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Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UnitedHealthcare of Wisconsin, Inc. (Contract H5253), Submitted to CMS

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Why OIG Did This Audit

- Under the Medicare Advantage (MA) program, CMS makes monthly payments to MA organizations based in part on the health status of the enrollees being covered.
- 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.
- This audit of UnitedHealthcare of Wisconsin, Inc. (United), is part of a series of audits of high-risk diagnosis codes that MA organizations submitted to CMS for use in its risk adjustment program.

What OIG Found

Most of the selected diagnosis codes that United submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements.

- For 183 of the 250 sampled enrollee-years, medical records did not support the diagnosis codes and resulted in $722,280 in overpayments.
- On the basis of our sample results, we estimated that United received at least $46.9 million in overpayments for 2020 and 2021.

As demonstrated by the errors found in our sample, United's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements could be improved.

What OIG Recommends

We made four recommendations, including that United refund to the Federal Government the $46.9 million in estimated overpayments. The full recommendations are in the report.

United disagreed with some of our findings and requested that we withdraw all our recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

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

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS.[2] Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 56 breast cancer diagnoses into 1 group.) This audit covered UnitedHealthcare of Wisconsin, Inc. (United), for contract number H5253, and focused on 11 groups of high-risk diagnosis codes for payment years 2020 and 2021.[3, 4]

OBJECTIVE

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

BACKGROUND

Medicare Advantage Program

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

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

[2] MA compliance audit reports issued by the Office of Inspector General (OIG) are published on the OIG website.

[3] All subsequent references to "United" in this report refer solely to contract number H5253.

[4] The 2020 and 2021 payment year data were the most recent data available at the start of the audit.

traditional fee-for-service (FFS) program.[5] Individuals who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

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

For 2024, CMS paid MA organizations $494 billion, which represented 44 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.[6]

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.[7] 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.[8]

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

[5] 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.

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

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

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

process results in an individualized risk score for each enrollee, which CMS calculates annually.

To determine an enrollee's health status for purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from acceptable data sources, including certain physicians and hospitals. MA organizations collect the diagnosis codes from providers based on information documented in the medical records and submit these codes to CMS. CMS then maps certain diagnosis codes, on the basis of similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs).[9] 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 receive diagnoses that map to four or more HCCs, CMS assigns an additional factor that increases the enrollee's risk score. Additionally, for enrollees who have certain combinations of HCCs (which CMS refers to as disease interactions), CMS assigns a separate factor that will also increase the risk score. For example, if MA organizations submit diagnosis codes for an enrollee that map to the HCCs for lung cancer and immune disorders, CMS assigns a separate factor for this disease interaction. By doing so, CMS increases the enrollee's risk score for each of the two HCC factors and by an additional factor for the disease interaction.

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

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

[9] During our audit period, CMS calculated risk scores based on the Version 22 and Version 24 CMS-HCC models.

sequestration reduction.[10] Thus, if the factors used to determine an enrollee's risk score are incorrect, CMS will make an improper payment to an MA organization. Specifically, if medical records do not support the diagnosis codes that an MA organization submitted to CMS, the HCCs are not validated, which causes overstated enrollee risk scores and overpayments from CMS.[11] Conversely, if medical records support the diagnosis codes that an MA organization did not submit to CMS, validated HCCs may not have been included in enrollees' risk scores, which may cause those risk scores to be understated and may result in underpayments.

High-Risk Groups of Diagnoses

Using data mining techniques and discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. For this audit, we focused on 11 high-risk groups:

- *Acute stroke*: An enrollee received an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on physician claims for one to five dates of service during the service year but did not have an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim.[12] In these instances, a diagnosis of history of stroke (which does not map to an HCC) typically should have been used.

- *Acute myocardial infarction*: An enrollee received a diagnosis (that mapped to the HCC for Acute Myocardial Infarction) on physician or outpatient claims for one to five dates of service during the service year but did not have an acute myocardial infarction diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician or outpatient claim). In these instances, a diagnosis indicating a history of a myocardial infarction (which does not map to an HCC) typically should have been used.

- *Embolism*: An enrollee received a diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease With Complications (Embolism HCCs) on only one date of service during the service year but did not have an anticoagulant medication

[10] 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. Sequestration was suspended for payment months May 2020 through March 2022, which covered 20 months of our audit period.

[11] 42 CFR § 422.310(e) requires MA organizations (when undergoing an audit conducted by the Secretary) to submit "medical records for the validation of risk adjustment data." For purposes of this report, we use the terms "supported" or "not supported" to denote whether the reviewed diagnoses were evidenced in the medical records. If our audit determines that the diagnoses are supported or not supported, we accordingly use the terms "validated" or "not validated" with respect to the associated HCC.

[12] For all the high-risk groups, an enrollee could have had more than one claim (with a diagnosis code that mapped to the HCC under review) on a date of service.

dispensed on his or her behalf. An anticoagulant medication is typically used to treat an embolism. In these instances, a diagnosis of history of embolism (an indication that the provider is evaluating a prior acute embolism diagnosis, which does not map to an HCC) typically should have been used.

- *Lung cancer*: An enrollee received a lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) on only one date of service during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period either before or after the diagnosis. In these instances, a diagnosis of history of lung cancer (which does not map to an HCC) typically should have been used.

- *Breast cancer*: An enrollee received a breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one date of service during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of breast cancer (which does not map to an HCC) typically should have been used.

- *Colon cancer*: An enrollee received a colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) on only one date of service during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of colon cancer (which does not map to an HCC) typically should have been used.

- *Prostate cancer*: An enrollee 74 years old or younger received a prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one date of service during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of prostate cancer (which does not map to an HCC) typically should have been used.

- *Ovarian cancer*: An enrollee received an ovarian cancer diagnosis that mapped to either the HCC for Lymphoma and Other Cancers or to the HCC for Metastatic Cancer and Acute Leukemia (Ovarian Cancer HCCs) on only one date of service during the service year but did not have surgical therapy or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of ovarian cancer (which does not map to an HCC) typically should have been used.

- *Sepsis*: An enrollee received a sepsis diagnosis (that mapped to the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock) on only one date of service

on a physician or outpatient claim during the service year but did not have a sepsis diagnosis on a corresponding inpatient hospital claim. A sepsis diagnosis generally results in an inpatient hospital admission.

- *Pressure Ulcer*: An enrollee received a pressure ulcer diagnosis[13] that mapped to either the HCC for Pressure Ulcer of Skin With Full Thickness Skin Loss or the HCC for Pressure Ulcer of Skin With Necrosis Through to Muscle, Tendon, or Bone (Pressure Ulcer HCCs) on only one date of service during the service year but did not have a pressure ulcer diagnosis on another inpatient, outpatient, or physician claim for either the calendar year before or the calendar year after the service year. Individuals diagnosed with the most severe types of pressure ulcers generally receive treatment on multiple occasions.

- *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 (that mapped to a possibly unvalidated HCC). For example, International Classification of Diseases (ICD)-10 diagnosis code E43 (which maps to the HCC for Protein-Calorie Malnutrition) could be mis-keyed as diagnosis code I43 (which maps to the HCC for Congestive Heart Failure and in this example would be unvalidated).[14] Using an analytical tool that we developed, we identified 3,973 scenarios in which diagnosis codes could have been mis-keyed because numbers were transposed, or other data-entry errors occurred that could have resulted in the assignment of an unvalidated HCC.

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

UnitedHealthcare of Wisconsin, Inc.

United is an MA organization based in Minneapolis, Minnesota. As of December 2021, United provided coverage under contract number H5253 to 676,374 enrollees. For the 2020 and 2021 payment years (audit period), CMS paid United approximately $16.6 billion to provide coverage to its enrollees.[15]

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to 1 of the 11 high-risk groups during the 2019 and 2020 service years, for which

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

[14] See footnote 1 for an explanation of the ICD coding system.

[15] All of the overpayment amounts that we identified in this report reflect the budget sequestration reduction percentages that were in effect during our audit period.

United received increased risk-adjusted payments for payment years 2020 and 2021, respectively. Because enrollees could be classified into more than one high-risk group or could have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment year, which we refer to as "enrollee-years."

We identified 28,410 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes ($64,458,294). We selected for audit a sample of 250 enrollee-years, which comprised: (1) a stratified random sample of 200 (out of 28,279) enrollee-years for the first 10 high-risk groups, and (2) a nonstatistical sample of 50 (out of 131) enrollee-years for the remaining high-risk group.

Table 1 details the number of sampled enrollee-years for each high-risk group.

Table 1: Sampled Enrollee-Years

High Risk Group	Number of Sampled Enrollee Years
(1) Acute stroke	20
(2) Acute myocardial infarction	20
(3) Embolism	20
(4) Lung cancer	20
(5) Breast cancer	20
(6) Colon cancer	20
(7) Prostate cancer	20
(8) Ovarian cancer	20
(9) Sepsis	20
(10) Pressure ulcer	20
Total for Stratified Random Sample	**200**
(11) Potentially mis-keyed diagnosis codes	50
Total for All High-Risk Groups	**250**

United provided medical records as support for the selected diagnosis codes associated with 247 of the 250 sampled enrollee-years.[16] We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. For the HCCs that were not validated, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or if we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

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

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

FINDINGS

With respect to the 11 high-risk groups covered by our audit, most of the selected diagnosis codes that United submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 67 of the 250 sampled enrollee-years, the medical records validated the reviewed HCCs.[17] For the remaining 183 enrollee-years, however, either the medical records that United provided did not support the diagnosis codes or United could not locate the medical records to support the diagnosis codes; therefore, the associated HCCs were not validated and resulted in $722,280 in overpayments.

As demonstrated by the errors found in our sample, United's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that United received at least $46.9 million in overpayments for 2020 and 2021.[18, 19]

FEDERAL REQUIREMENTS

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

[17] For 1 enrollee-year, United informed us that it could not locate the associated medical record because the record was seized as part of an on-going law enforcement investigation. CMS provides guidance for medical records that are unavailable because of "extraordinary circumstances" (Contract-Level Risk Adjustment Data Validation CMS Submission Instructions). Based on our assessment of the information provided by United, we determined that an extraordinary circumstance prevented United from locating the medical record for this enrollee-year, and we treated the sample item as a non-error.

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

[19] Specifically, we estimated that United received at least $46,913,121 of overpayments ($46,668,024 for the statistically sampled enrollee-years plus $245,097 for the nonstatistically sampled enrollee-years associated with the potentially mis-keyed diagnosis codes).

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

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

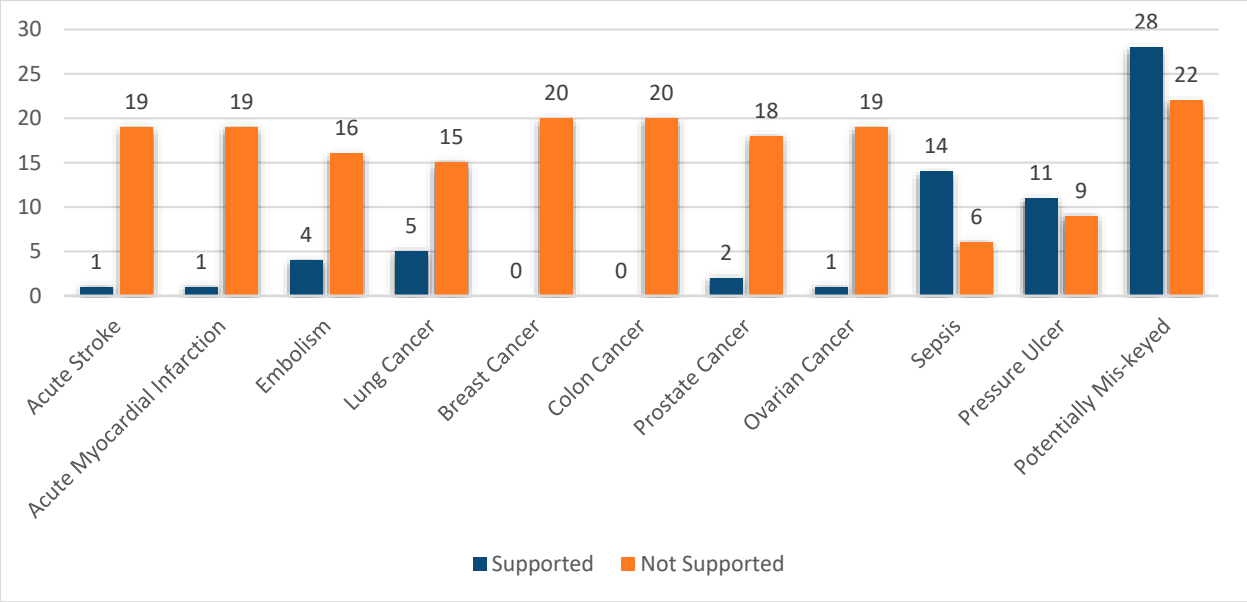
CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap. 7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7, § 40). The diagnosis must be coded according to the ICD, Clinical Modification, *Official Guidelines for Coding and Reporting* (42 CFR § 422.310(d)(1) and 45 CFR §§ 162.1002(c)(2)-(3)). Further, MA organizations must implement procedures to ensure that diagnoses come only from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities, and physicians (the Manual, chap. 7, § 40).

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

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

Most of the selected high-risk diagnosis codes that United submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, as shown in the figure on the following page, for 183 of the 250 sampled enrollee-years either the medical records that United provided did not support the diagnosis codes or United could not locate the medical records to support the diagnosis codes. In these instances, United should not have submitted the diagnosis codes to CMS and received the resulting overpayments.

Figure: Analysis of High-Risk Groups



Incorrectly Submitted Diagnosis Codes for Acute Stroke

United incorrectly submitted diagnosis codes for acute stroke for 19 of 20 sampled enrollee-years. Specifically:

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

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC under review. There is documentation of a past medical history of cerebrovascular accident (CVA) [diagnosis] which does not result in an HCC."[20]

- For 2 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of an acute cerebrovascular accident (CVA) that results in the assignment of the HCC under review."

- For 1 enrollee-year, United submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiparesis (which

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

was supported by the medical records).[21] The independent medical review contractor stated that "there is no documentation of [a] . . . CVA, however, the patient has [a] left sided hemiparesis [diagnosis] from an old CVA which should have been assigned instead of the submitted HCC." The diagnosis for hemiparesis maps to the HCC for Hemiplegia/Hemiparesis. Accordingly, United should not have received a payment for the acute stroke diagnosis but instead should have received a payment for the hemiparesis diagnosis.

- For the remaining 1 enrollee-year, United could not locate any medical records to support the acute stroke diagnosis; therefore, the HCC for Ischemic or Unspecified Stroke was not validated.

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and United received $37,931 in overpayments for these 19 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Myocardial Infarction

United incorrectly submitted diagnosis codes for acute myocardial infarction for 19 of 20 sampled enrollee-years. Specifically:

- For 9 enrollee-years, the medical records in each case did not support an acute myocardial infarction diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis on CMS's systems that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, United should not have received an increased payment for the acute myocardial infarction diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

- For 8 enrollee-years, the medical records indicated in each case that the individual had previously had an acute myocardial infarction, but the records did not justify an acute myocardial infarction diagnosis at the time of the physician's service.[22]

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC under review. There is documentation of a past medical history of myocardial infarction [diagnosis] which does not result in an HCC."

[21] Hemiparesis is weakness or inability to move on one side of the body. Moreover, hemiplegia (mentioned later in this bullet) is defined as complete paralysis or loss of function of one-half of the body, including one leg and arm, because of injury or disease in the motor centers of the brain.

[22] For 1 of these enrollee-years, we found in CMS's encounter data a diagnosis code submitted by United that mapped to an HCC for a less severe manifestation of the heart attack related-disease group. The less severe HCC had the same numerical factor as the HCC under review, so although we counted this sample item as an error, there was no payment effect.

- For the remaining 2 enrollee-years, the medical records in each case did not support an acute myocardial infarction diagnosis.

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

As a result of these errors, the HCC for Acute Myocardial Infarction was not validated, and United received $33,569 in overpayments for these 19 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

United incorrectly submitted diagnosis codes for embolism for 16 of 20 sampled enrollee-years. Specifically:

- For 10 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not justify a diagnosis that mapped to an Embolism HCC at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC under review. There is documentation of a past medical history of deep vein thrombosis (DVT) [diagnosis] which does not result in an HCC."[23]

- For the remaining 6 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Embolism HCC.

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

As a result of these errors, the Embolism HCCs were not validated, and United received $43,665 in overpayments for these 16 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

United incorrectly submitted diagnosis codes for lung cancer for 15 of 20 sampled enrollee-years. Specifically:

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

- For 9 enrollee-years, the medical records indicated in each case that the individual had previously had lung cancer, but the records did not justify a lung cancer diagnosis at the time of the physician's service.

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

- For 5 enrollee-years, the medical records in each case did not support a lung cancer diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis on CMS's systems that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, United should not have received an increased payment for the lung cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

- For the remaining 1 enrollee-year, the medical records did not support a lung cancer diagnosis. The independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC under review."

As a result of these errors, the HCC for Lung and Other Severe Cancers was not validated, and United received $102,240 in overpayments for these 15 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

United incorrectly submitted diagnosis codes for breast cancer for all 20 sampled enrollee-years. For all 20 enrollee-years, the medical records indicated in each case that the individual had previously had breast cancer, but the records did not justify a breast cancer diagnosis at the time of the physician's service.

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

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and United received $25,086 in overpayments for these 20 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

United incorrectly submitted diagnosis codes for colon cancer for all 20 sampled enrollee-years. Specifically:

- For 16 enrollee-years, the medical records indicated in each case that the individual had previously had colon cancer, but the records did not justify a colon cancer diagnosis at the time of the physician's service.

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

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

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

- For the remaining 1 enrollee-year, the medical record did not support the submitted colon cancer diagnosis. However, for this enrollee-year, we identified support for another diagnosis on CMS's systems that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, United should not have received an increased payment for the submitted colon cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and United received $47,190 in overpayments for these 20 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

United incorrectly submitted diagnosis codes for prostate cancer for 18 of 20 sampled enrollee-years. Specifically:

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

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

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

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and United received $22,215 in overpayments for these 18 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Ovarian Cancer

United incorrectly submitted diagnosis codes for ovarian cancer for 19 of 20 sampled enrollee-years. Specifically:

- For 13 enrollee-years, the medical records indicated in each case that the individual had previously had ovarian cancer, but the records did not justify an ovarian cancer diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC under review. There is documentation of a past medical history of ovarian cancer [diagnosis] which does not result in an HCC. Based on the documentation, the patient has a history of ovarian cancer, supported by a documented hysterectomy in the surgical history."

- For 3 enrollee-years, the medical records in each case did not support the submitted ovarian cancer diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis on CMS's systems that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, United should not have received an increased payment for the submitted ovarian cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

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

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

As a result of these errors, the Ovarian Cancer HCCs were not validated, and United received $98,203 in overpayments for these 19 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Sepsis

United incorrectly submitted diagnosis codes for sepsis for 6 of 20 sampled enrollee-years. Specifically:

- For 4 enrollee-years, the medical records indicated in each case that the individual had previously had sepsis, but the records did not justify a sepsis diagnosis at the time of the physician's service.

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

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

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

As a result of these errors, the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock was not validated, and United received $17,479 in overpayments for these 6 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Pressure Ulcer

United incorrectly submitted diagnosis codes for pressure ulcer for 9 of 20 sampled enrollee-years. Specifically:

- For 7 enrollee-years, the medical records in each case did not support the submitted pressure ulcer diagnosis.[24] However, for each of these enrollee-years, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, United should not have received an increased payment for the submitted pressure ulcer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

- For 1 enrollee-year, the medical record did not support a pressure ulcer diagnosis. The independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC under review. There is documentation of a sacral pressure ulcer, unspecified stage [diagnosis] which does not result in an HCC."[25]

- For the remaining 1 enrollee-year, United could not locate any medical records to support the pressure ulcer diagnosis; therefore, the Pressure Ulcer HCCs could not be validated.

[24] For 1 of these enrollee-years, the independent medical review contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code. For the remaining 6 enrollee-years, we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group.

[25] A sacral pressure ulcer, unspecified stage, refers to a pressure ulcer in an area of the lower spine called the sacrum.

As a result of these errors, the Pressure Ulcer HCCs were not validated, and United received $49,605 in overpayments for these 9 sampled enrollee-years.

Potentially Mis-keyed Diagnosis Codes

United submitted potentially mis-keyed diagnosis codes for 22 of 50 sampled enrollee-years. In each of these cases, the individuals associated with the enrollee-years received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition. Specifically:

- For 11 enrollee-years, the medical records in each case did not support the diagnosis for the unrelated condition. However, for each of these enrollee-years, we identified support for another diagnosis on CMS's systems that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, United 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 9 enrollee-years, the medical records in each case did not support the diagnosis for the unrelated condition. Because of these errors, United submitted unsupported diagnosis codes that mapped to unvalidated HCCs to CMS.[26]

  For example, for 1 enrollee-year, United submitted four diagnosis codes for mixed hyperlipidemia (E78.2), and only one diagnosis code for secondary malignant neoplasm of pleura (C78.2) to CMS.[27, 28] The independent medical review contractor limited its review to the secondary malignant neoplasm of pleura diagnosis, for which it did not find support.

- For the remaining 2 enrollee-years, the medical records indicated in each case that the individual had previously had the submitted diagnosis, but the records did not justify the diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC

[26] For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources (a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3)); the Manual, chap. 7, §§ 40 and 120.1). For 1 of these enrollee-years, the medical record that United provided to support the reviewed HCC was a stress echocardiogram, which is a diagnostic radiology service. Because this record did not meet CMS's requirements for acceptable data sources (it did not reflect a face-to-face encounter), we could not make a coding determination, and therefore the reviewed HCC could not be validated.

[27] Mixed hyperlipidemia is a condition characterized by elevated levels of both cholesterol and triglycerides in the blood.

[28] Malignant neoplasms are cancerous tumors that develop when cells grow and divide more than they should; pleura are the thin membranes surrounding the lungs and lining the chest cavity.

under review. There is documentation of a past medical history of malignant neoplasm metastatic to lung [diagnosis] which does not result in an HCC."

Appendix E contains the HCCs that were not validated for the 22 enrollee-years (Table 5) and the HCCs for the less severe manifestation of the related-disease group that were supported for the 11 enrollee-years (Table 6).

As a result of these errors, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated, and United received $245,097 in overpayments for these 22 sampled enrollee-years.

Summary of Incorrectly Submitted Diagnosis Codes

In summary, and with respect to the 11 high-risk groups covered by our audit, United received $722,280 in overpayments for 183 of the 250 sampled enrollee-years.

THE POLICIES AND PROCEDURES THAT UNITED HAD TO PREVENT, DETECT, AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS COULD BE IMPROVED

As demonstrated by the errors found in our sample, the policies and procedures that United had to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations (42 CFR § 422.503(b)(4)(vi)), could be improved.

As part of its preventative measures, United had compliance procedures in place that consisted of a variety of provider-specific outreach efforts to provide clarification on coding matters. These efforts included distribution of periodic newsletters and performance of annual internal compliance reviews of provider coding practices. United used the results of these reviews to provide training opportunities to providers on topics such as: coding guidelines, common coding errors, documentation requirements, and some areas identified in this audit.

United's compliance review process also included detection and correction measures to determine whether the diagnosis codes that United submitted to CMS were correct. For example, United reviewed previously submitted claims and if it found any diagnosis codes that were not supported, it allowed providers 30 days to provide additional supporting documentation. If United determined that the additional documentation did not support the diagnosis codes, it submitted those codes for deletion to CMS.

Additionally, United required its coders to adhere to various measures. Specifically, United required all newly hired coders to complete 156 hours of coding training and to undergo coding practice tests. The practice tests included modules on how to properly code cancers, acute strokes, and myocardial infarctions. All coders are required to maintain a 95-percent accuracy rate and are subject to multiple internal reviews throughout the year to help identify areas where further education may be needed.

United also had a data filter in place to identify acute stroke claims submitted on physicians' claims and to prevent those claims from being processed for payment. When asked about the errors that we identified for the acute stroke high-risk group, United officials stated that the data filter was designed to prevent the submission of inaccurate acute stroke diagnosis codes on in-home health and wellness visits and chart review claim type. However, these officials added that this filter applied only to those specific claim types and did not apply to diagnoses on claims originating from other sources, including those submitted directly from providers.

We acknowledge that United had compliance procedures in place during the audit period that included measures designed to ensure that diagnosis codes, including some of the diagnoses that we classified as high risk for being miscoded, comply with Federal requirements. However, because we found that 183 of the 250 sampled enrollee-years were not supported by medical records, we believe that these procedures, as they relate to diagnoses that are at high risk for being miscoded, could be improved.

UNITED RECEIVED OVERPAYMENTS

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that United received at least $46,913,121 in overpayments for our audit period.

RECOMMENDATIONS

We recommend that UnitedHealthcare of Wisconsin, Inc.:

- refund to the Federal Government the $46,913,121 of estimated overpayments;[29]

- determine, for the 81 enrollee-years that we did not review in the potentially mis-keyed diagnosis code high-risk group, whether the medical records in each case support the diagnosis for the unrelated condition and refund any resulting overpayments to the Federal Government;

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

- continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being

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

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.

UNITED COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, United disagreed with some of our findings and requested that we reconsider our draft report and withdraw all of our recommendations. More specifically, United did not agree with our findings for 33 of the 191 enrollee-years in error that our draft report had identified. For these 33 enrollee-years, United discussed (in an attachment to its written comments) why it believed that the medical records that it previously gave us validated the reviewed HCCs. United did not directly agree or disagree with our findings for the remaining 158 enrollee-years.

United stated that our recommendations "are based on audit and extrapolation methodologies that are fundamentally flawed and conclusions unsupported by the facts." Additionally, United indicated that it is not broadly obligated to perform additional reviews, and that its "robust compliance practices have proven effective."

With respect to our first recommendation, we reviewed United's comments and the additional information that it provided (in the attachment to those comments) and, accordingly, reduced the number of enrollee-years in error from 191 (in our draft report) to 183 and adjusted our calculation of overpayments for this final report. We maintain that our other recommendations remain valid.

A summary of United's comments and our responses follow. United's comments appear as Appendix F. We excluded an attachment (which United identified as Appendix A in its comments) because it contained personally identifiable information. We are separately providing United's comments and the attachment in its entirety to CMS.

UNITED REQUESTED THAT THE OIG WITHDRAW ITS RECOMMENDATION TO REFUND OVERPAYMENTS

United Did Not Agree With OIG's Findings for 33 Sampled Enrollee-Years

United Comments

United did not agree with our findings for 33 of the sampled enrollee-years (as shown in Table 2 on the following page) and discussed why it believed that the medical records that it previously gave us for these 33 enrollee-years validated the reviewed HCCs.

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

High Risk Group	Number of Sampled Enrollee Years
Potentially mis-keyed diagnoses	11
Acute myocardial infarction	5
Lung cancer	5
Sepsis	3
Breast cancer	2
Embolism	2
Ovarian cancer	2
Prostate cancer	2
Colon cancer	1
Total	**33**

United's comments elaborated on its disagreement with some of our findings. United stated that our audit "was premised on a review of clinical criteria for the sampled diagnoses, as opposed to a true coding review . . . ." Additionally, United stated that our methodology "is in direct conflict with CMS's official coding guidelines which say that the provider's statement that the patient has a particular condition is sufficient." United cited specific examples for 2 sampled enrollee-years and explained why it believed that the medical records that it previously gave us validated the reviewed HCCs. United stated that reversing the decisions on the 33 sampled enrollee-years "would reduce the OIG's estimated overpayment amount by about $9 [million] . . . ."

OIG Response

The independent medical review contractor reviewed the additional information that United provided for the 33 sampled enrollee-years.

- For 25 of the 33 enrollee-years, the independent medical review contractor reaffirmed that the HCCs were not validated.

- For 8 of the 33 enrollee-years, the contractor found support for the audited HCCs and therefore reversed its original decision and validated the HCCs.[30]

Accordingly, we revised some of our findings and reduced the number of enrollee-years in error from 191 (in our draft report) to 183 for this final report. We also reduced the associated monetary recommendation. The independent medical review contractor confirmed that the additional information that United gave to us had no impact on the decisions that the contractor had made for other sampled enrollee-years.

[30] The 8 enrollee-years were in the following high-risk groups: potentially mis-keyed diagnoses (4), lung cancer (2), and sepsis (2).

With respect to United's comments regarding our medical review methodology, we asked our independent medical review contractor to review all the medical records United gave us to determine whether the information documented in the medical records supported any diagnoses that mapped to the reviewed HCC. Medicare requirements are clear that for a diagnosis code that has been submitted to CMS to be appropriately included in the calculation of the risk score, the diagnosis needs to be documented in, and supported by, an acceptable medical record.

During its review, the independent medical review contractor did not make clinical judgments but rather used applicable coding and documentation standards to accurately assign the appropriate diagnosis codes that translate to HCCs. This methodology is in line with the methodology CMS follows in its Risk Adjustment Data Validation (RADV) audits and was communicated to United before our issuance of the draft report.

United Stated That the OIG Cannot Determine That Medicare Advantage Organizations Are Overpaid Without Applying a Fee-For-Service Adjuster

United Comments

United stated that CMS used traditional Medicare FFS data "with known discrepancies to set MA [payment] rates" and that because our audit identified the same types of coding errors, we "cannot determine that MA [organizations] are overpaid without applying an FFS adjuster." According to United, the high-risk diagnosis codes reviewed in our audit "were made and typically certified as accurate by providers," and the Federal Government is aware that "[p]roviders submit erroneous codes in both the FFS Medicare program and the MA program." Additionally, United noted that CMS has acknowledged that MA organizations "'cannot reasonably be expected to know whether every piece of data is correct.'"[31]

Furthermore, United cited Federal statute that requires CMS "to develop a risk adjustment model that ensures actuarial equivalence between MA payments and the cost that FFS Medicare would expect to incur if it provided the benefits directly."[32] United stated that "[t]his principle is so important to the MA payment model that [the Act] require[d] CMS to report to Congress the actuarial soundness of the agency's risk adjustment methodology."

United also pointed to the 2023 RADV Final Rule, "which eliminated the FFS Adjuster for Payment Years 2018 and beyond," and to a recent U.S. District Court ruling that vacated and

[31] United cited 65 Fed. Reg. 40170, 40268 (June 29, 2000).

[32] United cited 42 U.S.C. § 1395w-23(a)(1)(C).

remanded this final rule.[33, 34] United stated that the Court held "that the rule was invalid because CMS did not provide commenters with adequate notice about the rationale that it ultimately adopted as the basis for the rule." United also stated that following this decision and "pending its appeal, CMS's 2012 RADV methodology is applicable" and that "the use of an FFS Adjuster in extrapolation is required to ensure actuarial equivalence in MA payments."

Furthermore, United stated that for an audit to determine whether an MA organization was overpaid, it "would have to show that [the MA organization] had relatively more and costlier discrepancies than the FFS data collected in similar circumstances used to determine risk adjustment coefficients." According to United, "[b]ecause the OIG has failed to account for discrepancies in the underlying FFS data, it has no reasonable basis for its conclusions under [GAGAS] and its recommendation for United to refund the alleged overpayment lacks sufficient support."

OIG Response

Regarding United's statement that an FFS adjuster is required to ensure actuarial equivalence, we acknowledge a U.S. District Court ruling that vacated and remanded the final rule. However, this ruling does not impact our findings or cause us to change our recommendations. Notwithstanding this ruling, CMS has not issued any requirements that compel us to reduce our overpayment calculations. Our audit methodology correctly applied CMS requirements to properly identify the overpayment amount associated with the HCCs that were not validated for each sample item. We followed CMS's risk adjustment program requirements to determine the payment that CMS should have made for each enrollee-year and to estimate overpayments.

Moreover, United's comments implied that we are opining on the effectiveness of its entire compliance program and on its responsibilities to know that "every piece of data is correct." That was not our intention or our focus for this audit. Rather, we limited our audit to selected diagnoses that we determined to be at high risk for being miscoded. Our audit revealed a substantial error rate for all of these high-risk groups. Accordingly, we note that Federal regulations require MA organizations to implement procedures for "promptly responding to compliance issues as they are raised" and to "[correct] such problems promptly and thoroughly to reduce the potential for recurrence" (42 CFR § 422.503(b)(4)(vi)(G)). These Federal regulations apply to diagnosis codes originating on provider submissions—including the high-

[33] All subsequent references to "final rule" in this report refer solely to the CMS's 2023 RADV Final Rule, 88 Fed. Reg. 6643 (Feb. 1, 2023).

[34] United cited *Humana Inc. v. Becerra*, 801 F.Supp.3d 624 (N.D. Tex. Sept. 25, 2025), which can be found at: https://www.govinfo.gov/content/pkg/USCOURTS-txnd-4_23-cv-00909/pdf/USCOURTS-txnd-4_23-cv-00909-0.pdf (accessed on Aug. 27, 2026).

risk groups on which we focused—and submitted by MA organizations to CMS for risk adjustment purposes.

We also continue to recognize that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program, including the application of any FFS Adjuster requirements. If CMS deems it appropriate to apply an FFS Adjuster, it will, during the audit resolution process, adjust our overpayment finding by whatever amount it determines necessary. For these reasons, we believe that our recommended refund of overpayments based on our revised findings is appropriate.

United Stated That the Audit Results Are Biased Because the OIG Ignored Underpayments

United Comments

United stated the risk adjustment program "is not intended to determine the actual costs or conditions for particular enrollees. It is a statistical regression that assumes a distribution across a spectrum . . . ." According to United, for us to have identified overpayments in our audit we needed to "consider the existence of both over-coding and under-coding . . . ." United stated that our audit focused only on "diagnosis codes [we] believed were likely to be unsupported in the medical record," and even though we found codes that were determined to be unsupported, "the audit does not show that United was overpaid on the contract." United provided an example stating that although our audit might find that an MA organization was overpaid for one specifically targeted diagnosis, we "did not look beyond [our] predetermined sample to determine whether a[n MA organization] should have been paid for different (even higher-paying) diagnosis codes . . . ."

Additionally, United said that our "decision to limit the population of enrollees audited to those with a certain submitted diagnosis also increased the bias for identifying overpayments." United added that enrollees "without those diagnoses or any submitted diagnosis would likely contain numerous offsetting underpayments, which would lower the alleged overpayment or eliminate it entirely." United accordingly described our audit findings as presenting "an incomplete and inaccurate picture of the overall accuracy of the diagnosis data submitted."

Furthermore, United stated that our "strategy to narrowly target a small number of samples where there is an expectation of discrepancies is flawed and cannot serve as a valid measure of United's performance . . . ." United said that the high-risk groups in this audit "were judgmentally selected . . . based on criteria that the OIG itself developed, rather than through a statistically valid, representative sample of diagnoses across the United contract." To illustrate its point, United referred to other Federal Inspector General reports, noting that "Inspectors General have consistently determined that findings from a judgmentally selected sample

cannot be projected to the population," and that our report's projection is "inconsistent with this longstanding position."[35]

OIG Response

We disagree with United's assertion that our audit was biased toward identification of overpayments. Our objective was to determine whether selected high-risk diagnosis codes that United submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements. We identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into 11 specific high-risk groups. This process involved a carefully designed audit methodology (Appendix A). Our objective did not extend to diagnosis codes not previously submitted by United or to enrollees and their associated HCCs that were beyond the scope of our audit.

For the HCCs that were not validated, if the independent medical review contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or if we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

Additionally, we disagree that our audit methodology was flawed. Our audit methodology used auditor judgment to identify diagnoses that we determined to be at a higher risk for being miscoded and that were therefore at a higher risk of resulting in overpayment. We designed our methodology in accordance with GAGAS, and we believe that it provides a reasonable basis for our findings and conclusions based on our objective. We did not, as United said, project our findings from a judgmentally selected sample to the population; rather, we estimated our findings based on a statistical random sample of enrollee-years (Appendix C). The estimate is applicable only to our sampling frame of enrollee-years and does not extend to enrollee-years that were beyond the scope of our audit. Therefore, we believe that United's statement that we were inconsistent with longstanding positions taken by other Inspector General audits is incorrect.

[35] United referred to reports from the U.S. Department of Housing & Urban Development (report number 2024-FW-0001, issued Oct. 20,2023) and the General Services Administration (report number JE16-002, issued Mar. 30, 2016).

United Stated That the Sample Size Was Too Small for Reliable Statistical Extrapolation

United Comments

United stated that we did not provide "full detail" on the extrapolation methodology we used to calculate the estimated overpayments that we identified. United said that we "may have calculated [our] extrapolated amount by using the standardized . . . formula for a normalized 90% confidence interval," and added that that formula is "generally not recommended for use with very small sample sizes, such as those at the HCC-level in this audit (with only 20 enrollees sampled per condition)." United stated that it would be more appropriate to use a different statistical method that "was created to handle small sample sizes," and "would yield more accurate extrapolation results . . . ." According to United, our "assessment of extrapolated overpayments based on the standardized formula is therefore improper."

OIG Response

Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.[36] The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.[37] We properly executed our statistical sampling methodology in that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.[38] We communicated this information to United during our audit and in the draft report.

Small sample sizes, e.g., smaller than 100, have routinely been upheld by the Department of Health and Human Services (HHS) Departmental Appeals Board and Federal courts.[39] Because

[36] See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

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

[38] We computed the two-sided 90-percent confidence interval using the standard formula provided in chapter 5 of *Sampling Techniques*, Third Edition (1977) by William Cochran.

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

absolute precision is not required,[40] any imprecision in the sample may be remedied by recommending recovery at the lower limit, which was done in this audit. This approach results in an estimate that is lower than the actual overpayment amount 95 percent of the time, and thus it generally favors the auditee.

United Stated That the OIG Failed To Follow CMS's Risk Adjustment Data Validation Audit Rules

United Comments

United stated that we failed to follow CMS's RADV audit methodology and raised several points in this context:

- United stated that we should not recommend to CMS the recovery of overpayments if our audit design did not undergo notice-and-comment rulemaking. United said that doing so "would be arbitrary and capricious and would cause MA [organizations] to have to decide between calibrating their compliance programs to satisfy the OIG or CMS."

- United also stated that we did not provide it with the specific coding and documentation standards that we used to guide the medical record review process. United stated further that "CMS regulation requires [diagnosis] codes to be submitted pursuant to [ICD Coding Guidelines]." According to United, to the extent that we used any "additional, non-regulatory standards" or if our medical record review process "otherwise did not conform to CMS diagnosis coding guidance, this would have skewed the OIG's results and recommendations."

- Moreover, United stated that our audit methodology, which relied on the use of a coding supervisor as a "tiebreaker" in situations where two coders disagree, "conflicts with the approach used in CMS RADV audits." United also stated that if we followed CMS's methodology, it "would result in more diagnoses being appropriately validated because [CMS's methodology] recognizes that a diagnosis supported by any qualified coder's review should be considered valid, rather than introducing an additional subjective layer of review that could produce inconsistent outcomes."

OIG Response

We disagree with United's statements that our audit was required to follow CMS's RADV audit methodology and rules. Specifically:

- We do not agree with United's comments regarding the need for notice-and-comment rulemaking. We did not apply any new regulatory requirements or impose any new legal standards that would be subject to notice-and-comment rulemaking, and in that

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

sense our audit does not make changes to a CMS-administered program. Furthermore, the recommendations that we have made to United, and the recommendations in previous OIG reports in this series of audits, were addressed to the MA organizations, not to CMS.

- We do not agree with United's comment that we did not provide it with the specific coding and documentation standards used in our audit. The independent medical review contractor used the following guidance during its reviews of the diagnosis codes in the medical records: (1) the ICD-10-CM Official Guidelines for Coding and Reporting, (2) the American Hospital Association Coding Clinic for ICD-10-CM and ICD-10-PCS, and (3) the CMS-published *Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance*. We gave this information to United before we issued our draft report.

  With respect to United's reference to CMS's RADV methodology, we note that our audits are intended to provide an independent assessment of HHS programs and operations in accordance with the Inspector General Act of 1978, as amended (5 U.S.C. Ch. 4). Although our approach was generally consistent with the methodology CMS uses in its RADV audits, it did not mirror CMS's approach in all aspects, nor did it have to.

- With respect to United's comments on our use of a coding supervisor as a "tiebreaker" in instances when two coders disagree, the independent medical review contractor used both skilled coders and coding supervisors (when necessary) to review medical record documentation. This approach was in accordance with the relevant CMS guidance,[41] which states that "**reviewers** should evaluate all listed conditions for consistency . . . within the full provider documentation" (emphasis added). The coders and coding supervisors did not make clinical judgments; rather, they applied coding rules to accurately assign applicable ICD codes that translated to HCCs. We believe that the use of a coding supervisor to serve as the final decision maker (i.e., tiebreaker), was a reasonable method for determining whether the medical records adequately supported the reported diagnosis codes.

[41] CMS, Contract-Level Risk Adjustment Data Validation, Medical Record Reviewer Guidance, in effect as of Mar. 20, 2019. Available online at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/Medical-Record-Reviewer-Guidance.pdf (accessed on Oct. 26, 2022).

United Stated That CMS Has Already Recouped the Overpayments for Payment Year 2020 Through the Medical Loss Ratio Rebate Mechanism

United Comments

United stated that the overpayments identified for payment year 2020 "fail[ed] to account for the MLR [Medical Loss Ratio] rebate mechanism."[42] United said that it had remitted to CMS an amount "more than ten times greater than the . . . overpayment alleged by the OIG." United stated that because "CMS has already recovered these funds through the MLR rebate process . . . it is not entitled to a second recovery of the same funds."

OIG Response

United's statement—that CMS has "already recovered these funds through the MLR rebate process" and therefore "is not entitled to a second recovery of the same funds"—raises issues that fall outside the scope of our audit. The MLR rebate mechanism does not alter an MA organization's requirement to submit accurate and complete diagnosis codes for use in CMS's risk adjustment program.

As previously stated, the objective of this audit was to determine whether United submitted diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. OIG findings and recommendations do not represent final determinations by CMS. During the audit resolution process, CMS will determine whether an overpayment exists and will work with United to collect any overpayments consistent with CMS's policies and procedures. United should work with CMS regarding overpayments identified in this report in conjunction with MLR requirements.

UNITED REQUESTED THAT THE OIG WITHDRAW ITS NON-MONETARY RECOMMENDATIONS

United Stated That It Is Not Required To Review Additional Potentially Mis-Keyed Diagnoses or Conduct a Self-Audit of Periods After the Audit Period

United Comments

For our second and third recommendations, United indicated that it is not broadly obligated to perform additional reviews because "CMS regulations do not require United to conduct the type of self-audits that the OIG recommends." Additionally, United stated that "the U.S. Department of Justice, on behalf of CMS, has stated that '[MA organizations] are not required to audit every single diagnosis code they submit.'"[43] United added, though, that it is "willing to

[42] The MLR, as outlined in 42 CFR § 422.2410, requires health care insurers to spend at least 85 percent of premium dollars on medical care and to remit a rebate to CMS if they fail to meet that threshold.

[43] United cited the Joint Brief Regarding Cross-Motions for Summary Judgment at 5, *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, No. 2:16-cv-08697-FMO-PVC (C.D. Cal. Aug 6, 2024).

review the 81 potentially mis-keyed diagnoses referenced by the OIG . . . and refund any confirmed overpayments, provided the OIG supplies a complete list of those diagnoses."

Furthermore, United noted that our audit "does not establish that United's data have relatively more and costlier discrepancies than the FFS data CMS uses to calibrate the risk adjustment model." Therefore, according to United, "there is no basis for additional reviews." United stated that if MA organizations identified similar instances of noncompliance and refunded the resulting overpayment amounts, then they "would be substantially underpaid."

OIG Response

We commend United for its willingness to review the additional potentially mis-keyed diagnoses referenced in our report. After we received United's comments on our draft report, we gave United the list of diagnoses needed to perform the review.

We do not agree, though, with United's interpretation of applicable Federal regulations. Rather, we maintain that our second recommendation regarding the potentially mis-keyed diagnosis codes, and our third recommendation regarding similar instances of high-risk diagnoses that occurred after our audit period, remain valid and conform to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (Appendix D)).

These Federal regulations state that MA organizations must "implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements." These regulations also require MA organizations to implement procedures and a system for investigating "potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence" (42 CFR § 422.503(b)(4)(vi)(G)). Thus, CMS has, through the issuance of these Federal regulations, assigned the responsibility for dealing with potential compliance issues to the MA organizations.

In this regard, CMS has provided additional guidance in chapter 7, § 40, of the Manual, which states:

> If upon conducting an internal review of submitted diagnosis codes, the [MA organization] determines that any diagnosis codes that have been submitted do not meet risk adjustment submission requirements, the plan sponsor is responsible for deleting the submitted diagnosis codes as soon as possible . . . . Once CMS calculates the final risk scores for a payment year, [MA organizations] may request a recalculation of payment upon discovering the submission of inaccurate diagnosis codes that CMS used to calculate a final risk score for a previous payment year and that had an impact on the final payment. [MA organizations] must inform CMS immediately upon such a finding.

Accordingly, we maintain that both our second and third recommendations remain valid.

United Disagreed With Our Recommendation for Enhanced Compliance Procedures

United Comments

United disagreed with our fourth recommendation to enhance its compliance procedures because, it said, "its compliance program is effective and complies with all applicable regulatory requirements." United stated that its "robust compliance practices have proven effective, as demonstrated by its performance in the RADV audits for Payment Years 2011 [through] 2013, which recently found that United's diagnoses are among the most accurate in the industry." United noted that our draft report acknowledged that United had measures in place during the audit period to ensure that diagnosis codes comply with Federal requirements. Finally, United stated that our "recommendation for enhanced compliance procedures exceeds the auditing and monitoring that CMS requires of MA plans."

OIG Response

We do not fully agree with United's statements. We believe that the number of errors identified in our audit (183 of 250 enrollee-years (Appendix C)) demonstrates that United's compliance program could be improved. Thus, we continue to believe that United should continue to examine and enhance its compliance procedures with respect to these high-risk groups of diagnoses. Moreover, we acknowledge (as we stated in our draft report) that United had compliance procedures in place to promote the accuracy of diagnosis codes submitted to CMS to calculate risk-adjusted payments during our audit period. The continued improvement of United's existing procedures (based on the results of this audit) will assist United in attaining better assurance to the "accuracy, completeness and truthfulness" of the risk adjustment data that it submits in the future. Accordingly, we maintain that our fourth recommendation remains valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid United $16,567,845,774 to provide coverage to its enrollees for 2020 and 2021. We identified a sampling frame of 28,410 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2019 and 2020 service years. United received $560,302,642 in payments from CMS for these enrollee-years for 2020 and 2021. We selected for audit 250 enrollee-years with payments totaling $5,685,584.

The 250 enrollee-years included 20 acute stroke diagnoses, 20 acute myocardial infarction diagnoses, 20 embolism diagnoses, 20 lung cancer diagnoses, 20 breast cancer diagnoses, 20 colon cancer diagnoses, 20 prostate cancer diagnoses, 20 ovarian cancer diagnoses, 20 sepsis diagnoses, 20 pressure ulcer diagnoses, and 50 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 $1,254,827 for our sample.

Our audit objective did not require an understanding or assessment of United'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 November 2023 to November 2025.

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:

    - 96 diagnosis codes for acute stroke,
    - 16 diagnosis codes for acute myocardial infarction,
    - 74 diagnosis codes for embolism,
    - 17 diagnosis codes for lung cancer,
    - 56 diagnosis codes for breast cancer,

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

- We developed an analytical tool that identified 3,973 scenarios in which an ICD-10 diagnosis code, when mis-keyed into an electronic claim because of a data transposition or other data-entry error, could result in the assignment of an incorrect HCC to an enrollee's risk score. For each of the 3,973 scenarios, the tool identified a diagnosis code as well as the potentially mis-keyed diagnosis code. Accordingly, we considered the potentially mis-keyed diagnosis codes to be high risk.

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

  - Risk Adjustment Processing System (RAPS)[44] and Encounter Data System (EDS)[45] to identify enrollees who received high-risk diagnosis codes from a physician during the service years,

  - Risk Adjustment System (RAS)[46] to identify enrollees who received an HCC for the high-risk diagnosis codes,

  - Medicare Advantage Prescription Drug System (MARx)[47] to identify enrollees for whom CMS made monthly Medicare payments to United before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix B),

  - EDS[48] to identify enrollees who received specific procedures, and

  - Prescription Drug Event (PDE) file[49] to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.

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

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

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

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

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

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

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

- We identified a sampling frame of 28,410 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes for the 2019 and 2020 service years.

- We selected for audit a sample of 250 enrollee-years, which consisted of:

    - a stratified random sample of 200 (out of 28,279) enrollee-years for the first 10 high-risk groups, and

    - a nonstatistical sample of 50 (out of 131) enrollee-years for the potentially mis-keyed high-risk group (Appendix B).[50]

- We used an independent medical review contractor to perform a coding review for the 247 enrollee-years (footnote 16) to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.[51]

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

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

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

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

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

[50] We selected the 50 enrollee-years with the highest payments for the HCCs under review.

[51] The independent medical review contractor used senior coders, all of whom possessed one or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS), Certified Coding Specialist – Physician-Based (CCS-P), Certified Professional Coder (CPC), and Certified Risk Adjustment Coder (CRC). RHITs have completed a 2-year degree program and have passed an American Health Information Management Association (AHIMA) certification exam. The AHIMA also credentials individuals with CCS and CCS-P certifications and the American Academy of Professional Coders credentials both CPCs and CRCs.

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

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

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

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

- We estimated the total overpayment made to United for the high-risk groups included in the sampling frame for recovery purposes.

- We discussed the results of our audit with United officials.

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

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified United enrollees who: (1) were continuously enrolled in United throughout all of the 2019 or 2020 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 2019 or 2020 or in January of the following year, and (3) received a high-risk diagnosis during 2019 or 2020 that caused an increased payment to United for 2020 or 2021, respectively.

We presented the data for these enrollees to United 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 United. After we performed these steps, our finalized sampling frame consisted of 28,279 enrollee-years.

SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2020 or 2021.

SAMPLE DESIGN AND SAMPLE SIZE

The design for our statistical sample comprised 10 strata of enrollee-years. For the enrollee-years in each respective stratum, each individual received:

- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on physician claims for one to five dates of service during the service year but did not have an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim (13,412 enrollee-years);

- an acute myocardial infarction diagnosis (that mapped to the HCC for Acute Myocardial Infarction) on physician or outpatient claims for one to five dates of service during the service year but did not have an acute myocardial infarction diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician or outpatient claim (5,960 enrollee-years);

- an embolism diagnosis (that mapped to an Embolism HCC) on only one date of service during the service year but did not have an anticoagulant medication dispensed on his or her behalf (1,059 enrollee-years);

- a lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) on only one date of service during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the lung cancer diagnosis administered within a 6-month period before or after the diagnosis (739 enrollee-years);

- a breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one date of service during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the breast cancer diagnosis administered within a 6-month period before or after the diagnosis (2,522 enrollee-years);

- a colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) on only one date of service during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (972 enrollee-years);

- a prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors), for an individual 74 years old or younger, on only one date of service during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (1,742 enrollee-years);

- an ovarian cancer diagnosis (that mapped to an Ovarian Cancer HCC) on only one date of service during the service year but did not have surgical therapy or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (187 enrollee-years);

- a sepsis diagnosis (that mapped to the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock) on only one date of service on a physician or outpatient claim during the service year but did not have a sepsis diagnosis on a corresponding inpatient hospital claim (1,412 enrollee-years); or

- a pressure ulcer diagnosis (that mapped to a Pressure Ulcer HCC) on only one date of service during the service year but did not have a pressure ulcer diagnosis on another inpatient, outpatient, or physician claim for either the calendar year before or the calendar year after the service year (274 enrollee-years).

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

Table 3: Sample Design for Audited High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee-Years	CMS Payment for HCCs in Audited High-Risk Groups	Sample Size
1 – Acute stroke	13,412	$26,923,946	20
2 – Acute myocardial infarction	5,960	12,437,846	20
3 – Embolism	1,059	2,970,670	20
4 – Lung cancer	739	5,642,493	20
5 – Breast cancer	2,522	3,207,242	20
6 – Colon cancer	972	2,416,428	20
7 – Prostate cancer	1,742	2,206,831	20
8 – Ovarian cancer	187	1,039,341	20
9 – Sepsis	1,412	4,540,751	20
10 – Pressure ulcer	274	2,381,251	20
Total – First 10 Strata	**28,279**	**$63,766,799**	**200**

After we selected the 200 enrollee-years, we identified an additional group of 131 enrollee-years, from which we nonstatistically selected 50 enrollee-years that represented individuals who received 1 of the 3,973 potentially mis-keyed diagnosis codes (which mapped to a potentially unvalidated HCC) and multiple instances of diagnosis codes for unrelated conditions. Thus, we selected for audit a total of 250 enrollee-years.

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We sorted the items in each stratum by the enrollee-year (a combination of the enrollee identifier and the payment year being reviewed), then consecutively numbered the items in each stratum in the stratified sampling frame. After generating random numbers according to our sample design, we selected the corresponding frame items for review. We also selected a nonstatistical sample of 50 items, ranked by dollar amount, from the potentially mis-keyed group (footnote 50).

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to estimate the total amount of overpayments in the sampling frame made to United at the lower limit of the two-sided 90-percent confidence

interval (Appendix C). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Details and Results

Audited High-Risk Groups	Frame Size	CMS Payments for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payments for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With HCCs That Were Not Validated	Overpayments for HCCs That Were Not Validated (for Sampled Enrollee-Years)
1 – Acute stroke	13,412	$26,923,946	20	$39,627	19	$37,931
2 – Acute myocardial infarction	5,960	12,437,846	20	51,611	19	33,569
3 – Embolism	1,059	2,970,670	20	53,580	16	43,665
4 – Lung cancer	739	5,642,493	20	142,552	15	102,240
5 – Breast cancer	2,522	3,207,242	20	25,086	20	25,086
6 – Colon cancer	972	2,416,428	20	48,442	20	47,190
7 – Prostate cancer	1,742	2,206,831	20	24,733	18	22,215
8 – Ovarian cancer	187	1,039,341	20	107,757	19	98,203
9 – Sepsis	1,412	4,540,751	20	64,137	6	17,479
10 – Pressure ulcer	274	2,381,251	20	158,233	9	49,605
Totals for Statistical Sample	**28,279**	**$63,766,799**	**200**	**$715,159**	**161**	**$477,183**
11 – Potentially mis-keyed diagnoses	131	$691,495	50	$539,668	22	$245,097
Totals – All	**28,410**	**$64,458,294**	**250**	**$1,254,827**	**183**	**$722,280**

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

	Estimated Overpayment for Statistical Sample	Overpayment for Potentially Mis-keyed Diagnosis Group	Total Estimated Overpayments
Point estimate	$51,753,593	$245,097	$51,998,690
Lower limit	46,668,024	245,097	46,913,121
Upper limit	56,839,162	245,097	57,084,259

APPENDIX D: 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 E: BREAKOUT OF POTENTIALLY MIS-KEYED DIAGNOSIS CODES

Table 6: 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)		Overpayments for HCCs That Were Not Validated
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
9	C78.00	Secondary Malignant Neoplasm of Unspecified Lung	Metastatic Cancer and Acute Leukemia	E78.00	Pure Hypercholesterol-emia, Unspecified	$145,607
4	C78.2	Secondary Malignant Neoplasm of Pleura	Metastatic Cancer and Acute Leukemia	E78.2	Mixed Hyperlipidemia	55,596
4	G10	Huntington's Disease	Parkinson's and Huntington's Diseases	I10	Essential (Primary) Hypertension	18,810
1	C82.50	Diffuse Follicle Center Lymphoma, Unspecified Site	Lymphoma and Other Cancers	G82.50	Quadriplegia, unspecified	8,225
1	C18.4	Malignant Neoplasm of Transverse Colon	Colorectal, Bladder, and Other Cancers	N18.4	Chronic Kidney Disease, Stage 4 (Severe)	6,495
1	I62.9	Nontraumatic Intracranial Hemorrhage, Unspecified	Intracranial Hemorrhage	G62.9	Polyneuropathy, Unspecified	3,942
1	M34.1	CR(E)ST Syndrome	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	F34.1	Dysthymic Disorder	3,468

Number of Sampled Enrollee-years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayments for HCCs That Were Not Validated
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
1	C34.31	Malignant Neoplasm of Lower Lobe, Right Bronchus or Lung	Lung and Other Severe Cancers	C43.31	Malignant Melanoma of Nose	2,954
						$245,097

Table 7: Hierarchical Condition Categories (HCCs) That Were Not Validated; However, Support Was Found for a Different HCC

Count of Sampled Enrollee-Years*	Hierarchical Condition Category That Was Not Validated	Hierarchical Condition Category That Was Supported
4	Secondary Malignant Neoplasm of Unspecified Lung	Lung and Other Severe Cancers
3	Secondary Malignant Neoplasm of Unspecified Lung	Lymphoma and Other Cancers
2	Secondary Malignant Neoplasm of Unspecified Lung	Breast, Prostate, and Other Cancers and Tumors
1	Secondary Malignant Neoplasm of Unspecified Lung	Colorectal, Bladder, and Other Cancers
1	Lung and Other Severe Cancers	Breast, Prostate, and Other Cancers and Tumors

*The 11 enrollee-years identified in Table 7 are a subset of the enrollee-years in Table 6.

January 9, 2026

James I. Korn
Regional Inspector General for Audit Services
HHS OIG Office of Audit Services, Region VII
1201 Walnut Street, Suite 1309
Kansas City, MO 64106

Re: UnitedHealthcare's Response to OIG's Draft Report for Audit A-07-24-01214

Dear Mr. Korn:

UnitedHealthcare of Wisconsin, Inc. ("United") respectfully submits this response to the U.S. Department of Health and Human Services ("HHS") Office of Inspector General's ("OIG") Draft Report for Audit No. A-07-24-01214, titled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UnitedHealthcare of Wisconsin, Inc. (Contract H5253) Submitted to CMS* ("Draft Report").

The Medicare Advantage ("MA") program provides healthcare to more than 30 million seniors across the country and has been an increasingly popular choice – with enrollment increasing 80% over the last decade – because it produces better health outcomes, helps limit out-of-pocket costs, and provides a broader array of benefits for seniors than they would receive under traditional Medicare.

When it created MA, Congress instructed the Centers for Medicare and Medicaid Services ("CMS") to compensate Medicare Advantage Organizations ("MAOs") like United fairly for the risks they assume in providing these Medicare benefits. Specifically, Congress required CMS to ensure that payments to MAOs are actuarially equivalent to the payments the agency would expect to make to provide traditional Medicare benefits to the MAOs' enrollees.[1] United respectfully submits that the OIG's audit is inconsistent with these principles and undermines the actuarial foundation of the MA program. For this and other reasons, United requests that the OIG withdraw its Draft Report.

In its Draft Report, the OIG recommends that United:

- Refund an extrapolated alleged overpayment amount,
- Review potentially mis-keyed diagnoses that were not selected for audit,
- Conduct internal audits of additional time periods, and
- Make unspecified improvements to its compliance program.

The OIG's recommendations, however, are based on audit and extrapolation methodologies that are fundamentally flawed and conclusions unsupported by the facts.

- First, many of the diagnoses that the OIG found invalid were in fact supported by the medical records submitted by United.
- Second, the OIG failed to apply an appropriate adjuster to account for the same types of issues present in the underlying data used by CMS to generate risk adjustment

[1] *See* 42 U.S.C. § 1395W-23(a)(I)(C).

coefficients. Had such an adjuster been used, the extrapolated overpayment would have been substantially reduced or eliminated entirely.

- Third, the OIG ignored the fact that the diagnoses they reviewed were made by the beneficiaries' provider and typically certified as accurate by that provider. These were not diagnoses made up by United.
- Finally, the OIG's review was biased by design because it was limited to diagnosis codes that, in the OIG's view, are particularly likely to have been miscoded and excluded members where United was likely to have been underpaid. A comprehensive, contract-wide audit would likely have yielded results consistent with CMS's recently released Risk Adjustment Data Validation ("RADV") audits, which found no net overpayments across many UnitedHealthcare MA plans and confirmed that our coding practices are among the most accurate in the industry.

Given these concerns and those outlined below, United respectfully requests that the OIG reconsider its Draft Report and withdraw its recommendations.

I. The OIG's recommendations are based on flawed audit and extrapolation methodologies.

A. The OIG's recommended repayment amount is incorrect because many of the diagnoses that the OIG found invalid are supported by documentation in the relevant medical records.

Based on its review, United disagrees with many of the OIG's determinations that sampled diagnoses are not "substantiated" by documentation in the relevant medical records. United has submitted to the OIG 33 appeals outlined in Appendix A, demonstrating instances where, contrary to the OIG's determination, the sampled diagnoses are supported by provider medical record documentation. In these instances, medical records clearly set forth the audited diagnosis, and the diagnosis has a direct impact on the member's care and associated costs. Despite this, the OIG concluded that documentation was insufficient.

For example, medical records for sample 58 explicitly document the provider's diagnostic statement of "Acute deep vein thrombosis (DVT) of left lower extremity." This is a confirmed diagnosis and directly related to the clinical services being provided, demonstrating that medical records support the reported diagnosis. Likewise, for sample 245, the provider assessed "Metastatic disease to lungs," with no indication of eradication or excision and further noted "No curative options." The OIG's finding of an unsubstantiated diagnosis is inconsistent with provider documentation.

These discrepancies appear to largely be due to the fact that the OIG's audit was premised on a review of clinical criteria for the sampled diagnoses, as opposed to a true coding review, using OIG-developed standards not found in any relevant coding, clinical, or regulatory guidance. In fact, the OIG's methodology is in direct conflict with CMS's official coding guidelines, which say that the provider's statement that the patient has a particular condition is sufficient.[2] United asks the OIG to reconsider its conclusions with respect to the appealed samples and revise

[2] Section I(A)(19), ICD-10-CM Official Guidelines for Coding and Reporting FY 2019; Section I(A)(19), ICD-10-CM Official Guidelines for Coding and Reporting FY 2020 ("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."); *see also*, *United States v. Essence Grp. Holdings Corp.*, No. 17-3273-CV-S-BP, 2020 U.S. Dist. LEXIS 137953, at *18-19 (W.D. Mo. Apr. 29, 2020) (citing the foregoing coding guidelines to support the Court's finding that "a patient's medical condition can be coded even if the patient did not receive treatment for that condition in the prior year.").

both its identified and estimated overpayment amounts accordingly. Making just these corrections would reduce the OIG's estimated overpayment amount by about $9M, based on United's projections.

B. Because the same types of coding issues exist in Medicare Fee-for-Service ("FFS") data, the OIG cannot determine that MA plans are overpaid without applying an FFS adjuster.

The OIG stated in its Draft Report that it reviewed "high-risk" diagnosis codes that are subject to a high rate of discrepancy. These diagnoses were made and typically certified as accurate by providers. Providers submit erroneous codes in both the FFS Medicare program and the MA program. The government is aware of this and has acknowledged that MA plan risk adjustment data will contain discrepancies and that plans "cannot reasonably be expected to know whether every piece of data is correct, nor is that the standard that [CMS], the OIG, and DOJ believe is reasonable to enforce."[3]

As noted above, one of the key concepts in the Medicare risk adjusted payment model is "actuarial equivalence." The Social Security Act ("SSA") requires CMS to develop a risk adjustment model that ensures actuarial equivalence between MA payments and the cost that FFS Medicare would expect to incur if it provided the benefits directly.[4] This principle is so important to the MA payment model that the SSA requires CMS to report to Congress the actuarial soundness of the agency's risk adjustment methodology.

CMS has previously recognized that discrepancies exist in all provider data and acknowledged that it is unfair to use FFS data with known discrepancies to set MA rates and to expect no discrepancies in MAO risk adjustment data in an MA audit. Specifically, in order to account for the discrepancy rates in FFS data in the RADV audits, CMS announced in 2012 that it would apply an "FFS Adjuster" to extrapolated recovery amounts.[5] In 2023, CMS finalized its rule on RADV (the "RADV Final Rule"), which eliminated the FFS Adjuster for Payment Years 2018 and beyond.[6] Humana challenged this rule in federal court and, on September 25, 2025, the United States District Court for the Northern District of Texas vacated the RADV Final Rule, holding that the rule was invalid because CMS did not provide commenters with adequate notice about the rationale that it ultimately adopted as the basis for the rule.[7] Following the *Humana* decision and pending its appeal, CMS's 2012 RADV methodology is applicable. In accordance with that methodology, the use of an FFS Adjuster in extrapolation is required to ensure actuarial equivalence in MA payments.

Because the OIG's audit targeted suspected high-discrepancy diagnoses that exist in all provider data, and the OIG has not calculated or applied an appropriate FFS Adjuster, the need for an appropriately calculated FFS Adjuster is even more apparent. Without one, there is no basis for concluding that the discrepancies identified in this audit represent an actual overpayment. To determine if a plan were overpaid, an audit would have to show that a plan had relatively more and costlier discrepancies than the FFS data collected in similar

[3] Medicare+Choice Program, 65 Fed. Reg. 40,169, 40,268 (June 29, 2000).
[4] *See* 42 U.S.C. § 1395W-23(a)(l)(C).
[5] CMS Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits (Feb. 24, 2012) (stating that "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)")
[6] Policy and Technical Changes to the Medicare Advantage Program for Years 2020 and 2021, 88 Fed. Reg. 6643 (Feb. 1, 2023).
[7] *Humana Inc. v. Becerra*, No. 4:23-cv-00909-O (N.D. Tex. Sept. 25, 2025).

circumstances used to determine risk adjustment coefficients. In order to make that determination, the OIG would need to apply an FFS Adjuster specific to the audit's targeted population of codes utilizing the same selection criteria. Because the OIG has failed to account for discrepancies in the underlying FFS data, it has no reasonable basis for its conclusions under generally accepted government auditing standards and its recommendation for United to refund the alleged overpayment lacks sufficient support.

C. The audit's results are biased because the OIG largely ignores member underpayments.

The risk adjustment model is not intended to determine the actual costs or conditions for particular enrollees. It is a statistical regression that assumes a distribution across a spectrum, with providers over-coding some conditions while under-coding others. To identify an overpayment under this model, consistent with the requirement of actuarial equivalence, the OIG must consider the existence of both over-coding and under-coding in the plan's risk adjustment data.

The OIG focused its audit only on diagnosis codes it believed were likely to be unsupported in the medical record. While it has found some codes that were not supported, the audit does not show that United was overpaid on the contract. To do that, the OIG would have had to look across the contract for potential overpayments and underpayments. This principle is demonstrated in the contract-wide RADV audits that CMS conducted for Payment Years 2011-2013, which recently found that overpayments on some members were routinely balanced by underpayments on others.

The OIG's targeted audit methodology is inconsistent with the principle of actuarial equivalence that is a cornerstone of the MA program. The OIG did not build a representative sample of member diagnosis codes from across the full range of reported diagnoses. Rather, the OIG identified diagnosis codes that it believed were at particularly high risk of being miscoded in one direction – miscoding that generates alleged overpayments – and limited its review to payments that were associated with the identified high-risk diagnosis codes.[8] This deliberately one-sided review does not produce an accurate account of overall payment accuracy. For example, the OIG may have determined that the plan was inappropriately paid for one diagnosis that it had specifically targeted for review but did not look beyond its predetermined sample to determine whether a plan should have been paid for different (even higher-paying) diagnosis codes for the same member or a different member. As such, the OIG cannot properly make any conclusion regarding whether the plan was actually overpaid.

In addition, the OIG's decision to limit the population of enrollees audited to those with a certain submitted diagnosis also increased the bias for identifying overpayments. The members without those diagnoses or any submitted diagnosis would likely contain numerous offsetting underpayments, which would lower the alleged overpayment or eliminate it entirely. For example, a member with a chronic, risk-adjustable condition may visit providers multiple times during the year yet have no reported HCCs, resulting in the plan being underpaid. These underpayments are neither identified nor accounted for in this audit. The OIG's audit findings therefore present an incomplete and inaccurate picture of the overall accuracy of the diagnosis data submitted.

Ultimately, the OIG's strategy to narrowly target a small number of samples where there is an expectation of discrepancies is flawed and cannot serve as a valid measure of United's performance, even under the OIG's own standards. The high-risk diagnoses at issue were

[8] OIG Draft Report at 6-7.

judgmentally selected by the OIG based on criteria that the OIG itself developed, rather than through a statistically valid, representative sample of diagnoses across the United contract. Inspectors General have consistently determined that findings from a judgmentally selected sample cannot be projected to the population.[9] The OIG's decision to do so here is inconsistent with this longstanding position. Had the OIG conducted a comprehensive, contract-wide audit, the results would likely have aligned with those of the CMS Payment Year 2011-2013 RADV audits, which found that many UnitedHealthcare MA plans had no net overpayment.

D. The audit sample size is too small for reliable statistical extrapolation.

The OIG has not provided full detail on the extrapolation approach it applied to arrive at its estimate that United was overpaid by the extrapolated amount. Based on internal analysis, it appears the OIG may have calculated its extrapolated overpayment amount by using the standardized "Wald" formula for a normalized 90% confidence interval. However, this formula is generally not recommended for use with very small sample sizes, such as those at the HCC-level in this audit (with only 20 enrollees sampled per condition). The standardized Wald formula is typically applied with much larger sample sizes, and it can lead to particularly inaccurate results in cases where the sample has a validation rate at or close to 0%.[10] It would be more appropriate to use the Wilson score interval, which was created to handle small sample sizes and cases where the validation rate is at or close to 0%.[11] Application of the Wilson score interval would yield more accurate extrapolation results and, based on United's analysis, would reduce the extrapolated overpayment amount by between $3.5M and $7.7M, depending on whether confidence intervals are applied to the 2020 and 2021 samples on a combined basis or separately. The OIG's assessment of extrapolated overpayments based on the standardized formula is therefore improper.

E. The OIG failed to follow CMS's RADV audit rules.

The OIG should not recommend that CMS recover overpayments based on an audit design that conflicts with CMS's audit protocols, especially if it has not undergone notice-and-comment rulemaking. Doing so would be arbitrary and capricious and would cause MA plans to have to decide between calibrating their compliance programs to satisfy the OIG or CMS. Ultimately, CMS sets the substantive standard for what diagnoses count for risk adjustment subject to statutory limitations. The OIG should not deviate from the standards adopted by CMS.

The OIG did not identify the specific coding and documentation standards that were used in the audit to guide the medical record review. CMS regulation requires codes to be submitted pursuant to ICD-10-CM Official Coding Guidelines.[12] As described further in Appendix A, there

[9] *See, e.g.,* U.S. Dep't of Hous. & Urban Dev., Office of Inspector Gen., *Preventing Duplication of Benefits When Using Community Development Block Grant Disaster Recovery and Mitigation Funds*, Audit Report No. 2024-FW-0001 (Oct. 20, 2023) ("We selected a nonstatistical sample…Nonstatistical sample review results cannot be projected to the population."); U.S. Gen. Servs. Admin., Office of Inspector Gen., *Evaluation Report: GSA Management of Contractor HSPD-12 PIV Cards*, Report No. JE16-002 (Mar. 30, 2016), ("Because our testing samples were judgmentally selected, our findings cannot be generalized to the population…").

[10] Wallis, S. (2013). Binomial Confidence Intervals and Contingency Tests: Mathematical Fundamentals and the Evaluation of Alternative Methods. *Journal of Quantitative Linguistics*, *20*(3), 178–208, *available at* https://doi.org/10.1080/09296174.2013.799918).

[11] *Id.*

[12] 45 C.F.R. § 162.1002(c)(2) and (c)(3); *see also,* Medicare Managed Care Manual, Chapter 7, Section 40 ("All diagnosis codes submitted must be documented in the medical record and must be documented as a result of a face-to-face visit. The diagnosis must be coded according to *International Classification of Diseases (ICD), Clinical Modification Guidelines for Coding and Reporting*.")

are 33 instances – representing about $9M in estimated overpayments – where United believes the OIG invalidated diagnoses that are valid under CMS's official coding guidelines. To the extent that the OIG is using additional, non-regulatory standards, or if the review underlying the OIG's audit findings otherwise did not conform to CMS diagnosis coding guidance, this would have skewed the OIG's results and recommendations.

Moreover, the OIG audit methodology differs from CMS RADV audits in other important respects. For instance, the OIG's audit methodology relies on a coding supervisor to act as a tiebreaker in situations where two coders disagree regarding whether a medical record substantiates a diagnosis code.[13] Specifically, if the first coder does not find support for the diagnosis coded by the treating physicians in the relevant medical records, a second coder performs a separate review of the same medical records. If the second coder finds support, then the discrepancy between the two coders is resolved by a third person, a coding supervisor, who reviews the medical records to make the final determination.[14] This methodology conflicts with the approach used in CMS RADV audits, where diagnosis codes that appear to be unsubstantiated after the first round of coding are escalated to a second coder for confirmation; if the second coder determines the medical records substantiate a diagnosis that maps to the HCC, then the HCC is treated as substantiated without further review.[15] Using CMS's methodology would result in more diagnoses being appropriately validated because it recognizes that a diagnosis supported by any qualified coder's review should be considered valid, rather than introducing an additional subjective layer of review that could produce inconsistent outcomes.

F. CMS has already recouped the alleged overpayment attributable to Payment Year ("PY") 2020 through the Medical Loss Ratio ("MLR") rebate mechanism and is not entitled to a second recovery.

The OIG asserts that United was overpaid by approximately $21.6M for diagnosis codes attributable to PY2020. However, this assertion fails to account for the MLR rebate mechanism, through which CMS has already recouped significantly more than the alleged overpayment. Based on payments received in 2020 (including for diagnosis codes that the OIG now suggests are invalid), United's MLR fell below the required threshold and triggered a rebate obligation. United already remitted $241M in the form of an MLR rebate to CMS for that year – an amount more than ten times greater than the $21.6M overpayment alleged by the OIG. Had United not submitted the disputed diagnosis codes for PY2020, its risk-adjusted payments would have been approximately $21.6M lower and its rebate obligation would have been correspondingly reduced. CMS has already recovered these funds through the MLR rebate process, and it is not entitled to a second recovery of the same funds. At a minimum, the OIG's estimated overpayment should be reduced by the $21.6M attributable to PY2020.

II. United is not required to review additional potentially mis-keyed diagnoses or conduct a self-audit of periods that occurred after the audit period– conducting such reviews would result in MA plans being systematically underpaid.

For 81 diagnoses that the OIG did not review in the potentially mis-keyed category, the OIG recommends that United determine whether medical records support the diagnosis for the

[13] OIG Draft Report at 23-24 (Appendix A).
[14] *Id.*
[15] *See* CMS, Contract-Level 15 Risk Adjustment Data Validation, Medical Record Reviewer Guidance, ver. 2.0 (Jan. 10, 2020), *available at* https://www.cms.gov/files/document/medical-record-reviewer-guidance-january-2020.pdf.

submitted condition and refund any resulting overpayments.[16] The OIG also recommends that United identify similar instances of "noncompliance" for high-risk diagnoses that occurred after the audit period and refund any resulting overpayments.[17]

United is willing to review the 81 potentially mis-keyed diagnoses referenced by the OIG for PY2020-2021 and refund any confirmed overpayments, provided the OIG supplies a complete list of those diagnoses.

Notwithstanding this commitment, we do not agree that United is broadly obligated to perform additional reviews. CMS regulations do not require United to conduct the type of self-audits that the OIG recommends. In fact, the U.S. Department of Justice, on behalf of CMS, has stated that "MAOs are not required to audit every single diagnosis code they submit."[18] Further, as explained above in Section I, this audit does not establish that United's data have relatively more and costlier discrepancies than the FFS data CMS uses to calibrate the risk adjustment model. Without that showing, there is no basis for additional reviews. If MA plans were to identify and delete these diagnoses without a corresponding change to the way CMS calculates the risk adjustment coefficients, MA plans would be substantially underpaid.

III. United disagrees with the recommendation for enhanced compliance procedures because its compliance program has proven effective.

The OIG recommends that United enhance its compliance procedures "to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements."[19] United disagrees with this recommendation because its compliance program is effective and complies with all applicable regulatory requirements.[20] As previously noted, an MA plan's compliance oversight is not and cannot be expected to identify and correct all coding discrepancies submitted by providers to a plan.

The OIG acknowledged that United had compliance procedures in place to ensure that it submitted accurate diagnosis codes for use in CMS's risk adjustment program. The OIG also acknowledged that United had internal control procedures in place to detect and correct potential discrepancies. These procedures include routine reviews of risk adjustment controls and proposed updates; provider training and education on coding guidelines and documentation requirements; ongoing training and assessments for United coding professionals; chart reviews of network providers meeting certain criteria to confirm compliance with risk adjustment quality and submission standards; and safeguards to prevent submission of certain diagnosis codes based on in-home assessments or chart review that are unlikely to be supported.

United's robust compliance practices have proven effective, as demonstrated by its performance in the RADV audits for Payment Years 2011-2013, which recently found that United's diagnoses are among the most accurate in the industry. The OIG's recommendation for enhanced compliance procedures exceeds the auditing and monitoring that CMS requires of MA plans.

IV. Conclusion

[16] OIG Draft Report at 19.
[17] *Id*.
[18] Joint Brief Regarding Cross-Motions for Summary Judgment at 5, *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, No. 2:16-cv-08697-FMO-PVC (C.D. Cal. Aug. 6, 2024).
[19] *Id.* at 20.
[20] 42 C.F.R. § 422.503(b)(4)(vi) (requiring MA plans to "[a]dopt and implement an effective compliance program, which must include measures to prevent, detect and correct fraud, waste and abuse").

United respectfully disagrees with the OIG's four proposed recommendations and requests that they be withdrawn. If left unchanged, aspects of the OIG's audit and extrapolation methodologies could have concrete program-level consequences that are inconsistent with core tenets of the Medicare program. If the OIG audits MA records with stricter standards than those applied to the FFS data used to calibrate the risk adjustment payment model, MAOs will be systematically underpaid, compromising the long-term viability of the program Congress designed. For MA to remain a sustainable alternative to traditional Medicare, aggregate monthly payments must accurately reflect the risk assumed by MAOs in covering expected healthcare costs. Without this parity, private insurers may face reduced incentives to participate, which could affect competition and innovation in the market over time.

Uncertainty associated with audit risk may also influence plan design decisions, including adjustments to supplemental benefits, provider networks, or market participation. These effects are likely to be most acute among rural, low-income, or dually eligible populations, impacting access and choice for beneficiaries. For these reasons, addressing methodological concerns in the OIG's audit approach is important to supporting the continued success of the MA program and the beneficiaries it serves.

United has long supported the use of well-designed RADV audits to strengthen program integrity and oversight. If the OIG seeks to audit risk adjustment payments, United encourages a comprehensive RADV approach that evaluates MA plan risk scores for both under- and over-payments and incorporates an appropriate FFS Adjuster based on empirical data.

We appreciate the opportunity to respond to the OIG's Draft Report.

Sincerely,

/s/ Robert Hunter
Chief Executive Officer of Government Programs
UnitedHealthcare

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