Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE ADVANTAGE COMPLIANCE AUDIT OF SPECIFIC DIAGNOSIS CODES THAT UPMC HEALTH PLAN, INC. (CONTRACT H3907) SUBMITTED TO CMS

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Office of Inspector General

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Report in Brief
Date: November 2021
Report No. A-07-19-01188

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

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS

Why OIG Did This Audit

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

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

For this audit, we reviewed one MA organization, UPMC Health Plan, Inc. (UPMC), and focused on 10 groups of high-risk diagnosis codes. Our objective was to determine whether selected diagnosis codes that UPMC submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

How OIG Did This Audit

We sampled 280 unique enrollee-years with the high-risk diagnosis codes for which UPMC received higher payments for 2015 through 2016. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $975,223.

What OIG Found

With respect to the 10 high-risk groups covered by our audit, most of the selected diagnosis codes that UPMC submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 194 of the 280 enrollee-years, the diagnosis codes that UPMC submitted to CMS were not supported in the medical records and resulted in $681,099 of net overpayments for the 194 enrollee-years.

These errors occurred because the policies and procedures that UPMC had to ensure compliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. On the basis of our sample results, we estimated that UPMC received at least $6.4 million of net overpayments for these high-risk diagnosis codes in 2015 and 2016.

What OIG Recommends and UPMC Comments

We recommend that UPMC refund to the Federal Government the $6.4 million of estimated net overpayments; identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and continue its examination of existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

UPMC disagreed with our findings and recommendations. UPMC provided additional information which, according to UPMC, validated HCCs for 25 sampled enrollee-years. UPMC questioned both our audit methodology and the qualifications of our independent medical review contractor. UPMC also stated that we did not calculate overpayments according to CMS requirements and that it disagreed with our extrapolation methodology and our assessment of its compliance program. After reviewing UPMC's comments and the additional information that it provided, we revised the number of enrollee-years in error for this final report. We followed a reasonable audit methodology, used a qualified medical review contractor, correctly applied applicable Federal requirements underlying the MA program, and properly assessed UPMC's compliance program. We revised the amount in our first recommendation from $6.6 million (in our draft report) to $6.4 million but made no change to our other recommendations.

The full report can be found at https://oig.hhs.gov/oas/reports/region7/71901188.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, sex, 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. We are auditing MA organizations because some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS.[2] Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 29 major depressive disorder diagnoses into 1 group.) This audit covered UPMC [University of Pittsburgh Medical Center] Health Plan, Inc. (UPMC), for contract number H3907[3] and focused on 10 groups of high-risk diagnosis codes.

OBJECTIVE

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

[1] The providers code diagnoses using the International Classification of Diseases (ICD), Clinical Modification (CM), *Official Guidelines for Coding and Reporting* (ICD Coding Guidelines). The ICD is a coding system that is used by physicians and other health care providers to classify and code all diagnoses, symptoms, and procedures. Effective October 1, 2015, CMS transitioned from the ninth revision of the ICD coding guidelines (ICD-9-CM) to the tenth revision (ICD-10-CM). Each revision includes different diagnosis code sets.

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

[3] All subsequent references to "UPMC" in this report refer solely to contract number H3907.

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 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 2017, CMS paid MA organizations $209 billion, which represented 35 percent of all Medicare payments for that year.

Risk Adjustment Program

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

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

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

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

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

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

[7] CMS's bid-benchmark comparison also determines whether the MA organization must offer supplemental benefits or must charge a basic 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 sex). This process results in an individualized risk score for each enrollee that CMS calculates annually.

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

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

For enrollees who have certain combinations of HCCs (in either the Version 12 model or the Version 22 model), CMS assigns a separate factor that further increases the risk score. CMS refers to these combinations as disease interactions. For example, if MA organizations submit diagnosis codes (in the Version 12 model) for an enrollee that map to the HCCs for acute stroke, acute myocardial infarction, and chronic obstructive pulmonary disease (COPD), CMS assigns a separate factor for this disease interaction. By doing so, CMS increases the enrollee's risk score for each of the three HCC factors and by an additional factor for the disease interaction.

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 (and, when applicable, disease interaction factors) accumulate, an enrollee's risk score increases, and the monthly risk-adjusted payment to the MA organization also increases. In this way, the risk adjustment program compensates

[8] 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. CMS blended the two separate risk scores into a single risk score that it used to calculate a risk-adjusted payment. Accordingly, for 2015, an enrollee's blended risk score is based on the HCCs from both payment models. For 2016, CMS calculated risk scores on the Version 22 model.

MA organizations for the additional risk for providing coverage to enrollees expected to require more health care resources.

CMS multiplies the risk scores by the base rates to calculate the total Medicare monthly payment that an MA organization receives for each enrollee before applying the budget sequestration reduction.[9] Miscoded diagnoses submitted to CMS may result in HCCs that are not validated and incorrect enrollee risk scores, which may lead to improper payments (overpayments) from CMS to MA organizations. Conversely, correctly coded diagnoses that MA organizations do not submit to CMS may lead to improper payments (underpayments).

High-Risk Groups of Diagnoses

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

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

- *Acute Heart Attack*: An enrollee received one diagnosis that mapped to either the HCC for Acute Myocardial Infarction or to the HCC for Unstable Angina and Other Acute Ischemic Heart Disease (Acute Heart Attack HCCs) on only one physician claim but did not have that diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician's claim). A diagnosis for a less severe manifestation of a disease in the related-disease group typically should have been used.

- *Acute Stroke and Acute Heart Attack Combination*: An enrollee met the conditions of both the acute stroke and acute heart attack high-risk groups in the same year.[11]

- *Major Depressive Disorder*: An enrollee received a major depressive disorder diagnosis (which maps to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) during

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

[10] Unless otherwise specified, the HCCs described in this report have the same name under both the Version 12 and Version 22 models.

[11] We combined these enrollees into one group because an individual's risk scores could have been further increased if that enrollee also had a COPD diagnosis (which was not part of our audit). If our audit identified an error that invalidated either the acute stroke or acute heart attack HCC, then the disease interaction factor would also be identified as an error. By combining these enrollees in one group, we eliminated the possibility of including the disease interaction factor twice in overpayment calculations (if any).

the service year but did not have an antidepressant medication dispensed on his or her behalf. In these instances, the major depressive disorder diagnoses may not be supported in the medical records.

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

- *Vascular Claudication*: An enrollee did not receive a diagnosis related to vascular claudication (which maps to the HCC for Vascular Disease) for 2 years and then, in the subsequent year, received that diagnosis but had medication dispensed on his or her behalf that is frequently dispensed for a diagnosis of neurogenic claudication.[12] In these instances, the vascular claudication diagnoses may not be supported in the medical records.

- *Lung Cancer*: An enrollee received a lung cancer diagnosis, which maps to one of the Lung Cancer HCCs,[13] but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period either before or after the diagnosis. In these instances, a diagnosis of history of lung cancer (which does not map to an HCC) typically should have been used.

- *Breast Cancer*: An enrollee received a breast cancer diagnosis, which maps to one of the Breast Cancer HCCs,[14] but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. A diagnosis of history of breast cancer (which does not map to an HCC) typically should have been used.

- *Colon Cancer*: An enrollee received a colon cancer diagnosis, which maps to one of the Colon Cancer HCCs,[15] but did not have surgical therapy, radiation treatments, or

[12] Vascular claudication and neurogenic claudication are different diagnoses. Vascular claudication is a condition that can result in leg pain while walking and is caused by insufficient blood flow. Neurogenic claudication is a condition that can also result in leg pain but is caused by damage to the neurological system, namely the spinal cord and nerves.

[13] The Lung Cancer HCCs included the HCC for Lung, Upper Digestive Tract, and Other Severe Cancers from the Version 12 model and the HCC for Lung and Other Severe Cancers from the Version 22 model.

[14] The Breast Cancer HCCs included the HCC for Breast, Prostate, Colorectal and Other Cancers and Tumors from the Version 12 model and the HCC for Breast, Prostate and Other Cancers and Tumors from the Version 22 model.

[15] The Colon Cancer HCCs included the HCC for Breast, Prostate, Colorectal and Other Cancers and Tumors from the Version 12 model and the HCC for Colorectal, Bladder, and Other Cancers from the Version 22 model.

chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. A diagnosis of history of colon cancer (which does not map to an HCC) typically should have been used.

- *Potentially Mis-keyed Diagnosis Codes*: An enrollee received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition (which mapped to a possibly unvalidated HCC). For example, ICD-9 diagnosis code 250.00 (which maps to the HCC for Diabetes Without Complication) could be transposed as diagnosis code 205.00 (which maps to the HCC for Metastatic Cancer and Acute Leukemia and in this example would be unvalidated). Using an analytical tool that we developed, we identified 832 scenarios in which diagnosis codes mis-keyed because of data transposition or other data entry errors could have resulted in the assignment of an unvalidated HCC.

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

UPMC Health Plan, Inc.

UPMC is an MA organization based in Pittsburgh, Pennsylvania. As of December 31, 2016, UPMC provided coverage under contract number H3907 to approximately 126,600 enrollees. For the 2015 and 2016 payment years (audit period), CMS paid UPMC approximately $2.3 billion to provide coverage to its enrollees.[16]

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to 1 of the 10 high-risk groups during the 2014 and 2015 service years, for which UPMC received increased risk-adjusted payments for payment years 2015 and 2016, respectively. Because enrollees could be classified in more than one high-risk group or have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment year, which we refer to as "enrollee-years." We identified 4,290 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes ($10,364,351). We selected for audit a sample of 280 enrollee-years, which comprised: (1) a stratified random sample of 246 (out of 4,256) enrollee-years for the first 9 high-risk groups and (2) 34 enrollee-years for the remaining high-risk group.

Table 1 on the following page breaks out the numbers of sampled enrollee-years (of the 280) associated with each of the 10 high-risk groups.

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

Table 1: Sampled Enrollee-Years

High-Risk Group	Number of Sampled Enrollee-Years
(A) Acute stroke	30
(B) Acute heart attack	30
(C) Acute stroke / acute heart attack combination	6
(D) Major depressive disorder	30
(E) Embolism	30
(F) Vascular claudication	30
(G) Lung cancer	30
(H) Breast cancer	30
(I) Prostate cancer	30
Total for Stratified Random Sample	**246**
(J) Potentially mis-keyed diagnosis codes	34
Total for All High-Risk Groups	**280**

UPMC provided medical records as support for the selected diagnosis codes associated with the 280 enrollee-years. We used an independent medical review contractor to review the medical records to determine whether the selected diagnosis codes that UPMC submitted to CMS were supported. If the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

Appendix A contains the details of our audit scope and methodology, Appendix C contains our statistical sampling methodology, and Appendix D contains our sample results and estimates.

FINDINGS

With respect to the 10 high-risk groups covered by our audit, most of the selected diagnosis codes that UPMC submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 86 of the 280 sampled enrollee-years, either the medical records validated the reviewed HCCs (82 enrollee-years) or we identified another diagnosis

code (on CMS's systems) that supported the HCC under review (4 enrollee-years). For the remaining 194 enrollee-years, however, the diagnosis codes were not supported in the medical records.

These errors occurred because the policies and procedures that UPMC had to ensure compliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. As a result, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that UPMC received at least $6.4 million of net overpayments for 2015 and 2016.[17]

FEDERAL REQUIREMENTS

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

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

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

CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap.7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented on the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7 § 40). The diagnosis must be coded according to the 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, chap. 7 § 40).

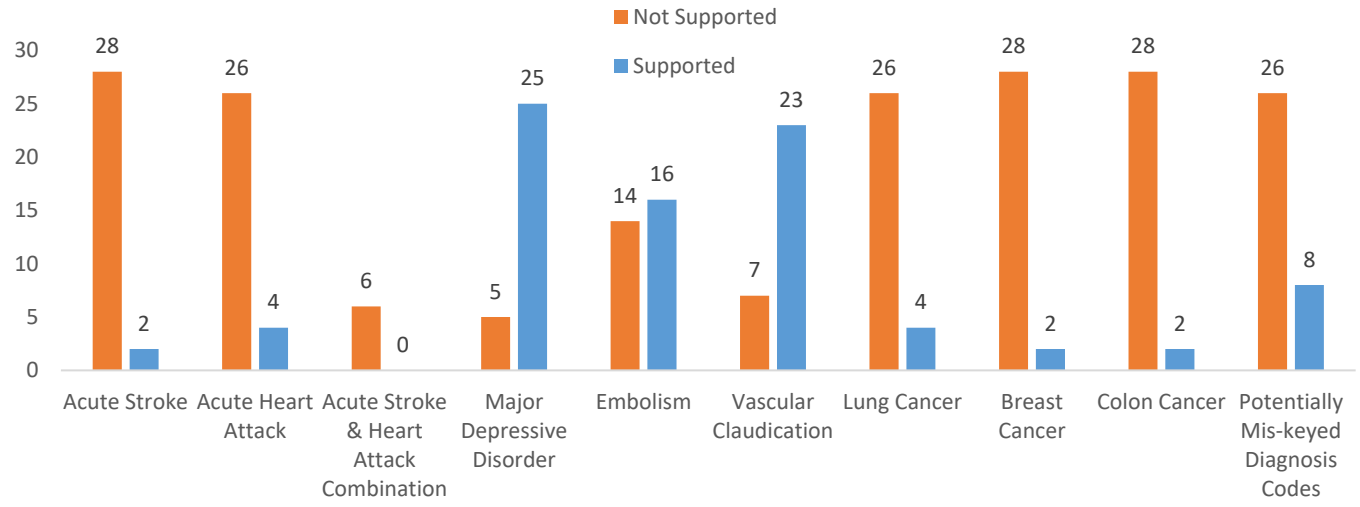
[17] Specifically, we estimated that UPMC received at least $6,401,297 ($6,178,158 for the statistically sampled groups plus $223,139 for the group of potentially mis-keyed diagnosis codes) of net overpayments. To be conservative, we recommend recovery at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

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

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

Most of the selected high-risk diagnosis codes that UPMC submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. As shown in the figure below, the medical records for 194 of the 280 sampled enrollee-years did not support the diagnosis codes. In these instances, UPMC should not have submitted the diagnosis codes to CMS and received the resulting net overpayments.

Figure: Analysis of High-Risk Groups



Incorrectly Submitted Diagnosis Codes for Acute Stroke

UPMC incorrectly submitted diagnosis codes for acute stroke for 28 of 30 sampled enrollee-years. Specifically:

- For 18 enrollee-years, the medical records indicated in each case that the individual had previously had a stroke, but the records did not justify an acute stroke diagnosis at the time of the physician's service.

For example, for 1 enrollee-year, the medical record (for a service that occurred in 2014) indicated that the individual had an acute [ischemic] stroke in 1995. The independent medical review contractor noted that "there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC [Ischemic or Unspecified Stroke] or a related HCC. There is mention of a history of a stroke [diagnosis] . . . ." The history of stroke diagnosis code does not map to an HCC.

- For 9 enrollee-years, the medical records did not contain sufficient information to support an acute stroke diagnosis.

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

- For the 1 remaining enrollee-year, UPMC submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiplegia[18] (which was supported in the medical records). The independent medical review contractor noted that "there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of [the HCC for Ischemic or Unspecified Stroke]. There is documentation of left sided weakness, as a late effect of an old [stroke], which results in [the] HCC [for Hemiplegia/Hemiparesis]." This error caused an underpayment.

As a result of these errors, the HCCs for Ischemic or Unspecified Stroke were not validated, and UPMC received $63,764 of net overpayments for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Heart Attack

UPMC incorrectly submitted diagnosis codes for acute heart attack for 26 of 30 sampled enrollee-years. Specifically:

- For 24 enrollee-years, the medical records did not support an acute myocardial infarction diagnosis. However, we identified support for another diagnosis that should have been included in the enrollee-years' risk scores. In some instances, the diagnosis mapped to a less severe manifestation of the related-disease group.

    - For 16 enrollee-years, we identified support for an old myocardial infarction diagnosis.

[18] Hemiplegia is defined as total or partial paralysis of one side of the body that results from disease of or injury to the motor centers of the brain.

- For 4 enrollee-years, which occurred in 2015, the old myocardial infarction diagnosis mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, UPMC should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the old myocardial infarction diagnosis.

  For example, for 1 enrollee-year, the medical record indicated that the individual was seen for a routine followup. The independent medical review contractor noted that "there is no documentation of any condition that will result in assignment of . . . [the Unstable Angina and Other Acute Ischemic Heart Disease] HCC. There is documentation of a history of myocardial infarction which results in [the] HCC [for Angina Pectoris/Old Myocardial Infarction]."

- For 12 enrollee-years, which occurred in 2016, the old myocardial infarction diagnosis did not map to an HCC.[19] UPMC should not have received an increased payment for acute myocardial infarction.

- For 4 enrollee-years, which occurred in 2015 and 2016, we identified support for an unspecified angina pectoris diagnosis,[20] which mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, UPMC should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the unspecified angina pectoris diagnosis.

- For the remaining 4 enrollee-years, which occurred in 2015, we identified support for both an old myocardial infarction diagnosis and an unspecified angina pectoris diagnosis, both of which mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, UPMC should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the old myocardial infarction and unspecified angina pectoris diagnoses.

- For the other 2 enrollee-years, the medical records did not support either an acute myocardial infarction diagnosis or an old myocardial infarction diagnosis.

[19] In contrast to the enrollee-years that occurred in 2015 (for which CMS used the Version 12 model), for 2016, CMS used only the Version 22 model, which did not include an HCC for Old Myocardial Infarction, to calculate risk scores (footnote 8).

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

As a result of these errors, the Acute Heart Attack HCCs were not validated, and UPMC received $39,236 of overpayments for these 26 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Stroke and Acute Heart Attack Combination

UPMC incorrectly submitted diagnosis codes for all 6 of the sampled enrollee-years for which physicians had documented conditions for both the acute stroke and acute heart attack high-risk groups in the same year (footnote 11).

Table 2 on the following page breaks out the findings for the 6 enrollee-years for which the medical records did not support the submitted diagnosis codes.

Table 2: Acute Stroke and Acute Heart Attack Combination Findings

Count of Enrollee-Years	Acute Stroke HCC		Acute Heart Attack HCC	
	Medical Record Validated HCC	Support for Different HCC Found	Medical Record Validated HCC	Support for Different HCC Found
3	No	No	No	Yes – Angina Pectoris / Old Myocardial Infarction[21]
1*	No	Yes – Hemiplegia/ Hemiparesis	No	No
1**	No	No	No	Yes – Unstable Angina and Other Acute Ischemic Heart Disease
1	No	No	No	No

* For this 1 enrollee-year, the independent medical review contractor noted that "there is no documentation of the condition that will result in . . . the assignment of [the Acute Myocardial Infarction] HCC." In addition, the contractor noted that "there is no documentation of any condition that will result in . . . the assignment of [the Ischemic or Unspecified Stroke] HCC; however, there is documentation of [a diagnosis for an] old cerebrovascular accident with right hemiparesis which results in [the Hemiplegia/Hemiparesis] HCC." Accordingly, UPMC should not have received an increased payment for the ischemic or unspecified stroke diagnosis but should have received an increased payment for the hemiparesis diagnosis.

** For this 1 enrollee-year, the independent medical review contractor noted that "there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted [Ischemic or Unspecified Stroke] HCC . . . ." The contractor also noted that "there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of [the Acute Myocardial Infarction] HCC; [t]he correct diagnosis [code] should have been other forms of acute ischemic heart disease resulting in [the Unstable Angina and Other Acute Ischemic Heart Disease] HCC." Accordingly, UPMC should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the other forms of acute ischemic heart disease diagnosis.

As a result of these errors, the HCCs for Ischemic or Unspecified Stroke and Acute Heart Attack were not validated, and UPMC received $12,798 of overpayments for these 6 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder

UPMC incorrectly submitted diagnosis codes for major depressive disorder for 5 of 30 sampled enrollee-years.

[21] One enrollee-year, which occurred in 2015, received an old myocardial infarction diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Each of the remaining 2 enrollee-years, which occurred in 2016, received an old myocardial infarction diagnosis that did not map to an HCC (footnote 19).

- For 4 enrollee-years, the medical records did not support a major depressive disorder diagnosis.[22]

  For example, for 1 enrollee-year, the independent medical review contractor noted that "there is documentation of a diagnosis of depression which does not result in an HCC. The document does not specify a diagnosis of major depression anywhere in the note."

- For the 1 remaining enrollee-year, UPMC could not locate any medical records to support the major depressive disorder diagnosis; therefore, the HCCs for Major Depressive, Bipolar, and Paranoid Disorders were not validated.

As a result of these errors, the HCCs for Major Depressive, Bipolar, and Paranoid Disorders were not validated, and UPMC received $13,840 of overpayments for these 5 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

UPMC incorrectly submitted diagnosis codes for embolism for 14 of 30 sampled enrollee-years. Specifically:

- For 9 enrollee-years, the medical records did not contain sufficient information to support an embolism diagnosis.

  For example, for 1 enrollee-year, the independent medical review contractor noted that "there is no documentation of any condition that result[s] in the assignment of . . . [an Embolism] HCC. A diagnosis of deep vein thrombosis . . . was not documented in the medical record. There is documentation of pain in leg, which does not result in an HCC."

- For the remaining 5 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not justify an embolism diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor noted that "there is no documentation of any current condition . . . that translates to the assignment of [an Embolism] HCC. However, there is documentation of a past medical history of deep vein thrombosis which does not result in an HCC."

As a result of these errors, the Embolism HCCs were not validated, and UPMC received $33,151 of overpayments for these 14 sampled enrollee-years.

[22] In three of these cases, the independent medical review contractor identified support for a diagnosis code for a lesser form of depression, which does not map to an HCC.

Incorrectly Submitted Diagnosis Codes for Vascular Claudication

UPMC incorrectly submitted diagnosis codes for vascular claudication for 7 of 30 sampled enrollee-years. Specifically:

- For 6 enrollee-years, the medical records did not support a vascular claudication diagnosis.

  For example, for 1 enrollee-year, the independent medical review contractor noted that "there is no documentation of any condition that will result in the assignment of . . . [the Vascular Disease] HCC. There is documentation of bilateral lower extremity numbness, which does not result in an HCC."

- For the 1 remaining enrollee-year, UPMC could not locate any medical records to support the vascular claudication diagnosis; therefore, the HCCs for Vascular Disease were not validated.

As a result of these errors, the HCCs for Vascular Disease were not validated, and UPMC received $17,037 of overpayments for these 7 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

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

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

  For example, for 1 enrollee-year, the medical review contractor noted that "[t]here is documentation of lung resection in 2011. Chest CT-Scan performed on date of service [September 22, 2014] did not show any evidence of recurrence. A [diagnosis of] history of lung cancer that does not result in an HCC should have been assigned."

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

  For example, for 1 enrollee-year, the medical review contractor noted that "there is no documentation of any condition that will result in an assignment of the submitted [Lung Cancer] HCC. There is documentation of a lung mass that does not result in an HCC."

- For 5 enrollee-years, the medical records did not support the submitted lung cancer diagnoses. However, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, UPMC should not have received an increased payment for the submitted lung cancer diagnoses

but it should have received a lesser increased payment for the other diagnosis identified.

Table 3 identifies the HCCs for the less severe manifestation of the related-disease groups that were supported for the 5 enrollee-years.

Table 3: Hierarchical Condition Categories (HCCs) for a Less Severe Manifestation of the Related-Disease Group That Were Supported (Instead of a Lung Cancer HCC)

Count of Enrollee-Years	Less Severe Hierarchical Condition Category
2	Colorectal, Bladder and Other Cancers (Version 22 model)
1*	Breast, Prostate, Colorectal and Other Cancers and Tumors (Version 12 model) and Breast, Prostate and Other Cancers and Tumors (Version 22 model)
1**	Breast, Prostate and Other Cancers and Tumors (Version 22 model)
1	Lymphoma and Other Cancers (Version 22 model)

* For this enrollee-year, which occurred in 2015, the risk score is based on HCCs from both the Version 12 and Version 22 payment models (footnote 8).

** For this enrollee-year, which occurred in 2016, the risk score is based on HCCs from only the Version 22 payment model (footnote 8).

- For the 1 remaining enrollee-year, UPMC could not locate any medical records to support the lung cancer diagnosis; therefore, the Lung Cancer HCC was not validated.

As a result of these errors, the Lung Cancer HCCs were not validated, and UPMC received $176,796 of overpayments for these 26 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

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

- For 23 enrollee-years, the medical records indicated in each case that the individual had previously had breast cancer, but the records did not justify a breast cancer diagnosis at the time of the physician's service.

  For example, the medical review contractor noted that "[t]here is documentation of surgical history of breast cancer with no indication of a recurrence or an active

treatment. A past medical history of breast cancer [diagnosis] that does not result in an HCC should have been assigned instead of the submitted [Breast Cancer] HCC."

- For 5 enrollee years, the medical records did not support a breast cancer diagnosis.

  For example, for 1 enrollee-year, the medical review contractor noted that the "[p]atient presented for a Medicare Wellness Exam. There is no documentation of any diagnosis that would result in the submitted [Breast Cancer] HCC."

As a result of these errors, the Breast Cancer HCCs were not validated, and UPMC received $41,613 of overpayments for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

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

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

  For example, for 1 enrollee-year, the medical review contractor noted that "[t]here is documentation that colon cancer was treated surgically over two years prior with no evidence of disease currently. A past medical history of [a] colon cancer [diagnosis] should have been assigned which does not result in a [Colon Cancer] HCC."

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

  For example, for 1 enrollee-year, the medical review contractor noted that "there is no documentation of any condition that will result in assignment of [the Colon Cancer] HCC. There is mention of a family history of cancer," which does not result in an HCC.

- For the 1 remaining enrollee-year, UPMC could not locate any medical records to support the colon cancer diagnosis; therefore, the HCCs for Colon Cancer were not validated.

As a result of these errors, the Colon Cancer HCCs were not validated, and UPMC received $59,725 of overpayments for these 28 sampled enrollee-years.

Potentially Mis-keyed Diagnosis Codes

UPMC submitted potentially mis-keyed diagnosis codes for 26 of 34 enrollee-years. In each of these cases, the enrollee-years received multiple diagnoses for a condition but received only

one—potentially mis-keyed—diagnosis for an unrelated condition. Appendix F contains the potentially mis-keyed diagnosis codes that we identified for the 26 enrollee-years.

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

  For example, for 1 enrollee-year, UPMC submitted six diagnosis codes for diabetes mellitus (250.00) and only one diagnosis code for acute myeloid leukemia (205.00) to CMS. The independent medical review contractor limited its review to the acute myeloid leukemia diagnosis, for which it did not find support.

- For the remaining 5 enrollees, the medical records did not support the diagnosis for the unrelated condition. However, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, UPMC should not have received an increased payment for the submitted diagnosis but it should have received a lesser increased payment for the other diagnosis identified.

  For example, for 1 enrollee-year, the medical records did not support a dissection of aorta, unspecified site diagnosis, which maps to the HCC for Vascular Disease With Complications. The independent medical review contractor noted that "there is no documentation of any condition that would result in the assignment of . . . [the Vascular Disease With Complications] HCC." However, we identified support for a peripheral vascular disease, unspecified diagnosis, which maps to the HCC for Vascular Disease, a less severe manifestation of the related-disease group. Accordingly, UPMC should not have received payment for the dissection of thoracic aorta diagnosis but should have received a lesser increased payment for the abdominal aortic aneurysm, without rupture diagnosis.

Appendix F contains the HCCs that were not validated for the 26 enrollee-years (Table 8) and the HCCs for the less severe manifestation of the related-disease group that were supported for the 5 enrollee-years (Table 9).

As a result of these errors, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated, and UPMC received $223,139 of overpayments for these 26 sampled enrollee-years.

THE POLICIES AND PROCEDURES THAT UPMC USED TO ENSURE COMPLIANCE WITH FEDERAL REQUIREMENTS WERE NOT ALWAYS EFFECTIVE

The errors we identified occurred because the policies and procedures that UPMC had to ensure compliance with CMS's program requirements, as mandated by Federal regulations (42 CFR § 422.503(b)(4)(vi) (Appendix E)), were not always effective.

The compliance procedures that UPMC had in place during our audit period included preventative measures by which it performed outreach to its providers in order to educate them on several topics, including the importance of using correct diagnosis codes to improve medical record documentation. UPMC also had procedures in place to detect whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. For one of these procedures, UPMC identified diagnosis codes for review and then analyzed the associated medical records in order to identify errors. However, this procedure was not designed to identify systematic errors or to target specific diagnosis codes. Therefore, UPMC's compliance procedures to prevent and detect incorrect high-risk diagnoses during our audit period were not always effective.

UPMC officials explained that after our audit period, UPMC placed more emphasis on the prevention and detection of incorrect high-risk diagnosis codes. For instance, UPMC said that it updated its outreach efforts to include specific guidance on accurate coding for acute stroke, acute heart attack, and various cancer diagnoses. Furthermore, UPMC officials stated that they added steps to include reviews that focus entirely on high-risk diagnosis codes. Thus, according to UPMC officials, UPMC has taken steps to ensure that it submits accurate high-risk diagnoses to CMS.

UPMC RECEIVED NET OVERPAYMENTS

As a result of the errors we identified, the reviewed HCCs were not validated for 194 enrollee-years. On the basis of our sample results, we estimated that UPMC received at least $6.4 million of net overpayments ($6.2 million for the statistically sampled groups plus $223,139 for the group of potentially mis-keyed diagnosis codes) in 2015 and 2016 (Appendix D).

RECOMMENDATIONS

We recommend that UPMC Health Plan, Inc.:

- refund to the Federal Government the $6,401,297 of estimated net overpayments;
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
- continue its examination of existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

UPMC COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, UPMC disagreed with our findings and recommendations. Although UPMC did not specifically disagree with 178 of the 200 enrollee-years that our draft report identified in error, UPMC disagreed with our findings for the remaining 22 enrollee-years and provided additional information as to why it believed the HCCs were validated. Additionally, UPMC stated that we should adjust our findings for 3 enrollee-years "for HCCs found by [UPMC] during the review of the [enrollee-years] but not" originally submitted to CMS.

UPMC also said that we departed from established CMS standards for the evaluation of proper payments to MA organizations and added that our audit was not designed to fairly determine whether overall payments to UPMC were appropriate and in accordance with CMS requirements. Additionally, UPMC questioned the qualifications of our independent medical review contractor and stated that our review methodology did not meet CMS requirements. Further, UPMC stated that our application of those requirements for the calculation of overpayments was inappropriate and that we did not account for certain adjustments in our overpayment amounts, including the "coding pattern adjustment" and the impact of sequestration. UPMC also did not agree with the extrapolation methodology that we used to calculate the recommended net overpayment amount. Lastly, UPMC did not agree with our assessment of its compliance program.

We reviewed UPMC's comments and the additional information that it provided and, accordingly, reduced the number of enrollee-years in error from 200 to 194 and adjusted our calculation of net overpayments. In addition, our draft report did not consider the effects of sequestration and therefore did not reduce the net overpayment by 2 percent. After consideration of UPMC's comments and budget sequestration, we reduced the first recommendation from $6,607,049 to $6,401,297 for this final report. We made no changes to our second and third recommendations.

A summary of UPMC's comments and our responses follows. UPMC's comments appear as Appendix G. We excluded an attachment (which UPMC identified as an Appendix in its comments) that contained personally identifiable information. We also excluded two attachments (which UPMC referred to as Exhibit A and Exhibit B and cited in its comments). Exhibit A is a letter from a statistical expert and Exhibit B is the CMS "Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Validation Contract-Level Audits" (Feb. 12, 2012). We are separately providing UPMC's comments and attachments in their entirety to CMS.

UPMC DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S FINDINGS FOR 22 SAMPLED ENROLLEE-YEARS AND STATED THAT IT SHOULD HAVE RECEIVED AN INCREASED PAYMENT FOR 3 SAMPLED ENROLLEE-YEARS

UPMC Comments

UPMC did not agree with our findings for 22 of the sampled enrollee-years (as shown in Table 4) and provided additional information (including medical records and explanations) supporting its belief that the HCCs were validated.

Table 4: Summary of Specific Enrollee-Years for Which UPMC Disagreed With Our Findings

High-risk group	Number of Enrollee-Years
Acute Stroke	1
Acute Heart Attack	1
Acute Stroke and Acute Heart Attack Combination	1
Major Depressive Disorder	2
Embolism	1
Vascular Claudication	3
Lung Cancer	2
Breast Cancer	2
Colon Cancer	3
Potentially Mis-keyed Diagnosis Codes	6
Total	**22**

Additionally, UPMC stated that 3 enrollee-years, all from the acute stroke group, had support for diagnosis codes that UPMC should have submitted to CMS but did not. Specifically, UPMC agreed that the reviewed HCC was not supported but found support for other HCCs on the medical records that it provided. Accordingly, UPMC stated that it believed that these HCCs should reduce its net overpayments.

Office of Inspector General Response

For the 22 enrollee-years, our independent medical review contractor reviewed the additional medical records and explanations that UPMC provided and reaffirmed that for 16 enrollee-years the HCCs were unvalidated.

> For example, for 1 enrollee-year from the breast cancer group, the contractor upheld its original decision upon reconsideration and stated that the medical record documentation noted "a past surgical history of left and right lumpectomy/mastectomy and post-operative chemotherapy for breast cancer.

> The last treatment was noted in 1994, no recurrence is noted, and no active or current treatment is documented on the date of service under review." As a result, the contractor noted that a diagnosis of "Past medical history of breast cancer, should have been assigned and does not result in an HCC."

For the other 6 enrollee-years, our contractor reversed its original decision after reviewing the additional information that UPMC submitted, and stated that the HCCs were validated.

> For example, for 1 enrollee-year from the lung cancer group, UPMC submitted an additional medical record that, it said, validated the HCC for Lung and Other Severe Cancers. Our contractor reversed its original decision after reconsideration of the new record. The contractor stated: "Based on review of the medical record/s submitted, [the] HCC [for Lung and Other Severe Cancers] was substantiated based on the assessment of [a diagnosis] of malignant neoplasm of the lung."

With respect to the 3 enrollee-years for which UPMC asserted that diagnosis codes should have been submitted to CMS but were not, our independent medical review contractor did not agree with UPMC. For 2 of these enrollee-years, the contractor determined that the medical records did not support the diagnosis codes. For the other enrollee-year, UPMC stated that the medical records supported a diagnosis code that resulted in the HCC for Vascular Disease. If the contractor had determined that this diagnosis code should have been submitted to CMS instead of the reviewed acute stroke diagnosis code, we would have included the financial impact of the HCC for Vascular Disease in our calculation of overpayments. However, the contractor determined that this diagnosis should not have been submitted instead of the reviewed acute stroke diagnosis, and we therefore considered it as outside the scope of the review.

As a result, we reduced the number of enrollee-years in error from 200 (in our draft report) to 194 for this final report. We also revised our findings and reduced the associated monetary recommendation. Lastly, our contractor confirmed that there is no impact on decisions made for other sampled enrollee-years as a result of UPMC's arguments, and stated that there were "no systemic quality issues" in its reviews.

UPMC STATED THAT THE OFFICE OF INSPECTOR GENERAL DEPARTED FROM CMS STANDARDS FOR THE EVALUATION OF PROPER PAYMENTS TO MEDICARE ADVANTAGE ORGANIZATIONS

UPMC Comments

UPMC stated that we departed from established CMS standards for the evaluation of proper payments to MA organizations. Specifically, UPMC said that we had "undertaken to conduct an audit that is at odds with CMS's risk adjustment audit standards and CMS's position on how overpayments are to be determined in such an audit." UPMC also said that our report did not indicate that CMS has approved the statements and conclusions included in it—an authority, according to UPMC, that is exclusively delegated to CMS.

UPMC added that we focused solely on diagnosis codes "perceived to be prone to error," without advance notice, which UPMC described as "problematic" because it was unable to factor in the risk that "one-sided audits" would be conducted when it submitted its bid proposals to CMS.

Furthermore, UPMC stated that we had not fully disclosed the auditing standards, approaches, and protocols that we used in this audit. UPMC stated that our approach differed from the publicly announced, and publicly commented on, audit protocols in place at CMS. UPMC also stated that from one audit to another we have taken "inconsistent approaches" in the criteria we used to identify diagnoses that were at higher risk of being miscoded. Additionally, UPMC drew contrasts between this audit, in which we reviewed 10 groups of high-risk diagnosis codes, and other recent audits in which we reviewed a fewer number of high-risk groups.

Office of Inspector General Response

In accordance with the Inspector General Act of 1978, 5 U.S.C. App., our audits are intended to provide an independent assessment of Department of Health and Human Services (HHS) programs and operations. We conduct our audits in accordance with generally accepted government auditing standards, which require that audits be planned and performed 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 UPMC submitted to CMS for use in the risk adjustment program were adequately supported—and thus complied with Federal requirements—in the medical records. Although our approach was generally consistent with the methodology used by CMS in its Risk Adjustment Data Validation (RADV) audits, it did not mirror CMS's approach in all aspects, nor did it have to.

Furthermore, we did not solicit CMS's approval of the statements and conclusions in this report, nor are we required to do so. The Office of Inspector General (OIG) is an independent and objective oversight unit of HHS. Action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures.

UPMC's statement that we did not provide advance notice of our audit methodology, and that therefore it was unable to factor that risk into its bid proposals to CMS, is not relevant. According to 42 CFR § 422.254(b)(1), "[t]he monthly aggregate bid amount submitted by an MA organization for each plan is the organization's estimate of the revenue required . . . for providing coverage to an MA eligible beneficiary with a national average risk profile." CMS uses the amounts from the bid proposals to create contracts with MA organizations (like UPMC). As a provision of its contract with CMS, UPMC agreed that the OIG has the right to inspect, evaluate and audit any pertinent information for any particulate contract period. However, neither Federal regulations nor the contract with CMS permit changes to bid proposal amounts in anticipation of OIG audits.

Furthermore, we disagree with UPMC's comments that we did not fully disclose the auditing standards, approaches, and protocols used in our audit. We communicated the objective, scope, and methodology of the audit multiple times throughout the engagement. We answered UPMC officials' questions and confirmed our audit approach and results at an exit conference. Additionally, the methodology and approaches that we have used to identify high-risk diagnosis codes for this series of audits have evolved. As a result, the methodology used in this audit did not exactly mirror the methodology used in other audits, nor did it have to.

UPMC DID NOT AGREE THAT THE OFFICE OF INSPECTOR GENERAL FAIRLY DESIGNED THE AUDIT TO DETERMINE THAT OVERALL PAYMENTS MADE TO UPMC WERE APPROPRIATE AND IN ACCORDANCE WITH CMS REQUIREMENTS

UPMC Comments

UPMC stated that our audit was not designed to consider the entirety of UPMC's coding and risk adjustment submissions to CMS. UPMC said that we targeted HCCs that we determined were prone to errors and that we did not assess the overall accuracy of payments by CMS to UPMC. Specifically, UPMC stated that our review methodology was designed to target "submitted but not supported" diagnosis codes but did not consider "supported but not submitted" diagnosis codes. UPMC added that for the sampled enrollee-years, the medical records that we did not review may have contained support for diagnosis codes that UPMC did not submit. Therefore, according to UPMC, our audit "did not render a full and balanced picture of [UPMC's] risk adjustment coding processes, procedures, and overall accuracy."

Furthermore, UPMC cited a letter from a statistician it hired to review our draft report: "in order to determine whether UPMC was overpaid, an auditor must review all available medical records for the enrollee, giving credit for supported, but unsubmitted" diagnosis codes. The statistician added that instead of following "this proper approach," we reviewed only the records associated with the high-risk diagnosis codes "included in the scope of [our] audit."

Office of Inspector General Response

UPMC is correct in that we designed our audit to determine whether selected high-risk diagnosis codes that UPMC submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements. For each of the sampled enrollee-years, UPMC had previously submitted to CMS only one claim with a high-risk diagnosis code that mapped to the reviewed HCC. We asked UPMC to provide a copy of the associated medical record for review. Recognizing that other medical records could support the diagnosis, we also informed UPMC that it could submit up to four more medical records of its choosing that could support the reviewed HCC. These additional medical records, when originally coded, did not contain a diagnosis code that mapped to the reviewed HCC. It was UPMC's decision alone as to how many more records (up to four) to submit to us for each of the sampled enrollee-years.

In this regard, our independent medical review contractor reviewed all of the relevant medical records that UPMC provided to determine whether the reviewed HCCs were validated. In doing so, we considered instances in which the medical review contractor found a diagnosis or HCC that should have been used instead of the diagnosis or HCC that was submitted to CMS, and on that basis we made our determinations.

Further, we limited our review to the portions of the payments that were associated with the high-risk diagnosis codes selected for review. The identification of: (1) all possible diagnosis codes that UPMC could have submitted on behalf of the sampled enrollee-years and (2) enrollees for whom UPMC did not submit any risk-adjusted diagnosis codes was beyond the scope of our audit.

UPMC QUESTIONED THE QUALIFICATIONS OF THE INDEPENDENT MEDICAL REVIEW CONTRACTOR AND THE OFFICE OF INSPECTOR GENERAL'S REVIEW METHODOLOGY

UPMC Comments

UPMC questioned the qualifications of our independent medical review contractor and stated that our review methodology did not conform to CMS requirements and procedures. Specifically:

- UPMC stated that the coding reviewers employed by our independent medical review contractor did "not appear to have the requisite backgrounds and certifications that CMS might require" to perform a RADV audit. UPMC said that all of the coding reviewers should have had, at a minimum, the following qualifications: a credential with either the American Health Information Management Association (AHIMA) or the American Academy of Professional Coders (AAPC), along with the Certified Risk Adjustment Coder (CRC) certification. Furthermore, UPMC stated that a Registered Health Information Technician (RHIT)-only certified coder "should not have been utilized in this audit." UPMC added that "[g]iven CMS's RADV audit standards, it would have been inappropriate to put an RHIT-only certified coder at any level of the coding review."

- UPMC also questioned our use (as described in Appendix A) of a physician as a "tie breaker" in instances when two coding reviewers disagree, stating that this practice is "not consistent with CMS coding review procedures in RADV audits." UPMC said that instead of using a physician as tie breaker, we "should have used the same method that CMS uses during a RADV audit," in that as long as one of the two coders substantiated a diagnosis code for the HCC under review, then the HCC is considered to be validated.

- In addition, UPMC stated that we did not provide it with the specific coding guidance that our independent medical review contractor followed. As an example, UPMC questioned whether we followed "CMS RADV standards . . . [that] expressly state that documentation of a treatment or management plan is not required to validate a chronic

condition as long as the condition is 'mentioned' in writing by an acceptable provider in connection with a face to face [patient] encounter."

Office of Inspector General Response

As stated above, 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. Although our approach was generally consistent with the methodology used by CMS in its RADV audits, it did not mirror CMS's approach in all aspects, nor did it have to. Specifically:

- With respect to UPMC's statement questioning whether the coding reviewers were certified, we informed UPMC during our audit work that the coding reviews had been performed by professional coders credentialed by the AHIMA and the AAPC.[23] We also informed UPMC of the exact certifications held by each coding reviewer who worked on this particular review. These coders were duly experienced in coding ICD-9-CM and ICD-10-CM diagnosis codes for hospital inpatient, outpatient, and physician medical records. The independent medical review contractor's coding reviewers were fully qualified, on the basis of certifications as well as experience, to accurately and objectively perform the work for which they were employed.

- Additionally, the independent medical review contractor's use of senior coders to perform coding reviews, as well as its use of a physician—who was board certified and who did not apply clinical judgment when serving as the final decisionmaker—reflected a reasonable method to determine whether the medical records adequately supported the reported diagnosis codes.

- With respect to UPMC's comments that we did not provide it with specific coding guidance, our independent medical review contractor performed its review to determine whether the diagnoses in the sampled enrollees' medical records were coded according to the ICD Coding Guidelines. We provided UPMC with the procedures that the contractor followed to make its determinations (Appendix A).

UPMC DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S APPLICATION OF CMS REQUIREMENTS FOR CALCULATIONS OF OVERPAYMENTS

UPMC Comments

UPMC stated that our audit methodology contradicted CMS requirements. Specifically, UPMC stated that we did not ensure that a payment principle known as "actuarial equivalence" was used to determine overpayment amounts.

[23] For this audit, our independent medical review contractor used senior coders all of whom possessed one or more of the following qualifications and certifications: RHIT, Certified Professional Coder (CPC), and CRC. RHITs have completed a 2-year degree program and have passed an AHIMA certification exam. The AAPC credentials both CPCs and CRCs.

UPMC cited the provision of the Act that mandates that risk-adjusted payments be made in a manner that ensures "actuarial equivalence" between CMS payments for health care coverage under MA and CMS payments under Medicare's traditional FFS program. "Thus, to comply with the statute, CMS must set [MA] payment rules such that reimbursement to Medicare Advantage Organizations is expected to equal traditional Medicare reimbursement for the same population of Medicare beneficiaries." In this regard, UPMC cited notice-and-comment Federal rulemaking and asserted that "it would be erroneous to extrapolate overpayments from audits of Medicare Advantage diagnosis codes without adjusting for the errors in the traditional Medicare claims data used to set Medicare Advantage payment rates."

UPMC stated that CMS announced that this adjustment, "called a 'Fee-for-Service Adjuster' [(FFSA)] . . . is necessary to properly determine Medicare Advantage overpayments, and *that an overpayment occurs only if the error rate [identified as the result of an MA review] exceeds the error rate for traditional Medicare*" (emphasis in original). Furthermore, UPMC said that the use of extrapolation without an FFSA would contradict CMS requirements. In this regard, UPMC stated that "the OIG cannot establish a substantive legal standard governing payment for services by performing an audit that adopts an evolving, unpublished and inconsistently applied standard that contradicts CMS's RADV standards." UPMC added that therefore, the use of extrapolation in a recommended refund amount would require MA organizations to "pay out money on the back end" and would force CMS "to set higher reimbursement levels on the front end." UPMC also stated that CMS is "reconsidering the use" of an FFSA, but has not eliminated it yet; thus, the RADV methodology (using an FFSA) that CMS introduced in 2012 remains operative.

UPMC also referred to a May 2012 OIG final report of an audit of PacifiCare of Texas (PacifiCare), in which we withdrew our draft report's recommendation that the error rate from the audit be extrapolated to the entire population.[24] UPMC stated that PacifiCare asserted, in its comments on that draft report, that an extrapolation would contradict the "actuarial equivalence" payment principle. Accordingly, OIG withdrew its recommendation in acknowledgement of "*the potential impact of these error rates on the CMS model*" (emphasis added by UPMC).

Office of Inspector General Response

Our audit methodology correctly applied CMS requirements to properly equate individual unsubstantiated HCC submissions with overpayments.

We used the results of the independent medical review to determine which reviewed HCCs were not substantiated and, in some instances, to identify HCCs that should have been used but were not used in the sampled enrollees' risk score calculations. We followed the requirements

[24] *Risk Adjustment Data Validation of Payments Made to PacifiCare of Texas for Calendar Year 2007 (Contract Number H4590)* (A-06-09-00012, May 30, 2012).

of CMS's risk adjustment program to calculate overpayments and underpayments for each enrollee-year and used those amounts to estimate net overpayments.

UPMC commented that we did not consider actuarial equivalence in our overpayment calculations. To this point, and to UPMC's comment that we withdrew a recommendation in a previous report that was similar to the monetary recommendation in this report, we recognize that CMS is responsible for making operational and program payment determinations for the MA program, including the application of any FFSA requirements. Moreover, CMS has not issued any requirements that compel us to reduce our net overpayment calculations.[25] If CMS deems it appropriate to apply an FFSA, it will adjust our overpayment finding by whatever amount it determines necessary.

With regard to UPMC's comment about our use of extrapolation, we did not establish a substantive legal standard that contradicted CMS's RADV standards. Our use of extrapolation to determine a recommended refund of estimated net overpayments is appropriate. The steps that we followed in our audit methodology allowed us to obtain evidence that provided reasonable assurance with regard to the findings and recommendations, including our estimation of net overpayments.[26]

UPMC STATED THAT THE OFFICE OF INSPECTOR GENERAL DID NOT TAKE INTO ACCOUNT CERTAIN ADJUSTMENTS TO THE CALCULATED OVERPAYMENT AMOUNTS

UPMC Comments

UPMC stated that the net overpayment amount we calculated did not include the statutory "coding pattern adjustment," which CMS publishes annually and which "reflects changes in treatment and coding practices in the fee-for-service sector and reflects coding patterns between Medicare Advantage plans and providers under [P]art[s] A and B."

Additionally, UPMC stated that we did not consider the impact on MA organizations of sequestration as established by the Budget Control Act of 2011 (footnote 9). Under this legislation, payments to health care providers and health plans were reduced by 2 percent across the board. UPMC said that therefore, any overpayment calculations should have incorporated the 2 percent net reduction amount.

[25] 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). To UPMC's point about CMS's 2012 statement, we reiterate that CMS has not issued any guidance that compels us to reduce our overpayment calculations.

[26] 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 the OIG), if a disallowance is taken, MA organizations have the right to appeal the determination that an overpayment occurred through the Secretary's RADV appeals process.

Office of Inspector General Response

Our calculated overpayment or underpayment amounts for each enrollee-year do take into account the coding pattern adjustment. Specifically, we calculated a revised risk score in accordance with CMS's risk adjustment program that includes the coding pattern adjustment as required by CMS.

We agree with UPMC that we did not consider but should have considered the impact of the budget sequestration reduction in our draft report. Accordingly, we revised all of the payment amounts, including our recommended refund of estimated net overpayments, for this final report.

UPMC DID NOT AGREE WITH THE EXTRAPOLATION METHODOLOGY THAT THE OFFICE OF INSPECTOR GENERAL USED TO CALCULATE THE RECOMMENDED NET OVERPAYMENT AMOUNT

UPMC Comments

UPMC disagreed with how we calculated the net overpayment amount that we recommended for UPMC to refund to the Federal Government. UPMC noted that CMS uses the lower bound of the 99-percent confidence interval level for its RADV audits. UPMC stated that our use of the lower bound of a 90-percent confidence interval "results in a higher extrapolated overpayment than CMS's approach."

UPMC also cited another passage from the statistician's letter discussed earlier, which stated that we used "an incorrect statistical distribution to extrapolate UPMC's net overpayment," which caused us to overstate the lower limit of the estimated overpayment. Therefore, our use of the "Normal Distribution (bell-shaped curve)" resulted in an "overstated" lower limit of the proper confidence interval.

UPMC also said that we did not explain how our sampling frame was ordered and uniquely numbered for random selection. UPMC stated that the supporting documentation we provided to it did not demonstrate the method we used to apply the random numbers to the items in each stratum.

Office of Inspector General Response

Our estimation methodology does not need to mirror CMS's estimation methodology. Our policy recommends recovery at the lower limit of a two-sided 90-percent confidence interval. We believe that the lower limit of a two-sided 90-percent confidence interval provided a reasonably conservative estimate of the total amount overpaid to UPMC for the enrollee-years and time period covered in our sampling frame. This approach, which is routinely used by HHS

for recovery calculations,[27] results in a lower limit (the estimated overpayment amount to refund) that is designed to be less than the actual overpayment total 95 percent of the time.

Additionally, we believe that we appropriately used the "Normal Distribution" to construct the 90 percent confidence interval. The "Normal Distribution" is appropriate to use when stratum sizes are sufficiently large. For this audit, the sample sizes for 8 of the 9 strata were equal to 30, indicating that the applicable statistical distribution was used for this review and that we did not overstate the lower limit of the confidence interval.

With respect to UPMC's comment that we did not state how our sampling frame was ordered and uniquely numbered, the legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology.[28] We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software to apply the correct formulas for the extrapolation.

Specifically, the sampling frame was sorted by beneficiary identification number within each stratum. We then consecutively numbered the items in each stratum to finalize the sampling frame. Next, random numbers were generated for our sample with the OIG, Office of Audit Services (OAS), statistical software. Finally, we selected the corresponding frame items for review. We believe that our method for assigning random numbers was appropriate for this audit. In addition, we provided UPMC with sufficient information to recreate the statistical sample and to calculate our estimate given the overpayment amounts in our sample, including the sampling plan and the files we used for the random number selection.

UPMC DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S ASSESSMENT OF ITS COMPLIANCE PROGRAM

UPMC Comments

UPMC did not agree with our assessment of its compliance program. Specifically, UPMC stated that it "has a well-developed and well-executed coding compliance program along with dedicated educational efforts." Additionally, UPMC said that CMS regulations "do not establish

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

[28] *See John Balko & Assoc. v. Sebelius*, 2012 WL 6738246 at *12 (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); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

or create a 100 percent accuracy standard or requirement for risk adjustment data." Instead, CMS regulations require that MA organizations "take reasonable steps to ensure the 'accuracy, completeness, and truthfulness' of the risk adjustment data they submit." In this regard, UPMC stated: "The risk adjustment process created by CMS acknowledged [MA organization] concerns about healthcare provider mistakes and incomplete or inaccurate provider generated data," and therefore it would be unfair and unrealistic to hold MA organizations to a 100-percent accuracy certification standard. Therefore, UPMC requested that we reconsider our conclusion that its policies and procedures to ensure compliance with Federal requirements were not always effective.

Office of Inspector General Response

Our description of UPMC's policies and procedures as "not always effective" in ensuring compliance with CMS's program requirements serves to point directly to our third recommendation to continue to enhance these policies and procedures. In this context, UPMC mentioned that it now performs internal reviews designed to identify high-risk diagnosis codes "such as cancer, stroke, single occurrences, etc." The continued improvement of those policies and procedures, based on the results of this audit as well as the results of UPMC's internal high-risk diagnosis code reviews, will assist UPMC in attaining better assurance with regard to the "accuracy, completeness, and truthfulness" of the risk adjustment data that it submits in the future.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid UPMC $2,260,255,838 to provide coverage to its enrollees for 2015 and 2016. We identified a sampling frame of 4,290 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2014 and 2015 service years; UPMC received $62,548,943 in payments from CMS for these enrollee-years for 2015 and 2016. We selected for audit 280 enrollee-years with payments totaling $4,900,086.

The 280 enrollee-years included 30 acute stroke diagnoses, 30 acute heart attack diagnoses, 6 acute stroke diagnosis and acute heart attack diagnosis combinations, 30 embolism diagnoses, 30 vascular claudication diagnoses, 30 major depressive disorder diagnoses, 30 lung cancer diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, and 34 potentially mis-keyed diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $975,223.

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

We performed audit work from June 2019 through December 2020.

METHODOLOGY

To accomplish our objective, we performed the following steps:

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

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

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

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

    - 6 diagnosis codes for acute stroke,
    - 35 diagnosis codes for acute heart attack,
    - 29 diagnosis codes for major depressive disorder,
    - 51 diagnosis codes for embolism,
    - 4 diagnosis codes for vascular claudication,

- 24 diagnosis codes for lung cancer,
- 65 diagnosis codes for breast cancer, and
- 20 diagnosis codes for colon cancer.

- We developed an analytical tool that identified 832 scenarios in which either ICD-9 or ICD-10 diagnosis codes, when mis-keyed into an electronic claim because of a data transposition or other data entry error, could result in the assignment of an incorrect HCC to an enrollee's risk score. For each of the 832 occurrences, the tool identified a potentially mis-keyed diagnosis code and the likely correct diagnosis code. Accordingly, we considered the mis-keyed diagnosis codes to be high risk.

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

  - Risk Adjustment Processing System (RAPS)[29] to identify enrollees who received high-risk diagnosis codes from a physician during the service years,

  - Risk Adjustment System (RAS)[30] to identify enrollees who received an HCC for the high-risk diagnosis codes,

  - Medicare Advantage Prescription Drug (MARx)[31] to identify the total payments that CMS calculated, before applying the budget sequestration reduction, for UPMC for the payment years,

  - Encounter Data System (EDS)[32] to identify enrollees who received specific procedures, and

  - Prescription Drug Event (PDE)[33] to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.

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

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

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

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

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

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

- We selected for audit a sample of 280 enrollee-years that included: (1) a stratified random sample of 246 enrollee-years and (2) 34 enrollee-years as identified by our analytical tool.

- We used an independent medical review contractor to perform a coding review for the 280 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.[34]

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

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

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

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

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

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

- We used the results of the independent medical review contractor to calculate overpayments or underpayments for each enrollee-year. Specifically, we calculated:

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

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

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

- We discussed the results of our audit with UPMC officials on December 8, 2020.

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

[34] For this audit, our independent medical review contractor used senior coders all of whom possessed one or more of the following qualifications and certifications: RHIT, CPC, and CRC. RHITs have completed a 2-year degree program and have passed an AHIMA certification exam. The AAPC credentials both CPCs and CRCs.

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 Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS	A-07-17-01173	10/28/2021
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS	A-07-19-01187	5/21/2021
Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS	A-07-16-01165	4/19/2021
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS	A-02-18-01028	2/24/2021
Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements	A-07-17-01170	4/30/2019

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified UPMC enrollees who: (1) were continuously enrolled in UPMC throughout all of the 2014 or 2015 service year and January of the following year, (2) were not classified as being enrolled in hospice or as having end-stage renal disease status at any time during 2014 or 2015 or in January of the following year, and (3) received a high-risk diagnosis during 2014 or 2015 that caused an increased payment to UPMC for 2015 or 2016, respectively.

We presented the data for these enrollees to UPMC for verification and performed an analysis of the data included on CMS's systems to ensure that the high-risk diagnosis codes increased CMS's payments to UPMC. After we performed these steps, our finalized sampling frame consisted of 4,256 enrollee-years.

SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2015 or 2016.

SAMPLE DESIGN

The design for our statistical sample comprised of 9 strata of enrollee-years with either:

- an acute stroke diagnosis (which maps to the HCC for Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim (918 enrollee-years);

- a diagnosis that mapped to an Acute Heart Attack HCC on only one physician claim but did not have that diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician claim (844 enrollee-years);

- an acute stroke diagnosis and a diagnosis that mapped to an Acute Heart Attack HCC in the same year and that met the criteria mentioned in the previous two bullets (6 enrollee-years);

- a major depressive disorder diagnosis (which maps to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) on one claim during the service year but for which antidepressant medication was not dispensed (609 enrollee-years);

- a diagnosis that mapped to an Embolism HCC but for which an anticoagulant medication was not dispensed (260 enrollee-years);

- a vascular claudication diagnosis (which maps to the HCC for Vascular Disease) but for which medication was dispensed for neurogenic claudication (345 enrollee-years);

- a diagnosis that mapped to a Lung Cancer HCC on only one claim but that did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the lung cancer diagnosis administered within a 6-month period before or after the diagnosis (211 enrollee-years);

- a diagnosis that mapped to a Breast Cancer HCC on only one claim but that did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the breast cancer diagnosis administered within a 6-month period before or after the diagnosis (763 enrollee-years); or

- a diagnosis that mapped to a Colon Cancer HCC on only one claim but that did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (300 enrollee-years).

The specific strata are shown in Table 5.

Table 5: Sample Design for Audited High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee-Years	CMS Payment for HCCs in Audited High-Risk Groups*	Sample Size
1 – Acute stroke	918	$2,215,284	30
2 – Acute heart attack	844	1,760,512	30
3 – Acute stroke / acute heart attack combination	6	25,944	6
4 – Major depressive disorder	609	1,539,559	30
5 – Embolism	260	600,362	30
6 – Vascular claudication	345	774,034	30
7 – Lung cancer	211	1,487,311	30
8 – Breast cancer	763	1,032,089	30
9 – Colon cancer	300	657,216	30
Total – First Nine Strata	**4,256**	**$10,092,311**	**246**

*Rounded to the nearest whole dollar amount.

After we selected the 246 enrollee-years, we identified an additional group of 34 enrollee-years (for a total of 280 sampled enrollee-years) that represented individuals who received 1 of the 832 potentially mis-keyed diagnosis codes (which mapped to a potentially unvalidated HCC) and multiple instances of diagnosis codes that were likely keyed correctly.

SOURCE OF RANDOM NUMBERS

We generated the random numbers with the OIG, OAS, statistical software.

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the items in each stratum in the stratified sampling frame. We generated the random numbers for our sample according to our sample design, and we then selected the corresponding frame items for review. We also selected all 34 items from the potentially mis-keyed group.

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to estimate the total amount of net overpayments to UPMC at the lower limit of the two-sided 90-percent confidence interval (Appendix D). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time. We also identified the overpayments from the 34 potentially mis-keyed diagnosis codes and added that amount to the estimate for the statistical sample to obtain the total net overpayments.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 6: Sample Results

Audited High-Risk Groups	Frame Size	CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With Incorrect Diagnosis Codes	Net Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)
1 – Acute stroke	918	$2,215,284	30	$72,181	28	$63,764
2 – Acute heart attack	844	1,760,512	30	60,546	26	39,236
3 – Acute stroke / acute heart attack combination	6	25,944	6	25,944	6	12,798
4 – Major depressive disorder	609	1,539,559	30	78,542	5	13,840
5 – Embolism	260	600,362	30	71,374	14	33,151
6 – Vascular claudication	345	774,034	30	67,081	7	17,037
7 – Lung cancer	211	1,487,311	30	219,612	26	176,796
8 – Breast cancer	763	1,032,089	30	44,154	28	41,613
9 – Colon cancer	300	657,216	30	63,749	28	59,725
Total – First Nine Strata	**4,256**	**$10,092,311**	**246**	**$703,183**	**168**	**$457,960**
10 – Potentially Mis-keyed Diagnoses	34	$272,040	34	$272,040	26	$223,139
Totals – All	**4,290**	**$10,364,351**	**280**	**$975,223**	**194**	**$681,099**

Table 7: Estimated Net Overpayments in the Sampling Frame
(*Limits Calculated at the 90-Percent Confidence Level)*

	Estimated Net Overpayment for Statistical Sample	Overpayment for Potentially Mis-keyed Diagnosis Group	Total Estimated Net Overpayments
Point Estimate	$6,731,083	$223,139	$6,954,222
Lower Limit	6,178,158	223,139	6,401,297
Upper Limit	7,284,009	223,139	7,507,148

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: BREAKOUT OF POTENTIALLY MIS-KEYED DIAGNOSIS CODES

Table 8: Potentially Mis-keyed Diagnosis Codes and Associated Overpayments

Number of Sampled Enrollee-years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
7	205.00	Acute Myeloblastic Leukemia, Not Having Achieved Remission	Metastatic Cancer and Acute Leukemia	250.00	Diabetes Mellitus Without Mention of Complication, Type II or Unspecified Type, Not Stated as Uncontrolled	$122,103
4	482.0	Pneumonia Due to Klebsiella Pneumoniae	Aspiration and Specified Bacterial Pneumonias	428.0	Congestive Heart Failure, Unspecified	23,136
3	E32.9	Disease of Thymus, Unspecified	Other Significant Endocrine and Metabolic Disorders	F32.9	Major Depressive Disorder, Single Episode, Unspecified	5,963
2	205.01	Acute Myeloid Leukemia, in Remission	Metastatic Cancer and Acute Leukemia	250.01	Diabetes Mellitus Without Mention of Complication, Type 1, Not Stated as Uncontrolled	41,039
2	433.01	Occlusion and Stenosis of Basilar Artery With Cerebral Infarction	Ischemic or Unspecified Stroke	433.10	Occlusion and Stenosis of Carotid Artery Without Mention of Cerebral Infarction	1,857
1	441.01	Dissection of Aorta, Thoracic	Vascular Disease With Complications	414.01	Coronary Atherosclerosis of Native Coronary Artery	4,177
1	200.00	Reticulosarcoma, Unspecified Site, Extranodal and Solid Organ Sites	Lymphatic, Head and Neck, Brain, and Other Major Cancers (Version 12 model) and Lymphoma and Other Cancers (Version 22 model)	250.00	Diabetes Mellitus Without Mention of Complication, Type II or Unspecified Type, Not Stated as Uncontrolled	6,297

Number of Sampled Enrollee-years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
1	205.80	Other Myeloid Leukemia, Without Mention of Having Achieved Remission	Lung, Upper Digestive Tract, and Other Severe Cancers (Version 12 model) and Lung and Other Severe Cancers (Version 22 model)	250.80	Diabetes With Other Specified Manifestations, Type II or Unspecified Type, Not Stated as Controlled	$8,224
1	174.9	Malignant Neoplasm of Breast (Female), Unspecified	Breast, Prostate, Colorectal and Other Cancers and Tumors (Version 12 model) and Breast, Prostate, and Other Cancers and Tumors (Version 22 model)	714.9	Unspecified Inflammatory Polyarthropathy	1,559
1	714.9	Unspecified Inflammatory Polyarthropathy	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	174.9	Malignant Neoplasm of Breast (Female), Unspecified	2,995
1	441.00	Dissection of Aorta, Unspecified Site	Vascular Disease With Complications	414.00	Coronary Atherosclerosis of Unspecified Type of Vessel, Native or Graft	1,934
1	447.6	Arteritis, Unspecified	Vascular Disease	446.7	Takayasu's Disease	2,769
1	I24.9	Acute Ischemic Heart Disease, Unspecified	Unstable Angina and Other Acute Ischemic Heart Disease	I42.9	Cardiomyopathy, Unspecified	1,086
26						**$223,139**

Table 9: Hierarchical Condition Categories (HCCs) That Were Not Validated, but We Found Support for an HCC for a Less Severe Manifestation of the Related-Disease Group

Count of Enrollee-Years	More Severe Hierarchical Condition Category That Was Not Validated	Less Severe Hierarchical Condition Category That Was Supported
2	Metastatic Cancer and Acute Leukemia (Versions 12 and 22 models)	Lymphatic, Head and Neck, Brain, and Other Major Cancers (Version 12 model) and Lymphoma and Other Cancers (Version 22 model)
1	Vascular Disease With Complications	Vascular Disease
1	Metastatic Cancer and Acute Leukemia (Versions 12 and 22 models)	Breast, Prostate, Colorectal and Other Cancers and Tumors (Version 12 model) and Breast, Prostate and Other Cancers and Tumors (Version 22 model)
1	Unstable Angina and Other Acute Ischemic Heart Disease	Angina Pectoris

UPMC LIFE CHANGING MEDICINE

UPMC Health Plan

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May 26, 2021

Via Email and Overnight Delivery
Mr. Patrick J. Cogley
Regional Inspector General for Audit Services
Office of Audit Services, Region VII
601 East 12th Street, Room 0429
Kansas City, MO 64106

Re: UPMC Health Plan, Inc. Response to Draft Audit Report No. A-07-19-01188

Dear Mr. Cogley:

UPMC Health Plan, Inc. ("UPMCHP") appreciates the opportunity to respond to the United States Department of Health and Human Services ("HHS") Office of Inspector General's ("OIG's") Draft Report No. A-07-19-01188, entitled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS* (the "Draft Report" or "OIG Draft Report"), which was provided to UPMCHP on April 27, 2021.

For the reasons set forth below, UPMCHP respectfully submits that OIG should not finalize the Draft Report or any of its recommendations because:

1) The OIG's Audit departed from established Centers for Medicare and Medicaid Services ("CMS") standards for evaluating proper payments to MA plans;
2) The OIG Audit was not designed to fairly determine whether overall payments to UPMCHP were appropriate and in accordance with the rules of CMS;
3) The OIG Audit's coding review structure, coder qualifications and coding review results are flawed;
4) OIG's use of extrapolation is inappropriate under the circumstances and contradicts CMS's position regarding how to determine overpayments to Medicare Advantage plans; and
5) OIG's conclusions regarding the efficacy of UPMCHP's policies and procedures are not supported by the facts or by CMS's rules and program requirements.

In addition, although UPMCHP previously submitted – and is resubmitting here – documentation that substantiates several of the challenged codes in the Draft Report, OIG has to date not accounted for that documentation in the Draft Report.

I. OIG Audit Departed from Established CMS Standards for Evaluating Proper Payments to MA Plans

CMS is the agency designated by Congress to oversee and administer the Medicare Advantage ("MA") program.[1] In addition, Congress has directed the HHS Secretary to "establish by regulation … standards" for the MA program, provide that regulations that impose "new, significant regulatory requirements" be issued before the beginning of the calendar year in which the changes are to take effect."[2]

Accordingly, on a prospective basis, and through notice and comment rulemaking and other program information, CMS has provided written notice to Medicare Advantage Organizations ("MAOs") regarding how Risk Adjustment Data Validation ("RADV") audits will be conducted.[3] The OIG, however, has undertaken to conduct an audit that is at odds with CMS's risk adjustment audit standards and CMS's position on how overpayments are to be determined in such an audit. And the OIG has done so by applying its competing position in a retroactive manner with no advance notice to MAOs.

The Draft Report states that this audit of UPMCHP is part of a "series of audits" in which OIG is "reviewing the accuracy of diagnosis codes that MAOs submitted to CMS."[4] The OIG stated that the objective of this particular audit "was to determine whether selected diagnosis codes that UPMC submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements."[5] The objective of the OIG Audit is inconsistent with the type of RADV audit that CMS might conduct on an MAO for which there is a well-known and publicized methodology that has been the subject of MA plan input. Because OIG's audit objective was not the same as the objective of a CMS RADV audit, OIG crafted unique and still not fully disclosed auditing standards, approaches and protocols which differ from the publicly announced, and publicly commented upon, audit protocols in place at CMS. This is particularly inappropriate given that OIG has recognized that CMS will determine any overpayment, and any disagreement with audited amounts will be subject to review through the CMS RADV process.[6]

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[1] 42 U.S.C. §1395b-9.
[2] 42 U.S.C. §1395w-26(b)(1), (4).
[3] 42 C.F.R. §422.311; Medicare Risk Adjustment Data Validation Program, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Overview; 2021 Program Audit Process Overview Medicare Parts C and D Oversight and Enforcement Group Division of Audit Operations Updated October 2020, https://www.cms.gov/files/document/2021-program-audit-process-overview.pdf..
[4] Draft Report p. 1.
[5] *Id.*
[6] Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS, OIG Report No. A-07-19-01187 (May 2021), p. 21, n. 20 ("Anthem Audit").

OIG did not appear to follow CMS's program regulations, guidance and requirements for conducting a risk adjustment coding audit. With respect to statistical sampling, OIG indicated to UPMCHP during the exit conference that it did not utilize CMS's Guidance Regarding the Use of Statistical Sampling for Overpayment Estimation in conducting the audit.[7]

Indeed, the audits released to date by the OIG in this "series of audits" indicate that OIG has utilized different approaches from one audit to another.[8] In one audit, OIG reviewed two groups of "high risk diagnosis codes."[9] In a second audit, OIG focused on all enrollees on whose behalf the MAO submitted at least one diagnosis code that mapped to an HCC used in the enrollees' risk scores.[10] In a third audit, OIG reviewed seven groups of "high risk diagnosis codes."[11] In a fourth audit, OIG reviewed seven groups of "high risk diagnosis codes."[12] In this audit of UPMCHP, OIG reviewed ten groups of "high risk diagnosis codes" which included: lung cancer, breast cancer and colon cancer diagnosis codes, none of which were included in any of the other OIG audits.

The OIG has also taken inconsistent approaches when it has reviewed the same "high risk group" from one audit to another. For example, for its self-described "high risk group" "Major Depressive Disorder", one audit looked at a sample of enrollees with "one or two claims during the service year, rather than on several claims, which would have reflected long-term treatment"[13] while another audit looked to a single instance of an enrollee having "one claim during the service year but did not have an antidepressant medication dispensed on his or her behalf."[14]

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

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[7] CMS Manual System, Department of Health & Human Services (DHHS), Pub 100-08 Medicare Program Integrity Centers for Medicare & Medicaid Services (CMS) Transmittal 828, September 28, 2018.

[8] Some Diagnosis Codes That Essence Healthcare, Inc. Submitted to CMS Did Not Comply with Federal Requirements, OIG Audit Report No. A-07-17-01170 (April 2019) ("Essence Audit").
[9] *Id.*
[10] Medicare Advantage Compliance Audit of Diagnosis Codes that Humana, Inc. (Contract H1036) Submitted to CMS, OIG Report No. A-07-16-01165 (April 2021) ("Humana Audit").
[11] Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS, OIG Report No. A-02-18-01028 (February 2021) ("BC Michigan Audit").
[12] Anthem Audit, pp. 4 -5.
[13] Essence Audit p. 3.
[14] Anthem Audit, p. 5.

Furthermore, conducting a review focused solely on diagnosis codes perceived to be prone to error, without advance notice to MAOs of the plan to conduct such audits, is also problematic because MAOs so audited were unable to price in the risk that one-sided audits would be conducted when they submitted their bids to CMS.

Respectfully, the OIG's exercise of audit authority here, including its unpublished adoption of an audit approach that varies from one MAO to another, appears misplaced and is in sharp contrast to CMS audit practices. Additionally, the Draft Report does not indicate that CMS has approved the statements and conclusions in the Draft Report even though both are within the authority exclusively delegated to CMS.[15]

II. The OIG Audit Was Not Designed to Fairly Determine Whether Overall Payments to UPMCHP Were Appropriate and in Accordance With the Rules of CMS

UPMCHP is concerned that OIG's audit was not designed to consider the entirety of UPMCHP's coding and risk adjustment submissions to CMS. OIG's audit design targeted only hierarchical condition codes ("HCCs") deemed by OIG most likely to be prone to errors. The audit did not assess the overall accuracy of payments by CMS to UPMCHP, including both "overpayments" and "underpayments." In other words: the OIG audit looked only for overpayments and not underpayments.

The initial notice by the OIG notifying UPMCHP of its intention to conduct an audit indicated that the "objective of [OIG's] audit is to determine whether the diagnosis codes that UPMC Health Plan, Inc., submitted to CMS for use in CMS's risk score calculations complied with Federal requirements." However, in that same notice the OIG said that "[f]or this audit we plan to limit our review to specific diagnosis codes that mapped to selected hierarchical condition categories."[16]

Contrary to the audit notification letter, the stated objective in the Draft Report was *not* to determine whether the diagnosis codes submitted by UPMCHP complied with federal requirements. The Draft Report states that the objective of the audit "was to determine whether *selected* diagnosis codes that UPMCHP submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements."[17]

Unlike CMS, OIG started its audit with "data mining" techniques and "discussions with medical professionals at a Medicare administrative contractor" to identify "diagnosis codes and HCCs that were at high risk for noncompliance."[18] OIG focused solely on ten "high-risk groups." OIG's methodology was designed to target "submitted but unsupported" risk adjusting diagnosis

[15] *See*, Anthem Report, p. 21, n. 20.
[16] Letter to J. Wisniewski UPMCHP from P. Cogley OIG dated June 12, 2019.
[17] Draft Report p. 1 (emphasis added).
[18] *Id*.

codes while avoiding altogether "supported but not submitted" risk adjusting diagnosis codes. Consequently, OIG's audit did not render a full and balanced picture of UPMCHP's risk adjustment coding processes, procedures, and overall accuracy.

UPMCHP has asked a statistician expert to review the Draft Report and the expert expressed the same concerns about the slanted audit design:

> **"OIG's methodology is designed to target "submitted but unsupported" Risk Adjusting diagnosis codes not "supported but not submitted" Risk Adjusting diagnosis codes**. The OIG audit methodology as designed does not account for all Risk Adjusting diagnosis codes that are substantiated, but not submitted, for the sampled enrollees. Instead, the methodology was designed to primarily find "overpayments" for the enrollees subject to review. The OIG requested and reviewed only the medical records related to the high-risk diagnosis codes selected for review. Other records for selected enrollees that were never requested or reviewed by the OIG may contain supported, but unsubmitted, Risk Adjusting diagnosis codes for which UPMC did not receive any payment. Consequently, in order to determine whether UPMC was overpaid, an auditor must review all available medical records for the enrollee, giving credit for supported, but unsubmitted, Risk Adjusting diagnosis codes. Instead of following this proper approach, the OIG made no attempt to review records other than those specifically related to the high risk conditions included in the scope of its audit even going so far as to acknowledge the existence, but then ignore, instances of supported, but unsubmitted, risk adjusting diagnosis codes for select members that were audited by incorrectly claiming that these codes were out-of-scope."[19]

III. The OIG Audit's Coding Review Structure, Coder Qualifications and Coding Review Results are Flawed

In addition to designing an audit that focused solely on HCCs prone to lacking medical records support while avoiding cases that might have supported but not reported HCCs, it appears that OIG did not follow CMS audit standards and guidance in other respects as well.

(a) Not All of the OIG Contract Coders Appear to Have the Requisite Backgrounds and Certifications that CMS Requires in Performing Risk Adjustment Coding Reviews.

[19] *See* Exhibit A, Letter of Benjamin Wilner, Ph.D., dated May 25, 2021.

The contract coders utilized by OIG do not appear to have the requisite backgrounds and certifications that CMS might require in performing a risk adjustment coding review. According to CMS:

> "CMS RADV reviewers are certified coders, *experienced in risk adjustment data validation* that are familiar with a variety of medical record layouts, electronic medical record entries, and handwritten medical record documentation."[20]

OIG states that its independent medical review contractor used senior coders all of whom possessed one or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS), Certified Coding Specialist – Physician-Based (CCS-P), Certified Professional Coder (CPC), and Certified Risk Coder (CRC).[21] Although UPMCHP requested detailed information as to which OIG contract coders had which certifications, and which coders made which findings, OIG did not provide that breakdown of qualification by coder.

UPMCHP respectfully submits that all of the OIG contract coders should have had, at a minimum the following qualifications: a credential with either the ("AHIMA") (e.g., CCS) or the AAPC[22] (such as a CPC) along with the Certified Risk Adjustment Coder (CRC) certification. CRC certification typically requires at least 40 hours of actual course time in addition to written examinations.[23] A CRC certified coder would appear to meet the CMS requirement of a "certified [coder], experienced in risk adjustment data validation."[24]

Only the combination of both the certifications and experience in risk adjustment coding would demonstrate the level of proficiency required to adequately conduct an audit of this nature. The coders used in this audit should have a proven mastery of advanced skills in assigning correct diagnosis (ICD-10-CM) codes for a wide variety of clinical cases and services for risk adjustment models and a thorough comprehension of coding guidelines and regulations including compliant documentation practices at the provider level.

UPMCHP respectfully submits that an RHIT-only certified coder would not be utilized by CMS in conducting a RADV audit and an RHIT-only certified coder should not have been utilized in this audit. Additionally, because this was a risk adjustment data audit, and considering CMS's

[20] CMS, Contract-Level 15 Risk Adjustment Data Validation, Medical Record Reviewer Guidance In effect as of 01/10/2020* Version 2.0, p. 14 (emphasis added).
[21] Draft Report p. 22, footnote 25.
[22] AAPC was previously known as the American Academy of Professional Coders.
[23] AAPC, Certified Risk Adjustment Coder (CRC) Certification Exam, https://www.aapc.com/certification/crc/.
[24] CMS, Contract-Level 15 Risk Adjustment Data Validation, Medical Record Reviewer Guidance In effect as of 01/10/2020* Version 2.0, p. 14

view that CMS RADV reviewers should be certified coders "experienced in risk adjustment data validation,"[25] all of the coders utilized in this OIG audit should have had CRC certification.

UPMCHP has not been provided with information on which coders with which qualifications were at what level of review (i.e., first level or second level or third level), although that background information on the coders was requested by UPMCHP on March 8. Given CMS's RADV audit standards, it would have been inappropriate to put an RHIT-only certified coder at any level of the coding review. Experience in coding hospital inpatient/outpatient and physician medical records would not provide sufficient coding experience to perform a comprehensive coding review for a targeted MA risk adjustment validation audit.

Furthermore, OIG's use of a physician to act as a "tie breaker" when two coders disagreed is not consistent with CMS coding review procedures in RADV audits. Per CMS guidance, once a provider has rendered a diagnosis, clinical judgment plays no role in the process of determining or reviewing the appropriateness of any diagnosis code assigned based on that diagnosis.[26]

OIG should have used the same method that CMS uses during a RADV audit to reconcile a disagreement between two coders. In a RADV audit by CMS, if a coder views an HCC as unsubstantiated, the HCC is escalated to a second coder for "Discrepant Confirmation."[27] If the second coder determines that the medical record in question substantiates a diagnosis code that maps to the HCC, then CMS treats the HCC as substantiated without further analysis. CMS's approach reflects a true coding analysis, rather than an assessment of clinical support for a particular condition, which need not exist in every record to substantiate coding the condition.

(b) It is Unclear What Coding Guidelines and Guidance the OIG Contract Coders Relied Upon

UPMCHP was not provided with the specific coding guidance that the OIG contract coders relied upon in doing their work and thus cannot assess their findings against their instructions. The information was not provided even though requested by UPMCHP during the exit conference of January 26, 2021 and subsequently.

For several years CMS has published "The Contract-Level Risk Adjustment Data Validation (RADV) Medical Record Reviewer Guidance" to provide information on the RADV medical record process. These guidelines are used by coders to evaluate the medical records submitted by plans to validate audited diagnoses. For example, CMS RADV standards for Service Year 2014 expressly state that documentation of a treatment or management plan is not required to

[25] *Id.*
[26] *See* CMS, ICD-10-CM Official Guidelines for Coding and Reporting FY 2019, at 13 (effective October 1, 2018) ("The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. the provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis.").
[27] *See* CMS, Risk Adjustment Data Validation (RADV) Medical Record Intake Process and Guidance to Coders CY2011 version 4.0 at 18-19 (May 8, 2014) ("RADV Guidance.").

validate a chronic condition as long as the condition is "mentioned" in writing by an acceptable provider in connection with a face-to-face encounter.[28] It appears that these guidelines were not followed in this audit, but UPMCHP has not been provided access to what OIG used instead.[29]

Additionally, the OIG Audit did not capture many of the nuances in the operation of coding reviews and submissions, such as the treating physician coding "history of" a condition that may have later been changed to an active diagnosis. OIG coders "failed" several diagnoses because a diagnosis by the physician was written in the "past medical history" section of the medical record. CMS recognizes that all chronic conditions need to be coded, even when there is not current treatment involved, because the existence of that chronic condition potentially informs treatment plans for other conditions and increases the cost of care for that MA plan member:

> "[t]he criteria for selection of the conditions to be reported as "other diagnoses" include the severity of the condition, use or consideration of alternative measures in the treatment of the principal diagnosis due to a coexisting condition, increased nursing care required in the care of patients due to the disabling features of the coexisting condition, use of diagnostic or therapeutic services for the particular coexisting condition, the need for close monitoring of medications, or modifications of nursing care plans. If there is documentation in the medical record to indicate the patient has COPD, it should be coded. Even if this condition is listed only in the history section with no contradictory information, the condition should be coded. Chronic conditions such as, but not limited to, hypertension, Parkinson's disease, COPD, and diabetes mellitus are chronic systemic diseases that ordinarily should be coded even in the absence of documented intervention or further evaluation. Some chronic conditions affect the patient for the rest of his or her life and almost always require some form of continuous clinical evaluation or monitoring during hospitalization, and therefore should be coded."[30]

UPMC reiterates its prior request for citations to all of the written guidance and instructions relied upon by the contract coders in conducting this audit.

(c) UPMCHP Takes Issue With Multiple Coding Findings Made by the OIG Contract Coders

[28] CMS, Risk Adjustment Data Validation (RADV) Medical Record Intake Process and Guidance to Coders CY2011 ver. 4.0 p. 5 (May 8, 2014)

[29] Contract-Level 15 Risk Adjustment Data Validation Medical Record Reviewer Guidance In effect as of 01/10/2020* Version 2.0, https://www.cms.gov/files/document/medical-record-reviewer-guidance-january-2020.pdf-0.

[30] CMS, Contract-Level 15 Risk Adjustment Data Validation, Medical Record Reviewer Guidance In effect as of 01/10/2020* Version 2.0, pp. 52 - 53.

In addition to the above-described general concerns about the coders' qualifications and the undisclosed criteria that the OIG's contractor relied upon, UPMCHP takes issue with multiple specific coding findings made by the OIG contract coders.

UPMCHP provided its written objections to 25 of OIG's samples on March 12, 2021 with a request for reversal of those findings by the OIG and its contract coders. It appears that these objections are not addressed in the Draft Report.

UPMCHP hereby resubmits the pertinent materials it previously submitted to OIG on March 12, 2021 and reiterates its request that certain coding findings by OIG's coders be reversed because of additional documentation and medical history information provided to OIG by UPMCHP. Specifically:

- Based on information provided by UPMCHP, OIG should reverse the diagnosis and coding findings on 22 of the samples in which a rebuttal was submitted by UPMCHP.
- Based on the information provided by UPMCHP, the OIG should credit UPMCHP for 3 samples for HCCs found by the plan during the review of samples but not submitted by the plan or paid by CMS during the plan years.

UPMCHP respectfully requests that the OIG revise the Draft Report in light of the additional medical information on the 25 samples previously submitted to OIG for review on March 12, 2021 and resubmitted again with this response.

A redacted summary of objections, follows below:

Sample No.	UPMCHP Respectfully Disagrees With the OIG's Coding Decision and Has Provided Documentation to Indicate That the Original Coding Decision is Supported
3	The diagnosis of Major Depression is supported, HCC 58, Major Depressive, Bipolar, and Paranoid Disorders (v22).
22	Office visit documentation 5/30/2014 supports the condition of "Major Depression" HCC 55 and/or HCC 58.
36	Operative report in the medical record 10/19/2015 validates HCC 100, Ischemic or Unspecified Stroke.
86	Consultation notes 3/17/2014 support HCC 86, Acute Myocardial Infarction (v22), HCC 81, Acute Myocardial Infarction (v12).
96	ER note 11/23/2015 supports HCC 86, Acute Myocardial Infarction (v22).
126	Medical record clearly supports diagnosis of deep vein thrombosis and the assignment of HCC 108, Vascular Disease (v22).
130	Office visit of 12/31/2015 supports diagnosis of peripheral vascular disease (PVD) and assignment of HCC 108, Vascular Disease (v22).
133	Inpatient consultation progress note of 2/7/2014 supports diagnosis of peripheral vascular disease (PVD) and assignment of HCC 108, Vascular Disease (v22).
136	Documentation from office visit dated 9/15/2015 validates HCC 108, Vascular Disease (v22).
169	Encounter progress note 6/1/2015 validates HCC 9, Lung and Other Serious Cancers (v22).
177	Medical record 2/13/2015 validates HCC 9, Lung and Other Serious Cancers (v22).

193	Progress note 10/5/2015 validates diagnosis of breast cancer, which translates to HCC 12, Breast, Prostate, and Other Cancers and Tumors.
203	Progress note 8/11/2015 validates diagnosis of breast cancer, which translates to HCC 12, Breast, Prostate, and Other Cancers and Tumors.
228	Documentation in the chart exceeds the requirements necessary to validate HCC 11, Colorectal, Bladder and Other Cancers (v22).
237	Colon cancer was being monitored and assessed therefore validating HCC 11, Colorectal, Bladder and Other Cancers (v22).
239	Colon cancer was being monitored and assessed therefore validating HCC 11, Colorectal, Bladder and Other Cancers (v22).
251	Medical record 7/2/2014 explicitly supports HCC 8, Metastatic Cancer and Acute Leukemia (v22), HCC 7, Metastatic Cancer and Acute Leukemia (v12).
252	Office visit letter 12/1/2014 supports HCC 107, Vascular Disease with Complications and HCC 104, Vascular Disease.
253	Discharge summary supports HCC 111, Aspiration and Specified Bacterial Pneumonias (v12), HCC 114, Aspiration and Specified Bacterial Pneumonias (v22).
258	Office visit letter 1/21/2014 supports HCC 107, Vascular Disease with Complications and HCC 104, Vascular Disease.
262	Cardiothoracic surgery operative report supports HCC 86, Acute Myocardial Infarction (v22), HCC 81, Acute Myocardial Infarction (v12).
272	Emergency room evaluation note 11/12/2014 supports HCC 19, Diabetes without Complications (v12), HCC 19 Diabetes without Complications (v22).

Additionally, UPMCHP submits that upon medical record review, several of the samples reviewed by the OIG had the following documented diagnoses, which were not originally submitted by UPMC during the Service Year, which should result in a payment credit for an additional HCC for that enrollee.

Sample No.	Additional Diagnosis Code Should Have Been Submitted by UMPCHP to Support and Additional HCC and that OIG Should Give Credit to UPMCHP for the Additional HCC(s).
43	Credit should be given for HCC 103, Hemiplegia / Hemiparesis (v22).
48	Credit should be given for HCC 105, Vascular Disease (v12) / HCC 108, Vascular Disease (v22).
60	Credit should be given for HCC 103, Hemiplegia / Hemiparesis (v22).

These errors were compounded by the fact that OIG coders did not review a member's entire enrollment year for all conditions that trigger an HCC in order to – in in fairness – ensure that UPMCHP received credit for supported HCCs. UPMCHP respectfully submits, that OIG should not finalize its audit report until such time as the entire enrollment year for each sampled member has been reviewed.

Additionally, UPMCHP respectfully submits that there were significant gaps in OIG's sampling plan and the manner in which it was executed. According to the same statistician expert retained by UPMCHP to review the OIG's draft report, "the sampling methodology implicit in the draft report contains multiple statistical errors that invalidates the OIG's numerical conclusion."[31]

> **"The OIG sampling plan and supporting workpapers do not specify how the Sample Items in each strata were ordered and uniquely numbered for random selection.** Selecting a sample requires two steps. First, one has to generate random numbers. Second, those random numbers need to be applied to the items in each stratum in order to select the items to be sampled.
>
> Even if the OIG's workpapers provide seed numbers that show that the random numbers are truly random, one cannot tell that the sample items the OIG analyzed are truly random. The OIG draft report and workpapers do not demonstrate the method it used to apply the random numbers to the items in each stratum. While the OIG draft report states that the OIG "…consecutively numbered the items in each stratum in the stratified sampling frame," it did not state how the items were ordered prior to numbering. The OIG should provide additional information as to how the items were ordered and confirm that there was no purposeful ordering."[32]

These statistical errors should at the least require a withdrawal of the OIG Draft Report while these errors are addressed.

IV. OIG's Use of Extrapolation Is Inappropriate Under the Circumstances and Contradicts CMS's Position on the Method to be Used to Determine Overpayments to Medicare Advantage Plans

(a) As CMS Has Acknowledged, Extrapolating Audit Results to an Overpayment Amount Requires an Adjustment to Account for the Fact that the Claims Data Used to Set Medicare Advantage Payment Rates Were Not Audited and Also Contained Diagnosis Coding Errors

The OIG's assertion that an overpayment amount can be derived by extrapolating its audit results contradicts the statutory requirement that CMS must reimburse MAOs in a manner that ensures "actuarial equivalence" with reimbursement by Medicare Part A and B (together, "traditional Medicare"). Indeed, it has been CMS's position since 2012 that to extrapolate audit results, it is necessary to apply an adjustment to take into account the fact that Medicare Advantage payment

[31] *Id.*
[32] *Id.*

rates were themselves set in the first place based on unaudited diagnosis coding information.[33] It is logically and actuarially unsound to apply a stricter level of audit scrutiny to diagnosis codes that are used to determine payments to an MAO than was applied to the traditional Medicare claims data that were used to set the rates and diagnosis-based risk adjustments for Medicare Advantage. Doing so would ***guarantee*** that CMS would reimburse MAOs ***less*** than it pays under traditional Medicare for the same population of patients, which in turn would violate the "actuarial equivalence" requirement.

With respect to extrapolation based on RADV audit results, as of January 2019, CMS had indicated that it will not seek to recover overpayment amounts from MA plans on an extrapolated basis until an extrapolation methodology is finalized by CMS:

> "*Although [RADV] audits will be designed so that the individuals selected will form a statistically significant sample that would support an extrapolated recovery, we will not seek to recover on an extrapolated basis until an extrapolation methodology is finalized. At the very least, these audits will support enrollee level recoveries."[34]

The Medicare statute requires that CMS set Medicare Advantage payment rates in a manner "so as to ensure actuarial equivalence" between Medicare Advantage and traditional Medicare.[35] Two modes of payment are "actuarially equivalent when their present values are equal under a given set of actuarial assumptions."[36] Thus, to comply with the statute, CMS must set Medicare Part C payment rules such that reimbursement to Medicare Advantage Organizations is expected to equal traditional Medicare reimbursement for the same population of Medicare beneficiaries when the same assumptions are followed.

As a United States District Court has explained, to set Medicare Advantage payments, CMS considers the average monthly expenditure for an average beneficiary under traditional Medicare in the past year, and adds a geographical adjustment.[37] CMS applies additional risk adjustments based on the patient's demographic factors and medical diagnoses that are grouped into different HCCs. To model the estimated marginal cost of treating diagnoses in different HCCs, CMS

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[33] *See* CMS, "Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Validation Contract-Level Audits" (Feb. 24, 2012), 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 ("2012 Notice"). A copy of the CMS 2012 Notice is attached hereto as **Exhibit B**.

[34] Medicare Advantage Risk Adjustment Data Validation (RADV) Training, January 29, 2019, p. 29. https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/RADV-Industry-Slide-Deck.pdf.

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

[36] *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 185 (D.D.C. 2018), *appeal pending*, No. 18-5326 (D.C. Cir.) (quoting *Stephens v. U.S. Airways Grp., Inc.*, 644 F.3d 437, 440 (D.C. Cir. 2011).

[37] *UnitedHealthcare*, 330 F. Supp. 3d at 178-79.

relies on data contained in reimbursement claims submitted to traditional Medicare by physicians and other providers. "In conducting these analyses, CMS relies entirely on the diagnosis codes submitted by healthcare providers under traditional Medicare."[38] Claims data submitted to traditional Medicare, however, invariably contain coding errors, including diagnosis codes that have not been documented in the underlying patient medical records. "Humans being human, diagnoses in healthcare records may be miscoded, inappropriately added, or otherwise faulty by accident or mal intent."[39]

CMS thus sets Part C payment rates and risk adjustments based on traditional Medicare claims data and presume that any mismatches would be the same. "In consequence, the rates at which CMS pays Medicare Advantage insurers are based on flawed data across the millions of people in traditional Medicare."[40]

Because CMS sets Part C payment rates and risk adjustments based on unaudited traditional Medicare claims data, a Medicare Advantage overpayment arises from coded diagnoses that lack medical records support ***only to the extent to which the error rate exceeds the error rate for the traditional Medicare claims data used to set the payment rates***.

CMS has agreed with the point we are making – that before a Part C audit error rate may properly be extrapolated, it is necessary to adjust for the fact that the data underlying the rate-setting also contained diagnosis coding errors. Indeed, in connection with its RADV audits, CMS previously considered ***and rejected*** the OIG's notion that audit results can be extrapolated to an overpayment without first adjusting for the diagnosis coding errors contained in the traditional Medicare claims data used for rate-setting.

In 2008, CMS announced its intention to adopt a pilot program that would apply RADV audit results to extrapolate the error rate in the audited sample across the entire insurance contract, with the MAO responsible for refunding any overpayment to CMS based on the extrapolated error rate.[41] In response, many commenters made the same points that we have made above. For example, the American Academy of Actuaries "strongly advised CMS that it was not actuarially sound to compare unaudited figures to calculate per-capita payments and then audited figures to calculate overpayments."[42] According to the American Academy of Actuaries, "[t]his type of data inconsistency not only creates uncertainty, it also may create systematic underpayment, undermining the purpose of the risk-adjustment system and potentially resulting in payment

[38] *Id.*
[39] *Id*.
[40] *Id*. at 184.
[41] *See* 74 Fed. Reg. 54634, 54674 (Oct. 22, 2009) (describing history of RADV audit program).
[42] *UnitedHealthcare*, 330 F. Supp. 3d at 181.

inequities."[43]

CMS considered these comments and agreed that it would be erroneous to extrapolate overpayments from audits of Medicare Advantage diagnosis codes without adjusting for the errors in the traditional Medicare claims data used to set Medicare Advantage payment rates. After it "carefully reviewed more than 500 comments," CMS announced that such an adjustment (using what CMS called a "Fee-for-Service Adjuster" or "FFS Adjuster") is necessary to properly determine Medicare Advantage overpayments, and ***that an overpayment occurs only if the error rate exceeds the error rate for traditional Medicare claims data***:

> "[T]o determine the final payment recovery amount, CMS will apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount. If the FFS Adjuster amount is greater than the preliminary recovery amount, the final recovery amount is equal to zero.
>
> The FFS adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims). The actual amount of the adjuster will be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data."[44]

Recently, CMS has stated that it is reconsidering the use of an FFS Adjuster, but it has not retracted its 2012 Notice.[45]

Holding an MAO liable for extrapolated overpayments without an FFS Adjuster, as the Draft Report proposes to do, would contradict existing Medicare policy and would conflict with

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[43] *Id.* (quoting Letter from Thomas Wildsmith (VP, American Academy of Actuaries Health Practice Council) to Cheri Rice (Acting Director, CMS Medicare Plan Payment Group) dated Jan. 21, 2011)

[44] Ex. B, CMS 2012 Notice*; see also* CMS, "Fact Sheet: Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract" (Feb. 24, 2012), https://www.cms.gov/newsroom/fact-sheets/notice-final-payment-error-calculation-methodology-part-c-medicare-advantage-risk-adjustment-data ("Payment recovery amounts will be subject to a fee-for-service adjuster. The fee for service adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error is different from the documentation standard used to develop the Part C risk-adjustment model.").

[45] In 2018, CMS announced that it had performed a study that may support changing RADV audit procedures to allow for extrapolation of error rates without applying an FFS Adjuster. *See* 83 Fed. Reg. 54982 (Nov. 1, 2018). CMS has thereafter invited commenters to address whether the actuarial equivalence requirement "mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform our proposal not to apply an FFS Adjuster." 84 Fed. Reg. 30983 (June 28, 2019). CMS then stated that the conclusions in the study are "provisional" and that CMS's position is "tentative," while the agency considers public comments. Defendants' Reply in Support of Their Rule 60(b) Motion for Partial Reconsideration, *UnitedHealthcare Ins. Co. v. Azar*, No. 16-157 (RMC) (D.D.C.), filed Nov. 6, 2019 [Dkt. 97] at 23.

CMS's responsibilities under the Medicare statute, which requires that any action that "establishes or changes a substantive legal standard governing … the payment for services" follow notice and comment rulemaking before implementation:

> "No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation . . ."[46]

As a corollary, the Medicare statute bars the retroactive application of a change in rules without a specific finding by the Secretary that the retroactive application of the rule is necessary:

> "A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that - (i) such retroactive application is necessary to comply with statutory requirements; or (ii) failure to apply the change retroactively would be contrary to the public interest."[47]

Accordingly, the OIG cannot establish a substantive legal standard governing payment for services by performing an audit that adopts an evolving, unpublished and inconsistently applied standard that contradicts CMS's RADV standards. Notice and comment rulemaking is required to ensure awareness and consistency.[48] The fact that CMS performs "RADV audits" while the OIG performs various sorts of "targeted audits" highlights the conflict between the two auditors.

Any change under 42 U.S.C. § 1395hh can be accomplished only via a notice and comment process by CMS, and not through standards announced and unilaterally applied in an OIG audit.

Moreover, if followed, the OIG's recommendation that error rates determined in audits be extrapolated to a contract-level overpayment amount jeopardizes the integrity of the Medicare Advantage program. If MAOs are compelled to pay out money on the back end – where the HCCs contain no more errors than the traditional Medicare claims data used to set payment rates

[46] 42 U.S.C. § 1395hh(a)(2).
[47] 42 U.S.C. § 1395hh(e)(1)(A).
[48] *See Azar v. Allina Health Services*, 139 S.Ct. 1804 (2019) (holding that notice and comment requirements of the Medicare statute apply more broadly than the Administrative Procedures Act); *see also* HHS Office of Gen. Counsel Advisory Opinion 20-05 (stating that under *Azar v. Allina Health Services*, a "substantive legal standard" that has not been adopted following notice and comment rulemaking may not serve as the basis for an enforcement action).

– then CMS will be forced to set higher reimbursement levels on the front end.[49] The American Academy of Actuaries explained the disruption that would result from setting payment rates based on unaudited claims data while auditing medical records to validate payment amounts:

> "This type of data inconsistency not only creates uncertainty, it also may create systematic underpayment, undermining the purpose of the risk-adjustment system and potentially resulting in payment inequities. In addition, the uncertainty related to a plan's ultimate post-audit risk score could make it difficult for actuaries to estimate the plan's risk score and certify the plan bid."[50]

The policy and program implications of changing the standards for what constitutes an overpayment in midstream are significant, and only the properly promulgated standards should apply here.

(b) The OIG's Proposed Extrapolation Did Not Take Into Account Certain Additional Adjustments

In addition to overlooking the need for an FFS Adjuster in order to adhere to the "actuarial equivalence" requirement of the statute, the OIG has proposed extrapolation that would not attempt to back out amounts that are already taken into account by the statutory "coding pattern adjustment." This adjustment "reflects changes in treatment and coding practices in the fee-for-service sector and reflects coding patterns between Medicare Advantage plans and providers under part[s] A and B."[51] The Coding Pattern Adjustment per the annual Call Letters was 5.16% for Payment Year 2015 and 5.41% for Payment Year 2016.[52]

In addition, the OIG did not consider the impact of sequestration on MAOs. Sequestration was established in 2014 by the Budget Control Act.[53] Under the Budget Control Act, payments to health care providers and health plans were reduced by 2% across the board. Any overpayment estimate should be similarly reduced, since the plan was only paid 98% of the risk adjusted payment amount.

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[49] In litigation, the Government appears to have conceded that treating unsupported HCCs as overpayments without an FFS Adjuster would mean that CMS's payment model is mis-calibrated, and would generate payments for Medicare Advantage organizations that are *too low* to achieve actuarial equivalence. *See* Defendants' Reply in Support of Their Rule 60(b) Motion for Partial Reconsideration, *UnitedHealthcare Insurance Company v. Azar*, No. 16-157 (RMC) (D.D.C.), filed Nov. 6, 2019 [Dkt. 97] at 23.

[50] *See* Letter from Thomas Wildsmith (VP, American Academy of Actuaries Health Practice Council) to Cheri Rice (Acting Director, CMS Medicare Plan Payment Group) dated Jan. 21, 2011.

[51] 42 U.S.C. § 1395w-23(a)(1)(C)(ii).

[52] 2015 Announcement, April 7, 2014, pgs 3 and 29; https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2015.pdf; 2016 Announcement, April 6, 2015, pgs 3 and 4; https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2016.pdf

[53] Budget Control Act of 2011 (Pub.L. 112–25).

The OIG has also not considered the impact of a change in the risk adjustment on the plan's bid. Lowering the risk score would have the impact of increasing the plan's Per Member Per Month cost, which would, among other things, reduce the plan's rebate obligation.

(c) The OIG Has Previously Recognized that CMS is Responsible for Determining What Constitutes an Overpayment to a Medicare Advantage Organization

The OIG has previously recognized the complexity of extrapolating an audit result to an overall overpayment determination and has previously deferred to CMS's experienced judgment on this issue. In a May 2012 report of its audit of PacifiCare of Texas, the OIG initially recommended extrapolating MAO's error rate for unsupported HCCs across the entire contract year.[54] In response, the MAO explained that making such an extrapolation would contradict that statutory requirement of actuarial equivalence; the MAO explained that "differences between HCCs derived from medical records and HCCs derived from claims are not payment errors," and that it was "inappropriate" to use HCCs from medical records to compute capitation payments in the audit context when CMS set capitation payments from HCCs contained in traditional Medicare claims data that contains unaudited errors.[55]

Due to these concerns, the OIG withdrew its recommendation that the error rate from the audit be extrapolated to the entire contract, and it recommended instead that the MAO work with CMS to determine the correct contract level adjustments:

> "While an analysis to determine the potential impact of error rates inherent in FFS data on MA payments was beyond the scope of our audit, we acknowledge that CMS is studying this issue and its potential impact on audits of MA organizations. ***Because of the potential impact of these error rates on the CMS model we used to recalculate MA payments for the beneficiaries in our sample, we (1) modified one recommendation to have PacifiCare refund only the overpayments identified for the sampled beneficiaries rather than refund the projected overpayments*** and (2) added a recommendation that PacifiCare work with CMS to determine the correct contract level adjustments for the projected overpayments."[56]

As it did in its 2012 audit of PacifiCare of Texas, the OIG should withdraw its recommendation for an extrapolation and defer to the role of CMS to determine how overpayments should be

[54] OIG, "Risk Adjustment Data Validation of Payments Made to PacifiCare of Texas for Calendar Year 2007 (Contract Number H4590)," No. A-06-09-00012 (May 2012).
[55] *Id*. at Appendix D, pp. 8-11.
Id. at ii, 8 (emphasis added).

evaluated in the Medicare Advantage context in light of Medicare policy considerations and the statutory actuarial equivalence and other requirements.

(d) CMS Calls for Audits to Use the Lower Bound of the 99th Percent Confidence Interval But the OIG Audit Used the Lower Bound of the 90th Percent Confidence Interval

In its 2012 Notice, in addition to stating the need for an FFS Adjuster, CMS stated that overpayments would be determined from extrapolated audits at the lower bound of the 99 percent confidence interval. The OIG is not applying that standard, however. Instead, it is using the "lower limit of the two-sided 90-percent confidence interval."[57] The OIG's approach results in a higher extrapolated overpayment than CMS's approach. The Draft Report does not explain why the CMS standard was not followed.

The statistician expert retained by UPMCHP to review the OIG Draft Report took exception to both the OIG's use of extrapolation in this audit and the manner in which OIG executed its extrapolation calculation:[58]

- **"The confidence interval used by the OIG to determine the lower bound of the alleged payment error is inconsistent with the confidence interval prescribed by CMS for Medicare Advantage RADV audits.** The OIG draft report states that the OIG estimated the "total amount of net overpayments to UPMC at the lower limit of the two-sided 90-percent confidence interval." CMS's RADV error calculation methodology specifies that the net payment error be calculated at the lower limit of the two-sided 99-percent confidence interval. OIG's use of a 90-percent confidence interval results in a significantly higher net overpayment estimate than specified by CMS's guidance."

- **"OIG's extrapolation calculation does not utilize the proper statistical distribution, which results in an overstated net overpayment estimate.** The OIG used an incorrect statistical distribution to extrapolate UPMC's net overpayment, which caused it to overstate the lower bound of the estimated overpayment. When one samples items, the average value follows what is a called a t-Distribution. As the sample size increases, the t-Distribution approaches the Normal Distribution (bell-shaped curve). The confidence interval associated with the t-Distribution is larger than the confidence interval associated with the Normal Distribution. Because the OIG used the Normal Distribution in its UPMC calculations, it overstated the lower bound of the proper confidence interval. In particular, the OIG's use of the Normal Distribution understated the difference between

[57] Draft Report p. 26.
[58] See Exhibit A, Letter of Benjamin Wilner, Ph.D., dated May 25, 2021.

> the average and the lower bound of a two-sided 99-percent confidence interval by 1.5%."[59]

For all the reasons set forth above, extrapolation is not proper in this case and the extrapolation as performed would not be supported in any event.

V. OIG's Conclusion that "Policies and Procedures that UPMCHP Used to Ensure Compliance With Federal Requirements Were Not Always Effective" Is Not Supported by the Facts or CMS's Rules and Program Requirements

UPMCHP respectfully requests OIG reconsider its conclusion that: "Policies and Procedures that UPMCHP Used to Ensure Compliance With Federal Requirements Were Not Always Effective."[60]

UPMCHP has a well-developed and well-executed coding compliance program along with dedicated educational efforts. UMPCHP's coding compliance plan thoroughly addresses how issues are identified, audited, corrected, and continuously monitored.

The UPMCHP coders are credentialed by either AHIMA or AAPC. They follow the ICD-10-CM coding guidelines sourced from the official interpretive guide of the Coding Clinic, published quarterly by the central office of the American Hospital Association. Coding Clinic content is approved by the American Health Information Management Association, the American Hospital Association, Centers for Medicare and Medicaid Services, and the National Center for Health Statistics.

UMPCHP provides different educational platforms not only for their coding staff but for their physician practices as well. These include Provider Coding Education Curriculum and monthly coder educational meetings and the opportunity for the certified coders to obtain Continuing Education Unit (CEU). UPMCHP has a balanced audit program with random and focused reviews of its coders and providers. Education is a key component of the audit program.

As other audited MAOs have pointed out, CMS regulations do not establish or create a 100 percent accuracy standard or requirement for risk adjustment data.[61] For purposes of this

[59] "The z-value of a two-sided 99-percent confidence interval is 2.5758. The t-value of a two-sided 99-percent confidence interval with 131 degrees of freedom (calculated using the Welch-Satterthwaite equation) is 2.6142. This t-value exceeds the z-value by 1.5%. If one applies the same methodology, the difference between the average and the lower bound of a two-sided 90-percent confidence interval would be understated by 0.7% if the OIG utilized the Normal Distribution rather than the t-Distribution."
[60] Draft Report p. 18.
[61] Humana Audit, p. 34.

response, UPMCHP paraphrases many of the points raised to the OIG on this issue by other MAOs.[62]

CMS regulations state that MAOs should take reasonable steps to ensure the "accuracy, completeness, and truthfulness" of the risk adjustment data they submit based on "best knowledge, information and belief."[63] The risk adjustment process created by CMS acknowledged MAO concerns about healthcare provider mistakes and incomplete or inaccurate provider generated data.[64] Commentators to CMS explained that "it would be unfair and unrealistic to hold [MA] organizations to a '100 percent accuracy' certification standard."[65] CMS acknowledged that risk adjustment data are submitted to MAOs from many sources and as such present significant verification challenges and that MAOs "cannot reasonably be expected to know that every piece of data is correct, nor is that the standard the [CMS], the OIG, and DoJ believe is reasonable to enforce."[66] CMS has stated that MAOs "will be held responsible for making good faith efforts to certify the accuracy, completeness and trustfulness of encounter data submitted."[67] CMS recognizes that "encounter data [can] come into [MAOs] in great volume from a number of sources, presenting significant verification challenges for the organization."[68] OIG has also stated previously that no MAO can assure an "absolute guarantee of accuracy."[69]

Based on the parameters OIG set, the mere fact that some forms, according to OIG's coders' limited assessment, contained unsubstantiated codes or HCCs does not establish that UPMCHP's policies and procedures have failed or "were not always effective." Through its narrow and not fully-disclosed approach, OIG has essentially created a perfection standard that CMS and OIG both have said previously is not reasonable to enforce.[70] CMS's risk adjustment data submission process seems to anticipate occasional data inaccuracies and errors in submissions by MAOs.

UPMCHP has a robust compliance and training and education program for its employees, staff and contracted physicians. In its Draft Report, the OIG even recognized the preventive measures UPMCHP had in place during the Service Years and Payment Years reviewed in this audit:

> "The compliance procedures that UPMC had in place during our audit period included preventative measures by which it performed outreach to its providers in order to educate them on several topics, including the importance of using correct diagnosis codes to improve medical record documentation. UPMC also had procedures in place to detect

[62] *See* Humana Audit, p. 34 – 36; Anthem Audit, p. 46 – 47.
[63] 42 CFR §422.504(l)
[64] Medicare Program: Medicare+Choice Program, 65 Fed. Reg. 40,169, 40,250, 40,268 (June 29, 2000).
[65] *See id* at 40,268.
[66] *Id.*
[67] *Id.*
[68] *Id.*
[69] *See* Publication of the OIG's Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans, 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999).
[70] Medicare Program: Medicare+Choice Program, 65 Fed. Reg. 40,268 (June 29, 2000).

> whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. For one of these procedures, UPMC identified diagnosis codes for review and then analyzed the associated medical records in order to identify errors."[71]

With respect to current operations and any necessary remediation, OIG acknowledged in its report that UPMCHP has placed more emphasis on the prevention and detection of incorrect high-risk codes through 1) additional guidance on coding for acute stroke, acute heart attack, etc. and 2) adding steps to its data submission process to include reviews that focus entirely on "high-risk diagnosis codes."[72]

VI. Responses to Audit Recommendations

1) Recommendation: Refund to the Federal Government $6,607,049 of estimated net overpayments.

For reasons stated above, UPMCHP believes that the requested refund was calculated on a basis that is not consistent with CMS's standards for determining Part C overpayments and with standard actuarial or coding practices. UPMC respectfully submits that whether the results of the OIG's series of audits provide and appropriate basis for extrapolation is an issue that CMS should address on a comprehensive and consistent basis with all the MAOs that are being audited.

2) Recommendation: Identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government.

For reasons stated above, UPMCHP believes that the requested refund was calculated on a basis that is not consist with CMS's standards for determining Part C overpayments and with standard actuarial or coding practices.

UPMCHP anticipates discussing this recommendation further with CMS, and respectfully submits that the question of whether and how to conduct audits of additional time periods should be considered by CMS on a comprehensive and consistent basis applying consistent standards to any MAOs that are being audited.

[71] Draft Report p. 18
[72] *Id.*

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

With respect to UPMCHP's current compliance procedures and operations and any necessary remediation, OIG acknowledged in its report that UPMCHP has placed more emphasis on the prevention and detection of incorrect high-risk codes through 1) additional guidance on coding for acute stroke, acute heart attack, etc. and 2) adding steps to its data submission process to include reviews that focus entirely on "high-risk diagnosis codes."[73]

In addition to existing practices for internal audit based on CMS RADV policies and procedures, provider chart review and education, UPMCHP performs a number of targeted audits based on high risk conditions to identify codes for redaction such as cancer, stroke, single occurrences, etc. UPMCHP will continue to review and monitor both claims and supplemental submissions for additional audit opportunities in these areas. In addition, the retrospective coding team removes any incorrect code(s) found while reviewing records for supplemental, missed codes. All of UPMCHP retrospective coders and supplemental vendors are audited on a regular and routine basis by the UPMCHP Quality Assurance Department. Finally, UPMC Revenue Cycle utilizes a "bill hold" for designated claims to verify accuracy based on proper documentation and coding and will either add or redact codes from claims as appropriate.

VII. Conclusion

UPMCHP appreciates the opportunity to comment on the Draft Report. UPMCHP respectfully submits that OIG should not finalize the Draft Report or any of its three recommendations because as UPMCHP has outlined above, the OIG has not provided the requested information and has changed audit methodology unilaterally. The audit raises multiple important and complex legal and policy issues regarding how to identify and quantify overpayments to Medicare Advantage plans. Some of these are issues that are currently before CMS as it considers whether to make revisions to the RADV audit process.

As the OIG has requested, information on specific coding and sample cases that contain private health information have been transmitted to the OIG through its protected portal.

We appreciate the professional courtesies exhibited by the OIG staff in all of their interactions with UPMCHP, and we appreciate the opportunity to set forth our response to the draft you have provided. Please contact me if you have any questions or concerns, or if you would like to discuss anything in this response letter in more detail.

[73] Draft Report, p. 18.

Sincerely,

Gordon Gebbens
Senior Vice President of Finance
and Chief Financial Officer

cc: Ms. Sheryl A. Kashuba
General Counsel

Mr. John Wisniewski
Chief Actuary

Attachments

Exhibit A - Letter of Benjamin S. Wilner, Ph.D., dated May 25, 2021

Exhibit B - CMS, "Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Validation Contract-Level Audits" (Feb. 24, 2012)

NOTE: Additional medical record documentation supporting this letter has been separately transmitted to OIG via a protected portal established by OIG.