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Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UCare Minnesota (Contract H2459) 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 its 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 UCare Minnesota (UCare) is part of a series of audits in which we are reviewing 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 UCare submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements.

- For 254 of the 294 sampled enrollee-years, the medical records that UCare provided did not support the diagnosis codes and resulted in $869,498 in net overpayments.
- On the basis of our sample results, we estimated that UCare received at least $4.7 million in net overpayments for 2018 and 2019.

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

What OIG Recommends

We recommend that UCare:

1. refund to the Federal Government the $4.7 million of estimated net overpayments;
2. identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
3. continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnoses that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

UCare disagreed with some of our findings and all of 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 54 breast cancer diagnoses into 1 group.) This audit covered UCare Minnesota (UCare), for contract number H2459, and focused on 10 groups of high-risk diagnosis codes for payment years 2018 and 2019.[3]

OBJECTIVE

Our objective was to determine whether selected diagnosis codes that UCare 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] See Appendix B for a list of related Office of Inspector General (OIG) reports.

[3] All subsequent references to "UCare" in this report refer solely to contract number H2459.

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

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

For 2023, CMS paid MA organizations $466.7 billion, which represented 45 percent of all Medicare payments for that year.

Risk Adjustment Program

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

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

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

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

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

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

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

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

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

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

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

For enrollees who have certain combinations of HCCs, CMS assigns a separate factor that further increases the risk score. CMS refers to these combinations as disease interactions. For example, if MA organizations submit diagnosis codes for an enrollee that map to the HCCs for lung cancer and immune disorders, CMS assigns a separate factor for this disease interaction. By doing so, CMS increases the enrollee's risk score for each of the two HCC factors and by an additional factor for the disease interaction.

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

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

[8] During our audit period, CMS calculated risk scores based on the Version 22 CMS-HCC model for payment year 2018 and the Version 23 CMS-HCC model for payment year 2019.

sequestration reduction.[9] Thus, if the factors used to determine an enrollee's risk score are incorrect, CMS will make an improper payment to an MA organization. Specifically, if medical records do not support the diagnosis codes that an MA organization submitted to CMS, the HCCs are not validated, which causes overstated enrollee risk scores and overpayments from CMS.[10] Conversely, if medical records support the diagnosis codes that an MA organization did not submit to CMS, validated HCCs may not have been included in enrollees' risk scores, which may cause those risk scores to be understated and may result in underpayments.

High-Risk Groups of Diagnoses

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

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

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

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

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

[10] 42 CFR § 422.310(e) requires MA organizations (when undergoing an audit conducted by the Secretary) to submit "medical records for the validation of risk adjustment data." For purposes of this report, we use the terms "supported" or "not supported" to denote whether or not the reviewed diagnoses were evidenced in the medical records. If our audit determines that the diagnoses are supported or not supported, we accordingly use the terms "validated" or "not validated" with respect to the associated HCC.

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

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

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

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

- *Ovarian cancer*: An enrollee received one 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 claim 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 one sepsis diagnosis (that mapped to the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock) on only one 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 one pressure ulcer diagnosis[11] 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 claim 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.

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

UCare Minnesota

UCare is an MA organization based in Minneapolis, Minnesota. As of December 2019, UCare provided coverage under contract number H2459 to 102,484 enrollees. For the 2018 and 2019 payment years (audit period), CMS paid UCare approximately $1.7 billion to provide coverage to its enrollees.[12, 13]

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to 1 of the 10 high-risk groups during the 2017 and 2018 service years, for which UCare received increased risk-adjusted payments for payment years 2018 and 2019, respectively. Because enrollees could be classified into more than one high-risk group or could have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment year, which we refer to as "enrollee-years."

We identified 2,389 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes ($5,725,472). We selected for audit a stratified random sample of 294 enrollee-years as shown in Table 1 on the following page.

[11] Pressure ulcer diagnoses are categorized in to 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.

[12] The 2018 and 2019 payment year data were the most recent data available at the start of the audit.

[13] All of the payment amounts that CMS made to UCare and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

Table 1: Sampled Enrollee-Years

High-Risk Group	Number of Sampled Enrollee-Years
(1) Acute stroke	30
(2) Acute myocardial infarction	30
(3) Embolism	30
(4) Lung cancer	30
(5) Breast cancer	30
(6) Colon cancer	30
(7) Prostate cancer	30
(8) Ovarian cancer	30
(9) Sepsis	30
(10) Pressure ulcer	24
Total for All High-Risk Groups	**294**

UCare provided medical records as support for the selected diagnosis codes associated with 290 of the 294 sampled enrollee-years.[14] We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. For the HCCs that were not validated, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or if we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group, we included the financial impact of the resulting HCC (if any) in our calculation of net overpayments.

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

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

[14] UCare could not locate medical records for the remaining 4 sampled enrollee-years. (See footnote 15.)

FINDINGS

With respect to the 10 high-risk groups covered by our audit, most of the selected diagnosis codes that UCare submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 40 of the 294 sampled enrollee-years, the medical records validated the reviewed HCCs.[15] For the remaining 254 enrollee-years, however, either the medical records that UCare provided did not support the diagnosis codes or UCare could not locate the medical records to support the diagnosis codes; therefore, the associated HCCs were not validated and resulted in $869,498 in net overpayments.

As demonstrated by the errors found in our sample, UCare'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 UCare received at least $4.7 million in net overpayments for 2018 and 2019.[16]

FEDERAL REQUIREMENTS

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

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

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

[15] For 1 of the 32 enrollee-years, UCare informed us that it could not locate the associated medical record because the record had been destroyed in a flood. 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 UCare, we determined that an extraordinary circumstance prevented UCare from locating the medical record for this enrollee-year, and we treated the sample item as a non-error.

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

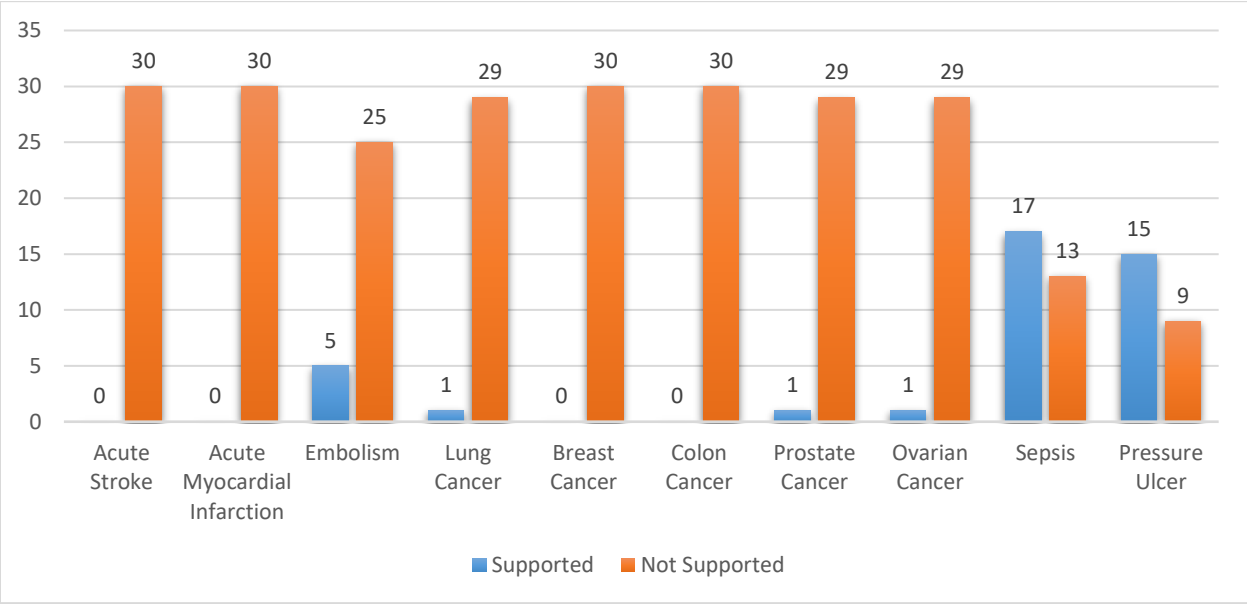
CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap. 7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7, § 40). The diagnosis must be coded according to the International Classification of Diseases, 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 UCARE MINNESOTA SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Most of the selected high-risk diagnosis codes that UCare submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, as shown in the figure, for 254 of the 294 sampled enrollee-years either the medical records that UCare provided did not support the diagnosis codes or UCare could not locate the medical records to support the diagnosis codes. In these instances, UCare should not have submitted the diagnosis codes to CMS and received the resulting net overpayments.

Figure: Analysis of High-Risk Groups



Incorrectly Submitted Diagnosis Codes for Acute Stroke

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

- For 25 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 an acute cerebrovascular accident (CVA) that results in the assignment of the HCC under review. There is documentation of a past medical history of . . . [a] CVA [diagnosis] which does not result in an HCC."[17]

- For 4 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC under review. Stroke work up did not show any acute pathology. 'No evidence of stroke' was documented."

- For the remaining 1 enrollee-year, UCare submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiparesis (which was supported by the medical records).[18] The independent medical review contractor stated that "there is no documentation of [a] . . . CVA, however, the patient has hemiparesis following [a stroke] affecting [the] left non-dominant side from a past medical history of CVA which should have been assigned instead of the [HCC under review]." The diagnosis for hemiparesis maps to the HCC for Hemiplegia/Hemiparesis. Accordingly, UCare should not have received a payment for the acute stroke diagnosis but instead should have received a payment for the hemiparesis diagnosis. This error caused an underpayment.

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and UCare received $54,631 in net overpayments for these 30 sampled enrollee-years.

[17] 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.

[18] 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.

Incorrectly Submitted Diagnosis Codes for Acute Myocardial Infarction

UCare incorrectly submitted diagnosis codes for acute myocardial infarction for all 30 sampled enrollee-years. Specifically:

- For 17 enrollee-years, the medical records indicated in each case that the individual 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.

  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."

- For 7 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, UCare 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 the remaining 6 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. There is documentation of a suspected diagnosis of an NSTEMI (non-ST elevated myocardial infarction) [diagnosis] which would not be coded as a confirmed diagnosis per outpatient coding guidelines."[19]

As a result of these errors, the HCC for Acute Myocardial Infarction was not validated, and UCare received $51,073 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

UCare incorrectly submitted diagnosis codes for embolism for 25 of 30 sampled enrollee-years. Specifically:

[19] A non-ST-elevation myocardial infarction, often referred to as an NSTEMI or a non-STEMI, is a type of heart attack, which is a less severe form than an ST-elevation myocardial infarction (STEMI) because it inflicts less damage to the heart.

- For 22 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 [diagnosis] which does not result in an HCC."[20]

- For the remaining 3 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 UCare received $82,814 in overpayments for these 25 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

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

- For 18 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 6 enrollee-years, the medical records in each case did not support a lung 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."

[20] 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 the remaining 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, UCare 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.

As a result of these errors, the HCC for Lung and Other Severe Cancers was not validated, and UCare received $238,858 in overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

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

- For 29 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."

- For the remaining 1 enrollee-year, the medical record did not support a breast cancer diagnosis. Specifically, 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 Breast, Prostate, and Other Cancers and Tumors was not validated, and UCare received $38,512 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

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

- For 25 enrollee-years, the medical records indicated in each case that the individual had previously had colon cancer, but the records did not justify a colon cancer diagnosis at the time of the physician's service.

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

- For 1 enrollee-year, the medical record did not support a colon cancer diagnosis. Specifically, 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 malignant neoplasm of unspecified part of colon [diagnosis] with a colonoscopy performed as a preventive measure. [21] This is insufficient documentation to assign either a historical or an active colon cancer [diagnosis] on the date of service."

- For the remaining 1 enrollee-year, UCare could not locate any medical records to support the colon cancer diagnosis; therefore, the HCC for Colorectal, Bladder, and Other Cancers was not validated.

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and UCare received $73,807 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

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

- For 27 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."

[21] A malignant neoplasm of unspecified part of the colon is a cancerous and abnormal growth of cells on a part of the colon.

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

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and UCare received $37,196 in overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Ovarian Cancer

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

- For 23 enrollee-years, the medical records indicated in each case that the individual 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."

- For 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."

- For the remaining 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, UCare 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.

[22] For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources and specialty types (42 CFR § 422.310(d)(3); the Manual, chap. 7, §§ 40 and 120.1). For 1 of these enrollee-years, the medical record that UCare provided to support the reviewed HCC was a genetic counseling medical record that was signed and credentialed by a certified genetic counselor. Because this record did not meet CMS's requirements for an acceptable physician specialty type, we could not validate the reviewed HCC.

As a result of these errors, the Ovarian Cancer HCCs were not validated, and UCare received $165,298 in overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Sepsis

UCare incorrectly submitted diagnosis codes for sepsis for 13 of 30 sampled enrollee-years. Specifically:

- For 8 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. There is documentation of the patient having a diagnosis of acute gram negative bacteremia without sepsis [diagnosis] which does not result in an HCC."[23]

- For 5 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."

As a result of these errors, the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock was not validated, and UCare received $48,586 in overpayments for these 13 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Pressure Ulcer

UCare incorrectly submitted diagnosis codes for pressure ulcer for 9 of 24 sampled enrollee-years. Specifically:

- For 4 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, UCare 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.

[23] Acute gram-negative bacteremia is a bacterial infection of the bloodstream, which can result in sepsis.

[24] For 3 of the enrollee-years, our medical review contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code. For the remaining enrollee-year, we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group.

- For 3 enrollee-years, the medical records in each case did not support a pressure ulcer 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. There is documentation of a pressure ulcer of the left lateral, distal leg, unspecified stage [diagnosis] which does not result in an HCC."[25]

- For the remaining 2 enrollee-years, UCare could not locate any medical records to support the pressure ulcer diagnosis; therefore, the Pressure Ulcer HCCs could not be validated.

As a result of these errors, the Pressure Ulcer HCCs were not validated, and UCare received $78,723 in overpayments for these 9 sampled enrollee-years.

Summary of Incorrectly Submitted Diagnosis Codes

In summary and with respect to the 10 high-risk groups covered by our audit, UCare received $869,498 in net overpayments for 254 of the 294 sampled enrollee-years.

THE POLICIES AND PROCEDURES THAT UCARE MINNESOTA 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 UCare 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, UCare had compliance procedures in place that consisted of a variety of provider-specific outreach efforts that provided clarification on coding matters. These efforts included the distribution of a provider manual and monthly newsletters to educate providers on the submission of accurate risk adjustment data. UCare also offered provider coding classes and additional education materials that outlined specific guidance on how to accurately code some of the high-risk areas identified in this audit (acute stroke and cancer), and when to code a condition as active as opposed to historical.

Additionally, UCare required its coders to adhere to various preventative measures. Specifically, UCare required all newly hired coders to complete a coding assessment to identify codes with at least 95-percent accuracy; moreover, all coders are subject to multiple inter-rater

[25] A pressure ulcer of the left lateral, distal leg refers to a pressure ulcer on the outer lower portion of the left leg.

reliability reviews throughout the year.[26] UCare uses the results of these reviews to identify additional areas for training or coaching. Coders are also required to complete coding compliance program training annually.

As part of its detection and correction measures, UCare has annually conducted focused reviews of claims submitted by providers. The areas selected for review have been based on trends noted in government audits, as well as internal audits and analyses, to identify potential data outliers and included a high-risk area identified in this audit (myocardial infarction). If the reviews identified any coding errors, UCare provided guidance to providers on how to submit the corrections to CMS. UCare also implemented a data filter to identify and retract stroke diagnosis codes originating from a physician office location. The filter did not identify claims originating from outpatient hospital-based clinics, so acute strokes that were diagnosed in these settings were not flagged for retraction.

When asked about the errors that we identified in this audit, UCare stated that it is "continually reviewing our processes and will look at these on a high level." UCare officials told us that it is in the process of updating the data filter to include all office-based settings for acute stroke and will be creating an additional filter that applies the same logic for myocardial infarction claims.

We acknowledge that UCare has compliance procedures that include 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 254 of the 294 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.

UCARE MINNESOTA RECEIVED NET OVERPAYMENTS

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that UCare received at least $4,761,271 in net overpayments for our audit period.

[26] Inter-rater reliability reviews verify the accuracy of medical record decisions and identify the consistency of decisions between two reviewers.

RECOMMENDATIONS

We recommend that UCare Minnesota:

- refund to the Federal Government the $4,761,271 of estimated net overpayments;[27]

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

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

UCARE MINNESOTA COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, UCare disagreed with some of our findings and all of our recommendations. UCare also requested that we withdraw all of our recommendations. More specifically, UCare did not agree with our findings for 22 of the 262 enrollee-years in error that we identified in our draft report. For these 22 enrollee-years, UCare discussed (in an attachment to its written comments) why it believed that the medical records that it previously gave us validated the reviewed HCCs. UCare did not directly agree or disagree with our findings for the remaining 240 enrollee-years.

UCare described our audit methodology and results as "fundamentally flawed." Additionally, UCare stated that it "already conducts robust auditing and monitoring" and that its "compliance procedures are appropriate and regularly reevaluated for improvement." UCare's comments also included a general discussion of the MA program and the risk adjustment payment model.

With respect to our first recommendation, we reviewed UCare's comments and the additional information that it provided and reduced the number of enrollee-years in error from 262 (in our draft report) to 254 and adjusted our calculation of net overpayments for this final report. Accordingly, we reduced the recommended refund in our first recommendation from $4,913,489 to $4,761,271 for this final report. We maintain that our second and third recommendations remain valid.

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

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

UCARE MINNESOTA REQUESTED THAT THE OFFICE OF INSPECTOR GENERAL WITHDRAW ITS RECOMMENDATION TO REFUND OVERPAYMENTS

UCare Minnesota Did Not Agree With the Office of Inspector General's Findings for 22 Sampled Enrollee-Years

UCare Minnesota Comments

UCare did not agree with our findings for 22 of the sampled enrollee-years (as shown in Table 2) and discussed why it believed that the medical records that it previously gave us for these 22 enrollee-years validated the reviewed HCCs.

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

High-Risk Group	Number of Sampled Enrollee-Years
Sepsis	10
Acute stroke	3
Acute myocardial infarction	2
Embolism	2
Prostate cancer	2
Lung cancer	1
Colon cancer	1
Ovarian cancer	1
Total	**22**

Office of Inspector General Response

Our independent medical review contractor reviewed the additional information that UCare provided for the 22 enrollee-years.

- For 14 of the 22 enrollee-years, our independent medical review contractor reaffirmed that the HCCs were not validated.

- For the remaining 8 enrollee-years, our contractor found support for the audited HCCs and therefore reversed its original decision and validated the HCCs.

  For example, for 1 enrollee-year from the sepsis high-risk group, UCare cited the medical record's reference to a Systemic Inflammatory Response Syndrome diagnosis

that maps to the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.

After reviewing UCare's explanation for this enrollee-year, our contractor reversed its original decision. The contractor stated: "Decision reversed at reconsideration; agree with the auditee. There is documentation of Systemic Inflammatory Response Syndrome (SIRS) [diagnosis] that results in the assignment of [the] HCC [for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock]."

Accordingly, we revised some of our findings and reduced the number of enrollee-years in error from 262 (in our draft report) to 254 for this final report. We also reduced the associated statistical estimates and monetary recommendation. The independent medical review contractor confirmed that the additional information that UCare gave to us had no impact on the decisions that the contractor had made for other sampled enrollee-years.

UCare Minnesota Stated That the Office of Inspector General Targeted Only Potential Overpayments and Ignored Potential Underpayments

UCare Minnesota Comments

UCare stated that our audit "targeted only potential *overpayments, rather than both overpayments and underpayments*. . . ." (Emphasis in original.) Specifically, UCare stated that we based our audit "on a limited set of very narrowly defined situations," which resulted in a sampling frame of encounters that were at a high-risk of being miscoded. By limiting our audit to only these specific encounters, UCare stated that we ignored the codes that were "likely supported" and "fail[ed] to account for. . . codes that were never submitted. . . ." Furthermore, UCare stated that we "inappropriately identified" the diagnoses selected for review as being high-risk diagnosis codes because the "vast majority" of diagnosis codes submitted for these conditions were coded "appropriately."

UCare also referred to CMS's risk adjustment data validation (RADV) audit methodology, which gives MA organizations the opportunity to submit additional diagnoses that were not previously submitted. These additional diagnoses may map to a different HCC and could result in underpayments when the risk score is recalculated, thus resulting in a reduced improper payment calculation. UCare stated that "the goal of the audit process in MA should not be to find every instance of an unsupported code. . . only when it benefits the government."

To illustrate this point, UCare stated that it "conducted an analysis" that targeted 10 chronic conditions (which UCare listed in its footnote 6 of its written comments) that "were not submitted for members in consecutive years" and "calculated the value of potential underpayments" associated with these conditions. UCare added that it determined that the underpayments identified for only one of these conditions was enough to offset the extrapolated overpayment we identified.

Office of Inspector General Response

We disagree with UCare's assertion that our audit focused only on finding overpayments. Our objective was to determine whether selected high-risk diagnosis codes that UCare 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 10 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 UCare or to 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 net overpayments. Specifically, for this audit, the net overpayment calculation included an underpayment that we identified in the Acute Stroke high-risk group.

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 net 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.

UCare Minnesota Stated That the Office of Inspector General Failed To Ensure Actuarial Equivalence Between Traditional Medicare and Medicare Advantage

UCare Minnesota Comments

UCare stated that our audit methodology did not account for a payment principle known as "actuarial equivalence," because we did not apply an adjustment called a Fee-for-Service (FFS) adjuster. Specifically, UCare stated that "[p]ayments to MA [organizations] are meant to equate to what CMS would have had to pay to cover the costs associated with the same population under traditional FFS Medicare." According to UCare, MA payment rates are set using "[u]naudited" FFS data and CMS introduced the FFS adjuster to "account for the inherent error rate in the FFS data."

UCare referred to an October 2018 CMS study that "purport[ed] to show that a[n] FFS adjuster was not necessary." In addition, UCare cited CMS's February 2023 final rule, which "confirmed that [CMS] would not apply a[n] FFS adjuster to the RADV error rate prior to extrapolation;"

UCare added that it disagreed with CMS's reasoning in this regard.[28, 29] Furthermore, UCare stated that "even if the lack of a[n] FFS adjuster were appropriate . . . the same would not hold true for OIG [Office of Inspector General] audits." Specifically, UCare stated that "CMS concluded that the overall reimbursement to MA [organizations] would still be appropriate without a[n] FFS adjuster because, across a plan's enrollment, the inaccuracies 'mitigate each other due to offsetting effects.'" According to UCare, this "would not be the case in OIG's . . . audits[,] where there is no opportunity for such inaccuracies to 'mitigate each other.'"

UCare stated that therefore, because our "methodology fails to account for errors in the FFS data, it violates the statutory requirement of actuarial equivalence," and "the recovery of extrapolated payments based on OIG's findings would be inappropriate."

Office of Inspector General Response

Regarding UCare's statement that we did not consider "actuarial equivalence" in our audit methodology, we note that CMS stated that it "will not apply an FFS adjuster in RADV audits," which UCare acknowledged in its comments.[30] Our audit methodology correctly applied CMS requirements to properly identify the net overpayment amount associated with the unvalidated HCCs for each sampled enrollee-year. We followed CMS's risk adjustment program requirements to determine the payment that CMS should have made for each enrollee and to estimate net overpayments. For these reasons, we believe that a recommended refund of estimated net overpayments based on our findings is appropriate. We continue to recognize that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program. (See footnote 27.)

UCare Minnesota Stated That Both CMS and the Office of Inspector General Lack the Authority To Extrapolate

UCare Minnesota Comments

UCare stated that both CMS and OIG lack the statutory authority to extrapolate overpayments and recommend a refund. Specifically, UCare cited a Medicare statute that permits Medicare contractors to extrapolate only when there is a sustained or high level of payment error or when education intervention has failed to correct errors.[31] UCare stated that neither of these conditions existed in the context of this audit.

[28] 88 Fed. Reg. 6643, 6656 (Feb. 1, 2023). UCare also referred to a lawsuit that another health care entity has filed in Federal court that challenges this final rule.

[29] All subsequent references to "final rule" in this report refer solely to the CMS final rule issued on February 1, 2023.

[30] 88 Fed. Reg. at 6644 (Feb. 1, 2023).

[31] 42 U.S.C. § 1395ddd(f)(3).

In addition, UCare stated that we conducted this audit under the Inspector General Act of 1978 (IGA), "which does not authorize OIG to extrapolate results of its audits and recover overpayments." Additionally, UCare said that although the preamble to CMS's final rule states that CMS can collect extrapolated amounts that OIG calculates, "the regulations . . . only mention extrapolation in the context of RADV audits, not in the context of OIG audits conducted under the IGA." Moreover, UCare said that "the preamble to a final rule is not itself a regulation," and that "the courts have held that . . . 'when there is a discrepancy between the preamble and the [United States] Code, it is the codified provisions that control.'"[32] UCare stated that therefore, both CMS and OIG "lack the statutory and regulatory authority to engage in extrapolation" for this audit.

Office of Inspector General Response

We do not agree with UCare's assertion that we do not have statutory authority under the IGA to calculate extrapolated overpayments. Neither Federal statute nor any other authority limits our ability to calculate overpayments or recommend a recovery based on extrapolation. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare.[33] Furthermore, the final rule does not specify a sampling or extrapolation methodology; rather, it requires a reasonable methodology for CMS and OIG audits.

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.[34] 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 to apply the correct formulas for the extrapolation. We believe

[32] UCare cited a passage from a Federal court ruling in *AT&T Corp. v. FCC*, 970 F.3d 344, 350-1 (D.C. Cir. 2020).

[33] *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).

[34] 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).

that this methodology provides a reasonable basis for our extrapolated monetary recommendation.

UCare Minnesota Stated That the Office of Inspector General's Audit Methodology Should Not Have Been Adopted Without Notice-and-Comment Rulemaking

UCare Minnesota Comments

UCare stated that "Federal agencies must engage in the notice and comment rulemaking process when adopting substantive legal standards relating to the Medicare program." UCare cited a U.S. Supreme Court ruling that the Department of Health and Human Services (HHS) must follow notice-and-comment rulemaking when issuing Medicare policies that establish or change substantive legal standards, even if they are not formal regulations.[35]

In this context, UCare said that because "OIG's audit methodology differs in fundamental ways from that of CMS," our approach for these audits "amounts to the adoption of a substantive legal standard, and thus should not have been implemented without notice and comment rulemaking."

In addition, UCare referred to previous OIG reports in which, according to UCare, we stated that our recommendations "to CMS" are permissible under the IGA. According to UCare, if CMS were permitted to follow our recommendations, it "would enable OIG and CMS to impermissibly adopt a new substantive legal standard without engaging in the required notice and comment rulemaking process."

Office of Inspector General Response

We disagree with UCare's comments regarding the need for notice-and-comment rulemaking for the methodology we used in this audit. We did not apply any new regulatory requirements that would be subject to notice-and-comment rulemaking, and in that sense our audit does not make major changes to a CMS-administered program. Further, the recommendations that we have made to UCare, and the recommendations that we have made in previous OIG reports, were made to the MA organizations, not to CMS, and do not enable us to adopt new standards. Rather, our audits are intended to provide an independent assessment of HHS programs and operations in accordance with the IGA—an assessment for which action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with CMS's policies and procedures. (See footnote 27).

[35] *Azar v. Allina Health Services*, 139 S. Ct. 1804, 1816 (2019).

UCare Minnesota Stated That Neither CMS nor the Office of Inspector General Is Permitted To Impose Its Audit Methodology Retroactively

UCare Minnesota Comments

UCare expanded upon its earlier comments on both the FFS adjuster and notice-and-comment rulemaking, by citing several court cases to support UCare's opinion that neither CMS nor OIG can impose a "new audit methodology retroactively." Specifically, UCare said that "[u]nder the Social Security Act, rules cannot be applied retroactively unless they are necessary to comply with statutory requirements or a failure to apply the change retroactively would be contrary to the public interest." With respect to the final rule and the non-application of an FFS adjuster, UCare cited another Federal court ruling that states: "'if the new rule effects a substantive change from the agency's prior regulation or practice, then it is impermissibly retroactive.'"[36] UCare added that therefore, even if extrapolating audit results without an FFS adjuster might be acceptable for future years, that would be inappropriate for the payment years included in this audit.

Furthermore, UCare said that "CMS has decided not to collect extrapolated amounts for payment years 2011 through 2017, contrary to what it had proposed in the 2018 proposed rule. Clearly, it is feasible to ignore past payment years when implementing extrapolation."

Accordingly, UCare stated that "retroactive application of CMS's new extrapolation policy will likely impose serious financial burdens on some MA [organizations]." UCare added that this could "potentially [lead] to even greater concentration within the industry, and fewer options for seniors, both to the detriment of consumers. This is neither necessary to comply with statutory requirements nor in the public interest."

Office of Inspector General Response

Regarding UCare's statement that we imposed "new" methodology retroactively by not applying an FFS adjustor, we note that before issuance of the final rule, CMS had never issued any requirements that compelled us to reduce our net overpayment calculations. Furthermore, because we are not recommending the application of any new statutory or regulatory requirements, UCare's references to court rulings regarding the Social Security Act's prohibition of retroactive application of rules are not applicable to this audit. We recognize that OIG audit findings and recommendations do not represent final determinations by CMS. Accordingly, we will provide CMS with our independent medical review contractor's results for its consideration as part of the audit resolution process.

[36] UCare quoted from *Kirwa v. United States Department of Defense*, 285 F. Supp. 3d 257, 271 (D.D.C. 2018).

UCare Minnesota Stated That the Office of Inspector General Was Not Sufficiently Transparent About Its Audit Methodology

UCare Minnesota Comments

UCare stated that we were not sufficiently transparent about the methodology used in our audits. Specifically, UCare stated we did not identify our independent medical review contractor or disclose the credentials of the reviewers. UCare also stated that we did not reveal the coding policies and procedures or documentation standards that the medical review contractor used to conduct its coding reviews. Furthermore, UCare said we did not disclose the determinations made by the reviewers at each level of the review process. UCare stated the "lack of transparency makes it impossible for MA [organizations] to fully evaluate OIG's audit methodology and results."

Office of Inspector General Response

We disagree with UCare's comments that our audit methodology was not transparent. It is not our practice to name our independent medical review contractor, and we contend that that name would not provide information about the contractor's qualifications beyond what we state in this audit report. Furthermore, during the course of our audit and again in our draft report, we informed UCare that our medical reviews were performed by professional coders credentialed by the American Health Information Management Association (AHIMA) and the American Academy of Professional Coders (AAPC). (See footnote 45 in Appendix A.)

Our independent medical review contractor used the following coding and documentation standards: (1) the CMS-published Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance, (2) ICD-10-CM Official Guidelines for Coding and Reporting, (3) and the AHA Coding Clinic for ICD-10-CM and ICD-10-PCS. Before issuing our draft report, we gave UCare information regarding the coding guidelines and guidance used during the course of our audit.

As explained in our audit methodology (Appendix A), the coding review followed a specific process to determine whether there was support for a diagnosis code and the associated HCC. At the conclusion of this process, we used only the final coding review determination for each sampled enrollee-year to calculate overpayments or underpayments. During our audit, we gave UCare the final coding review determinations for each sampled enrollee-year.

UCare Minnesota Stated That the Office of Inspector General's Audit Methodology Was Arbitrary and Capricious

UCare Minnesota Comments

UCare stated that our audit methodology is "arbitrary and capricious because it differs dramatically not only from CMS's approach but also from one OIG audit to the next." To

illustrate its point, UCare pointed out that the number of high-risk groups for our audits have "varied from as few as two to as many as ten," and that our "definition of a given 'high-risk diagnosis code' group has varied from audit to audit."

Additionally, UCare stated that by extrapolating errors from targeted high-risk groups, we were, in effect, demanding that MA organizations achieve 100-percent coding accuracy—an expectation that UCare described as "unrealistic." UCare pointed out that CMS has recognized that MA organizations "'cannot reasonably be expected to know that every piece of data is correct.'"[37]

UCare added that Federal regulations (42 CFR § 422.504(l)) require only that MA organization officials "certify to the accuracy, completeness, and truthfulness of the data 'based on best knowledge, information, and belief.'" Therefore, according to UCare, our "implicit requirement of 100 [percent] accuracy is impractical and impossible to achieve."

Office of Inspector General Response

We disagree with UCare's statement that our audit methodology was arbitrary and capricious because it differed from CMS's approach and from the methodologies that we used in other audits. The methodologies and approaches that we have used to identify high-risk diagnosis codes for these targeted audits have evolved over time. As a result, the methodology used in this audit did not mirror the methodology used in earlier audits. Further, we agree with UCare that our audit methodology is different from that of the CMS RADV audit methodology. Although our approach was generally consistent with the methodology used by CMS in its RADV audits, it did not mirror CMS's approach in all aspects, nor did it have to.

Moreover, we disagree with UCare's comment that our extrapolation of errors demands that MA organizations achieve 100-percent accuracy. For this audit, we reviewed diagnoses that were at a higher risk of being miscoded. We found that most of these diagnoses were indeed miscoded (254 enrollee-years (out of 294) had unsupported diagnosis codes (Appendix D)) and resulted in net overpayments made by the Federal government. Our extrapolation of these net overpayments does not demand 100-percent accuracy for every claim that UCare submitted to CMS; rather, it serves as the basis for our recommendations for UCare to refund overpayments that it received for the high-risk diagnoses we found to be in error.

Furthermore, 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."[38] Accordingly, we believe that UCare is responsible for addressing the issues that resulted in that error rate.

[37] The CMS comment that UCare quoted appears in the final rule at 65 Fed. Reg. 40170, 40268 (June 29, 2000).

[38] 42 CFR § 422.503(b)(4)(vi)(G).

UCARE MINNESOTA REQUESTED THAT THE OFFICE OF INSPECTOR GENERAL WITHDRAW ITS RECOMMENDATION TO IDENTIFY SIMILAR INSTANCES OF NONCOMPLIANCE THAT OCCURRED BEFORE OR AFTER OUR AUDIT PERIOD

UCare Minnesota Comments

UCare disagreed with our second recommendation to identify similar instances of noncompliance that occurred before or after our audit period and requested that we withdraw this recommendation from our final report. According to UCare, "MA regulations do not require MA [organizations] to perform the audits OIG recommends, nor does OIG have the authority to require such audits."

Furthermore, UCare stated that we did not identify "any statute, regulation, or guidance issued by CMS that requires MA [organizations] to conduct audits of specific 'high-risk diagnoses' and make associated repayments." UCare also stated that our recommendation to perform additional similar audits is, again, effectively "implement[ing] a rule without notice and comment rulemaking."

Although UCare disagreed with this recommendation, it also said that it had taken "proactive steps" to identify and remove certain diagnosis codes from its submissions to CMS. Specifically, UCare stated that before our audit, it had "implemented a data filter to identify and retract stroke diagnosis codes originating from a physician office location." In addition, UCare stated that after our audit, it had implemented data filters to remove or delete certain high-risk encounters and had also "enhanced its oversight activities."

Office of Inspector General Response

We do not agree with UCare's interpretation of Federal requirements. We recognize that MA organizations have the latitude to design their own federally mandated compliance programs. However, contrary to UCare's assertions, we believe that our second recommendation conforms to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (Appendix E)).

These Federal regulations state that MA organizations must "implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance 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.

We believe that the error rate identified in our audit (254 of 294 enrollee-years (Appendix D)) demonstrates that UCare has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope.

UCARE MINNESOTA REQUESTED THAT THE OFFICE OF INSPECTOR GENERAL WITHDRAW ITS RECOMMENDATION THAT UCARE IMPROVE ITS COMPLIANCE PROGRAM

UCare Minnesota Comments

UCare disagreed with our third recommendation that it continue to examine its existing compliance procedures for diagnoses that are at high risk for being miscoded and enhance those procedures as necessary. Specifically, UCare disagreed with our conclusion that its "compliance program is not adequate in its current form." UCare stated that the "results of OIG's one-way audit based on data mined coding patterns do not prove that UCare's compliance program was insufficient." Furthermore, UCare stated that its compliance program does not "need to achieve 100 [percent] accuracy to be deemed effective."

UCare also stated that our "audit of old claims data from services provided in 2017 and 2018 is not representative of UCare's current compliance practices, which were not reviewed by OIG." UCare also noted that we acknowledged in our draft report that UCare had measures in place to prevent, detect, and correct noncompliance with CMS's program requirements. UCare stated that it "continuously works to improve and update its compliance program" which, according to UCare, is "already robust and compliant with all applicable legal and regulatory requirements." Therefore, UCare requested that we withdraw this recommendation from our final report.

Office of Inspector General Response

UCare's comments on our third recommendation imply that we are opining on the effectiveness of its entire compliance program. That was not our intention or our focus for this audit. Rather, we limited our audit to selected diagnoses that we determined to be at high risk for being miscoded. Our audit revealed a 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).

UCare is correct in that our audit examined its compliance procedures that were in place during our audit period and not its current compliance program. However, with respect to Federal regulations that require correction of known compliance issues (as identified in the results of this audit), we believe that the continued improvement of UCare's existing procedures and internal data quality reviews will assist UCare in attaining better assurance with regard to the "accuracy, completeness and truthfulness" of the risk adjustment data that it submits in the future. Accordingly, we maintain that our third recommendation remains valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid UCare $1,702,365,104 to provide coverage to its enrollees for 2018 and 2019. We identified a sampling frame of 2,389 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2017 and 2018 service years. UCare received $34,291,227 in payments from CMS for these enrollee-years for 2018 and 2019. We selected for audit 294 enrollee-years with payments totaling $5,265,105.

The 294 enrollee-years included 30 acute stroke diagnoses, 30 acute myocardial infarction diagnoses, 30 embolism diagnoses, 30 lung cancer diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, 30 prostate cancer diagnoses, 30 ovarian cancer diagnoses, 30 sepsis diagnoses, and 24 pressure ulcer diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $1,135,970 for our sample.

Our audit objective did not require an understanding or assessment of UCare'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 April 2022 through May 2024.

METHODOLOGY

To accomplish our objective, we performed the following steps:

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

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

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

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

    - 94 diagnosis codes for acute stroke,
    - 17 diagnosis codes for acute myocardial infarction,
    - 63 diagnosis codes for embolism,
    - 17 diagnosis codes for lung cancer,
    - 54 diagnosis codes for breast cancer,

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

- 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)[39] and Encounter Data System (EDS)[40] to identify enrollees who received high-risk diagnosis codes from a physician during the service years,

  - Risk Adjustment System (RAS)[41] to identify enrollees who received an HCC for the high-risk diagnosis codes,

  - Medicare Advantage Prescription Drug System (MARx)[42] to identify enrollees for whom CMS made monthly Medicare payments to UCare, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C),

  - EDS[43] to identify enrollees who received specific procedures, and

  - Prescription Drug Event (PDE) file[44] to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.

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

- We selected for audit a stratified random sample of 294 enrollee-years (Appendix C).

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

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

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

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

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

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

- We used an independent medical review contractor to perform a coding review for the 294 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.[45]

- 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.

    - 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 net overpayment made to UCare during the audit period.

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

- We calculated the recommended recovery amount in accordance with CMS's regulations that limit the use of extrapolation in Risk Adjustment Data Validation audits for recovery purposes.[46]

- We discussed the results of our audit with UCare officials on January 18, 2024.

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

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

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Humana Health Plan, Inc. (Contract H2649) Submitted to CMS	A-02-22-01001	9/23/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HealthAssurance, Pennsylvania, Inc. (Contract H5522) Submitted to CMS	A-05-22-00020	9/23/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Independent Health Association, Inc. (Contract H3362) Submitted to CMS	A-07-19-01194	6/26/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MediGold (Contract H3668) Submitted to CMS	A-07-20-01198	2/16/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That SelectCare of Texas, Inc. (Contract H4506) Submitted to CMS	A-06-19-05002	11/27/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Aetna, Inc. (Contract H5521) Submitted to CMS	A-01-18-00504	10/2/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS	A-07-20-01197	8/3/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS	A-07-20-01202	7/10/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. (Contract H3952) Submitted to CMS	A-03-20-00001	5/31/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS	A-05-19-00013	4/4/2023

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified UCare enrollees who: (1) were continuously enrolled in UCare throughout all of the 2017 or 2018 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 2017 or 2018 or in January of the following year, and (3) received a high-risk diagnosis during 2017 or 2018 that caused an increased payment to UCare for 2018 or 2019, respectively.

We presented the data for these enrollees to UCare 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 UCare. After we performed these steps, our finalized sampling frame consisted of 2,389 enrollee-years.

SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2018 or 2019.

SAMPLE DESIGN AND SAMPLE SIZE

The design for our statistical sample comprised of 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 only one physician claim during the service year but did not have an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim (266 enrollee-years);

- an acute myocardial infarction diagnosis (that mapped to the HCC for Acute Myocardial Infarction) on only one physician or outpatient claim during the service year but did not have an acute myocardial infarction diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician or outpatient claim (410 enrollee-years);

- an embolism diagnosis (that mapped to an Embolism HCC) on only one claim during the service year but did not have an anticoagulant medication dispensed on his or her behalf (154 enrollee-years);

- a lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the lung cancer diagnosis administered within a 6-month period before or after the diagnosis (124 enrollee-years);

- a breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the breast cancer diagnosis administered within a 6-month period before or after the diagnosis (615 enrollee-years);

- a colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (210 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 claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (394 enrollee-years);

- an ovarian cancer diagnosis (that mapped to an Ovarian Cancer HCC) on only one claim 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 (40 enrollee-years);

- a sepsis diagnosis (that mapped to the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock) on only one physician or outpatient claim during the service year but did not have a sepsis diagnosis on a corresponding inpatient hospital claim (152 enrollee-years); or

- a pressure ulcer diagnosis (that mapped to a Pressure Ulcer HCC) on only one claim 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 (24 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	266	$523,456	30
2 – Acute myocardial infarction	410	823,724	30
3 – Embolism	154	468,267	30
4 – Lung cancer	124	1,007,352	30
5 – Breast cancer	615	820,619	30
6 – Colon cancer	210	558,472	30
7 – Prostate cancer	394	497,375	30
8 – Ovarian cancer	40	248,296	30
9 – Sepsis	152	558,378	30
10 – Pressure ulcer	24	219,533	24
Total	**2,389**	**$5,725,472**	**294**

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We sorted the items in each stratum by the enrollee-year (a combination of the enrollee identifier and the year being reviewed), 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.

ESTIMATION METHODOLOGY

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

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 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	Net Overpayments for HCCs That Were Not Validated (for Sampled Enrollee-Years)
1 – Acute stroke	266	$523,456	30	$59,125	30	$54,631
2 – Acute myocardial infarction	410	823,724	30	59,207	30	51,073
3 – Embolism	154	468,267	30	96,068	25	82,814
4 – Lung cancer	124	1,007,352	30	259,618	29	238,858
5 – Breast cancer	615	820,619	30	38,512	30	38,512
6 – Colon cancer	210	558,472	30	77,826	30	73,807
7 – Prostate cancer	394	497,375	30	38,453	29	37,196
8 – Ovarian cancer	40	248,296	30	175,485	29	165,298
9 – Sepsis	152	558,378	30	112,143	13	48,586
10 – Pressure Ulcer	24	219,533	24	219,533	9	78,723
Total	**2,389**	**$5,725,472**	**294**	**$1,135,970**	**254**	**$869,498**

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

Point estimate	$4,934,733
Lower limit	$4,761,271
Upper limit	$5,108,195

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

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

> Any entity seeking to contract as an MA organization must . . . .
>
> (4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following . . . .
>
> (vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:
>
> (A) Written policies, procedures, and standards of conduct that—
>
> (1) Articulate the organization's commitment to comply with all applicable Federal and State standards;
>
> (2) Describe compliance expectations as embodied in the standards of conduct;
>
> (3) Implement the operation of the compliance program;
>
> (4) Provide guidance to employees and others on dealing with potential compliance issues;
>
> (5) Identify how to communicate compliance issues to appropriate compliance personnel;
>
> (6) Describe how potential compliance issues are investigated and resolved by the organization; and
>
> (7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials . . . .
>
> (F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The

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

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

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

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

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

July 9, 2024

James Korn
Regional Inspector General for Audit Services
U.S. Department of Health & Human Services
Office of Inspector General
Office of Audit Services, Region VII
1201 Walnut Street, Suite 1338
Kansas City, MO 64106

Re: Response to OIG Draft Report Number: A-07-22-01209

Dear Mr. Korn,

UCare Minnesota ("UCare") submits this letter in response to the U.S. Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG") draft report, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UCare Minnesota (Contract H2459) Submitted to CMS* (the "Draft Report"). UCare respectfully requests that OIG withdraw its recommendations to repay an extrapolated amount of $4.9 million in overpayments, conduct additional instances of specific, targeted audits, and take additional steps to enhance its current compliance procedures. UCare also urges OIG to adopt a balanced approach to its reviews of Medicare Advantage Organizations ("MAOs") to promote parity and fairness in its audit process. UCare disagrees with OIG's findings for the following reasons, as described in more detail below: (1) OIG's audit methodology and results are fundamentally flawed and inappropriate in the context of a population-based payment model such as that used in the Medicare Advantage ("MA") context; (2) UCare already conducts robust auditing and monitoring to detect similar instances of inaccurate diagnosis codes and is not required to replicate OIG's audit for additional years; and

(3) UCare's compliance procedures are appropriate and regularly reevaluated for improvement and OIG's implicit requirement of 100% accuracy is impractical and impossible to achieve.

I. Background and Policy Considerations

The Centers for Medicare & Medicaid Services ("CMS") pays MAOs what amounts to a fixed monthly payment for each living enrollee, and the MAO covers items and services in exchange that are traditionally paid under Parts A and B of Medicare. Accordingly, MAOs are, with some exceptions, responsible for any Medicare covered care that the enrollee requires. Although calculated at a member level, these payments are derived from a non-competitive bid process that results in a prospective population-based payment. Originally, under the MA program, the government paid MAOs the same amount per enrollee, regardless of health status, which created an incentive for MAOs to try to avoid enrolling sicker individuals, who were likely to have higher health care costs.

The risk adjustment payment model was created to address two main policy and programmatic concerns. First, MA was slow to catch on, especially in rural areas, due to MAOs' concern that plans would be adversely selected by sicker populations, which could (and did) destabilize premiums. Second, regulators and enforcement agencies were mindful of the incentive for MAOs to "cherry pick" healthy patients and "lemon drop" sicker patients to reduce health care costs.

The MA Hierarchical Condition Category ("HCC") Risk Adjustment model was fully implemented in 2007[1], and it addressed these concerns by providing that the payment to an MAO had to be actuarially equivalent to what it would have cost to serve the same population under traditional Medicare. Payments are thus adjusted based on the health of the population subject to each plan's bid. The risk adjustment process accounts for the fact that some members are less healthy than others (and thus are likely to incur higher health care costs) and helps to better align incentives for plans to take risk on the less healthy members. Since the introduction of the HCC model, MA has flourished in providing Medicare beneficiaries with several choices of MAOs with robust benefit packages to better serve their health care needs.

The risk adjustment payment model is rooted in fee-for-service ("FFS") diagnosis coding and the costs associated with treating patients with those diagnoses. In the FFS model, providers are compensated based on actual services provided, not the acuity or cost of a given patient. Accordingly, FFS providers, and their staff, are unsurprisingly focused on documentation to support a particular level of service or procedure code. Providers often lack sufficient training regarding appropriate diagnostic coding (and the approximately 70,000 ICD-10-CM diagnosis codes) to achieve comprehensive, specific and accurate diagnostic coding and reporting as required under the model.[2] A shortcoming of the model is that while MAOs are responsible for reporting all conditions that are coded, they do not have actual control of the documentation and diagnostic practices of providers who submit claims. MAOs are explicitly prohibited from diagnosing patient conditions (or un-diagnosing those conditions, *i.e.,* noting them as "cured") as this could violate prohibitions on the unlicensed practice of medicine; thus, the choice or assignment of diagnoses remains solely within the ambit of licensed providers.

Given both the expected inaccuracies in provider-based coding and the inability of MAOs to control the diagnostic practices of even their own network providers (not to mention non-network providers, with which MAOs have little to no business relationship), it is unrealistic to expect perfect coding accuracy. As discussed in more detail below, CMS, the federal agency charged with regulating MA, has historically understood this, but OIG's audits, given their use of data mining to target only codes most likely to involve errors, effectively impose a 100% accuracy requirement on MAOs, despite the fact that this is not the stated purpose of the audits.

[1] CMS, *Risk Adjustment Methodology: An Overview of Risk Adjustment* at 3.

[2] The ICD-10-CM (International Classification of Diseases, Tenth Revision, Clinical Modification) is system of codes used by healthcare providers to classify diagnoses.

In its audit of UCare, OIG employed data mining to identify so-called "high-risk groups" (which it also refers to as "high-risk diagnosis codes") to determine whether errors existed in two years of payments made to UCare. OIG's audit was designed to find only errors whose correction would benefit the government (overpayments) and failed to consider errors whose correction would benefit UCare (underpayments). OIG then used its highly skewed audit results to support its compliance function recommendation without considering all relevant factors. In doing so, OIG's approach failed to measure whether CMS's payments to UCare were meaningfully accurate. Accordingly, the results of OIG's audit have limited utility in the context of MA's population-based payment methodology. UCare believes that a more instructive and meaningful inquiry would be to consider both underpayments and overpayments and determine whether payments were improper overall, as well as the errors inherent in the FFS data upon which the foundation of the MA model rests. As described below, OIG's audit approach is vexing because, practically speaking, it only tests whether errors exist in a limited sample composed of non-random data mined codes (chosen because they are likely to be erroneous) among the millions of codes submitted by a given health plan. OIG also lacks critical tools to account for diagnostic errors in the Medicare FFS data, which is necessary to determine whether there have actually been improper payments to an MAO. For these reasons and the reasons discussed below, we urge OIG to reconsider its recommendations.

II. OIG should withdraw its recommendation that UCare repay an extrapolated amount of $4.9 million dollars to CMS.

A. OIG's methodology fails to reveal whether UCare actually received an improper payment because it ignores potential underpayments.

OIG's audit targeted only potential *overpayments, rather than both overpayments and underpayments*, by focusing only on a limited set of very narrowly defined situations that it refers to as "high-risk diagnosis codes." The diagnosis codes at issue in this audit – acute stroke (HCC 100), acute myocardial infarction (HCC 86), embolism (HCC 108), lung cancer (HCC 9), breast cancer (HCC 12), colon cancer (HCC 11), prostate cancer (HCC 12), ovarian cancer (HCC 10), sepsis (HCC 2), and pressure ulcer (HCC 158) – are inappropriately identified as being "high-risk diagnosis codes." Rather, the vast majority of these diagnosis codes submitted by providers to UCare and then to CMS are coded appropriately. We believe the same to be true of other MAOs. OIG's audit methodology focuses in on a very limited subset of these particular codes, using data mining techniques outlined in OIG's recently published "Toolkit," to construct a universe of suspect encounters most likely to be invalid.[3] This is equivalent to sorting thousands of barrels of apples, putting all of the bruised and overripe apples into a single barrel, and then using that single barrel as the sole basis to evaluate the merits of the farmer. Not only does OIG ignore the normal apples (codes that are likely supported), but it also fails to account for the apples that are still on the tree, *i.e.*, codes that were never submitted (underpayments).

[3] OIG, *Toolkit: To Help Decrease Improper Payments in Medicare Advantage Through Identification of High-Risk Diagnosis Codes* (December 2023).

In CMS's Risk Adjustment Data Validation ("RADV") audits, CMS permits underpayments to offset findings of overpayments in certain circumstances. As CMS recently explained:

> Occasionally, upon review of these medical records, CMS will uncover "additional" diagnoses supported by the medical records that were not submitted for payment by MAOs during the data collection period for enrollees selected in the sample. Under current contract level RADV policy, when CMS uncovers these additional diagnoses that map to CMS–HCCs during medical record review of audited CMS–HCC(s), these newly-discovered diagnosis codes are used to recalculate risk scores in certain circumstances, which may result in an updated (reduced) improper payment calculation.[4]

Notably, however, this is not the case with OIG's audits, which fail to consider underpayments. OIG only allows MAOs to support the audited HCC, or an HCC within the same category, with an alternative diagnosis code that is supported in the medical record. Moreover, both OIG and CMS fail to take into account the fact that overpayments may be offset by underpayments for enrollees for whom no codes were submitted.

The government itself has argued that "one-sided reviews," which UCare contends are used by OIG, are inappropriate when conducted by MAOs:

> [W]e hold that when, as alleged here, Medicare Advantage organizations design retrospective reviews of enrollees' medical records deliberately to avoid identifying erroneously submitted diagnosis codes that might otherwise have been identified with reasonable diligence, they can no longer certify, based on best knowledge, information and belief, the accuracy, completeness and truthfulness of the data submitted to CMS.[5]

Perfect coding by providers and 100% accuracy in submission is not realistically achievable in the MA context, and it is unfair and unrealistic to hold providers and MAOs to this unattainable standard. Such a standard would sandbag MAOs with administrative costs that would result in decreased benefits, lower provider reimbursement rates, and higher premiums. It will always be possible for OIG to design narrowly focused audits that locate pockets of inaccurate provider coding when it is in the government's favor. But audits that focus on cherry-picked codes do not show that an MAO was overpaid or failed its compliance obligations in any meaningful way in a prospective population-based payment system. An MAO could, similarly, use data mining

[4] CMS, Final Rule, *Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021*, 88 Fed. Reg. 6643, 6652 (Feb. 1, 2023).

[5] *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1175 (9th Cir. 2016).

techniques to design narrowly targeted audits that would find pockets of underpayments and then respond that it was underpaid.

To illustrate this point, UCare conducted an analysis that targeted chronic conditions that do not resolve and were not submitted for members in consecutive years. Despite a condition's chronicity, CMS requires MAOs to resubmit all member conditions on an annual basis. If not submitted, that MAO is effectively underpaid for those patients and the costs associated with those conditions. For this analysis, UCare identified instances where a chronic condition was submitted for a member in year one (2016 or 2017) but not captured in year two (2017 or 2018). UCare calculated the value of potential underpayments for several chronic conditions that were not captured in a subsequent year. The value associated with just one condition, congestive heart failure (HCC 85), was enough to offset the approximately $5 million dollars of the extrapolated overpayment identified by OIG for the ten "high risk" diagnoses audited. If UCare was to adopt an audit strategy similar to OIG's, except target potential underpayments, UCare believes that it could handily identify $17 million dollars in underpayments for just ten chronic conditions.[6]

In short, the goal of the audit process in MA should not be to find every instance of an unsupported code and only when it benefits the government. This is both impractical and inconsistent with principles of fair contracting. Rather, the goal should be to ensure that, when the overall payment to an MAO is considered, this payment does not exceed what it would have cost CMS to cover the same members under traditional FFS Medicare. Based on UCare's analysis, the payment to UCare for these DOS not only did not exceed this amount but UCare was significantly underpaid for these years. OIG's approach is accordingly materially flawed and, ultimately, will not benefit the MA program.

B. OIG's methodology fails to ensure required actuarial equivalence between traditional Medicare and MA because it ignores errors in the FFS data.

Another issue with OIG's methodology is that, by extrapolating its findings without the use of a FFS adjuster, it fails to ensure requisite actuarial equivalence. Payments to MAOs are meant to equate to what CMS would have had to pay to cover the costs associated with the same population under traditional FFS Medicare. This is ensured through the statutory requirement of "actuarial equivalence." The statute provides that:

> [T]he Secretary shall adjust the payment amount … for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status … so as ***to ensure actuarial equivalence***.[7]

[6] Ten conditions included in this analysis: HCC 85 (Congestive heart failure), HCC 111 (Chronic obstructive pulmonary disease), HCC 96 (Specified heart arrythmias), HCC 103 (Hemiplegia, hemiparesis), HCC 18 (Diabetes with chronic complications), HCC 112 (Fibrosis of lung and other chronic lung disorders), HCC 78 (Parkinson's and Huntington's diseases), HCC 189 (Amputation status, lower limb / amputation complications), HCC 77 (Multiple sclerosis) and HCC 70 (Quadriplegia).

[7] 42 U.S.C. § 1395w-23(a)(1)(C)(i) (emphasis added).

HHS has explained that "MA plans are required to offer a benefit package that is actuarially equivalent to traditional Medicare's benefit package (e.g., having the same value, based on the estimated spending that would be incurred by the insurer)."[8]

Unaudited FFS data is used to develop the MA risk adjustment payment. If the error rates are comparable in both FFS and MA data sets, then MAOs are still being paid the equivalent of what it would have cost CMS to cover the same population under FFS Medicare. However, if the payment rates are set using erroneous FFS data, but MAOs are effectively held to a 100% accuracy rate through audit recovery, this will result in underpayments to MAOs.

Notably, CMS has recognized that MAOs are coding "accurately" if their coding is comparable to that in the FFS Medicare program, stating:

> Given the fact that the MA payment methodology is based on fee-for-service payments, and that the risk adjustment methodology is designed to compare the risk scores of MA plan enrollees to other plan enrollees and beneficiaries not enrolled in MA plans, for this comparison to be valid, MA plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid. This means that MA organizations are coding "accurately" when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared.[9]

CMS first stated in 2010 that it intended to begin extrapolating the results of its RADV audits. At that time, MAOs raised concerns regarding the discrepancy between the unaudited FFS data and the audited MA data.[10] In 2012, CMS responded with an announcement that it would apply a "FFS adjuster" to the results of its RADV audits prior to extrapolation to account for the inherent error rate in the FFS data.[11] This would mean that, if the MA plan's error rate was lower than the error rate in the FFS data, no extrapolated payment would be recovered. Since that time, MAOs, including UCare, have relied on those representations in making their actuarial calculations and in submitting their annual bids to CMS.

[8] HHS, *Payment for Medicare Advantage Plans: Policy Issues and Options* (June 2009).

[9] CMS, *Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies* (April 6, 2009).

[10] *Id.*

[11] CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation for Contract-Level Audits* (Feb. 24, 2012) ("[T]o determine the final payment recovery amount, CMS will apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount. . . . The FFS adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims). The actual amount of the adjuster will be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data.").

However, in 2018, CMS released a study purporting to show that a FFS adjuster was not necessary.[12] It also released a proposed rule stating that CMS no longer intended to use a FFS adjuster prior to extrapolation.[13] Numerous comments submitted in response to the proposed rule discussed the flaws with CMS's study and with its conclusion that no FFS adjuster was needed.[14]

Nonetheless, in 2023, CMS released its final rule for RADV audits that confirmed that it would not apply a FFS adjuster to the RADV error rate prior to extrapolation.[15] At this time, CMS gave a completely different rationale for the lack of a FFS adjuster, asserting, based on the court's decision in *UnitedHealthcare Ins. Co. v. Becerra*,[16] that the actuarial equivalence requirement does not apply to the obligation to return improper payments.[17] This rationale was nowhere to be found in the proposed rule. Moreover, this explanation makes little sense, as it would allow CMS to nominally comply with the actuarial equivalence requirement on the front end when setting payment amounts, but then evade it on the back end through extrapolated contract-wide audit recoveries based on a comparison of audited MA data to unaudited FFS data.[18]

CMS stated in the final rule that it would begin extrapolating audit findings starting with payment year 2018. The final rule has been challenged in a lawsuit filed by Humana Inc. and its subsidiary Humana Benefit Plan of Texas, Inc.[19] In its complaint, Humana notes that:

[12] CMS, *Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits* (Oct. 26, 2018).

[13] CMS, Proposed Rule, *Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021*, 83 Fed. Reg. 54982 (Nov. 1, 2018).

[14] CMS, Final Rule, 88 Fed. Reg. 6643, 6656 (Feb. 1, 2023).

[15] *Id.*

[16] 16 F.4th 867 (D.C. Cir. 2021).

[17] CMS, Final Rule, 88 Fed. Reg. 6643, 6656 (Feb. 1, 2023) ("The first basis for our decision not to apply a FFS Adjuster is because we believe that the actuarial equivalence provision of the statute applies only to how CMS risk adjusts the payments it makes to MAOs, and not to the obligation to return improper payments for diagnosis codes submitted by MAOs to CMS lacking medical record support. This position is consistent with the D.C. Circuit's decision in UnitedHealthcare.").

[18] CMS also stated that the existence of the coding intensity adjustment factor in MA showed that CMS was not required to adopt a FFS adjuster because "it would be unreasonable to interpret the [Social Security] Act as requiring a minimum reduction in payments in one provision (the coding pattern provision), while at the same time prohibiting CMS in an adjacent provision (the actuarial equivalence provision) from enforcing those longstanding requirements (by requiring an offset to the recovery amount calculated for CMS audits)." CMS, Final Rule, 88 Fed. Reg. 6643, 6656 (Feb. 1, 2023). This is a flawed argument. CMS could apply a FFS adjuster and still enforce documentation requirements. Moreover, the FFS adjuster and the coding intensity adjustment address two separate issues. The coding intensity adjustment factor is intended to adjust for different coding patters in MA and FFS, not for inaccurate coding. CMS, *Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* at 18-19 (Apr. 5, 2010) ("the MA coding adjustment factor is not intended to adjust for inaccurate coding, but for the impact on risk scores of coding patterns that differ from FFS coding."). The FFS adjuster is meant to adjust for errors in the FFS data. The existence of an adjustment for coding intensity in no way suggests that the application of a FFS adjuster is unnecessary.

[19] *Humana Inc. v. Becerra*, 4:23-cv-00909-O (N.D. Tex.) (complaint filed Sept. 1, 2023).

> When external expert actuaries retained by Humana replicated the study eliminating [certain errors with CMS's methodology], they found that the presence of diagnosis codes in fee-for-service Medicare claims data not documented in the associated medical records deflated Medicare Advantage payment rates by at least 9.9 percent as compared to payment rates derived from audited data that included only diagnosis codes documented in the medical record. In short, when properly analyzed, even CMS's flawed and incomplete study actually confirmed that eliminating the FFS Adjuster would disrupt actuarial equivalence. CMS's own internal documents seemed to acknowledge this fact, describing an earlier version of the study that had estimated Medicare Advantage payments would be 8.1 percent higher if the agency's risk-adjustment 'model had been built using perfect data.'[20]

UCare disagrees with CMS's reasoning regarding the non-application of a FFS adjuster. Moreover, even if the lack of a FFS adjuster were appropriate in the case of CMS's RADV audits (which it is not), the same would not hold true for OIG's audits that target "high-risk diagnosis codes." In its 2018 study, CMS stated that it found a claim-level error rate in the FFS data that ranged from 21% to 46%.[21] However, CMS concluded that the overall reimbursement to MAOs would still be appropriate without a FFS adjuster because, across a plan's enrollment, the inaccuracies "mitigate each other due to offsetting effects."[22] Even if this were the case in the context of traditional CMS's RADV audits, which look at a random sample or cohort of codes and account for underpayments, it would not be the case in OIG's targeted "high-risk diagnosis code" audits where there is no opportunity for such inaccuracies to "mitigate each other." Moreover, if a FFS adjuster were used in the context of these OIG audits, it would need to be a far larger offset than the adjuster that would apply to RADV audits, as it would need to reflect the error rate that occurs in the FFS data for these same "high-risk diagnosis codes."

Because OIG's methodology fails to account for errors in the FFS data, it violates the statutory requirement of actuarial equivalence. And although it might be up to CMS, rather than OIG, to apply a FFS adjuster, CMS has made clear (through the preamble to its recent final rule) that it does not intend to do so. Given this, the recovery of extrapolated payments based on OIG's findings would be inappropriate.

C. Both OIG and CMS lack the authority to extrapolate from OIG's findings in this audit.

[20] *Humana Inc. v. Becerra*, 4:23-cv-00909-O (N.D. Tex.) (Complaint filed Sept. 1, 2023) at ¶¶ 59-60

[21] CMS, *Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits* (Oct. 26, 2018).

[22] *Id.*

The statute regarding limitations on the use of extrapolation in audit recoveries permits extrapolation only for Medicare contractors, and then only when there is a sustained or high level of payment error or education intervention has failed to correct the errors.[23] None of these conditions exists here. In fact, CMS previously acknowledged that it lacked the statutory authority to extrapolate in RADV audits and unsuccessfully sought authorization from Congress to do so.[24]

Further, even if CMS did have the statutory authority to extrapolate in the context of RADV audits, there is no statutory authority that enables CMS or OIG to extrapolate in the context of this OIG audit. OIG conducted this audit under the Inspector General Act of 1978 ("IGA"), which does not authorize OIG to extrapolate results of its audits and recover overpayments. Moreover, despite CMS's assertion in the preamble to the February 1, 2023 final rule that "CMS can collect extrapolated amounts calculated by the OIG,"[25] the regulations promulgated in that final rule only mention extrapolation in the context of RADV audits, not in the context of OIG audits conducted under the IGA.[26] It is well recognized that the preamble to a final rule is not itself a regulation. Rather, the courts have held that "publication in the Federal Register does not suggest that the matter published was meant to be a regulation" and that "when there is a discrepancy between the preamble and the Code, it is the codified provisions that control."[27] In short, both OIG and CMS lack the statutory and regulatory authority to engage in extrapolation in the context of the present audit.

D. OIG's audit methodology constitutes a new substantive legal standard that should not have been adopted without notice and comment rulemaking.

Federal agencies must engage in the notice and comment rulemaking process when adopting substantive legal standards relating to the Medicare program.[28] The Supreme Court has stated that: "Notice and comment gives affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes—and it affords the agency a chance to avoid errors and make a more informed decision."[29]

[23] 42 U.S.C. § 1395ddd(f)(3).

[24] HHS, CMS, *Fiscal Year 2011 Justification of Estimates for Appropriations Committees* at 177 (stating that proposal would "[c]larify in statute that CMS can extrapolate the error rate found in the risk adjustment validation (RADV) audits to the entire MA plan payment for a given year when recouping overpayments").

[25] CMS, Final Rule, 88 Fed. Reg. 6643, 6645, n.6 (Feb. 1, 2023) ("CMS contract-level RADV audits focus on specific MAO contracts to determine and recoup improper payments. The HHS–OIG also undertakes audits of MAOs, similar to RADV audits, as part of its oversight functions. CMS can collect the improper payments identified during those HHS–OIG audits, including the extrapolated amounts calculated by the OIG.").

[26] 42 CFR § 422.310(e) ("For RADV audits, CMS may extrapolate RADV Contract-Level audit findings for payment year 2018 and subsequent payment years."); 42 CFR § 422.311(a) (discussing extrapolation in the context of the RADV audit process).

[27] *AT&T Corp. v. FCC*, 970 F.3d 344, 350-51 (D.C. Cir. 2020).

[28] 42 U.S.C. § 1395hh(a)(2).

[29] *Azar v. Allina Health Services*, 139 S. Ct. 1804, 1816 (2019).

In *Azar v. Allina Health Services*, the Supreme Court of the United States held that the notice and comment rulemaking obligation is broader under the Medicare Act (which requires notice and comment when the government adopts or changes a "substantive legal standard") than under the Administrative Procedure Act ("APA") (which requires notice and comment when the government adopts or changes a "substantive rule").[30] The HHS Office of General Counsel has noted that when Medicare manuals and similar guidance "set forth payment rules that are not closely tied to statutory or regulatory standards, the government generally cannot use violations of that guidance in enforcement actions, because under *Allina*, it was not validly issued."[31]

OIG's audit methodology differs in fundamental ways from that of CMS, the agency charged with Medicare program administration and rulemaking, in which a random representative sample is used to determine whether the overall payment to an MAO was appropriate. As discussed in more detail below, OIG's methodology is also applied inconsistently between audits. As such, OIG's approach in this audit amounts to the adoption of a substantive legal standard, and thus should not have been implemented without notice and comment rulemaking.

OIG has stated in other audit reports that it is only making recommendations to CMS and that it is permitted to do so under the IGA.[32] However, were CMS permitted to follow the recommendations of OIG in this audit report, this would enable OIG and CMS to impermissibly adopt a new substantive legal standard without engaging in the required notice and comment rulemaking process. Nothing in the IGA suggests that Congress intended to allow agencies to use it as a means of circumventing their obligation to engage in notice and comment rulemaking. In short, the approach used in the UCare audit amounts to a new substantive standard that should not have been adopted without notice and comment rulemaking.

E. Neither CMS nor OIG is permitted to impose its audit methodology retroactively.

Another problem with OIG's approach is that OIG imposes its new audit methodology retroactively. As discussed above, above, CMS had long assured MAOs that it would apply a FFS adjuster before extrapolating audit results. It reversed its position in a proposed rule in 2018, stating

[30] *Azar v. Allina*; *Compare* Medicare Act, 42 U.S.C. § 1395hh(a)(2) ("No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a *substantive legal standard governing … the payment for services*… under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).") *with* APA, 5 U.S.C. § 553 (requiring notice and comment for any "*substantive rule*") (emphasis added).

[31] HHS Office of the General Counsel, *Impact of Allina on Medicare Payment Rules* (October 31, 2019); *see also* HHS Office of the General Counsel, *Advisory Opinion 20-05 on Implementing Allina* (December 3, 2020) ("to the extent that guidance documents set forth Medicare policies or rules that are not closely tied to statutory or regulatory standards, the government generally cannot use violations of that guidance to inform the basis for any enforcement action, because under Allina, it was not validly issued").

[32] *See, e.g.,* BCBS of Tennessee audit (2022) ("With respect to BCBST's comments that the Inspector General Act of 1978, 5 U.S.C. App does not authorize us to extrapolate, we note that neither the statute nor any other authority limits our ability to recommend a recovery to CMS based on extrapolation.").

that it would not in fact adopt a FFS adjuster. In a final rule issued in 2023, CMS announced that it would retroactively apply this policy to audits of payment years 2018 and beyond.

The present audit covers payment years 2018 and 2019, which correspond to 2017 and 2018 dates of service. UCare submitted bids to CMS for these years in 2016 and 2017. In doing so, UCare reasonably relied on CMS's assurance that it would not extrapolate audit findings without using a FFS adjuster. Even if it were appropriate to extrapolate audit results without the use of a FFS adjuster in future years, it would not be appropriate to do so for the payment years at issue here.

As the Supreme Court has recognized, there is a strong presumption against applying statutes and regulations retroactively:

> [T]he presumption against retroactive legislation is deeply rooted in our jurisprudence, and embodies a legal doctrine centuries older than our Republic. Elementary considerations of fairness dictate that individuals should have an opportunity to know what the law is and to conform their conduct accordingly; settled expectations should not be lightly disrupted. For that reason, the principle that the legal effect of conduct should ordinarily be assessed under the law that existed when the conduct took place has timeless and universal appeal. In a free, dynamic society, creativity in both commercial and artistic endeavors is fostered by a rule of law that gives people confidence about the legal consequences of their actions.[33]

Under the Social Security Act, rules cannot be applied retroactively unless they are necessary to comply with statutory requirements or a failure to apply the change retroactively would be contrary to the public interest.[34] In the preamble to its February 1, 2023 final rule, CMS asserted that the extrapolation provisions in the rule are not retroactive because MAOs have always been required to submit only codes that can be backed up with medical records.[35] This is disingenuous.

A new rule is "retroactive" if it "is 'substantively inconsistent' with a prior agency practice and attaches new legal consequences to events completed before its enactment."[36] Stated another

[33] *Landgraf v. USI Film Products*, 511 U.S. 244, 265–66 (1994) (citations, footnotes, and internal quotation marks omitted).

[34] 42 U.S.C. §1395hh(e)(1)(A) ("A substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that (i) such retroactive application is necessary to comply with statutory requirements; or (ii) failure to apply the change retroactively would be contrary to the public interest.").

[35] CMS, Final Rule, 88 Fed. Reg. 6643, 6650-51, 6653 (Feb. 1, 2023).

[36] *Northeast Hospital Corporation v. Sebelius*, 657 F.3d 1, 14 (D.C. Cir. 2011), *quoting Arkema Inc. v. EPA*, 618 F.3d 1, 7 (D.C. Cir. 2010).

way, "if the new rule effects a substantive change from the agency's prior regulation or practice, then it is impermissibly retroactive."[37] Thus, the Supreme Court has held that retroactive application of a new rule to recoup amounts previously paid to hospitals was impermissible.[38] Similarly, the D.C. Circuit has held that the "Secretary's decision to apply her present interpretation" of a statute to previous fiscal years violated the rule against retroactive rulemaking.[39]

While it is true that MAOs have always been required to refund a risk adjustment payment if they learned that a particular diagnosis code was unsupported, this is a far cry from saying that they should have known that CMS would completely reverse its long-held position that extrapolated amounts would not be recovered in the absence of a FFS adjuster in the context of RADV audits. And it is even more of a stretch to suggest that MAOs should have expected recoupment without a FFS adjuster in the context of OIG's heavily data mined "high-risk diagnosis code" based audits.

CMS also asserted in the final rule that, even if the provisions were retroactive, the retroactive application of the provisions would be appropriate under the statute because it is in the public interest and necessary to comply with statutory requirements. Again, this is disingenuous. CMS has decided not to collect extrapolated amounts for payment years 2011 through 2017, contrary to what it had proposed in the 2018 proposed rule. Clearly, it is feasible to ignore past payment years when implementing extrapolation.

Moreover, in making bids and designing benefits packages for past years, MAOs relied on CMS's long-standing assurance that it would apply a FFS adjuster before seeking to collect extrapolated amounts. Given this, retroactive application of CMS's new extrapolation policy will likely impose serious financial burdens on some MAOs, and, in particular, on smaller MAOs, potentially leading to even greater concentration within the industry, and fewer options for seniors, both to the detriment of consumers. This is neither necessary to comply with statutory requirements nor in the public interest.

F. OIG is not sufficiently transparent about its audit methodology and reached incorrect conclusions regarding whether certain diagnosis codes were supported by the medical records.

OIG is not sufficiently transparent about the methodology used in its audits. It does not identify its medical review contractors, making it impossible to determine whether there is a conflict of interest. It does not reveal the credentials of the reviewers. It does not reveal the coding policies and procedures used. It does not disclose the determinations made at each level of review.

[37] *Kirwa v. United States Department of Defense*, 285 F. Supp. 3d 257, 271 (D.D.C. 2018) (citation and internal quotation marks omitted).

[38] *Bowen v. Georgetown University Hospital*, 488 U.S. 204 (1988).

[39] *Northeast Hospital Corporation v. Sebelius*, 657 F.3d 1, 16 (D.C. Cir. 2011).

And it does not reveal the documentation standards applied during the audits. This lack of transparency makes it impossible for MAOs to fully evaluate OIG's audit methodology and results.

Additionally, UCare disagrees with a number of OIG's conclusions that specific codes were unsupported. As described in more detail in the enclosed **Attachment A**, OIG failed to follow industry standard coding guidelines that support the conditions audited in the record provided. UCare requests that OIG take into consideration the support outlined by UCare in **Attachment A**, reevaluate the relevant medical records, apply appropriate coding standards, and provide UCare with revised error rates.

G. OIG's audit methodology is arbitrary and capricious because, among other things, the outcomes vary dramatically based on whether OIG or CMS conducts a given audit, and on which criteria OIG chooses to use for a particular audit.

Agency actions can be set aside when they are arbitrary and capricious.[40] OIG's MA audits are arbitrary and capricious for a variety of reasons. These audits: (1) target only overpayments and specifically ignore underpayments; (2) fail to account for errors in the FFS data; and (3) were adopted without adequate opportunity for notice and comment.

Further, OIG's approach is arbitrary and capricious because it differs dramatically not only from CMS's approach but also from one OIG audit to the next, offering far too much discretion to OIG to essentially reopen closed contract years to search for imperfections. While most OIG audits have, like this audit, targeted "high-risk diagnosis codes," at least six audits released since the beginning of 2019 have instead used samples of enrollees.[41] Where "high-risk diagnosis codes" were used, the categories have varied from one audit to the next, consisting of differing subsets of fourteen different categories.[42]

Further, the number of "high-risk diagnosis code" groups used in an audit has varied from as few as two[43] to as many as ten.[44] And among the audits that involved "high-risk diagnosis codes," the categories used have varied. For instance, while the UCare audit includes groups for Pressure Ulcer and Sepsis, we have seen no other audit reports to date that include those groups.

[40] 5 U.S.C. § 701(a)(1)–(2).

[41] CarePlus (October 2023); Cigna HealthSpring of Florida (August 2022); Health Net of California (September 2023); Humana (April 2021); Inter Valley (September 2022); SCAN Health (February 2022).

[42] These categories are: Acute Heart Attack; Acute Stroke; Acute Stroke and Heart Attack; Cancer – Breast; Cancer – Colon; Cancer – Lung; Cancer – Ovarian; Cancer – Prostate; Embolism; Major Depressive Disorder; Potentially Miskeyed Codes; Pressure Ulcers; Sepsis; and Vascular Claudication.

[43] Essence (2019).

[44] SelectCare of Texas (November 2023); UPMC (November 2021); Cigna HealthSpring of Tennessee (December 2022); and this UCare audit.

Additionally, OIG's definition of a given "high-risk diagnosis code" group has varied from audit to audit. For example, in one audit, the "high-risk diagnosis code" group for acute stroke was defined as:

> An enrollee received an acute stroke diagnosis … ***on one or two physician claims*** during the service year but did not have that diagnosis on a corresponding ***inpatient hospital claim***.[45]

In another audit, the "high-risk diagnosis code" group for acute stroke was defined as:

> An enrollee received one acute stroke diagnosis … ***on one physician claim*** during the service year but did not have that diagnosis on a corresponding ***inpatient or outpatient hospital claim***.[46]

In the Draft Report, the "high-risk diagnosis code" group for acute stroke was defined as:

> Enrollee received an acute stroke diagnosis ***on only one physician claim*** but did not have that diagnosis on a corresponding ***inpatient hospital claim***.[47]

By extrapolating from the errors found in the highly targeted "high-risk groups,", OIG's audit methodology, in effect, demands that MAOs achieve 100% accuracy (at least in terms of avoiding overpayments). In contrast, the regulations provide only that an MAO's CEO or CFO must certify to the accuracy, completeness, and truthfulness of the data "based on best knowledge, information, and belief."[48] CMS has acknowledged that MAOs "cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], [OIG], and [the Department of Justice] believe is reasonable to enforce."[49]

Similarly, OIG has stated that:

> The requirement that the CEO or CFO certify as to the accuracy, completeness and truthfulness of data, based on best knowledge, information and belief, does not constitute an absolute guarantee of accuracy. Rather, it creates a duty on the [MA] organization to put in place an information collection and reporting system reasonably designed to yield accurate information. Further, the [MA] organization should exercise due diligence to ensure that these systems are working properly. The exact methods used by the [MA]

[45] Essence (April 2019) (emphasis added).

[46] Cigna HealthSpring Life & Health Insurance (March 2023) (emphasis added).

[47] Draft Report (emphasis added).

[48] 42 C.F.R. § 422.504(l).

[49] HCFA, Final Rule, *Medicare Program: Medicare+Choice Program*, 65 Fed. Reg. 40170, 40268 (June 29, 2000).

> organization to accomplish this can be determined by the organization, however, it should ordinarily conduct sample audits and spot checks of this system to verify whether it is yielding accurate information.[50]

III. OIG should withdraw its recommendation that UCare conduct additional auditing related to the "high-risk diagnosis codes" in this audit.

OIG recommends that UCare "identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after [the] audit period and refund any resulting overpayments to the Federal Government." UCare disagrees with this recommendation and respectfully requests that OIG remove this recommendation from its final report. MA regulations do not require MAOs to perform the audits OIG recommends, nor does OIG have the authority to require such audits.

In its response to similar arguments made by MAOs, OIG has stated time and again that, under federal regulations, MAOs must "implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS' program requirements" and that MAOs' compliance plans "must, at a minimum, include [certain] core requirements," which include "an effective system for routine monitoring and identification of compliance risks . . . [including] internal monitoring and audits and, as appropriate, external audits to evaluate . . . compliance with CMS requirements and the overall effectiveness of the compliance program."[51] But OIG has not, and cannot, identify any statute, regulation, or guidance issued by CMS that requires MAOs to conduct audits of specific "high-risk diagnoses" and make associated repayments.

OIG is effectively imposing a new rule on UCare by recommending that UCare perform additional audits of "high-risk diagnoses." As previously explained, OIG has no authority to impose new substantive requirements on MAOs, nor can it implement a rule without notice and comment rulemaking. As such, UCare does not agree with OIG's recommendation. Nonetheless, UCare has taken proactive steps to identify certain codes and remove them from its data submissions. Prior to the audit, as acknowledged by OIG in its Draft Report, UCare implemented a data filter to identify and retract stroke diagnosis codes originating from a physician office location. Subsequent to the audit, UCare has implemented data filters to remove or delete certain "high-risk" encounters from its universe and enhanced its oversight activities.

IV. OIG should withdraw its recommendation that UCare's compliance program be improved.

[50] OIG, Notice, *Publication of the OIG's Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans*, 64 Fed. Reg. 61893, 61900.

[51] *See, e.g.,* Geisinger audit at 40-41 (Appendix E) and MCS Advantage audit at 38-39 (Appendix E), *quoting* 42 CFR § 422.503(b)(4)(vi).

OIG has recommended that UCare "continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures."[52] While UCare continuously works to improve and update its compliance program, UCare disagrees with OIG's conclusion that UCare's compliance program is not adequate in its current form.

OIG states in the Draft Report:

> As demonstrated by the errors found in our sample, the policies and procedures that UCare had to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations … could be improved.

This suggests that a less than perfect audit result automatically demonstrates that the compliance program in place is inadequate. But the results of OIG's one-way audit based on data mined coding patterns do not prove that UCare's compliance program was insufficient. Rather, the results merely prove that providers are not 100% accurate when recording the diagnosis codes associated with the procedure codes that they submit for reimbursement. As discussed in more detail above, an MAO's compliance program does not need to achieve 100% accuracy to be deemed effective. OIG itself has acknowledged this, stating:

> The OIG recognizes the implementation of an effective compliance program may not entirely eliminate fraud, abuse and waste from an organization.[53]

Further, UCare already has a robust compliance program is already in place. OIG acknowledged this in the Draft Report, stating:

> As part of its preventative measures, in place that consisted of a variety of provider-specific outreach efforts that provided clarification on coding matters. These efforts included the distribution of a provider manual and monthly newsletters to educate providers on the submission of accurate risk adjustment data. UCare also offered provider coding classes and additional education materials that outlined specific guidance on how to accurately code some of the high-risk areas identified in this audit (acute stroke and cancer), and when to code a condition as active as opposed to historical.

[52] Draft Report at 19.

[53] OIG, Notice, *Publication of the OIG's Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans*, 64 Fed. Reg. 61893, 61895.

> Additionally, UCare required its coders to adhere to various preventative measures. Specifically, UCare required all newly hired coders to complete a coding assessment to identify codes with at least 95-percent accuracy; moreover, all coders are subject to multiple inter-rater reliability reviews throughout the year. UCare uses the results of these reviews to identify additional areas for training or coaching. Coders are also required to complete coding compliance program training annually.
>
> As part of its detection and correction measures, UCare has annually conducted focused reviews of claims submitted by providers. The areas selected for review have been based on trends noted in government audits, as well as internal audits and analyses, to identify potential data outliers and included a high-risk area identified in this audit (myocardial infarction). If the reviews identified any coding errors, UCare provided guidance to providers on how to submit the corrections to CMS. UCare also implemented a data filter to identify and retract stroke diagnosis codes originating from a physician office location. The filter did not identify claims originating from outpatient hospital-based clinics, so acute strokes that were diagnosed in these settings were not flagged for retraction.
>
> When asked about the errors that we identified in this audit, UCare stated that it is "continually reviewing our processes and will look at these on a high level." UCare officials told us that it is in the process of updating the data filter to include all office-based settings for acute stroke and will be creating an additional filter that applies the same logic for myocardial infarction claims.
>
> We acknowledge that UCare has compliance procedures that include 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.[54]

MAOs have broad discretion to design and implement their compliance programs, and specifically their auditing and monitoring function.[55] UCare is continually refining and reviewing processes to improve its compliance program. Its compliance program is no longer the same program it was during the payment years at issue in this audit. OIG's audit of old claims data from services provided in 2017 and 2018 is not representative of UCare's current compliance practices, which were not reviewed by OIG. Because UCare believes that its compliance program is already

[54] Draft Report at 18 (footnote omitted).

[55] OIG, Notice, 64 Fed. Reg. 61893, 61900. ("The exact methods used by the [MA] organization to accomplish this can be determined by the organization, however, it should ordinarily conduct sample audits and spot checks of this system to verify whether it is yielding accurate information.").

robust and compliant with all applicable legal and regulatory requirements, UCare respectfully requests that OIG withdraw its recommendation that UCare enhance its compliance program.

V. Conclusion

For the reasons noted above, UCare respectfully requests that OIG revise its Draft Report and withdraw its draft recommendations. We do note that OIG's audits have high utility in creating and testing selected conditional based logic to identify circumstances in which CMS should consider revising its own filtering logic applied to claim submissions to level the playing field for all MAOs. We urge OIG to work with CMS to use the results of its audits to inform risk adjustment model changes rather than attempting to address systemic issues relating to provider coding through random, inconsistent, and unfair penalties on individual MAOs.

Respectfully,

/s/ Daniel D. Santos
Daniel D. Santos
Executive Vice President, Chief Legal Officer, and
Interim Chief Compliance & Ethics Officer

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