

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE
COMPLIANCE AUDIT OF SPECIFIC
DIAGNOSIS CODES THAT WELLCARE
OF FLORIDA, INC., (CONTRACT
H1032) SUBMITTED TO CMS**

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Office of Inspector General

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Report in Brief

Date: August 2022

Report No. A-04-19-07084

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



Why OIG Did This Audit

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

To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS.

For this audit, we reviewed one MA organization, WellCare of Florida, Inc. (WellCare), and focused on seven groups of high-risk diagnosis codes.

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

How OIG Did This Audit

We sampled 250 unique enrollee-years with the high-risk diagnosis codes for which WellCare received higher payments for 2015 through 2016, respectively. We limited our audit to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$689,234.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc., (Contract H1032) Submitted to CMS

What OIG Found

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that WellCare submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 97 of the 250 sampled enrollee-years, the medical records supported the diagnosis codes that WellCare submitted to CMS. However, for the remaining 153 enrollee-years, the diagnosis codes were not supported in the medical records and resulted in net overpayments of \$410,110. These errors occurred because the policies and procedures that WellCare had to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. On the basis of our sample results, we estimated that WellCare received at least \$3.5 million of net overpayments in 2015 and 2016.

What OIG Recommends and WellCare Comments

We recommend that WellCare: (1) refund to the Federal Government the \$3.5 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 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.

WellCare disagreed with some of our findings and with our first recommendation. WellCare did not agree with our findings for 4 enrollee-years identified in our draft report and did not directly address our findings for the remaining enrollee-years. WellCare also disagreed with our audit methodology and stated that we improperly implied that MA organizations are expected to assure that 100 percent of the diagnosis codes received from providers and submitted to CMS are accurate. WellCare added that it would consider our second and third recommendations to evaluate and enhance its compliance procedures. After reviewing WellCare's comments and coordinating with the independent medical review contractor, we revised the number of enrollee-years in error from 156 (in our draft report) to 153, and reduced the amount in our first recommendation from \$3.6 million to \$3.5 million, for this final report.

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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. We are auditing MA organizations because some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.¹

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. Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 29 major depressive disorder diagnoses into 1 group.) This audit covered WellCare of Florida, Inc. (WellCare), for contract number H1032 and focused on seven groups of high-risk diagnosis codes for payment years 2015 and 2016.² (See Appendix B for a list of related Office of Inspector General (OIG) reports on MA organizations.)

OBJECTIVE

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

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

² All subsequent references to "WellCare" in this report refer solely to contract number H1032.

BACKGROUND

Medicare Advantage Program

The MA program offers beneficiaries managed care options by allowing them to enroll in private health care plans rather than having their care covered through Medicare's traditional fee-for-service program.³ Beneficiaries who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

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

For 2019, CMS paid MA organizations \$273.8 billion, which represented 34 percent of all Medicare payments for that year.

Risk Adjustment Program

Federal requirements mandate that payments to MA organizations be based on the anticipated cost of providing Medicare benefits to a given enrollee and, in doing so, also account for variations in the demographic characteristics and health status of each enrollee.⁴

CMS uses two principal components to calculate the risk-adjusted payment that it will make to an MA organization for an enrollee: (1) a base rate that CMS sets using bid amounts received from the MA organization and (2) 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.⁵ CMS compares each bid to a specific benchmark

³ 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.

⁴ The Social Security Act (the Act) §§ 1853(a)(1)(C) and (a)(3); 42 CFR § 422.308(c).

⁵ The Act § 1854(a)(6); 42 CFR § 422.254, *et seq.*

amount for each geographic area to determine the base rate that an MA organization is paid for each of its enrollees.⁶

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

To determine an enrollee's health status for purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from acceptable data sources, including certain physicians and hospitals. 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).⁷ Each HCC has a factor (which is a numerical value) assigned to it for use in each enrollee's risk score.

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

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

The risk adjustment program is prospective. Specifically, CMS uses the diagnosis codes that the enrollee received for one 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

⁶ CMS's bid-benchmark comparison also determines whether the MA organization must offer supplemental benefits or must charge a basic beneficiary premium for the benefits.

⁷ CMS transitioned from one HCC payment model to another during our audit period. As part of this transition, for 2015, CMS calculated risk scores based on both payment models. CMS refers to these models as the Version 12 model and the Version 22 model, each of which has unique HCCs. CMS blended the two separate risk scores into a single risk score that it used to calculate a risk-adjusted payment. Accordingly, for 2015, an enrollee's blended risk score is based on the HCCs from both payment models. For 2016, CMS calculated risk scores using the Version 22 model.

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

CMS multiplies the risk scores by the base rates to calculate the total monthly Medicare payment that an MA organization receives for each enrollee before applying the budget sequestration reduction.⁸ Miscoded diagnoses submitted to CMS may result in HCCs that are not validated and incorrect enrollee risk scores, which may lead to improper payments (overpayments) from CMS to MA organizations. Conversely, correctly coded diagnoses that MA organizations do not submit to CMS may lead to improper payments (underpayments).

High-Risk Groups of Diagnoses

Using data mining techniques and discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. For this audit, we focused on seven high-risk groups:⁹

- *Acute Stroke*: An enrollee received one acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim. In these instances, a diagnosis of history of stroke (which does not map to an HCC) typically should have been used.
- *Acute Heart Attack*: An enrollee received one diagnosis that mapped to either the HCC for Acute Myocardial Infarction or to the HCC for Unstable Angina and Other Acute Ischemic Heart Disease (Acute Heart Attack HCCs) on only one physician or outpatient claim but did not have that 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 for a less severe manifestation of a disease in the related-disease group typically should have been used.

⁸ 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.

⁹ Unless otherwise specified, the HCCs described in this report have the same name under both the Version 12 and Version 22 models.

- *Acute Stroke and Acute Heart Attack Combination:* An enrollee met the conditions of both the acute stroke and acute heart attack high-risk groups in the same year.¹⁰
- *Embolism:* An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or the HCC for Vascular Disease With Complications (Embolism HCCs) 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.
- *Major Depressive Disorder:* An enrollee received one major depressive disorder diagnosis (that mapped to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) during the service year but did not have an antidepressant medication dispensed on his or her behalf. In these instances, the major depressive disorder diagnoses may not be supported in the medical records.
- *Vascular Claudication:* An enrollee received one diagnosis related to vascular claudication (that mapped to the HCC for Vascular Disease) but had medication dispensed on his or her behalf that is frequently dispensed for a diagnosis of neurogenic claudication.¹¹ In these instances, the vascular claudication diagnoses may not be supported in the medical records.
- *Potentially Mis-keyed Diagnosis Codes:* An enrollee received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition (that mapped to a possibly unvalidated HCC). For example, ICD-9 diagnosis code 250.00 (which maps to the HCC for Diabetes Without Complication) could be transposed as diagnosis code 205.00 (which maps to the HCC for Metastatic Cancer and Acute Leukemia and in this example would be unvalidated). Using an analytical tool that we developed, we identified 832 scenarios in which diagnosis codes could have been mis-keyed because numbers were transposed, or other data entry errors occurred that could have resulted in the assignment of an unvalidated HCC.

¹⁰ We combined these enrollees into one group because an individual’s risk scores could have been further increased if that enrollee also had a COPD diagnosis (which was not part of our audit). If our audit identified an error that invalidated either the Acute Stroke or Acute Heart Attack HCC, then the disease interaction factor would also be identified as an error. By combining these enrollees in one group, we eliminated the possibility of including the disease interaction factor twice in overpayment calculations (if any).

¹¹ Vascular claudication and neurogenic claudication are different diagnoses. Vascular claudication is a condition that can result in leg pain while walking and is caused by insufficient blood flow. Neurogenic claudication is a condition that can also result in leg pain but is caused by damage to the neurological system, namely the spinal cord and nerves.

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

WellCare of Florida, Inc.

WellCare is an MA organization based in Tampa, Florida. As of December 31, 2016, WellCare provided coverage under contract number H1032 to approximately 93,600 enrollees. For the 2015 and 2016 payment years (audit period), CMS paid WellCare approximately \$2.3 billion to provide coverage to its enrollees.¹² In March 2019, Centene Corporation acquired WellCare.

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of the seven high-risk groups during the 2014 and 2015 service years, for which WellCare received increased risk-adjusted payments for payment years 2015 and 2016, respectively. Because enrollees could be classified into more than one high-risk group or could have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment year, which we refer to as “enrollee-years.”

We identified 3,773 unique enrollee-years and limited our audit to the portions of the payments that were associated with these high-risk diagnosis codes (\$8,316,042). We selected for audit a sample of 250 enrollee-years, which comprised: (1) a stratified random sample of 200 (out of 3,710) enrollee-years for the first 6 high-risk groups and (2) a nonstatistical sample of 50 (out of 63) enrollee-years for the remaining high-risk group. Table 1 on the following page details the number of sampled enrollee-years for each high-risk group.

¹² The 2015 and 2016 payment year data were the most recent data available at the start of the audit.

Table 1: Sampled Enrollee-Years

High-Risk Group	Number of Sampled Enrollee-Years
(1) Major Depressive Disorder	71
(2) Acute Stroke	30
(3) Acute Heart Attack	30
(4) Acute Stroke / Acute Heart Attack Combination	9
(5) Embolism	30
(6) Vascular Claudication	30
Total for Stratified Random Sample	200
(7) Potentially Mis-keyed Diagnosis Codes	50
Total for All High-Risk Groups	250

WellCare provided medical records as support for the selected diagnosis codes associated with 235 of the 250 enrollee-years.¹³ We used an independent medical review contractor to review the medical records to determine whether they supported the selected diagnosis codes that WellCare submitted to CMS. If the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

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

FINDINGS

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that WellCare submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 97 of the 250 sampled enrollee-years, the medical records validated the reviewed HCCs that WellCare submitted to CMS. However, for the remaining 153 enrollee-years, the medical records did not support the diagnosis codes that WellCare submitted to CMS and resulted in net overpayments of \$410,110.

¹³ WellCare did not provide medical records for the 15 remaining sampled enrollee-years.

These errors occurred because the policies and procedures that WellCare had to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. As a result, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that WellCare received at least \$3.5 million of net overpayments for 2015 and 2016.¹⁴

FEDERAL REQUIREMENTS

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

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

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

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

Federal regulations state that MA organizations must monitor the data that they receive from providers and submit to CMS. Federal regulations also state that MA organizations must "adopt and implement an effective compliance program, which must include measures that prevent,

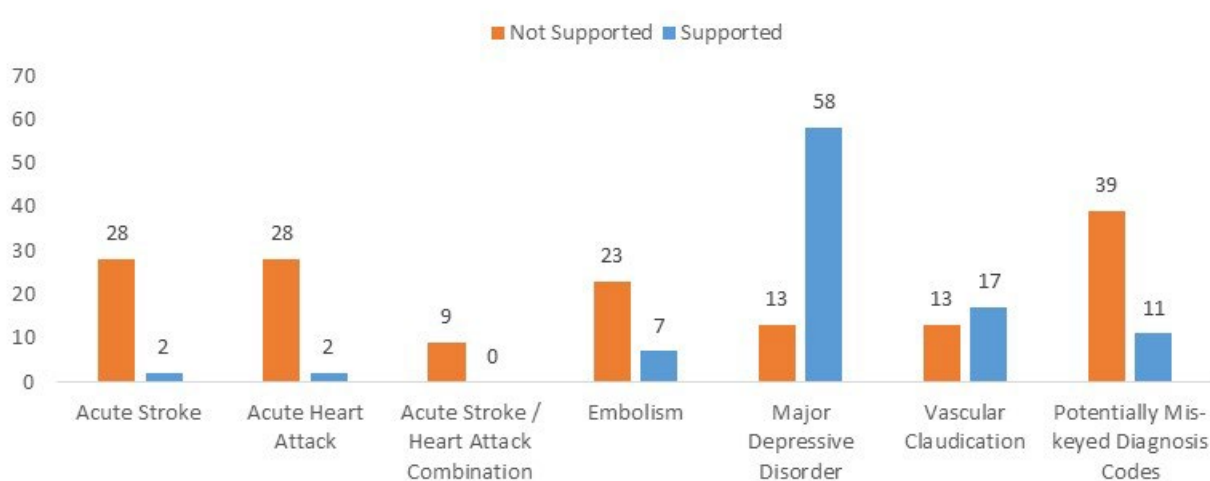
¹⁴ Specifically, we estimated that WellCare received at least \$3,518,465 (\$3,335,504 for the statistically sampled groups plus \$182,961 for the group of potentially mis-keyed diagnosis codes) of net overpayments. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 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.

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). (See Appendix E.)

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

Most of the selected high-risk diagnosis codes that WellCare submitted to CMS for use in CMS’s risk adjustment program did not comply with Federal requirements. As shown in the figure below, the medical records for 153 of the 250 sampled enrollee-years did not support the diagnosis codes. In these instances, WellCare 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

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

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

For example, for 1 enrollee-year, the medical record (for a service that occurred in 2014) indicated that the individual had a cerebrovascular accident (CVA) 10 years ago. The independent medical review contractor noted that “there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC [Ischemic or Unspecified Stroke] or a related HCC. There is mention of a history of a stroke [diagnosis]” The history of stroke diagnosis code does not map to an HCC.

- For 11 enrollee-years, the medical records did not contain sufficient information to support an acute stroke diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in assignment of HCC [for Ischemic or Unspecified Stroke] There was no indication in the medical documentation that states the patient had a past medical history or is being actively treated for a stroke.”

As a result of these errors, the HCCs for Ischemic or Unspecified Stroke were not validated, and WellCare received \$65,308 of overpayments for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Heart Attack

WellCare incorrectly submitted diagnosis codes for acute heart attack for 28 of 30 sampled enrollee-years. Specifically:

- For 17 enrollee-years, the medical records did not support an acute myocardial infarction diagnosis.
 - For 12 enrollee-years, we identified support for an old myocardial infarction diagnosis.
 - For 6 enrollee-years, which occurred in payment year 2015, the old myocardial infarction diagnosis mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, WellCare should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the old myocardial infarction diagnosis.

For example, for 1 enrollee-year, the medical record indicated that the physician saw the individual for a routine followup. The independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of HCC [for Unstable Angina and other Acute Ischemic Heart Disease]. There is documentation of an old myocardial infarction that results in HCC [for Angina Pectoris or Old Myocardial Infarction], which should have been assigned instead.”

- For 6 enrollee-years, which occurred in payment year 2016, the old myocardial infarction diagnosis did not map to an HCC.¹⁵ Accordingly, WellCare should not have received an increased payment for acute myocardial infarction.
 - For 4 enrollee-years, which occurred in either payment year 2015 or 2016, we identified support for an unspecified angina pectoris diagnosis, which mapped to an HCC for a less severe manifestation of the related-disease group.¹⁶ Accordingly, WellCare should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the less severe diagnoses.
 - For 1 enrollee-year, WellCare submitted an acute myocardial infarction diagnosis code in 2016 (which was not supported in the medical records) instead of a diagnosis code for sub-endocardial infarction (which was supported in the medical records).¹⁷ The independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of . . . [the Unstable Angina and Other Acute Ischemic Heart Disease] HCC; however, there is documentation of [a] sub-endocardial infarction, initial episode of care, which results in [the] HCC [for Acute Myocardial Infarction].” This error caused an underpayment.
- For 9 enrollee-years, the medical records did not support either an acute myocardial infarction diagnosis or an old myocardial infarction diagnosis.
- For the remaining 2 enrollee-years, WellCare did not provide any medical records to support the acute myocardial infarction diagnosis; therefore, the HCC for Acute Heart Attack was not validated.

As a result of these errors, the Acute Heart Attack HCCs were not validated, and WellCare received \$36,378 of net overpayments for these 28 sampled enrollee-years.

¹⁵ In contrast to the enrollee-years that occurred in 2015 (for which CMS used the Version 12 model), for 2016 CMS used only the Version 22 model, which did not include an HCC for Old Myocardial Infarction, to calculate risk scores (footnote 7).

¹⁶ Angina pectoris is a disease marked by brief sudden attacks of chest pain or discomfort caused by deficient oxygenation of the heart muscles, usually due to impaired blood flow to the heart.

¹⁷ Sub-endocardial infarction is typical chest pain that lasts more than 15 minutes, according to the National Institutes of Health. Available online at <https://pubmed.ncbi.nlm.nih.gov/1020751>. Accessed on Sep. 2, 2021.

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

WellCare incorrectly submitted diagnosis codes for all 9 of the sampled enrollee-years for which the physicians had documented conditions for both the acute stroke and acute heart attack high-risk groups in the same year (footnote 10).

Table 2 details the findings for the 8 enrollee-years for which the medical records did not support the submitted diagnosis codes.

Table 2: Acute Stroke and Acute Heart Attack Combination Findings

Count of Enrollee-Years	Acute Stroke HCC		Acute Heart Attack HCC	
	Medical Record Validated HCC	Support for Different HCC Found	Medical Record Validated HCC	Support for Different HCC Found
7	No	No	No	No
1*	No	No	Yes	No
<p>* For this enrollee-year, the independent medical review contractor noted that “there is no documentation of a condition that would result in an assignment of [the] HCC [for Ischemic or Unspecified Stroke]. There is documentation of CVA listed as a differential diagnosis which cannot be coded as a confirmed diagnosis.” The contractor also noted that the HCC for Unstable Angina and Other Acute Ischemic Heart Disease “was substantiated based on the assessment of non ST-elevation myocardial infarction . . .” Accordingly, WellCare should not have received an increased payment for the ischemic or unspecified stroke diagnosis.</p>				

For the 1 remaining enrollee-year, WellCare did not provide any medical records to support either diagnosis; therefore, the HCCs for Acute Heart Attack and Acute Stroke were not validated.

As a result of these errors, the HCCs for either Ischemic or Unspecified Stroke, or Acute Heart Attack, or both, were not validated, and WellCare received \$22,765 of overpayments for these 9 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

WellCare incorrectly submitted diagnosis codes for embolism for 23 of 30 sampled enrollee-years. Specifically:

- For 13 enrollee-years, the medical records did not contain sufficient information to support an embolism diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of . . . [the Embolism] HCC. There is documentation of venous papule in stasis dermatitis . . . which does not result in [an] HCC.”¹⁸

- For 8 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not justify an embolism diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of . . . [the Embolism] HCC. The medical documentation states that the patient has a history of deep vein thrombosis . . . which does not result in an HCC.”

- For the remaining 2 enrollee-years, WellCare did not provide any medical records to support the embolism diagnoses; therefore, the Embolism HCCs were not validated.

As a result of these errors, the Embolism HCCs were not validated, and WellCare received \$51,259 of overpayments for these 23 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder

WellCare incorrectly submitted diagnosis codes for major depressive disorder for 13 of 71 sampled enrollee-years. Specifically:

- For 8 enrollee-years, the medical records did not support a major depressive disorder diagnosis.¹⁹

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of . . . [the Major Depressive, Bipolar, and Paranoid Disorders] HCC. The medical documentation states that the patient has a diagnosis of depression which does not result in [an] HCC.”

- For the 5 remaining enrollee-years, WellCare did not provide any medical records to support the major depressive disorder diagnoses; therefore, the HCCs for Major Depressive, Bipolar, and Paranoid Disorders were not validated.

¹⁸ Venous papule in stasis dermatitis is “a common disorder, which is a consequence of impaired venous drainage of the legs,” according to the National Institutes of Health. Available online at <https://pubmed.ncbi.nlm.nih.gov/11240267/>. Accessed on Sep. 2, 2021.

¹⁹ In 4 of these cases, the independent medical review contractor identified support for a diagnosis code for a lesser form of depression, which did not map to an HCC. In 3 of these cases, the independent medical review contractor identified a history of major depressive disorder, which did not result in the assignment of an HCC. For 1 of these cases, the patient had an unrelated condition.

As a result of these errors, the HCCs for Major Depressive, Bipolar, and Paranoid Disorders were not validated, and WellCare received \$26,211 of overpayments for these 13 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Vascular Claudication

WellCare incorrectly submitted diagnosis codes for vascular claudication for 13 of 30 sampled enrollee-years. Specifically:

- For 10 enrollee-years, the medical records did not support a vascular claudication diagnosis.²⁰

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

- For the 3 remaining enrollee-years, WellCare did not provide any medical records to support the vascular claudication diagnosis; therefore, the HCC for Vascular Disease was not validated.

As a result of these errors, the HCCs for Vascular Disease were not validated, and WellCare received \$25,228 of overpayments for these 13 sampled enrollee-years.

Potentially Mis-keyed Diagnosis Codes

WellCare submitted potentially mis-keyed diagnosis codes for 39 of 50 enrollee-years. In each of these cases, the enrollee-years received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition.

- For 32 enrollee-years, the medical records did not support the diagnosis for the unrelated condition. Because of these errors, WellCare submitted unsupported diagnosis codes that mapped to unvalidated HCCs to CMS.

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

²⁰ All diagnoses must be made by an acceptable qualified provider, which is considered a hospital inpatient facility, hospital outpatient facility, or physician (the Manual, chap. 7, § 40). For 1 enrollee-year, WellCare provided a medical note from a registered nurse, and a registered nurse is not an acceptable qualified provider. Therefore, the independent medical review contractor determined that the medical record was from an ineligible provider and the HCC was not validated.

review contractor noted that the “code of 205.00 is not found upon review and no clear substitution can be found either.”

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

For example, for 1 enrollee-year, the medical records did not support a diagnosis that mapped to the HCC for Vascular Disease With Complications. The independent medical review contractor noted: “There is documentation of abdominal aortic aneurysm . . . resulting in [the] HCC [for Vascular Disease], which should have been assigned instead of the submitted HCC.” Accordingly, WellCare should not have received an increased payment for the Vascular Disease With Complications HCC but should have received a lesser increased payment for the Vascular Disease HCC.

- For the remaining 2 enrollee-years, WellCare did not provide any medical records to support the potentially mis-keyed diagnosis codes; therefore, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated.

Appendix F contains the HCCs that were not validated for the 39 enrollee-years (Table 6) and the HCCs for the less severe manifestation of the related-disease group that were supported for the 5 enrollee-years (Table 7).

As a result of these errors, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated, and WellCare received \$182,961 of overpayments for these 39 sampled enrollee-years.

THE POLICIES AND PROCEDURES THAT WELLCARE USED TO PREVENT, DETECT, AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS WERE NOT ALWAYS EFFECTIVE

These errors we identified occurred because the policies and procedures that WellCare had to prevent, detect, and correct noncompliance with CMS’s program requirements, as mandated by Federal regulations (42 CFR § 422.503(b)(4)(vi)), were not always effective.

WellCare had compliance procedures in place during our audit period to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. These procedures included a provider education program with an emphasis on the importance of following coding guidelines and improving medical record documentation. In addition, WellCare’s compliance procedures included routine internal medical reviews to compare diagnosis codes from a sample of claims to the diagnoses that were documented on the associated medical records. However, these internal medical reviews were not designed to

identify systematic errors or target specific or high-risk diagnosis codes, including those we identified as being at a higher risk for being miscoded. As a result, WellCare's compliance procedures to prevent and detect incorrect high-risk diagnoses during our audit period were not always effective. Additionally, when we inquired as to why WellCare was not always able to obtain medical records from its providers to support diagnosis codes submitted to CMS to calculate risk-adjusted payments, WellCare's officials stated that WellCare made multiple attempts to retrieve them, to no avail.

WELLCARE 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 WellCare received at least \$3.5 million in net overpayments (\$3.3 million for the statistically sampled high-risk groups plus \$182,961 for the potentially mis-keyed diagnosis codes) for 2015 and 2016. (See Appendix D.)

RECOMMENDATIONS

We recommend that WellCare of Florida, Inc.:

- refund to the Federal Government the \$3,518,465 of estimated net overpayments;
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
- continue its examination of existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

WELLCARE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, WellCare did not agree with some of our findings or our first recommendation. More specifically, WellCare did not agree with our findings for 4 of the 156 enrollee-years identified in our draft report and provided explanations as to why the medical records that it previously provided to us supported the reviewed HCCs.²¹ WellCare did not indicate that it disagreed with our findings for the remaining 152 enrollee-years.

²¹ In its comments on our draft report, WellCare stated that it disagreed with our findings for 5 enrollee-years. However, after further discussions with WellCare, we determined that the independent medical review contractor had previously validated the reviewed HCC for 1 of the 5 enrollee-years. Thus, we did not further revise our finding in this regard for this enrollee-year.

WellCare also stated that our audit methodology was flawed because we limited the number of medical records that it could submit for purposes of this audit, deviated from CMS review standards, and used biased sampling and extrapolation approaches that were more likely to identify overpayments than underpayments. Further, WellCare stated that it “has not received the underlying detail necessary to replicate [our] extrapolation methodology.” WellCare also said that we have improperly implied that MA organizations, like WellCare, are expected to assure that 100 percent of the diagnosis codes that are received from providers and submitted to CMS are accurate. WellCare stated that it would consider our second and third recommendations and that it “is engaged in a continual process of evaluating and enhancing its compliance procedures.”

After consideration of WellCare’s comments, we reduced the number of sampled enrollee-years in error from 156 to 153 and adjusted our calculation of net overpayments. Accordingly, we reduced the amount conveyed in our first recommendation from \$3,614,989 to \$3,518,465 for this final report.

A summary of WellCare’s comments and our responses follows. WellCare’s comments appear in their entirety as Appendix G.

WELLCARE DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL’S FINDINGS FOR 4 SAMPLED ENROLLEE-YEARS

WellCare Comments

WellCare did not agree with our draft report findings for 4 of the sampled enrollee-years (in the embolism, major depressive disorder, and potentially mis-keyed diagnosis codes high-risk groups) and provided explanations as to why the medical records that it previously gave us supported the reviewed HCCs.

Office of Inspector General Response

The independent medical review contractor reviewed the additional explanations for the 4 sampled enrollee-years and reconfirmed that the HCC for 1 of the enrollee-years (embolism high risk group) was not validated. Specifically, the contractor stated that the medical record did not support the monitoring or treatment of the HCC.

However, the independent medical review contractor found support in the medical records for the remaining 3 sampled enrollee years (in the major depressive disorder (2) and potentially mis-keyed diagnosis code (1) high-risk groups). Thus, the reviewed HCCs were validated and we reversed the original determinations.

For example, for 1 enrollee-year from the Major Depressive Disorder high-risk group, the independent medical review contractor reversed its original decision and stated: “Decision

reversed at reconsideration, agree with auditee. There is documentation of depression, recurrent, in remission [that supports the HCC].”

To ensure that the reversals for these 3 enrollee-years did not impact other determinations, our independent medical review contractor performed additional quality analyses and confirmed that there were no systemic issues in its medical review process for other sampled enrollee-years. Accordingly, we revised our findings for these 3 enrollee-years and reduced the associated monetary recommendation.

WELLCARE DID NOT AGREE WITH SEVERAL ASPECTS OF THE OFFICE OF INSPECTOR GENERAL’S AUDIT PROCESS

WellCare Comments

WellCare stated that our audit process limited the number of medical records it could submit for purposes of this audit, deviated from the CMS review standards, and applied review standards that were not promulgated pursuant to legal requirements. Specifically:

- WellCare referred to guidance that we provided to it describing how it should submit medical records for review and stated that “[t]he OIG audit process allowed WellCare to submit only two records, one of which was required to be for the specific date of service.” Relatedly, WellCare said that CMS “historically allowed entities to submit up to five records to support an HCC and none of these records are required to reflect a specific date of service.” WellCare further stated that our audit process, with respect to submitting medical records, imposed deadlines that limited WellCare’s ability to obtain medical records from providers. Furthermore, WellCare said that under CMS’s Risk Adjustment Data Validation (RADV) audits, MA organizations have 25 weeks to request medical records from providers and submit them to CMS, but we provided a shorter timeframe.
- WellCare also stated that we did not provide a process for appealing the medical record review findings and that this is contrary to CMS’s standard appeals processes. To this point, WellCare referred to Federal regulations that, according to WellCare, established that MA organizations “that do not agree with RADV results may appeal.”
- WellCare stated that our audit “methodology applied substantive standards that were not promulgated pursuant to the notice-and-comment requirements set forth in *Azar v. Allina Health Services*.”²² In this regard, WellCare said that “the Supreme Court held that substantive standards governing payments under Medicare must be promulgated pursuant to notice-and-comment rulemaking.” WellCare also stated that it “reserves its rights with respect to substantive standards set forth in the *Medicare Managed Care Manual*, the *Risk Adjustment Training Manual*, and other documents that were not

²² *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019).

promulgated in accordance with 42 U.S.C. § 1395hh(b) and notice-and-comment requirements.”

Office of Inspector General Response

We disagree with WellCare’s comments that our audit process limited the submission of medical records, deviated from the CMS review standards, and applied review standards that were not promulgated pursuant to legal requirements. Specifically:

- Each of the enrollee-years selected for this audit had only one high-risk diagnosis submitted on its behalf during the service year. WellCare is correct in that we asked for the medical records supporting those claims. However, WellCare is not correct in saying that we allowed it to provide only two medical records to support the sampled HCC. The guidance that we provided to WellCare, to which it referred in its comments, contained an example of how medical records that it submitted should be numbered. This guidance did not limit the number of records that could be provided to two. During our audit, we informed WellCare that it could submit up to five medical records for each sampled enrollee-year. In addition, we reached out to WellCare officials on several occasions to determine whether they had any additional medical records to submit as part of the medical review process. In response, WellCare submitted only 1 medical record for each of 218 sampled enrollee-years, 2 medical records for each of 17 sampled enrollee-years, and no medical records for 15 sampled enrollee-years.

Furthermore, with respect to WellCare’s statement that the timeframe that we provided for it to submit medical records was less than the 25-week timeframe allowed by CMS during its RADV audits, we gave WellCare a total of 33 weeks to submit medical records to us. More specifically, we gave WellCare 18 weeks to respond to our original medical records request. Moreover, WellCare requested, and we agreed to, a total of five extensions to provide the medical records, which resulted in 15 additional weeks. During that time, we continued to communicate with WellCare to ask whether it had additional medical records to submit. Lastly, after we received WellCare’s comments on our draft report, we offered it three other opportunities to provide additional medical records—up to five records in total for each HCC—but WellCare declined to submit any additional medical records.

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

- We disagree with WellCare’s assertion that our audit methodology applied substantive standards that were not promulgated pursuant to the notice-and-comment requirements set forth in *Azar v. Allina Health Services*. Specifically, the Manual is legally binding on an MA organization based not only on regulation, but also on its contract with CMS. Federal regulations 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.²³ In addition, MA organizations that contract with CMS must agree to follow CMS’s instructions, including the provisions of the Manual.²⁴ WellCare has agreed to operate in compliance with the Manual under the terms of its contract with CMS and is bound by the requirements of that contract, including any applicable provisions of the Manual.

WELLCARE DID NOT AGREE WITH THE SAMPLING AND EXTRAPOLATION METHODOLOGY THAT THE OFFICE OF INSPECTOR GENERAL USED TO CALCULATE THE ESTIMATED NET OVERPAYMENT AMOUNT

WellCare Comments

WellCare disagreed with the sampling and extrapolation methodology that we used to calculate the estimated net overpayments. Specifically:

- WellCare stated that the extrapolated estimate is flawed because the “audit procedures and methodology are skewed to identifying overpayments, rather than underpayments.” WellCare noted that we did not ask it to submit medical records to substantiate all HCCs that could have been submitted to CMS, which, according to WellCare, likely would have identified additional underpayments.
- WellCare stated that the “extrapolation methodology raises a number of questions regarding sampling, and WellCare has been unable to verify the statistical validity of the extrapolation.” WellCare said that it “has not received the underlying detail necessary to replicate the extrapolation calculation. OIG’s variance analysis was not well defined, and WellCare has been able to develop only a range of estimates in an attempt to understand and track OIG’s work.”
- WellCare stated that “it is not clear how OIG selected and stratified the sample.” WellCare added, “From what we are able to determine, the distribution of the sample does not align with the distribution of total members identified by high-risk group.”

²³ 42 CFR §§ 422.504(l) and 422.310(d)(1).

²⁴ 42 CFR § 422.504(a).

- WellCare questioned our use of the 90-percent confidence interval instead of, according to WellCare, “CMS’s published and binding RADV extrapolation methodology” that uses the lower limit of the 99-percent confidence interval.

Office of Inspector General Response

WellCare’s description of our sampling and estimation methodology as flawed and skewed is not accurate. 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.²⁵ 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.

More specifically:

- WellCare’s statement that the extrapolated estimate is flawed because the “audit procedures and methodology are skewed to identifying overpayments, rather than underpayments” is not correct. A valid estimate of net overpayments does not need to take into consideration all potential HCCs or underpayments within the audit period. Our estimate of net overpayments addresses only the portion of the payments related to the reviewed HCCs and does not extend to the HCCs that were beyond the scope of our audit. In accordance with our objective, and as detailed in Appendices C and D, we properly executed a statistically valid sampling methodology as explained above.
- We do not agree with WellCare’s comment that we did not provide the detail needed to replicate our extrapolation. We provided WellCare with the information necessary to recreate the statistical sample and calculate the estimated overpayments, including the sampling frame, sample design, randomly selected sample items, medical review determinations, and a breakdown of net overpayments by sampled enrollee-year.
- We disagree with WellCare’s statement that “it is not clear how OIG selected and stratified the sample.” As stated previously, and as detailed in Appendices C and D, we correctly implemented an appropriate stratified random sampling design and estimation procedure. Further, our sample was representative of the sampling frame in that we selected the items from each stratum using a simple random sample in which each item within each stratum had an equal probability of being selected. Due to the randomness of the sampling process, the composition of the sample may differ from the composition of the sampling frame. We accounted for such differences by using the lower limit of a

²⁵ 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); and *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

two-sided 90-percent confidence interval as our basis to recommend refunds of net overpayments.

- Our estimation methodology does not need to mirror CMS’s estimation methodology. OIG recommends recovery at the lower limit of a two-sided 90-percent confidence interval. We believe that the lower limit of a two-sided 90-percent confidence interval provided a reasonably conservative estimate of the total amount overpaid to WellCare for the enrollee-years and period covered in our sampling frame. This approach, which is routinely used by OIG for recovery calculations,²⁶ results in a lower limit (the estimated overpayment amount to refund) that is designed to be less than the actual overpayment total 95 percent of the time. For this reason, we maintain that our use of the lower limit of the two-sided 90-percent confidence interval is valid.

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

WellCare Comments

WellCare stated that our calculation of overpayments violated certain CMS requirements mandated under the MA program. Specifically, WellCare stated that our methodology did not acknowledge or address the relevance of the requirements for “actuarial equivalence” and the Fee-for-Service Adjuster (FFS Adjuster), which are described below.

WellCare said that “MA payments are statutorily required to be actuarially equivalent to the payments CMS makes for beneficiaries of a similar risk profile in traditional Medicare.” WellCare also stated that the payments cannot be considered actuarially equivalent if adjustments to the MA payments are made only from the results of audits. Thus, in the context of an audit, WellCare stated that if there is a difference in “the risk profile of a group of Medicare beneficiaries in MA and a group in traditional Medicare,” some adjustment to the audit results is necessary.²⁷ WellCare further stated that CMS agreed with this position and that in 2012 CMS developed a methodology for its RADV audits to apply an FFS Adjuster before extrapolating any audit results. WellCare also stated that in 2018, “CMS issued a proposed rule that would reverse course from its 2012 Methodology, and *not* apply an FFS Adjuster . . . However, CMS has not finalized that proposal” (emphasis in original). WellCare also stated:

²⁶ For example, HHS has used the two-sided 90-percent confidence interval when estimating recoveries in both the Administration for Child and Families and Medicaid programs. See e.g., *New York State Department of Social Services*, HHS Departmental Appeals Board (DAB) No. 1358, 13 (1992); and *Arizona Health Care Cost Containment System*, DAB No. 2981, 4-5 (2019). In addition, HHS contractors rely on the one-sided 90-percent confidence interval, which is less conservative than the two-sided interval, for recoveries arising from Medicare FFS overpayments. See e.g., *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff’d*, 860 F.3d 335 (5th Cir. 2017); and *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 17-18 (E.D.N.Y. 2012).

²⁷ WellCare noted that the difference in the risk profile represents that the documentation standard used in RADV audits to determine a contract’s payment error (medical records) is different from the documentation standard that CMS used to develop the Part C risk-adjustment model from traditional Medicare claims.

“CMS itself has acknowledged that audited [MA organizations] are underpaid if [an] FFS Adjuster is not applied.”

WellCare referred to provisions in the Act that mandate CMS to “adjust payments rates in a manner ‘so as to ensure actuarial equivalence’ between [MA] and traditional Medicare.” In this respect, WellCare stated that CMS requires the application of the FFS Adjuster for its own RADV audits to assess payment accuracy. WellCare also stated that in “identifying an extrapolated amount as an ‘overpayment,’ OIG must necessarily address actuarial equivalence and the need for an FFS Adjuster.”

Office of Inspector General Response

Our audit methodology correctly applied CMS requirements to properly calculate the overpayment amount associated with unsubstantiated HCCs for each sample item.

We used the results of the independent medical review contractor’s review to determine which HCCs were not substantiated and, in some instances, to identify HCCs that should have been used but were not used in the sampled enrollees’ risk score calculations. We followed CMS’s risk adjustment program requirements to determine the payment that CMS should have made for each enrollee. We used the overpayments and underpayments identified for each enrollee to estimate net overpayments.

Regarding WellCare’s comment that we did not consider actuarial equivalence in our overpayment calculations, we recognize that CMS is responsible for making operational and program payment determinations for the MA program, including the application of any FFS Adjuster requirements. Moreover, CMS has not issued any requirements that compel us to reduce our net overpayment calculations.²⁸ If CMS deems it appropriate to apply an FFS Adjuster, it will adjust our overpayment finding by whatever amount it determines necessary. Thus, we believe that the steps that we followed for this audit provide a reasonable basis for our findings and recommendations, including our estimation of net overpayments.²⁹

²⁸ In 2018, CMS proposed “not to include an FFS Adjuster in any final RADV payment error methodology” (Proposed Rule at 83 Fed. Reg. 54982, 55041). To WellCare’s point about CMS’s 2012 methodology statement, we reiterate that CMS has not issued any requirements that compel us to reduce our overpayment calculations.

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

WELLCARE STATED THAT THE OFFICE OF INSPECTOR GENERAL’S RECOMMENDATIONS IMPROPERLY IMPLIED THAT IT IS EXPECTED TO ASSURE 100-PERCENT ACCURACY OF DIAGNOSIS CODES

WellCare Comments

WellCare stated that our recommendations to refund an extrapolated amount and to conduct further audits (of similar instances of noncompliance that occurred before and after our audit period) “seemingly intend to implement a [100 percent] accuracy expectation.” Specifically, WellCare said that “[v]arious aspects of [our report] may be read to imply that [MA organizations’] compliance efforts must assure [100 percent] accuracy with respect to the vast quantities of diagnosis codes they receive from providers and are required to submit to CMS.” In this respect, WellCare said that our statement that its compliance procedures were not always effective should be eliminated because, according to WellCare, “no compliance program is expected to eliminate all types of errors.”

Moreover, WellCare stated that MA organizations receive millions of claims from the providers that reflect multiple diagnoses and result in an enormous volume of data that MA organizations must receive and submit to CMS. In this respect, WellCare stated that “[v]erifying [100-percent] of submitted risk adjustment data would be prohibitive for [MA organizations].” WellCare also said that the attestations that MA organizations make, as required by Federal regulations, with respect to risk adjustment data “[do] not impose a requirement for an [MA organization] to ensure that all submitted [diagnosis] codes, or all submitted [diagnosis] codes for OIG-identified ‘high-risk’ codes, are supported by medical records.” To support its position, WellCare referred to a court case in which, according to WellCare, the court cited the Federal Government’s representations when it ruled that “insurers” were required “to refund amounts they *know* were overpayments, i.e., payments they *are aware* lack support in a beneficiary’s medical record. That limited scope does not impose a self-auditing mandate.”³⁰

In this respect, WellCare requests that our report “expressly include and acknowledge statements made by the United States in the *UnitedHealthcare* litigation that [MA organizations] do not have an obligation to identify and delete every erroneous diagnosis, or even a large fraction of them.” Although WellCare stated that it would further consult with CMS regarding additional reviews, it requested that we revise our recommendations.

Office of Inspector General Response

We do not agree with WellCare’s interpretation of the Federal requirements. We also recognize that CMS applies a “good faith attestation” standard when MA organizations certify the large volume of data that they submit to CMS for use in the risk adjustment program. However, contrary to WellCare’s assertions, we believe that our recommendation for WellCare

³⁰ *UnitedHealthcare Ins. Co. v. Becerra*, 9 F.4th 868, 884, No. 18-5326 (D.C. Cir. Aug. 13, 2021) (emphasis in original).

to review whether similar instances of noncompliance for high-risk diagnoses that occurred before or after our audit period conforms to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (see Appendix E)). Further, WellCare’s interpretation of the Federal requirements did not cause us to revise our monetary recommendation.

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.” Further, these regulations specify that WellCare’s compliance plan “must, at a minimum, include [certain] core requirements,” which include “an effective system for routine monitoring and identification of compliance risks . . . [including] internal monitoring and audits and, as appropriate, external audits to evaluate . . . compliance with CMS requirements and the overall effectiveness of the compliance program.” These regulations also require MA organizations to implement procedures and a system for investigating “potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence.” Thus, CMS has, through the issuance of these Federal regulations, assigned the responsibility for dealing with potential compliance issues to the MA organizations.

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

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

When an MA organization identifies overpayments, the Overpayment Rule (42 U.S.C. §§ 1301-1320d-8, 1395-1395hhh) requires that if the MA organization learns that a diagnosis it submitted to CMS for payment lacks support in the associated individual’s medical record, the MA organization must refund that payment within 60 days.

We believe the error rates identified in our audit demonstrate that WellCare has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope. Accordingly, we continue to recommend that WellCare: (1) review whether similar instances of noncompliance related to high-risk diagnoses occurred before or after our audit period and (2) continue to examine its existing compliance procedures to identify areas where improvements can be made.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid WellCare \$2,314,506,206 to provide coverage to its enrollees for 2015 and 2016. We identified a sampling frame of 3,773 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2014 and 2015 service years; WellCare received \$61,761,552 in payments from CMS for these enrollee-years for 2015 and 2016. We selected for audit 250 enrollee-years with payments totaling \$4,743,542.

The 250 enrollee-years included 71 major depressive disorder diagnoses, 30 acute stroke diagnoses, 30 acute heart attack diagnoses, 9 acute stroke diagnosis and acute heart attack diagnosis combinations, 30 embolism diagnoses, 30 vascular claudication diagnoses, and 50 potentially mis-keyed diagnoses. We limited our audit to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$689,234 for our sample.

Our audit objective did not require an understanding or assessment of WellCare'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 2019 through November 2021.

METHODOLOGY

To accomplish our objective, we performed the following steps:

- We reviewed applicable Federal laws, regulations, and guidance.
- We discussed with CMS program officials the Federal requirements that MA organizations should follow when submitting diagnosis codes to CMS.
- We 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:
 - 58 diagnosis codes for embolism,
 - 35 diagnosis codes for acute heart attack,
 - 29 diagnosis codes for major depressive disorder,

- 6 diagnosis codes for acute stroke, and
- 4 diagnosis codes for vascular claudication.
- We developed an analytical tool that identified 832 scenarios in which either ICD-9 or ICD-10 diagnosis codes, when mis-keyed into an electronic claim because of a data transposition or other data entry error, could result in the assignment of an incorrect HCC to an enrollee's risk score. For each of the 832 occurrences, the tool identified a potentially mis-keyed diagnosis code and the likely correct diagnosis code. Accordingly, we considered the potentially mis-keyed diagnosis codes to be high risk.
- We used CMS's systems to identify the enrollee-years on whose behalf providers documented the high-risk diagnosis codes. Specifically, we used extracts from CMS's:
 - Risk Adjustment Processing System (RAPS) to identify enrollees who received high-risk diagnosis codes from a physician during the service years;³¹
 - Risk Adjustment System (RAS) to identify enrollees who received an HCC for the high-risk diagnosis codes;³²
 - Medicare Advantage Prescription Drug system (MARx) to identify enrollees for whom CMS made monthly Medicare payments to WellCare, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C);³³
 - Encounter Data System (EDS) to identify enrollees who received specific procedures;³⁴ and
 - Prescription Drug Event (PDE) file to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.³⁵
- We interviewed WellCare officials to gain an understanding of: (1) the policies and procedures that WellCare followed to submit diagnosis codes to CMS for use in the

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

³² The RAS identifies the HCCs that CMS factors into each enrollee's risk score calculation.

³³ The MARx identifies the payments made to MA organizations.

³⁴ The EDS contains information on each item (including procedures) and service provided to enrollees.

³⁵ The PDE file contains claims with prescription drugs that have been dispensed to enrollees through the Medicare Part D (prescription drug coverage) program.

risk-adjustment program and (2) WellCare’s monitoring of those submissions to prevent, detect, and correct noncompliance with Federal requirements.

- We selected for audit a sample of 250 enrollee-years, which consisted of: (1) a stratified random sample of 200 enrollee-years and (2) a nonstatistical sample of the remaining 50 enrollee-years.
- We used an independent medical review contractor to perform a coding review for the 250 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.³⁶
- The independent medical review contractor’s coding review followed a specific process to determine whether there was support for a diagnosis code and the associated HCC:
 - If the first senior coder found support for the diagnosis code on the medical record, the HCC was considered validated.
 - If the first senior coder did not find support on the medical record, a second senior coder performed a separate review of the same medical record:
 - If the second senior coder also did not find support, the HCC was considered to be not validated.
 - If the second senior coder found support, a physician independently reviewed the medical record to make the final determination.
 - If either the first or second senior coder asked a physician for assistance, the physician’s decision became the final determination.
- We used the results of the independent medical review contractor to calculate overpayments or underpayments (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.

³⁶ 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 Coder (CRC). RHITs have completed a 2-year degree program and have passed an American Health Information Management Association (AHIMA) certification exam. AHIMA also credentials individuals with CCS and CCS-P certifications and the American Academy of Professional Coders credentials both CPCs and CRCs.

- We estimated the total net overpayment made to WellCare during the audit period.
- We discussed the results of our audit with WellCare officials.

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

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS</i>	<u>A-03-18-00002</u>	8/23/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS</i>	<u>A-02-20-01009</u>	7/18/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health Network (Contract H1961) Submitted to CMS</i>	<u>A-06-18-05002</u>	5/25/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan, (Contract H2256) Submitted to CMS</i>	<u>A-01-19-00500</u>	2/14/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS</i>	<u>A-07-17-01169</u>	2/3/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS</i>	<u>A-02-18-01029</u>	1/5/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS</i>	<u>A-07-19-01188</u>	11/05/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS</i>	<u>A-07-17-01173</u>	10/28/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS</i>	<u>A-07-19-01187</u>	5/21/2021
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS</i>	<u>A-07-16-01165</u>	4/19/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS</i>	<u>A-02-18-01028</u>	2/24/2021
<i>Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements</i>	<u>A-07-17-01170</u>	4/30/2019

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

Our sampling frame included only WellCare enrollees who: (1) were continuously enrolled under contract number H1032 throughout all of the 2014 or 2015 service year and January of the following year, (2) were not classified as being enrolled in hospice or as having end-stage renal disease status at any time during 2014 or 2015 or in January of the following year, and (3) received a high-risk diagnosis during 2014 or 2015 that caused an increased payment to WellCare for 2015 or 2016, respectively.

We presented the data for these enrollees to WellCare for verification and performed an analysis of the data included in CMS's systems to determine whether the high-risk diagnosis codes increased CMS's payments to WellCare. After we performed these steps, our finalized sampling frame consisted of 3,773 enrollee-years.

SAMPLE UNIT

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

SAMPLE DESIGN AND SAMPLE SIZE

The design for our statistical sample included six strata of enrollee-years, consisting of the following diagnoses:

- a major depressive disorder diagnosis (that mapped to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) on one claim during the service year but for which antidepressant medication was not dispensed (1,723 enrollee-years);
- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim (710 enrollee-years);
- a diagnosis that mapped to an Acute Heart Attack HCC on only one physician or outpatient claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician or outpatient claim (592 enrollee-years);
- an acute stroke diagnosis and a diagnosis that mapped to an Acute Heart Attack HCC in the same year and that met the criteria mentioned in the previous two bullets (9 enrollee-years);

- a vascular claudication diagnosis (that mapped to the HCC for Vascular Disease) on one claim during the service year but for which medication was dispensed for neurogenic claudication during the service year (419 enrollee-years); and
- an embolism diagnosis that mapped to an Embolism HCC on one claim during the service year but for which an anticoagulant medication was not dispensed (257 enrollee-years).

The specific strata are shown in Table 3.

Table 3: Sample Design for Statistically Sampled High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee-Years	CMS Payment for HCCs in Audited High-Risk Groups*	Sample Size
Major Depressive Disorder	1,723	\$3,901,341	71
Acute Stroke	710	1,594,778	30
Acute Heart Attack	592	1,058,626	30
Acute Stroke / Acute Heart Attack Combination	9	37,629	9
Vascular Claudication	419	855,900	30
Embolism	257	602,587	30
Total – First Six Strata	3,710	\$8,050,861	200
* Rounded to the nearest whole dollar amount.			

After we selected the 200 enrollee-years, we identified an additional group of 63 enrollee-years from which we selected 50 enrollee-years (for a total of 250 sampled enrollee-years) that represented individuals who received 1 of the 832 potentially mis-keyed diagnosis codes (each of which mapped to a potentially unvalidated HCC) and multiple instances of diagnosis codes that were likely keyed correctly.

SOURCE OF RANDOM NUMBERS

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

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the items in each stratum in the stratified sampling frame. After generating 200 random numbers according to our sample design, we selected the

corresponding frame items for review. We also selected 50 items from the 63 potentially mis-keyed diagnosis group.

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to estimate the total amount of net overpayments to WellCare at the lower limit of the two-sided 90-percent confidence interval (Appendix D). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time. We also identified the overpayments from the nonstatistical sample of 50 items for the potentially mis-keyed diagnosis codes and added that amount to the estimate for the statistical sample to obtain the total net overpayments.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Details and Results

Audited High-Risk Groups	Frame Size	CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With Unvalidated HCCs	Net Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)
Major Depressive Disorder	1,723	\$3,901,341	71	\$161,986	13	\$26,211
Acute Stroke	710	1,594,778	30	69,521	28	65,308
Acute Heart Attack	592	1,058,626	30	54,190	28*	36,378
Acute Stroke / Acute Heart Attack Combination	9	37,629	9	36,994	9	22,765
Vascular Claudication	419	855,900	30	60,373	13	25,228
Embolism	257	602,587	30	63,783	23	51,259
Total – First Six Strata	3,710	\$8,050,861	200	\$446,847	114	\$227,149

* One unvalidated sample enrollee-year has no overpayment amount.

Potentially Mis-keyed Diagnoses	63	265,181	50	242,387	39**	182,961
Totals – All	3,773	\$8,316,042	250	\$689,234	153	\$410,110

** Two unvalidated sample enrollee-years have no overpayment amounts.

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

	Estimated Net Overpayment for Statistical Sample	Overpayment for Potentially Mis-keyed Diagnosis Group	Total Estimated Net Overpayments
Point Estimate	\$3,713,800	\$182,961	\$3,896,761
Lower Limit	3,335,504	182,961	3,518,465
Upper Limit	4,092,095	182,961	4,275,056

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

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

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

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

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

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

- (1) Articulate the organization's commitment to comply with all applicable Federal and State standards;
- (2) Describe compliance expectations as embodied in the standards of conduct;
- (3) Implement the operation of the compliance program;
- (4) Provide guidance to employees and others on dealing with potential compliance issues;
- (5) Identify how to communicate compliance issues to appropriate compliance personnel;
- (6) Describe how potential compliance issues are investigated and resolved by the organization; and
- (7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials. . . .

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external

audits, to evaluate the MA organization, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

- (G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.
 - (1) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.
 - (2) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.
 - (3) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

APPENDIX F: DETAILS OF POTENTIALLY MIS-KEYED DIAGNOSIS CODES

Table 6: Potentially Mis-keyed Diagnosis Codes and Associated Overpayments

Number of Sampled Enrollee-Years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
6	205.00	Acute Myeloblastic Leukemia, Not Having Achieved Remission	Metastatic Cancer and Acute Leukemia	250.00	Diabetes Mellitus Without Mention of Complication, Type II or Unspecified Type, Not Stated as Uncontrolled	\$55,144
5	174.0	Malignant Neoplasm of Nipple and Areola of Female Breast	Breast, Prostate, Colorectal and Other Cancers and Tumors (Version 12 Model) and Breast, Prostate, and Other Cancers and Tumors (Version 22 Model)	714.0	Rheumatoid Arthritis	9,376
4	482.0	Pneumonia Due to Klebsiella Pneumoniae	Aspiration and Specified Bacterial Pneumonias	428.0	Congestive Heart Failure, Unspecified	22,025
3	200.00	Reticulosarcoma, Unspecified Site, Extranodal and Solid Organ Sites	Lymphatic, Head and Neck, Brain, and Other Major Cancers (Version 12 Model) and Lymphoma and Other Cancers (Version 22 Model)	250.00	Diabetes Mellitus Without Mention of Complication, Type II or Unspecified Type, Not Stated as Uncontrolled	13,200
2	205.02	Acute Myeloblastic Leukemia, in Relapse	Metastatic Cancer and Acute Leukemia	250.02	Diabetes Mellitus Without Mention of Complication, Type II or Unspecified Type, Uncontrolled	30,714
2	441.01	Dissection of Aorta, Thoracic	Vascular Disease With Complications	414.01	Coronary Atherosclerosis of Native Coronary Artery	3,327

Number of Sampled Enrollee-Years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
2	E32.9	Disease of Thymus, Unspecified	Other Significant Endocrine and Metabolic Disorders	F32.9	Major Depressive Disorder, Single Episode, Unspecified	3,453
2	I24.9	Acute Ischemic Heart Disease, Unspecified	Unstable Angina and Other Acute Ischemic Heart Disease	I42.9	Cardiomyopathy, Unspecified	1,663
1	170.0	Malignant Neoplasm of Bones of Skull and Face, Except Mandible	Lymphatic, Head and Neck, Brain, and Other Major Cancers (Version 12 Model) and Lymphoma and Other Cancers (Version 22 Model)	710.0	Systemic Lupus Erythematosus	5,755
1	174.9	Malignant Neoplasm of Breast (Female), Unspecified	Breast, Prostate, Colorectal and Other Cancers and Tumors (Version 12 Model) and Breast, Prostate, and Other Cancers and Tumors (Version 22 Model)	714.9	Unspecified Inflammatory Polyarthropathy	1,386
1	200.70	Large Cell Lymphoma, Unspecified Site, Extranodal and Solid Organ Sites	Lymphatic, Head and Neck, Brain, and Other Major Cancers (Version 12 Model) and Lymphoma and Other Cancers (Version 22 Model)	250.70	Diabetes With Peripheral Circulatory Disorders, Type II or Unspecified Type, Not Stated as Uncontrolled	5,448
1	205.80	Other Myeloid Leukemia, Without Mention of Having Achieved Remission	Lung, Upper Digestive Tract, and Other Severe Cancers (Version 12 Model) and Lung and Other Severe Cancers (Version 22 Model)	250.80	Diabetes With Other Specified Manifestations, Type II or Unspecified Type, Not Stated as Uncontrolled	7,535

Number of Sampled Enrollee-Years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
1	205.81	Other Myeloid Leukemia, in Remission	Lung, Upper Digestive Tract, and Other Severe Cancers (Version 12 Model) and Lung and Other Severe Cancers (Version 22 Model)	250.81	Diabetes With Other Specified Manifestations, Type I, Not Stated as Uncontrolled	7,663
1	225.1	Benign Neoplasm of Cranial Nerves	Breast, Prostate, Colorectal and Other Cancers and Tumors (Version 12 Model) and Breast, Prostate, and Other Cancers and Tumors (Version 22 Model)	252.1	Hypoparathyroid-ism	1,226
1	249.20	Secondary Diabetes Mellitus With Hyperosmolarity, Not Stated as Uncontrolled, or Unspecified	Diabetes With Acute Complications	294.20	Dementia, Unspecified, Without Behavioral Disturbance	1,231
1	250.10	Diabetes With Ketoacidosis, Type II or Unspecified Type, Not Stated as Uncontrolled	Diabetes With Acute Complications	205.10	Chronic Myeloid Leukemia, Without Mention of Having Achieved Remission	0
1	433.01	Occlusion and Stenosis of Basilar Artery With Cerebral Infarction	Ischemic or Unspecified Stroke	433.10	Occlusion and Stenosis of Carotid Artery Without Mention of Cerebral Infarction	2,259
1	441.00	Dissection of Aorta, Unspecified Site	Vascular Disease With Complications	414.00	Coronary Atherosclerosis of Unspecified Type of Vessel, Native or Graft	1,618
1	714.9	Unspecified Inflammatory Polyarthropathy	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	174.9	Malignant Neoplasm of Breast (Female), Unspecified	3,110

Number of Sampled Enrollee-Years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
1	E10.21	Type 1 Diabetes Mellitus With Diabetic Nephropathy	Diabetes With Chronic Complications	F10.21	Alcohol Dependence, in Remission	4,732
1	E20.9	Hypoparathyroid-ism, Unspecified	Other Significant Endocrine and Metabolic Disorders	F20.9	Schizophrenia, Unspecified	2,097
39						\$182,961*
* Rounded to the nearest whole dollar amount.						

Table 7: Hierarchical Condition Categories (HCCs) That Were Not Validated, but We Found Support for an HCC for a Less Severe Manifestation of the Related-Disease Group

Count of Sampled Enrollee-Years	More Severe Hierarchical Condition Category That Was Not Validated	Less Severe Hierarchical Condition Category That Was Supported
3	Vascular Disease With Complications	Vascular Disease
1	Metastatic Cancer and Acute Leukemia	Lymphatic, Head and Neck, Brain, and Other Major Cancers (Version 12 Model)
1	Diabetes With Acute Complications	Diabetes Without Complication



January 18, 2022

Via Email and Overnight Delivery

Ms. Lori Pilcher
Regional Inspector General for Audit Services
Office of Audit Services, Region IV
61 Forsyth Street, SW, Suite 3T41
Atlanta, GA 30303

Re: WellCare of Florida, Inc. Response to Draft Audit Report No. A-04-19-07084

Dear Ms. Pilcher:

WellCare of Florida, Inc. (“WellCare”) appreciates the opportunity to respond to the United States Department of Health and Human Services (“HHS”) Office of Inspector General’s (“OIG”) Draft Report No. A-04-19-07084, entitled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that WellCare of Florida, Inc., (Contract H1032) Submitted to CMS* (the “Draft Report” or “OIG Draft Report”), which was provided to WellCare on November 18, 2021.

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

- **The Audit Methodology is Flawed:** The audit process inappropriately limited the submission of medical records; OIG deviated from the Centers for Medicare & Medicaid Services’ (“CMS”) review standards; and some standards were not promulgated pursuant to legal requirements.

In addition, OIG’s sampling and extrapolation approach is biased in identifying overpayments because it focuses on a population that is more likely to have overpayments and ignores populations that are more likely to have underpayments and therefore is not identifying WellCare members’ true risk profile. Furthermore, WellCare has not received the underlying detail necessary to replicate the extrapolation methodology; OIG used an inappropriate lower bound confidence interval; and the extrapolation failed to acknowledge the relevance of actuarial equivalence and the Fee For Service (“FFS”) Adjuster;

- **Medical Record Documentation Supported Certain Diagnoses:** OIG incorrectly concluded that medical record documentation did not support certain diagnoses when, in fact, it did; and
- **OIG Applied an Improper Standard:** OIG’s findings and recommendations improperly imply that plans are expected to assure 100% accuracy of provider-submitted codes.

WellCare has made significant investments in its Medicare risk adjustment compliance program, and we remain committed to improving the quality of data submitted. We have established robust policies and procedures related to risk adjustment and we continue to refine our practices to keep

pace with evolving industry standards. We therefore request that OIG reconsider its recommendations and work closely with WellCare to address the issues identified in our response letter before finalizing its Draft Report.

WellCare welcomes the opportunity to discuss OIG’s methodology, findings, and recommendations.

I. Error Determinations for Hierarchical Condition Categories

A. WellCare Identified Several Issues with OIG’s Methodology.

i. The Audit Process Inappropriately Limited the Submission of Medical Records.

a. Limitation on Medical Records Accepted for Review.

In connection with this audit, OIG provided guidance describing how WellCare should submit the applicable medical records for review. Specifically, OIG stated: “[P]rovide the medical record for the specific date of service of the sample item diagnosis. In the event that an additional medical record may provide further support for the diagnosis in review, please identify as Sample No. – 02.”¹ This standard is more limited than the scope of submissions typically permitted under CMS’s auditing processes. Under CMS’s Risk Adjustment Data Validation (“RADV”) standards, Medicare Advantage (“MA”) Organizations (“MAOs”) are not required to provide the medical record for any particular date of service, including the date of service for which the diagnosis was submitted and used in the auditing sample. Rather, since the Hierarchical Condition Category (“HCC”) is assigned based on the full year, MAOs may validate the HCC based on medical records for *any* date of service during the relevant year. Moreover, CMS’s standard RADV processes have historically allowed entities to submit up to five records to support an HCC and none of these records are required to reflect a specific date of service. The OIG audit process allowed WellCare to submit only two records, one of which was required to be for the specific date of service.

The OIG audit’s more limited scope for documentation submissions made it more difficult for WellCare to demonstrate documented support of the HCCs audited. The audit’s level of documentation specificity goes beyond what is necessary for achieving OIG’s goals and imposes additional burdens on WellCare, presents an incomplete picture for OIG, and can result in inefficiencies when OIG reviews both the specific date of service documentation requested and additional supporting documentation from another date of service, when the latter alone would have been sufficient to support the diagnosis.

b. Limitation on Time Period for Medical Records Submission.

In addition, the audit process imposed deadlines on the submission of medical records that limited WellCare’s ability to obtain medical records from providers. Under CMS’s RADV medical record submission standards, MAOs have 25 weeks to request medical records from providers and submit them to CMS. OIG, however, provided a shorter time period, instructing WellCare to send at least

¹ OIG email to WellCare, *OIG WellCare Medical Records Request*, May 21, 2019 (emphasis added).

half of the medical records in only two months, and the remainder within approximately four and a half months.²

This difference in timing is significant, as an unduly constrained time frame for providers to submit medical records to the MAO skews the audit results. MAOs do not hold or maintain beneficiaries' medical records and depend on the cooperation of providers to obtain and submit them for auditing. In many instances, providers may be reluctant or unable to supply the records, especially when the time period for submitting documentation is compressed and providers are juggling competing demands.

As one MAO expressed in its audit response, HCCs that OIG deems to be unsubstantiated may reflect providers' ability to comply with OIG's record collection deadline rather than the actual substantiation of HCCs in medical records.³ Indeed, WellCare was unable to obtain and submit medical records from providers to support a number of the HCCs, and believes that OIG's use of a shorter record collection time period led to flawed and unreliable results.

ii. OIG Deviated from CMS Review Standards.

Beyond this opportunity to comment on OIG's Draft Report, OIG does not provide a process for appealing the medical record review findings. This is contrary to CMS's standard appeals processes which afford an opportunity for challenging the agency's findings and conclusions. For example, 42 C.F.R. § 422.311 establishes that MAOs that do not agree with their RADV audit results may appeal, including for disputes related to medical record review determinations and payment error calculations.⁴ MAOs may even request a RADV hearing to be conducted by a Hearing Officer with formal proceedings.⁵ Beyond CMS's RADV process, under 42 C.F.R. § 422.330, when CMS identifies overpayments associated with payment data submitted by MAOs, it may send a data correction notice to the MAO and conduct a payment offset.⁶ If the MAO does not agree with the payment offset, it may appeal under a three-level appeal process.⁷ Recognizing the complexities involved in medical record documentation and MA payments, CMS implemented an appeal process as a standard part of the MA program to allow MAOs to challenge CMS's findings, which is customary in the industry. The inability to appeal the Draft Report's conclusions is thus inconsistent with the CMS standards ingrained in the MA program and makes it all the more critical that OIG's methodology be accurate, comprehensive, and fair.

² Subsequently OIG asked if WellCare had any additional medical records to submit, and WellCare submitted a few that it had received. However, in accordance with OIG's previous deadlines, it had ceased collection efforts.

³ See OIG, *Medicare Advantage Compliance Audit of Diagnosis Codes that Humana, Inc. (Contract H1036) Submitted to CMS, A-07-16-01165* (Apr. 2021) ("Humana Audit") at 29, available at <https://oig.hhs.gov/oas/reports/region7/71601165.pdf>.

⁴ 42 C.F.R. § 422.311(c).

⁵ *Id.*

⁶ 42 C.F.R. § 422.330.

⁷ *Id.*

iii. *The Audit Applied Review Standards that Were Not Promulgated Pursuant to Legal Requirements.*

We note as well, as other MAOs have,⁸ that the audit’s methodology applied substantive standards that were not promulgated pursuant to the notice-and-comment requirements set forth in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), and the subsequent implementation memorandum from the HHS Office of the General Counsel.⁹ In *Allina*, the Supreme Court held that substantive standards governing payments under Medicare must be promulgated pursuant to notice-and-comment rulemaking under 42 U.S.C. § 1395hh(b), regardless of whether such standards are framed as rules, policies, or otherwise. The HHS Office of the General Counsel has advised CMS that it may not bring enforcement actions for overpayment collections based on substantive standards in audits that have not been properly promulgated.¹⁰ OIG’s audits, of course, must similarly apply only properly promulgated and binding legal standards. WellCare reserves its rights with respect to substantive standards set forth in the Medicare Managed Care Manual, the Risk Adjustment Training Manual, and other documents that were not promulgated in accordance with 42 U.S.C. § 1395hh(b) and notice-and-comment requirements.¹¹

B. WellCare Respectfully Requests That OIG Reconsider the Draft Report’s Finding That Medical Records Do Not Substantiate Certain Audit HCCs.

OIG highlights examples of individual medical records where it believes that the HCCs under review are not validated. Specifically, the Draft Report alleges that WellCare incorrectly submitted diagnosis codes for embolism and major depressive disorder, in addition to submitting potentially mis-keyed diagnosis codes. However, even within the limitations of the audit procedures and review standards that OIG applied, as discussed above, the medical record documentation we provided clearly supports the HCCs highlighted in five instances. These five HCCs are discussed in Appendix A. We respectfully request that OIG reconsider its findings for these five HCCs.

II. Critical Flaws in the Audit’s Sampling and Extrapolation Approach

A. The Audit Sample is Biased to Identifying Underpayments.

The audit procedures and methodology are skewed to identifying overpayments, rather than underpayments. The Draft Report alleges that 156 sampled enrollee-years resulted in net

⁸ *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc (Contract H2663) Submitted to CMS*, A-07-17-01173 (Oct. 2021) (“Coventry Audit”), Appendix D, available at <https://oig.hhs.gov/oas/reports/region7/71701173.pdf>; *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS*, A-02-18-01029 (Jan. 2022) (“Healthfirst Audit”), Appendix G, available at <https://oig.hhs.gov/oas/reports/region2/21801029.pdf>.

⁹ Impact of *Allina* on Medicare Payment Rules at 1-3. Accessible at <https://www.law360.com/articles/1222453/attachments/0>.

¹⁰ *Id.*

¹¹ OIG has responded in other audit reports that MAOs’ contracts with CMS call for adherence to CMS instructions and guidance. However, CMS remains subject to the statutory requirements, which may not be avoided through language in a form agreement which may itself be in conflict with statutory requirements.

overpayments of \$416,407,¹² and identifies only one instance where an independent medical reviewer's error resulted in an underpayment.¹³ However, the reason the Draft Report identified merely one instance of underpayment is because WellCare was asked to submit only the medical records to substantiate specific HCCs submitted to CMS. WellCare did not collect and submit medical records to substantiate *all* HCCs that *could have* been submitted to CMS. Additional underpayments likely would have been identified if the full range of medical records were submitted.

As a result, actual and extrapolated repayment calculations reflected in the Draft Report are inflated and statistically invalid. WellCare respectfully requests that OIG revise its audit to address these biases.

B. There is Insufficient Data to Support Extrapolation.

OIG's extrapolation methodology raises a number of questions regarding sampling, and WellCare has been unable to verify the statistical validity of the extrapolation. For example, WellCare has not received the underlying detail necessary to replicate the extrapolation calculation. OIG's variance analysis was not well defined, and WellCare has been able to develop only a range of estimates in an attempt to understand and track OIG's work. Despite these efforts, it remains unclear how OIG performed the extrapolation. Specifically, we have not been able to determine whether OIG looked at each high-risk group, created a confidence interval for each, and then summed the amounts or whether OIG instead used the aggregate results across the high-risk groups to create a confidence interval. It is also unknown whether OIG based its confidence interval on error rates tied to: dollars in error over total dollars in the sample; HCCs in error over HCCs in the sample; or members in error over members in the sample.

Additionally, it is not clear how OIG selected and stratified the sample. From what we are able to determine, the distribution of the sample does not align with the distribution of total members identified by high-risk group. For example, the design of the audited high-risk groups included a sample size of 200 for the first six strata. Of these, 71 enrollee-years sampled related to major depressive disorder. Major depressive disorder therefore accounted for approximately 36% of the sample. However, had OIG considered the total frame count of 1,723 enrollee-years related to major depressive disorder of the 3,710 total enrollee-years analyzed, major depressive disorder would have accounted for approximately 46% of the members in the frame. If the results were aggregated by OIG before computing a confidence interval, a higher error rate of 58% would have been applied to this group than what was actually measured (21%). Because this group represents a larger percentage of the frame relative to the 200 sample, this approach likely skewed the final results. We estimate that this error accounted for roughly \$300,000 assessed against WellCare due to defective sampling and stratification.

¹² See OIG, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that WellCare of Florida, Inc. (Contract H1032) Submitted to CMS, A-04-19-07084* (Nov. 2021) ("Draft Report") at 7.

¹³ *Id.* at 11.

C. OIG Used the Lower Bound of a 90% Confidence Interval Rather Than 95% as OIG/CMS do in Other Contexts, or 99% as in the CMS RADV Extrapolation Methodology.

OIG calculated an extrapolated overpayment amount using the lower bound of a 90% confidence interval.¹⁴ As discussed by other MAOs in response to this statistical approach,¹⁵ CMS’s published and binding RADV extrapolation methodology utilizes the lower bound of a 99% confidence interval.¹⁶ In prior audits, OIG acknowledged that OIG’s “audit findings and recommendations do not represent final determinations by CMS” and that “[a]ction officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures.”¹⁷ Given this, it is unclear on what basis OIG is calculating and recommending that WellCare make a repayment using a different standard than what CMS would use. The Draft Report’s statement that the 90% confidence interval is statistically valid does not address the fact that the standard is materially different from what CMS would use if it were to initiate an extrapolated recovery.

Furthermore, use of a different and lower bound can have a meaningful impact on the financial results. If OIG retains an extrapolation in the final report, WellCare respectfully requests that OIG revise its approach to align with the binding extrapolation methodology, consistent with regulatory and industry standards.

D. The Draft Report Should Acknowledge and Address the Relevance of the FFS Adjuster.

MA payments are statutorily required to be “actuarially equivalent” to the payments CMS makes for beneficiaries of a similar risk profile in traditional Medicare.¹⁸ In its response to a recent OIG report, CMS explained that RADV audits are CMS’s primary mechanism for monitoring and assessing the accuracy of risk adjustment payments.¹⁹ Yet, the payments cannot be considered “actuarially equivalent” if only the MA payments are adjusted through audits. To validly compare the risk profile of a group of Medicare beneficiaries in MA and a group in traditional Medicare, the method for applying risk scores in the two populations should be the same. If they are not, some adjustment is necessary, as differences in risk scores for MA versus traditional Medicare

¹⁴ *Id.* at 24.

¹⁵ See, e.g., OIG, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS, A-07-19-01187* (May 2021) (“Anthem Audit”), available at <https://oig.hhs.gov/oas/reports/region7/71901187.pdf>; OIG, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS, A-07-19-01188* (Nov. 2021) (“UPMC Audit”) at 65, available at <https://oig.hhs.gov/oas/reports/region7/71901188.pdf>.

¹⁶ CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* (Feb. 24, 2012) at 4, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf>.

¹⁷ See, e.g., Anthem Audit at 21; UPMC Audit at 28; Healthfirst Audit at 21.

¹⁸ See 42 U.S.C. § 1395w-23(a)(1)(C)(i) (CMS must adjust payments rates in a manner “so as to ensure actuarial equivalence” between Medicare Advantage and traditional Medicare).

¹⁹ See OIG, *Some Medicare Advantage Companies Leveraged Chart Reviews and Health Risk Assessments to Disproportionately Drive Payments* (OEI-03-17-00474) (Sept. 2021), Appendix A: Agency Comments (dated Aug. 20, 2021), available at <https://oig.hhs.gov/oei/reports/OEI-03-17-00474.pdf>.

populations may reflect differences in how the risk scores are computed, not actual differences in the health (and therefore the expected cost) of the two populations.

In 2012, CMS agreed with this proposition in its final extrapolation methodology for its RADV audits. That final methodology provided for CMS to apply a “FFS Adjuster” before extrapolating any RADV audit results, in order to account “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 ([traditional Medicare] claims).”²⁰ At the time, CMS said it would perform a “RADV-like review” of traditional Medicare data to establish the amount of the FFS Adjuster.²¹

CMS itself has acknowledged that audited MAOs are underpaid if a FFS Adjuster is not applied.²² For example, CMS stated in one presentation that “[i]n RADV audits, we expect coding perfection from [MAOs],” while “[i]n [traditional] Medicare, some portion of diagnoses on [traditional Medicare] claims are not documented in medical records.”²³ In the context of RADV audits, CMS acknowledged, this leads to MAOs “being held to a different (higher) standard for diagnoses.”²⁴ Traditional Medicare data—which includes undocumented diagnoses—was used to calculate MA payment rates. CMS has accepted that this inclusion “tends to reduce risk adjustment values.”²⁵ The math simply does not add up properly without an adjustment, as demonstrated by CMS’s own examples showing that MAOs would be underpaid if audits essentially required data perfection without consideration of the data errors that exist in traditional Medicare.²⁶

As it stands today and during OIG’s audit period, the CMS extrapolation methodology requires application of an FFS Adjuster when CMS conducts its own RADV audits assessing payment accuracy. That methodology, and the 2012 notice that adopted it, appropriately implements the statutory requirement of “actuarial equivalence” in payments between MA and traditional Medicare.²⁷ In identifying an extrapolated amount as an “overpayment,” OIG must necessarily address actuarial equivalence and the need for an FFS Adjuster.

The audit’s use of data mining techniques targeting specific diagnoses that it believes are “at a higher risk for being miscoded,”²⁸ raises further issues with actuarial equivalence. The high-risk

²⁰ CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* (Feb. 24, 2012). In 2018, CMS issued a proposed rule that would reverse course from its 2012 Methodology, and *not* apply an FFS Adjuster. See CMS, *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. 54,982 (Nov. 1, 2018). However, CMS has not finalized that proposal.

²¹ *Id.* at 5.

²² See *UnitedHealthcare v. Azar*, 1:16-cv-00157-RMC (D.D.C. Oct. 2, 2017) (ECF 44-3) (CMS, “Model Calibration Factor”) (“*UnitedHealthcare*”); *UnitedHealthcare*, 1:16-cv-00157-RMC (D.D.C. Oct. 2, 2017) (ECF 44-4) (CMS, “Three RADV Policy Issues”).

²³ *UnitedHealthcare*, 1:16-cv-00157-RMC (D.D.C. Oct. 2, 2017) (ECF 44-3) (CMS, “Model Calibration Factor” at 6).

²⁴ *Id.*

²⁵ *Id.* at 7.

²⁶ *Id.* at 8–9.

²⁷ See 42 U.S.C. § 1395w-23(a)(1)(C)(i); CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* (Feb. 24, 2012).

²⁸ Draft Report at 16.

conditions that OIG identified may have been similarly at high risk of being miscoded in traditional Medicare. Therefore, any auditing or deletion practices that focus on the miscoding of high-risk diagnoses will inevitably ignore the same, persisting errors in traditional Medicare and will render any MAOs' risk adjustment and payments actuarially inequivalent. For these reasons, MAOs have continued to stress that such audits must be performed on statistically valid and randomly sampled codes from an MA Plan's entire contract, with the appropriate FFS Adjuster applied. Deviations from this approach quickly violate the principles of actuarial equivalence as Congress prescribed.

III. Standards and Expectations

A. Plans are Not Expected to Assure 100% Accuracy of Provider-Submitted Codes, as the Draft Report's Findings and Recommendations Imply.

Various aspects of the Draft Report may be read to imply that MAOs' compliance efforts must assure 100% accuracy with respect to the vast quantities of diagnosis codes they receive from providers and are required to submit to CMS. For example, the Draft Report's finding that the purported errors identified "occurred because the policies and procedures that WellCare had to prevent, detect, and correct compliance with CMS's program requirements, as mandated by Federal regulations, were not always effective"²⁹ suggests that OIG believes that WellCare is required to have policies and procedures in place that eliminate *all* unsupported codes. WellCare requests that OIG eliminate this finding; no compliance program is expected to eliminate all types of errors. Even where an audit reveals some errors, that does not mean policies and procedures were not effective. The Draft Report's finding that WellCare's policies and procedures were not "always" effective reflects an inappropriate and legally flawed expectation of perfection and 100% accuracy. Moreover, the Draft Report's characterization that WellCare's policies were not always effective in specifically identifying high-risk diagnoses for noncompliance creates an expectation that MAOs go beyond what is required by law.

Similarly, the Draft Report's recommendations to refund an extrapolated amount and conduct further audits seemingly intend to implement a 100% accuracy expectation. CMS regulations do not establish or require a 100% accuracy standard for risk adjustment data, generally or with respect to the "high risk" codes.³⁰

The care an MAO's enrollees receive results in millions of claims from the providers rendering that care. Typically, these claims reflect multiple diagnoses assigned by the providers and result in an enormous volume of data that MAOs must receive and submit to CMS.³¹ CMS then uses the submitted claims data to implement its risk adjustment model in accordance with its goal of promoting practicality and administrative simplicity.³² Accordingly, an MAO is largely dependent upon healthcare providers to generate the majority of its risk adjustment data.

²⁹ Draft Report at 15.

³⁰ See e.g., Anthem Audit at 46-47; Humana Audit at 34-36; and UPMC Audit at 65-67.

³¹ 42 CFR § 422.310(b) and 42 CFR § 422.310(d)(3).

³² See CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2004 Medicare+Choice (M+C) Payment Rates* at 5 (Mar. 28, 2003) (CMS selected a risk adjustment model intended to "improv[e] payment accuracy while minimizing the administrative data burden on" MAOs); see also Am. Acad. of Actuaries, *Risk Adjustor Work*

Verifying 100% of submitted risk adjustment data would be prohibitive for MAOs (and place extraordinary additional burdens on providers). Nor does the MA regulatory framework include an expectation or requirement that MAOs ensure 100% medical record support for codes generally or the specific “high risk” codes that OIG selected. Such a mandate would be impractical, financially unsustainable for MAOs, and inconsistent with the goal of administrative simplicity that underlies the HCC model. In recognition of these facts, CMS long has acknowledged that MAOs “cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the OIG, and DOJ believe is reasonable to enforce.”³³ Federal regulations require that MAOs submit all risk adjustment data from healthcare providers and requires an attestation in respect of risk adjustment data. However, that attestation does not impose a requirement for an MAO to ensure that all submitted codes, or all submitted codes for OIG-identified “high risk” codes, are supported by medical records. Rather, MAOs “will be held responsible for making good faith efforts to certify the accuracy, completeness, and trustfulness of encounter data submitted.”³⁴ OIG itself has acknowledged that MAOs are not able to provide an “absolute guarantee of accuracy.”³⁵

Moreover, an expectation to ensure 100% accuracy would disregard the known presence of unsubstantiated codes in the traditional Medicare data and would render the risk adjustment system actuarially inequivalent. In its appeal of the district court’s ruling in *UnitedHealthcare Ins. Co. v. Azar*, the United States recognized that broad monitoring obligations would implicate actuarial equivalence. The United States defended an asserted obligation to delete unsupported codes on grounds that the obligation was limited: “the [2014] Overpayment Rule requires only that insurers delete erroneous diagnoses when those errors are identified, *not that insurers conduct comprehensive audits.*”³⁶ The government conceded that MAOs do not have an obligation to identify and delete every erroneous diagnosis, or even a large fraction of them.³⁷ The court of appeals cited the government’s representations in its ruling, stating that the “[Overpayment] Rule only requires insurers to refund amounts they *know* were overpayments, *i.e.*, payments they *are aware* lack support in a beneficiary’s medical record. That limited scope does not impose a self-auditing mandate.”³⁸

Group, *Actuarial Review of the Health Status Risk Adjustor Methodology* at 30-31 (Jan. 14, 1999), available at <http://www.actuary.org/pdf/medicare/hcfariskadj.pdf> (model should be based on “data gained from administrative sources (typically from claim records or encounter files)” rather than clinical records because “clinical information from sources such as medical records and patient charts is nearly impossible to gather, except in the most manpower-intensive manner”).

³³ 65 Fed. Reg. 40170, 40268 (June 29, 2000).

³⁴ *Id.* at 40268; *see also id.* at 40250-40252 (“Attestation of encounter data is essential for guaranteeing the accuracy and completeness of data submitted for payment purposes, and to allow us to pursue penalties . . . where it can be proven that a plan knowingly submitted false data. However, in response to concerns from M+C organizations, we have restricted the attestation requirement to confirmation of the completeness of the data and the accuracy of coding . . . the attestation requirement is thus in no way a legal trap”).

³⁵ 64 Fed. Reg. 61893, 61900 (Nov. 15, 1999).

³⁶ *UnitedHealthcare*, No. 18-5326, Brief for Appellants, at 2-3 (D.C. Cir. Apr. 23, 2020) (emphasis added).

³⁷ *See Id.* at 39-40.

³⁸ *UnitedHealthcare Ins. Co. v. Becerra*, 9 F.4th 868, 884, No. 18-5326 (D.C. Cir. Aug. 13, 2021) (emphasis in original). The Draft Report also says that “Federal regulations state that MA organizations must monitor the data that they receive from providers and submit to CMS.” However, we note that no regulation is cited for this statement, particularly to the extent it implies an obligation to assure 100% accuracy.

WellCare respectfully requests that the final report acknowledge the more limited scope of MAOs' obligations. In particular, WellCare requests that the final report expressly include and acknowledge statements made by the United States in the *UnitedHealthcare* litigation that MAOs do not have an obligation to identify and delete every erroneous diagnosis, or even a large fraction of them. WellCare requests corresponding revisions to the Draft Report's recommendations, which we believe misstate the nature and extent of MAOs' obligations.

IV. Recommendations

1. Refund to the Federal Government the \$3,614,989 of estimated net overpayments;

WellCare requests that OIG withdraw the recommendation to refund the government on an extrapolated basis. As we have discussed above, OIG's extrapolated estimate is incorrect and flawed for a number of reasons having to do with the determinations of the sampled HCCs, deficiencies in the sampling and statistical methodology, and the failure to address actuarial equivalence. In addition, in other recent audit reports, OIG recognized that its findings and recommendations are "not final determinations by CMS" and that "[a]ction officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures."³⁹ OIG appears to be anticipating a process whereby CMS addresses the issues raised, makes a final payment determination, and then initiates a recoupment action.⁴⁰ Although OIG's responses to comments appear to recognize the tentative nature of its findings and CMS's role in determining whether an overpayment exists, if OIG retains a recommendation related to extrapolation, WellCare respectfully requests that OIG make those points clear through revisions in the report's text (rather than simply addressing the issue in its response to comments, as it has done in other recent audit reports).

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

WellCare will consider this recommendation and anticipates further discussions with CMS to ensure that it meets its obligations. WellCare believes that this recommendation reflects a number of flaws inherent in OIG's audit and that the Draft Report does not address a number of relevant factors, including the impact of actuarial equivalence, the scope of any diligence obligations associated with the Overpayment Rule, and other factors. WellCare anticipates working with CMS to understand its views regarding additional audits and repayments and to request that CMS address these issues in a consistent manner across MAOs.

³⁹ Anthem Audit at 21; UPMC Audit at 28; Healthfirst Audit at 21.

⁴⁰ This approach would be in line with the PacifiCare audit report. OIG, *Risk Adjustment Data Validation of Payments Made to PacifiCare of Texas for Calendar Year 2007 (Contract Number H4590), A-06-09-00012* (May 2012) ("PacifiCare Audit"), available at <https://oig.hhs.gov/oas/reports/region6/60900012.pdf>.

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

WellCare is engaged in a continual process of evaluating and enhancing its compliance procedures and will consider these recommendations. We also anticipate working with CMS to better understand its views regarding MAO's compliance efforts and obligations within the actuarial and legal context discussed above.

V. Conclusion

WellCare appreciates the opportunity to comment on the Draft Report. We look forward to receiving the final report after OIG has had an opportunity to consider the issues we have raised. If you have any questions concerning this response letter, please do not hesitate to contact me.

Sincerely,

/s/ Eryn Kantor
Eryn Kantor
Vice President, Medicare Compliance Officer

Appendix A

As discussed in Section I.B. of its response letter, WellCare believes that, even aside from the flaws in the audit procedures and review standards discussed in the response letter, the medical record documentation WellCare provided clearly supports the HCCs highlighted in the following five instances:

i. Embolism.

The Draft Report identifies one enrollee-year (Sample 170) where the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of . . . [the Embolism] HCC. The medical documentation states that the patient has a history of deep vein thrombosis . . . which does not result in an HCC.”⁴¹

In this instance, the independent medical record reviewer did not take into account the provider’s entire note. If the reviewer had considered the entire note, they would have understood that the phrase “history of” was in reference to another condition. The diagnostic statement in the medical record notes, “other pulmonary embolism and infarction.” The provider goes on to describe how the condition was “recently diagnosed at [the] hospital.” The specific encounter that OIG requested review of took place shortly after this hospital stay, where the pulmonary embolism was detected and, therefore, represents a new diagnosis. According to the American Hospital Association’s Coding Clinic, anticoagulant treatment for acute pulmonary embolism can be carried out for three to six months until the embolus dissolves.⁴² Given an average resolution or dissolution time of three to six months and that the patient was merely one month out from onset, there is no reason to presume a history of pulmonary embolism. The assignment of ICD-9-CM code 415.19, HCC 107 (V22), for pulmonary embolism was appropriate and sufficiently documented by the provider.

ii. Major Depressive Disorder.

The Draft Report states that WellCare incorrectly submitted diagnosis codes for major depressive disorder for fifteen sampled enrollee-years. Specifically, the Draft Report highlights that, for one-enrollee year, the independent reviewer contractor found that “there is no documentation of any condition that will result in assignment of . . . [the Major Depressive, Bipolar, and Paranoid Disorders] HCC.”⁴³ For additional enrollee-years, the Draft Report states that WellCare did not provide any medical records to support the major depressive disorder diagnoses. As a result, the Draft Report reflects a conclusion that the HCCs were not validated.

WellCare respectfully disagrees with these findings. For one enrollee-year (Sample 49) in question, while the diagnosis documented in the medical record maps to ICD-9-CM code 311, there is a handwritten addendum to the progress note signed by the clinical physician that provides further specificity on the condition. The addendum specifies “major depression: chronic,” which

⁴¹ Draft Report at 13.

⁴² See American Hospital Association Coding Clinic (Fourth Quarter 2009) at 85.

⁴³ Draft Report at 13.

results in ICD-9-CM code 296.20 and HCC 55 (V12)/ HCC 58 (V22). According to CMS's Contract-Level 15 RADV Medical Record Reviewer Guidance, diagnoses may be coded from acceptable amendments. Amendments are considered acceptable so long as they are: completed by the attending or treating physician; based on an observation of the patient on the date of service; and signed by the physician in a timely manner.⁴⁴ Since the handwritten addendum to the progress note meets these requirements, it is appropriate to use the more specific ICD-9-CM code 296.20 for the date of service.

In another instance (Sample 56), the independent medical record reviewer dismissed the physician's documentation of "depression, recurrent, in remission." This citation directly maps to the HCC at issue. In the 2015 ICD-9-CM Index to Diseases, under "depression," the specifier "recurrent" leads to code 296.3, which results in the HCC submitted. The record therefore supports code 296.3, HCC 58 (V22).

In both instances, the providers clearly documented the symptoms and treatment consistent with the diagnosis codes. To conclude otherwise would discredit their clinical assessment.

iii. Mis-Keyed Diagnosis Codes.

The Draft Report also asserts that WellCare submitted potentially mis-keyed diagnosis codes for 40 of 50 enrollee-years.⁴⁵ The Draft Report cites examples where it believes HCCs were substantiated based on the assessment of other conditions and that these instances represent potential mis-keyed diagnoses. However, the medical records substantiate the HCCs submitted and finding in the Draft Report is likely the result of incorrect mapping by the individual medical record reviewer.

For example, one record (Sample 219) at issue includes documentation of an inpatient stay where the associated discharge summary notes that the member was admitted with "aneurysmal dilation of the descending abdominal aorta." However, a review of the entire record, including the care rendered throughout hospitalization, shows that the discharging provider included notes on the performance of two abdominopelvic CTs. The *second* CT displayed "abdominal aortic aneurysm with aortic dissection." Under the 2015 ICD-9-CM Index to Diseases, coding for the subsequent diagnosis begins by locating the entry for "aneurysm," and then the subentries for "aorta," "dissecting," and "abdominal." This path ultimately leads to ICD-9-CM code 441.02, which results in the HCC 104 (V12) submitted.

The Draft Report described another enrollee sample (Sample 230) which follows a similar pattern and where the full diagnostic statement was "Aortic Aneurysm & Dissection Abdominal." Under the 2014 ICD-9-CM Index to Diseases, starting at the entry for "aneurysm," the correct pathway would be to locate subentries for "aorta," "dissecting," and "abdominal" until reaching code

⁴⁴ The enrollee at issue was seen in calendar year 2014, where CMS guidelines would be applicable. See CMS, *Contract-Level 15 Risk Adjustment Data Validation: Medical Record Reviewer Guidance* at 61 (Jan. 2020). Accessible at <https://www.cms.gov/files/document/medical-record-reviewer-guidance-january-2020.pdf>.

⁴⁵ See Draft Report at 14.

441.02, per ICD-9-CM.⁴⁶ This code captures the patient's condition accurately based on the diagnostic statement and is the most appropriate code available at the highest level of specificity HCC 104 (V12).

⁴⁶ See ICD9Data. Accessible at <http://www.icd9data.com/2014/Volume2/default.htm>.