estimates arising from any one particular new sample draw of members. It is equally important to re-emphasize that these would be the results *based on OIG's actual and current draw.*

Stratum Size Criticism

OIG provides neither the rationale for the stratum level sample sizes of 50, 50, and 100 members, respectively, nor the rationale for an overall sample size of 200 members for

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[7] Exposure amounts are derived by applying a similar extrapolation methodology described in CMS's RADV Methodology Memo "Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits." Extrapolated figures do not consider any Fee-for-Service Adjuster in any scenario. *Ibid.*

the audit. Sample size arguments must be accompanied with further technical arguments, as overly simple criticisms of sample sizes have been rejected in many settings as a basis to invalidate the sample results. Additionally, the increase in burden to all parties should be considered if the overall sample size were to be increased as a response.

Instead, the sample resulting from the relatively small strata and overall sample sizes should be addressed directly in terms of types of members present in the population but missing from the sample. Broad types of members or diagnoses that are present in the population but missing in the sample can make it inappropriate to extrapolate the sample results to these members.
Statistical bias can be introduced when samples are missing important, but relatively rare, members/conditions. This bias can be addressed through the use of a certainty stratum.. A certainty stratum is a subgroup of observations from the population that is not selected at random, but rather is selected and reviewed with certainty. Consequently, results corresponding to these observations are not used in any extrapolation calculation. Rather, the corresponding results are added to the extrapolated amounts derived from the random sample for a combined total estimate.

A certainty stratum is frequently used when there are highly skewed population data. This is the case in the OIG's audit with some members in the third stratum having large weighted health-related risk scores and potential exposure amounts relative to other members in the same stratum. Without a certainty stratum, the risk exists that one of these rare members with disproportionately large exposure risk could be selected in the random sample. As a result, the sample results could be non-representatively skewed upwards and then extrapolated over the population of members in the third stratum. Using a certainty stratum would allow OIG to derive more precise results with only minimal changes in overall sample size, while simultaneously avoiding this distortionary risk.

Overpayment Bias Criticism

OIG excluded from the sampling frame (the pool of members from which the sampled members were drawn) all members without any diagnoses mapping to an HCC in the payment year. This creates an immediate overpayment bias concern.

To the extent that members without any diagnoses mapping to an HCC in a payment year are *more likely* to be associated with underpayments than members with at least one mapping diagnosis, then the sample design is not representative of the population and specifically in a way that is biased to overemphasize overpayments.

Perfection Standard Criticism

The OIG states that "[a]s demonstrated by the errors found in our sample, the policies and procedures that Inter Valley Health Plan had to prevent, detect, and correct

noncompliance with CMS's program requirements…could be improved." Inter Valley Health Plan does not concur with this finding. In fact, a 92%+ validation rate is indicative of effective policies and procedures to detect potential coding errors.

Inter Valley Health Plan has a strong record of an effective and comprehensive compliance program. Inter Valley Health Plan's provider education program is designed to ensure that contracted providers update medical records accurately and according to industry standard coding guidelines. During the review period, 2014, physician education took place onsite at the physician's office and included distribution of materials with coding guidelines for commonly used diagnosis codes. After the onsite chart review, Health Plan staff would meet with the physician or office manager to discuss the findings from the chart review.

Inter Valley Health Plan's provider oversight includes ongoing compliance chart reviews to ensure linkage between medical record documentation and encounter data received by the health plan.

In November 2019, Inter Valley Health Plan added a Clinical Documentation Integrity (CDI) Manager to our Risk Adjustment, Audit, Revenue and Education Department. This individual meets with Primary Care Physicians to conduct training on accurate medical record documentation. Using coding guidelines and updates from Coding Clinic, educational job aids are prepared and distributed to physicians as part of an ongoing training. Job aids are reviewed and approved by a medical doctor prior to distribution.

One example of Inter Valley Health Plan's compliance program in action was the identification and resolution of diagnosis code issues for encounters with dates of service in 2014. During a routine medical record review of physicians with a contracted IPA, a Risk Adjustment Reviewer identified an error pattern within visits being reviewed which resulted in finding encounter data issues of a larger scale. The Plan initiated its SIU in response to these findings. Findings of this SIU investigation were reported to Inter Valley Health Plan's Board of Directors, Corporate Compliance Committee and CMS Regional Account Manager. With the cooperation of CMS, transactions were submitted to CMS to delete the incorrect diagnosis codes. Overpayments were collected by CMS during final payment processing prior to initiation of the OIG audit in 2018.

The OIG's recommendation that Inter Valley Health Plan's policies and procedures need improvement implies that the OIG requires a 100% validation rate, which equates to a perfection standard. Inter Valley Health Plan does not concur with an audit design where a perfection standard is the only acceptable outcome for the OIG to conclude that a Medicare Advantage Organization's (MAO's) policies and procedures do not need to be improved.

The 100% validation standard also suggests that a MAO should review each and every medical record associated with a diagnosis code submission. CMS does not specify in

"Chapter 21 – Compliance Program Guidelines of the Medicare Managed Care Manual" that a MAO's compliance program should include substantiating the validity of each diagnosis code against the medical record. It instead states that, "[t]he compliance program must, at a minimum, include the following core requirements:

1. Written Policies, Procedures and Standards of Conduct;
2. Compliance Officer, Compliance Committee and High Level Oversight;
3. Effective Training and Education;
4. Effective Lines of Communication;
5. Well Publicized Disciplinary Standards;
6. Effective System for Routine Monitoring and Identification of Compliance Risks; and
7. Procedures and System for Prompt Response to Compliance Issues."[8]

Inter Valley Health Plan's compliance program is designed to meet all of the core requirements.

Additionally, it is not logistically feasible for Inter Valley Health Plan to review each medical record associated with all diagnosis codes submitted on claims from providers. Reviewing every medical record would increase the administrative overhead per member to an extent that would not be tenable for Inter Valley Health Plan, a non-profit plan with approximately 24,000 enrollees, without significantly increasing the corresponding bid rates. Increasing Inter Valley Health Plan's bid rates would increase the cost of care for our members in the form of reduced supplemental benefits and/or increased premiums.

While one could consider that a perfection standard should be applied to the diagnosis codes subject to the audit and found by OIG to be unsupported in the medical records, the OIG's extrapolation methodology actually implies a perfection standard across the contract. Inter Valley Health Plan strongly disagrees with a perfection standard being applied to extrapolated overpayments. Overpayments identified in the sample represent instances of reported diagnosis codes that OIG found to be unsupported in the medical record. However, overpayments estimated from the sample that are applied to a population of non-audited diagnosis codes are not based on individual diagnosis codes having a lack of support in the medical record. Inter Valley Health Plan believes applying a perfection standard on extrapolated overpayments is unfair as this standard would cause payments to be returned related to diagnosis codes that are supported in the medical record.

Lastly, the perfection standard imposed on MAOs in the audit is not maintained by the OIG in the current audit methodology. The OIG states in the "Estimation Methodology" section that, "we used the OAS statistical software to estimate the total amount of net overpayments to Inter Valley Health Plan at the lower limit of the two-sided 90-percent

[8] CMS, Medicare Managed Care Manual – Chapter 21: Compliance Program Guidelines (Chapter 21 - Rev. 110, 01-11-13), *available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf.*

confidence interval (Appendix C). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time." That implies that 5% of the time OIG would be calculating an error rate that is higher than the true error rate. It does not reconcile that a 5% error rate is acceptable to OIG in their calculations, but it is no error rate is acceptable to the OIG regarding payments to MAOs.

Bid Rate Implications Argument

Further, the OIG's audit was focused on dates of service in 2014 for payment year 2015, which has already been "settled" with CMS. An auditing approach that claws back premiums for years that have been settled undermines the actuarial models used to determine the appropriate bid rates. Had Inter Valley Health Plan known when projecting the risk scores in its payment year 2015 bid calculations that millions of dollars in extrapolated premiums would be retracted at some point in the future, Inter Valley Health Plan would have increased its bid rates in an actuarially sound manner. Absent an increase, the bid rates in effect for payment year 2015 may not sufficiently cover the associated claims expenses and necessary administrative costs to operate the plan.

Actuarial Equivalence Argument

Finally, the OIG's extrapolation methodology excludes the application of a Fee-for-Service Adjuster which violates actuarial equivalence. The relative risk factors used to determine the value of each demographic and disease related variable in the calculation of each Medicare Advantage member's risk score relies upon traditional Medicare fee-for-service ("FFS") diagnosis code and cost data. The FFS diagnosis code data is not substantiated against the corresponding medical records and therefore, there are likely instances of errors or unsupported codes in the underlying FFS calibrating dataset.

The Social Security Act mandates that risk adjustment payments made for members enrolled with MAOs should be made in a way "to ensure actuarial equivalence" with payments made for members enrolled in Medicare FFS.[9] Simply put, payment amounts made in Medicare Advantage should be the same as the payments made under traditional Medicare FFS for an equivalent population of beneficiaries. When the OIG recommends a repayment by a MAO without contemplating the effects of the underlying diagnosis errors in the calibrating FFS data, actuarial equivalence is violated.

It is worth noting that CMS released a study in November 2018 titled "Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits" and a corresponding Technical Appendix.[10] In this study, CMS concluded that the underlying errors in Medicare FFS data did not create an underpayment bias for MAOs. Many industry experts including Ph.D. actuaries and statisticians criticized the

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[9] Social Security Act §1876.

[10] *See* "FFS Adjuster Executive Summary" and "FFS Adjuster Technical Appendix", *available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.*

methodology and assumptions utilized in CMS's study.[11] In fact, many comments submitted in response to CMS's proposed rule regarding the subject concluded that the underlying diagnosis codes errors in the FFS data creates an underpayment bias for MAOs if more accurate assumptions were utilized.[12]

Conclusion

Based on Inter Valley Health Plan's non-concurrence with the OIG's draft findings/recommendations, Inter Valley Health Plan respectively requests that the OIG reconsider the overpayment amount to be limited to the agreed upon overpayments identified for specific member-HCCs in the sample given the statements above noting the issues with the OIG's sampling and extrapolation methodologies, the unreasonable implied perfection standard by the OIG, and the lack of an adjustment to account for the impact of underlying diagnosis code errors in the Medicare FFS data used to calibrate the relative risk factors of the CMS-HCC model.

Sincerely,

Gail Blacklock, CHC
Compliance Officer

[11] *See* comments posted at *https://www.regulations.gov/document/CMS-2018-0133-0001/comment*.
[12] *See* generally Wakely Consulting Group, Actuarial Report on CMS' November 1, 2018 Proposed Rule (August 27, 2019), *available at https://downloads.regulations.gov/CMS-2018-0133-0254/attachment_15.pdf*.