

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE  
COMPLIANCE AUDIT  
OF SPECIFIC DIAGNOSIS CODES  
THAT MCS ADVANTAGE, INC.  
(CONTRACT H5577)  
SUBMITTED TO CMS**

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**March 2023  
A-02-20-01008**

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## Report in Brief

Date: March 2023

Report No. A-02-20-01008

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. Some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS. For this audit, we reviewed one MA organization, MCS Advantage, Inc., and focused on nine groups of high-risk diagnosis codes.

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

### How OIG Did This Audit

We sampled 280 unique enrollee-years with the high-risk diagnosis codes for which MCS received higher payments for 2016 through 2017. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$402,073.

## Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS

### What OIG Found

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes for the sampled enrollee-years that MCS submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 183 of the 280 sampled enrollee-years, the diagnosis codes were not supported in the medical records, resulting in \$220,577 of net overpayments.

These errors occurred because MCS's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations could be improved. On the basis of our sample results, we estimated that MCS received at least \$6.2 million of net overpayments for these high-risk diagnosis codes in 2016 and 2017.

### What OIG Recommends and MCS Comments

We recommend that MCS (1) refund to the Federal Government the \$220,577 of net overpayments; (2) identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and (3) continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements and take the necessary steps to enhance those procedures.

MCS disagreed with some of our findings, provided additional information for four sampled enrollee-years, and requested that we withdraw our recommendations. MCS stated that our recommendations are (1) based on flawed audit sampling and review methodologies, (2) inconsistent with the Social Security Act's actuarial equivalence mandate and CMS's data accuracy and compliance requirements, and (3) not supported by the factual record.

After reviewing MCS's comments and the information that MCS provided, we revised the number of sampled enrollee-years in error from 186 to 183 for this final report. After we had issued our draft report, CMS updated regulations for audits in its risk adjustment program to specify that extrapolated overpayments could only be recouped beginning with payment year 2018. Because our audit period covered payment years 2016 and 2017, we changed our first recommendation to specify a refund of only the net overpayments for the sampled enrollee-years. We made no changes to our second and third recommendations.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

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

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS.<sup>2</sup> 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 MCS Advantage, Inc. (MCS), for contract number H5577 and focused on nine groups of high-risk diagnosis codes for payment years 2016 and 2017.<sup>3</sup>

### OBJECTIVE

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

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<sup>1</sup> 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 version of the ICD Coding Guidelines (which we refer to as "ICD-9" in this report) to the tenth revision (which we refer to as "ICD-10" in this report). Each revision includes different diagnosis code sets.

<sup>2</sup> See Appendix B for related Office of Inspector General reports.

<sup>3</sup> All subsequent references to "MCS" in this report refer solely to contract number H5577.

## 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.<sup>4</sup> 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 2020, CMS paid MA organizations \$317.1 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.<sup>5</sup>

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

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

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<sup>4</sup> 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.

<sup>5</sup> The Social Security Act (the Act) §§ 1853(a)(1)(C) and (a)(3); 42 CFR § 422.308(c).

<sup>6</sup> The Act § 1854(a)(6); 42 CFR § 422.254 *et seq.*

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

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

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

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

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

The risk adjustment program is prospective. Specifically, CMS uses the diagnosis codes that the enrollee received for 1 year (known as the service year) to determine HCCs and calculate risk scores for the following calendar year (known as the payment year). Thus, an enrollee's risk score does not change for the year in which a diagnosis is made. Instead, the risk score changes for the entirety of the year after the diagnosis has been made. Further, the risk score calculation is an additive process—as HCC factors (and, when applicable, disease interaction factors) accumulate, an enrollee's risk score increases, and the monthly risk-adjusted payment to the MA organization also increases. In this way, the risk adjustment program compensates MA organizations for the additional risk of providing coverage to enrollees expected to require more health care resources.

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

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<sup>8</sup> During our audit period CMS calculated risk scores based on the Version 22 CMS-HCC model.

sequestration reduction.<sup>9</sup> Thus, if the factors used to determine an enrollee’s risk score are incorrect, CMS will make an improper payment to an MA organization. Specifically, if medical records do not support the diagnosis codes that an MA organization has submitted to CMS, the HCCs are unvalidated, which will cause overstated enrollee risk scores and overpayments from CMS.<sup>10</sup> Conversely, if medical records support diagnosis codes that an MA organization does not submit to CMS, validated HCCs may not be included in enrollees’ risk scores, which may cause the risk scores to be understated and may result in underpayments.

### High-Risk Groups of Diagnoses

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

- *Major depressive disorder*: An enrollee received a 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, a major depressive disorder diagnosis may not be supported in the medical records.
- *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 or outpatient hospital claim. In these instances, a diagnosis of history of stroke (which does not map to an HCC) typically should have been used.
- *Vascular claudication*: An enrollee received one diagnosis related to vascular claudication (that mapped to the HCC for Vascular Disease) during the service year, but had not received one of these diagnoses during the 2 preceding years and had medication dispensed on his or her behalf that is frequently dispensed for a diagnosis of

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

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

neurogenic claudication.<sup>11</sup> In these instances, the diagnosis related to vascular claudication may not be supported in the medical records.

- *Breast cancer:* An enrollee received one breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of breast cancer (which does not map to an HCC) typically should have been used.
- *Colon cancer:* An enrollee received a colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of colon cancer (which does not map to an HCC) typically should have been used.
- *Prostate cancer:* An enrollee 74 years of age or younger received one prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) during the service year but did not have surgical therapy, radiation treatments or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of prostate cancer (which does not map to an HCC) typically should have been used.
- *Lung cancer:* An enrollee received one lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period either before or after the diagnosis. In these instances, a diagnosis of history of lung cancer (which does not map to an HCC) typically should have been used.
- *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 during the service year 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 indicating a history of a myocardial infarction (which does not map to an HCC) typically should have been used.
- *Embolism:* An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease with Complications (Embolism

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<sup>11</sup> 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.

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

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

### **MCS Advantage, Inc.**

MCS is an MA organization based in San Juan, Puerto Rico. As of December 2017, MCS provided coverage under contract number H5577 to 191,297 enrollees. For the 2016 and 2017 payment years (audit period), CMS paid MCS approximately \$3 billion to provide coverage to its enrollees.<sup>12, 13</sup>

### **HOW WE CONDUCTED THIS AUDIT**

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of the nine high-risk groups during the 2015 and 2016 service years, for which MCS received increased risk-adjusted payments for payment years 2016 and 2017, 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 20,672 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$27,414,499). We selected for audit a stratified random sample of 280 enrollee-years as shown in Table 1 (following page).

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<sup>12</sup> The 2016 and 2017 payment year data were the most recent data available at the start of the audit.

<sup>13</sup> All of the payment amounts that CMS made to MCS and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

**Table 1: Sampled Enrollee-Years**

<b>High Risk Group</b>	<b>Number of Sampled Enrollee Years</b>
1. Major depressive disorder	40
2. Acute stroke	30
3. Vascular claudication	30
4. Breast cancer	30
5. Colon cancer	30
6. Prostate cancer	30
7. Lung cancer	30
8. Acute heart attack	30
9. Embolism	30
<b>Total for All High-Risk Groups</b>	<b>280</b>

MCS provided medical records as support for the selected diagnosis codes associated with 262 of the 280 sampled enrollee-years.<sup>14</sup> We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. For the HCCs that were not validated, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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. Appendix E contains Federal regulations regarding MA organizations' compliance programs.

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<sup>14</sup> MCS could not provide medical records for the remaining 18 sampled enrollee-years.

## FINDINGS

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes for the sampled enrollee-years that MCS submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 97 of the 280 sampled enrollee-years, the medical records validated the reviewed HCCs.<sup>15</sup> However, for the remaining 183 enrollee-years, either the medical records that MCS provided did not support the diagnosis codes or MCS could not locate the medical records to support the diagnosis codes and the associated HCCs were therefore not validated. As a result, MCS received \$220,577 in net overpayments.

As demonstrated by the errors found in our sample, MCS's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that MCS received at least \$6.2 million of net overpayments for 2016 and 2017.<sup>16</sup>

## FEDERAL REQUIREMENTS

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

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

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

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<sup>15</sup> For five of these enrollee-years, MCS submitted hardship exception requests to OIG indicating that medical records were destroyed in the aftermath of Hurricane Maria in September 2017; therefore, we did not consider these enrollee-years as errors in our sample.

<sup>16</sup> Specifically, we estimated that MCS received at least \$6,255,434 of net overpayments. To be conservative, we estimate net overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

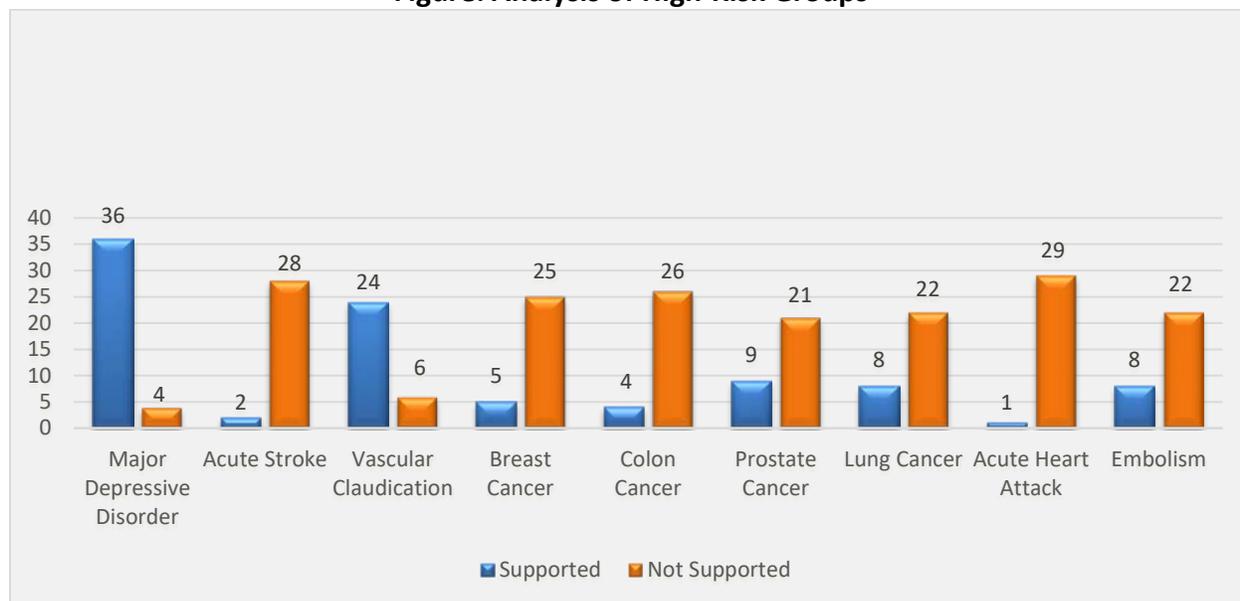
CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap. 7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face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

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

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

Most of the high-risk diagnosis codes that MCS submitted to CMS for use in CMS’s risk adjustment program did not comply with Federal requirements. Specifically, and as shown in the figure below, the medical records for 183 of the 280 sampled enrollee-years did not support the diagnosis codes. In these instances, MCS 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 Major Depressive Disorder**

MCS incorrectly submitted diagnosis codes for major depressive disorder for 4 of 40 sampled enrollee-years. Specifically, for the 4 enrollee-years, the medical records in each case did not contain sufficient information to support a major depressive disorder diagnosis. For all four enrollee-years, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [the Major Depressive, Bipolar, and Paranoid Disorders] HCC.”

As a result of these errors, the HCC for Major Depressive, Bipolar, and Paranoid Disorders was not validated, and MCS received \$6,740 in overpayments for these 4 sampled enrollee-years.

## **Incorrectly Submitted Diagnosis Codes for Acute Stroke**

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

- For 14 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC [for Ischemic or Unspecified Stroke] or a related HCC. The submitted record is a physician record. The patient was seen in an office visit. Test results indicate calcified plaque of the right carotid bulb<sup>17</sup> [diagnosis] which does not result in an HCC.”

- For 12 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 2016) indicated that the individual had an acute stroke in 2012. The independent medical review contractor noted that “there is no evidence of an acute stroke, however the patient has hemiparesis from an old stroke.” The hemiparesis diagnosis was submitted to CMS and the related HCC was factored into the payment for the enrollee-year. The history of acute stroke diagnosis code does not map to an HCC.

- For the remaining 2 enrollee-years, MCS was unable to provide medical record documentation to support the acute stroke diagnoses; therefore, the HCC for Ischemic or Unspecified Stroke was not validated.

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<sup>17</sup> Specifically, the patient was diagnosed as having a condition which reduces blood flow to the brain and can cause a stroke.

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and MCS received \$38,087 in overpayments for these 28 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Vascular Claudication**

MCS incorrectly submitted diagnosis codes for vascular claudication for 6 of 30 sampled enrollee-years. Specifically:

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

Specifically, for all 3 enrollee-years, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of HCC [Vascular Disease] . . . .”

- For the remaining 3 enrollee-years, MCS was unable to provide medical record documentation to support the vascular claudication diagnoses; therefore, the Vascular Disease HCC was not validated.

As a result of these errors, the HCC for Vascular Disease was not validated, and MCS received \$7,173 in overpayments for these 6 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Breast Cancer**

MCS incorrectly submitted diagnosis codes for breast cancer for 25 of 30 sampled enrollee-years. Specifically:

- For 12 enrollee-years, the medical records in each case did not support a breast cancer diagnosis.

For example, for 8 enrollee-years, the independent medical review contractor noted that the medical records included a negative or non-conclusive mammography which does not support the assignment of the Breast, Prostate, and Other Cancers and Tumors HCC.

- For 11 enrollee-years, the medical records indicated in each case that the individual had previously had breast cancer, but the records did not justify a breast cancer diagnosis at the time of the physician’s service.

For example, for 2 enrollee-years, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [Breast, Prostate, and Other Cancers and Tumors] HCC. There is documentation of a past medical history of breast cancer [diagnosis] which does not result in an HCC.”

- For 1 enrollee-year, MCS submitted a breast cancer diagnosis code (which was not supported in the medical records) instead of a diagnosis code for metastatic breast cancer (which was supported in the medical records). The independent medical review contractor noted that “there is documentation of a past medical history of breast cancer with metastasis [diagnosis] that results in [the HCC for Metastatic Cancer and Acute Leukemia] which should have been assigned instead of the submitted [HCC for Breast, Prostate, and Other Cancers and Tumors].” Because this HCC was a more severe manifestation of the related disease group, this error caused an underpayment.
- For the remaining 1 enrollee-year, MCS was unable to provide medical record documentation to support the breast cancer diagnosis; therefore, the Breast, Prostate, and Other Cancers and Tumors HCC was not validated.

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and MCS received \$7,202 in net overpayments for these 25 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Colon Cancer**

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

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

For example, for 7 enrollee-years, the independent medical review contractor noted “there is no documentation of a diagnosis that results in the assignment of [Colorectal, Bladder, and Other Cancers] HCC. There is documentation of a past medical history of colon cancer [diagnosis], which does not result in an HCC.”

- For 7 enrollee-years, the medical records in each case did not contain sufficient information to support a colon cancer diagnosis.

For example, for 5 enrollee-years the independent medical review contractor noted “there is no documentation of any condition that will result in assignment of [Colorectal, Bladder, and Other Colon Cancers] HCC.”

- For 2 enrollee-years, the medical records in each case did not support a colon cancer diagnosis; however, for each of these enrollee-years, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, MCS should not have received an increased payment for the colon cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

For example, for 1 enrollee-year the independent medical review contact noted “there is no documentation of any condition that will result in the assignment of [Colorectal, Bladder, and Other Cancers] HCC”. However, the assignment of “[Breast, Prostate, and Other Cancers and Tumors] HCC was substantiated based on the assessment of malignant neoplasm of the lower arm (diagnosis).”

- For the remaining 1 enrollee-year, MCS was unable to provide medical record documentation to support the colon cancer diagnosis; therefore, the Colorectal, Bladder, and Other Cancers HCC was not validated.

As a result of these errors, the Colorectal, Bladder, and Other Cancers HCC was not validated, and MCS received \$29,758 in overpayments for these 26 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Prostate Cancer**

MCS incorrectly submitted diagnosis codes for prostate cancer for 21 of 30 sampled enrollee-years. Specifically:

- For 14 enrollee-years, the medical records indicated in each case that the individual had previously had prostate cancer, but the records did not justify a prostate cancer diagnosis at the time of the physician’s service.

For example, for 5 enrollee-years, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [Breast, Prostate, and Other Cancers and Tumors] HCC. There is documentation of a past medical history of prostate cancer [diagnosis] that does not result in an HCC.”

- For 5 enrollee-years, the medical records in each case did not support a prostate cancer diagnosis.

For all 5 enrollee-years, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [Breast, Prostate, and Other Cancers and Tumors] HCC.”

- For the remaining 2 enrollee-years, MCS was unable to provide medical record documentation to support the prostate cancer diagnoses; therefore, the Breast, Prostate, and Other Cancers and Tumors HCC was not validated.

As a result of these errors, the Breast, Prostate, and Other Cancers and Tumors HCC was not validated, and MCS received \$12,426 in overpayments for these 21 sampled enrollee-years.

## Incorrectly Submitted Diagnosis Codes for Lung Cancer

MCS incorrectly submitted diagnosis codes for lung cancer for 22 of 30 sampled enrollee-years. Specifically:

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

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [Lung and Other Severe Cancers] HCC. There is documentation of left lung mass<sup>18</sup> [diagnosis] that does not result in an HCC.”

- For 7 enrollee-years, the medical records in each case did not support a lung cancer diagnosis; however, for each of these enrollee-years, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, MCS should not have received an increased payment for the lung cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

For example, for 3 enrollee-years, the independent medical review contractor noted that there is no documentation of any condition that will result in the assignment of [Lung and other Severe Cancers] HCC. However, we identified documentation supporting the [Breast, Prostate, and Other Cancers and Tumors] HCC.

- For 3 enrollee-years, the medical records indicated in each case that the individual had previously had lung cancer, however, the records did not justify a lung cancer diagnosis at the time of the physician’s service.

For all 3 enrollee-years, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [Lung and Other Severe Cancers] HCC. There is documentation of a past medical history of lung cancer [diagnosis] that does not result in an HCC.”

- For 2 enrollee-years, MCS was unable to provide medical record documentation to support the lung cancer diagnoses; therefore, the Lung and Other Severe Cancers HCC was not validated.
- For the 1 remaining enrollee-year, MCS submitted a lung cancer diagnosis code (which was not supported in the medical records) instead of a diagnosis code for secondary malignant neoplasm of unspecified lung (which was supported in the medical records).

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<sup>18</sup> A lung mass is defined as an abnormal spot or area in the lungs larger than 3 centimeters (cm), about 1.5 inches, in size. Around 4 to 5 percent of masses found in the lungs turn out to be lung cancer.

The independent medical review contractor noted that the “HCC [for Lung, Upper Digestive Tract, and Other Severe Cancers] was substantiated based on the assessment of secondary malignant neoplasm of the lung (diagnosis).” This error caused an underpayment.

As a result of these errors, the Lung and Other Severe Cancers HCC was not validated, and MCS received \$66,348 in net overpayments for these 22 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Acute Heart Attack**

MCS incorrectly submitted diagnosis codes for acute heart attack for 29 of 30 sampled enrollee-years. Specifically:

- For 13 enrollee-years, the medical records in each case did not support a myocardial infarction diagnosis; however, for each of these enrollee-years, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, MCS should not have received an increased payment for the myocardial infarction diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

For example, for 7 enrollee-years, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [Unstable Angina and Other Acute Ischemic Heart Disease] HCC. However, we identified a diagnosis that will result in the assignment of the [Angina Pectoris] HCC.”

- For nine enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Acute Heart Attack HCC.

For example, for 4 enrollee-years, the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of [Acute Myocardial Infarction] HCC.”

- For 6 enrollee-years, the medical records in each case noted that the individual had a past history of an old myocardial infarction,<sup>19</sup> but the records did not justify a myocardial infarction diagnosis at the time of the physician’s service.

For example, for 2 enrollee-years, the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of [Unstable Angina and Other Acute Ischemic Heart Disease] HCC. There is

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<sup>19</sup> An “old myocardial infarction” is a distinct diagnosis that represents a myocardial infarction that occurred more than 4 weeks previously, has no current symptoms directly associated with that myocardial infarction, and requires no current care.

documentation of a past medical history of myocardial infarction which does not result in an HCC.”

- For the remaining 1 enrollee-year, MCS was unable to provide medical record documentation that mapped to an Acute Heart Attack HCC; therefore, an Acute Heart Attack HCC was not validated.

As a result of these errors, the Acute Heart Attack HCCs were not validated, and MCS received \$27,329 in overpayments for these 29 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Embolism**

MCS incorrectly submitted diagnosis codes for embolism for 22 of 30 sampled enrollee-years. Specifically:

- For 19 enrollee-years, the medical records in each case did not 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 the assignment of [Vascular Disease] HCC. There is documentation of ruled out deep vein thrombosis [diagnosis] that would not be coded based on inpatient guidelines of ruled out diagnoses.”

- For 2 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 [Vascular Disease] HCC. There is documentation of a personal history of deep vein thrombosis [diagnosis] that does not result in an HCC.”

- For the remaining 1 enrollee-year, MCS was unable to provide medical record documentation to support a diagnosis that mapped to an Embolism HCC; therefore, an Embolism HCC was not validated.

As a result of these errors, the Embolism HCCs were not validated, and MCS received \$25,515 in overpayments for these 22 sampled enrollee-years.

### **Summary of Incorrectly Submitted Diagnosis Codes**

In summary and with respect to the nine high-risk groups covered by our audit, MCS received \$220,577 in net overpayments for the 183 sampled enrollee-years.

## **MCS'S POLICIES AND PROCEDURES TO PREVENT, DETECT, AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS COULD BE IMPROVED**

The errors we identified occurred because MCS's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations (42 CFR § 422.503(b)(4)(vi)), could be improved.

During our audit period, MCS had compliance procedures to determine whether the diagnosis codes used to calculate risk-adjusted payments were correct. These procedures included preventive measures (e.g., MCS educated providers on several topics, including the quality of the medical record documentation and guidance on listing accurate diagnosis codes on claims). In addition, MCS educated its providers to actively monitor, evaluate, assess, and treat conditions related to diagnoses during face-to-face encounters and emphasized that conditions related to codes that no longer exist should be clearly documented as historical in patients' records.

MCS's compliance procedures also included detective and corrective measures such as internal audits of the diagnosis codes that its providers submitted. MCS focused on diagnosis codes that (1) MCS had identified as having potential errors and (2) had been submitted only one time during the year by a single provider. In addition, MCS conducted specific reviews of certain high-risk diagnosis codes that it had identified as being at a higher risk for being miscoded.<sup>20</sup> Although MCS provided guidance to coders on how to review diagnoses that MCS had designated as high risk, including diagnosis codes for acute stroke, acute heart attack, and embolism, its compliance procedures were limited in that they only provided for the correction of errors found in its reviews and did not include steps to identify the root cause of the errors or to detect and correct systemic errors (if identified).

MCS did not provide medical records for 13 of the enrollee-years. MCS indicated that, in some instances, the provider no longer existed, therefore medical records could not be obtained. We requested MCS to provide us the reason(s) for the large number of enrollee-years with miscoded diagnoses identified during the review. However, MCS did not provide any reasons for these errors.

Based on our assessment of the policies and procedures that were in place for our audit period, and because the diagnosis codes for 183 of the 280 sampled enrollee-years were not supported by the medical records, we believe that MCS's compliance procedures to prevent, detect, and correct incorrect high-risk diagnosis codes could be improved.

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<sup>20</sup> The reviews performed by MCS included various HCCs. Only one of the HCCs reviewed by MCS corresponded to an HCC in our sample.

## **MCS 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 MCS received at least \$6.2 million in net overpayments for 2016 and 2017 (Appendix D).<sup>21</sup>

Because of Federal regulations that limit the use of extrapolation in Risk Adjustment Data Validation (RADV) audits for recovery purposes, we are reporting the estimated net overpayment amount but are recommending a refund of only the \$220,577 in net overpayments that MCS received for the 183 sampled enrollee-years.<sup>22</sup>

## **RECOMMENDATIONS**

We recommend that MCS Advantage, Inc.:

- refund to the Federal Government the \$220,577 of 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 its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

## **MCS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, MCS disagreed with our findings related to 6 of the 186 sampled enrollee-years identified as errors in our draft report and requested that we withdraw our recommendations.<sup>23</sup> Specifically, MCS stated that our recommendations are (1) based on flawed audit sampling and review methodologies, (2) inconsistent with the Social Security Act's actuarial equivalence mandate and CMS's data accuracy and compliance

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<sup>21</sup> Specifically, we estimated that MCS received at least \$6,255,434 of net overpayments. To be conservative, we estimate net overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

<sup>22</sup> After we had issued our draft report, CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643, (Feb. 1, 2023)).

<sup>23</sup> Under separate cover, MCS also provided what it described as a Medical Records Appendix with detailed information on 4 of the 6 sampled enrollee-years. The Medical Records Appendix highlighted medical records (e.g., diagnoses, assessments, and treatment plans) previously submitted by MCS, as well as additional supporting information. For the 2 remaining enrollee-years, MCS provided explanations as to its disagreements with our findings.

requirements, and (3) not supported because factual (medical) records validated the audited HCCs. MCS stated that, although it objects to our audit methodology, it would submit corrections to CMS related to the unvalidated HCCs identified in the draft report and refund the associated payments to the Federal government.

After reviewing MCS's comments and for the reasons detailed below, we reduced the number of sampled enrollee years in error from 186 to 183 and maintain that the remainder of our findings are valid. After we had issued our draft report, CMS updated Federal regulations for RADV audits to specify that extrapolated overpayments could only be recouped beginning with payment year 2018. Because our audit period covered payment years 2016 and 2017, we changed our first recommendation to only reflect the net overpayments of \$220,577 that MCS received for the 183 sampled enrollee-years. We made no changes to our second and third recommendations.

A summary of MCS's comments and our responses follows. MCS's comments appear in their entirety as Appendix F.

## **MCS DID NOT AGREE WITH OIG'S DETERMINATIONS FOR 4 ENROLLEE-YEARS AND THE CLASSIFICATION OF 2 ENROLLEE-YEARS AS ERRORS**

### **MCS Comments**

MCS disagreed with our findings related to 4 of the sampled enrollee-years (in the vascular claudication (sample 95), colon cancer (sample 135), and lung cancer high-risk groups (samples 154 and 191)) and provided explanations as to why it believed that the medical records that it previously provided us validated the reviewed HCCs. MCS noted that these 4 enrollee-years are examples and "are not exhaustive of [its] objections, but these particular cases are strongly supported by the medical record."

For example, for one of the sampled enrollee-years (sample 135), MCS disagreed with the independent medical review contractor's conclusion that there was no documentation to support a condition that would result in the assignment of the HCC for Colorectal, Bladder, and Other Cancers. MCS stated that the medical records included a gastroenterologist's diagnosis of colon cancer in the progress notes. MCS further stated that the medical record included documentation of a positive fecal occult blood test and an evaluation and treatment plan which satisfies what it described as monitor, evaluate, assess, and treat (MEAT) criteria and, therefore, should be considered a validated HCC.<sup>24</sup>

MCS also stated that it did not with agree our classification of 2 enrollee-years (samples 113 and 211)—for which we determined that the HCC was not validated but the "documentation

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<sup>24</sup> In its comments, MCS describes enrollee-years as having met "MEAT requirements" and "MEAT criteria." We note that these are not Federal requirements. Rather, MCS cited an article from the AAPC entitled *Include MEAT in Your Risk Adjustment Documentation*.

sustained” another HCC with a higher severity—as errors. Specifically, MCS stated that, “because the documentation sustained that the patient has the condition besides the severity of it,” we should consider reviewed HCCs as validated.

## **OIG Response**

After reviewing the explanations that MCS submitted, our independent medical review contractor sustained its original decision for 1 of the 4 enrollee-years (sample 154) that MCS disputed in its comments. For this enrollee-year (in the colon cancer high-risk group), our contractor stated that there is documentation of a past medical history of malignant neoplasm of colon status post surgery and treatment noted to be completed in 1991. Specifically, our contractor stated, “There is no medical record documentation evidence of an active cancer diagnosis. The provider noted the patient is to have a colonoscopy every 6 years for follow-up.” This “past medical history” diagnosis does not result in an HCC.

However, for the remaining 3 sampled enrollee years (in the following high-risk groups: vascular claudication (sample 95), colon cancer (sample 135), and lung cancer (sample 191)), our independent medical review contractor found support in the medical records that validated the reviewed HCCs, and reversed its original determinations. For example, for 1 enrollee-year from the colon cancer high-risk group (sample 135), our contractor stated, “Although the patient is noted as not having a colonoscopy in over three years and a colonoscopy was included in the plan, the physician documentation indicates a definitive diagnosis of colon cancer . . . that results in assignment of [the Colorectal, Bladder, and Other Cancers HCC].”

Accordingly, we reduced the number of sampled enrollee-years in error from 186 (in our draft report) to 183 and reduced the associated monetary recommendation. 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.

With regard to MCS’s comments about our classification of 2 enrollee-years as errors (samples 113 and 211), we considered audited HCCs that were not validated as errors, regardless of whether we identified a diagnosis that should have been submitted to CMS instead of the submitted diagnosis and resulted in another HCC and was classified as an underpayment in this report). Accordingly, we did not make further changes to this final report.

## **MCS DID NOT AGREE WITH THE OIG’S SAMPLING, REVIEW AND AUDIT METHODOLOGIES**

### **OIG’s Sampling and Review Methodologies Were Biased to Identify Overpayment**

#### *MCS Comments*

MCS stated that OIG’s sampling and review methodologies were “biased to identify overpayments.” Specifically, MCS stated that we did not collect and review potential unrelated diagnoses or an adequate sample size for certain HCCs. MCS stated that we focused only on

enrollees who received a high-risk diagnosis during the audit period that caused an increased payment to MCS and did not seek to identify or account for all potential, unrelated, HCCs that were not submitted to CMS but were supported by the medical records. MCS also said that “[b]y ignoring other diagnoses that were or were not submitted to CMS for risk adjustment purposes, OIG’s sample did not include potential underpayments.” Further, MCS stated that we did not explain how it arrived at its sample size for each stratum. MCS also stated that sample sizes chosen for each stratum did not vary based on the distribution of enrollee-years or the total of CMS payments, and that increasing the sample size between strata could have improved the precision or accuracy of the sample.

Lastly, MCS stated that our deviations from CMS’s RADV audit standards presents additional issues.<sup>25</sup> According to MCS, our method was skewed to identify overpayments, thereby causing an inflated estimated net overpayment. Moreover, according to MCS, our utilization of an approach that differed from CMS’ RADV audit standards unfairly exposes MCS to potentially paying twice for the same coding error. MCS stated that “there would be no way to tie OIG’s extrapolation to specific HCCs, so MCS could be potentially liable again under RADV audits for HCCs that fell within OIG’s extrapolation.”

#### *OIG Response*

We disagree with MCS’s statements regarding our sampling and review methodologies. As stated above, our recommendation to refund overpayments is no longer based on an estimation and is now limited to the net overpayments associated with the sampled enrollee-years. However, we believe that the results of our sampling and estimations continue to show that MCS has compliance issues that need to be addressed and provides a reasonable basis for our findings and conclusions.

For this audit, our objective was to determine whether selected high-risk diagnosis codes that MCS submitted to CMS for use in CMS’s risk adjustment program complied with Federal requirements. It was beyond the scope of our audit to identify all possible diagnosis codes that MCS could have submitted on behalf of the sampled enrollee-years. 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. Further, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and

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<sup>25</sup> CMS RADV audits consist of reviews of medical record documentation that audited MA organizations provide to substantiate the diagnosis codes that MA organizations submit to CMS. RADV audits are the primary tools that CMS uses to identify improper payments made to MA organizations.

Medicaid.<sup>26</sup> 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.<sup>27</sup>

In accordance with our objective and as detailed in Appendices A and C, we properly executed a statistically valid sampling methodology in that we defined our sampling frame (MCS enrollees with a high-risk diagnosis) and sample unit, randomly selected our sample, applied relevant criteria to evaluate the sample, and used statistical sampling software to apply the correct formulas to estimate the net overpayments made to MCS. With regard to MCS's comment specific on our strata sample sizes, we agree that increasing the strata size of certain strata could have improved precision of the sample. However, sample size is incorporated into the computation of the confidence interval, with a smaller sample size generally resulting in a smaller lower limit. Because absolute precision is not required, any imprecision in the sample may be remedied by recommending recovery at the lower limit, which was done in this audit.<sup>28</sup> For these reasons, MCS's description of our net overpayment calculations as biased is not accurate.

With regard to MCS's comment that we deviated from CMS's RADV audit standards, we note that our approach was generally consistent with the methodology that CMS uses in its RADV audits; however, it did not mirror CMS's approach in all aspects, nor did it have to. Our audit methodology correctly applied CMS requirements to properly identify the overpayment amount associated with the unvalidated HCCs for each sample item. Specifically, we used the results of the independent medical review contractor's review to determine which HCCs were not validated and, in some instances, to identify HCCs that should have been used but were not used in the associated enrollees' risk score calculations. We followed CMS's risk adjustment program requirements to determine the payment that CMS should have made for each enrollee and to calculate net overpayments.

Finally, if MCS is selected for a RADV audit by CMS, we encourage MCS to work with CMS to ensure that duplicate recoveries, if any, are not made.

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

<sup>27</sup> See *John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at \*34-35 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634-37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at \*17 (S.D. Fla. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at \*13 (S.D. Tex. 2012).

<sup>28</sup> See *Pruchniewski v. Leavitt*, 2006 U.S. Dist. LEXIS 101218 at \*51-52 (M.D. Fla. 2006).

## **OIG’s Audit Methodology Was Inconsistent With CMS’s Approach**

### *MCS Comments*

MCS stated that our audit methodology was inconsistent with CMS’s RADV audit approach because we permitted an “independent physician to step in and act as a tie breaker to resolve disagreements between senior coders.” MCS stated that CMS, in conducting a contract-level RADV audit, accepts an HCC “as substantiated without further analysis” if either the first or second coder finds support on a medical record. In this respect, MCS stated that the OIG’s “flawed approach cannot be used to seek repayments from MCS.”

### *OIG Response*

Our audits are intended to provide an independent assessment of Department of Health and Human Services (HHS) programs and operations in accordance with the Inspector General Act of 1978, 5 U.S.C. App. Although our approach was generally consistent with the methodology CMS uses in its RADV audits, it did not mirror CMS’s approach in all aspects, nor did it have to. Specifically, the contractor used both skilled senior coders and physicians (when necessary) to review medical record documentation in accordance with the relevant CMS guidance,<sup>29</sup> which states, “**reviewers** should evaluate all listed conditions for consistency within the full provider documentation” (emphasis added). The coders and physicians did not make clinical judgments, but rather applied coding rules to accurately assign applicable International Classification of Diseases codes that translated to HCCs. Thus, the contractor’s use of senior coders to perform coding reviews, as well as its use of a physician—who was board-certified—reflected a reasonable method to determine whether the medical record adequately supported the reviewed diagnoses codes. Although we limited the recommended recovery in this final report to the overpayments associated with the sampled enrollee-years (as discussed above), we did not make any changes based on MCS’s comments on our audit methodology.

## **OIG Did Not Account for Actuarial Equivalence or Apply a Fee-for-Service Adjuster**

### *MCS Comments*

MCS stated that “[t]he fundamental premise of the MA payment system is that CMS pays MAOs an amount that is ‘actuarially equivalent’ to the expected cost that CMS would have otherwise incurred had it provided Medicare benefits directly to the MAO’s enrollees on a fee-for-service (‘FFS’) basis.” In this respect, MCS stated that CMS used unaudited traditional Medicare (FFS) claims data to develop CMS’s risk-adjustment model. According to MCS, CMS stated (in 2012) that “it would calculate recovery amounts for unsupported HCCs during its RADV audits by

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<sup>29</sup> CMS, Contract-Level Risk Adjustment Data Validation, Medical Record Reviewer Guidance, for reviews 3/20/2019. Available online at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/Medical-Record-Reviewer-Guidance.pdf>. Accessed on Sep. 19, 2022.

adjusting for errors in traditional Medicare data.”<sup>30</sup> MCS further stated that we “did not apply an FFS adjuster or other mechanism to account for errors in the data when conducting this audit.” Therefore, MCS requested that we withdraw our “repayment calculation until CMS performs an actuarially sound audit by which it can recalculate any payment that might be due.”

#### *OIG Response*

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

MCS commented that we did not consider actuarial equivalence in our overpayment calculations. To this point, we recognize that CMS is responsible for making operational and program payment determinations for the MA program and note that CMS has not issued any requirements that compel us to further reduce our net overpayment calculations. Moreover, CMS stated (after we issued our draft report) that it “will not apply an adjustment factor (known as an FFS Adjuster) in RADV audits.”<sup>31</sup>

### **OIG Did Not Calculate Extrapolated Overpayments Consistent With CMS’s Practice**

#### *MCS Comments*

MCS disagreed with how we calculated our estimated overpayments. Specifically, MCS stated that our use of the two-sided 90-percent confidence interval in estimating overpayments is inconsistent with CMS’s practice for RADV audits, which calculates a net payment error at the “lower bound of the 99 percent [confidence interval].” MCS stated that our approach results in a higher extrapolated overpayment.

#### *OIG Response*

OIG is an independent oversight agency; therefore, we do not need to mirror CMS’s estimation methodology. As detailed in Appendices A and C, and as previously stated, we properly executed a statistically valid sampling and estimation methodology. Although we have limited the recommended recovery to the overpayments associated with the sampled enrollee-years

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<sup>30</sup> MCS referenced CMS’s “Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits” (Feb. 24, 2012).

<sup>31</sup> 88 Fed. Reg. 6643 (Feb. 1, 2023).

for this final report, our policy is to recommend recovery at the lower limit of a two-sided 90-percent confidence interval. The lower limit of a two-sided 90 percent confidence interval provided a reasonably conservative estimate of the total amount of net overpayments to MCS for the enrollee-years and time period covered in our sampling frame. This approach, which is routinely used by HHS for recovery calculations,<sup>32</sup> results in a lower limit (the estimated net overpayment amount) 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 and reiterate that we did not change our first recommendation based upon MCS’s comments about our sampling approach; rather, we made the change based upon the regulations that CMS updated.

### **OIG Erroneously Suggests That MCS is Responsible for Guaranteeing Complete Accuracy of Submitted Data**

#### *MCS Comments*

According to MCS, we stated that “MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS” but we did so without incorporating CMS’s “good faith efforts standard.” MCS said that 42 CFR § 422.504(l) provides that MA organizations must certify that, “based on best knowledge, information, and belief,” the data they submit is “accurate, complete, and truthful.”

MCS stated that, absent more specific mandates, we have attempted to not only expand the MA compliance program requirements but to also alter the CMS guidance that MCS has relied upon in reviewing diagnosis code submissions (for example, the HCCs that we audited). MCS also stated that it receives risk adjustment data from numerous sources and that it has implemented robust policies and procedures to review the accuracy of this information.

Consequently, MCS requested that we adjust our report to reflect the “good faith efforts” standard and remove any suggestion that MCS failed to meet this good faith standard with respect to the audited HCCs.

#### *OIG Response*

We do not agree with MCS’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. We also

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<sup>32</sup> For example, HHS has used the two-sided 90-percent confidence interval when calculating recoveries in both the Administration for Child and Families and Medicaid programs. See e.g., *New York State Department of Social Services*, HHS Departmental Appeals Board (DAB) No. 1358, 13 (1992); *Arizona Health Care Cost Containment System*, DAB No. 2981, 4-5 (2019). In addition, HHS contractors rely on the one-sided 90-percent confidence interval, which is less conservative than the two-sided interval, for recoveries arising from Medicare FFS overpayments. See e.g., *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff’d*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 17-18 (E.D.N.Y. 2012).

recognize that MA organizations have the latitude to design their own compliance programs. In this respect, MCS's comments infer that we have opined on the entirety of its policies and procedures (which include its good faith efforts) regarding risk adjustment data. That was not our intention and this is reflected in our statement that we believe that the policies and procedures that MCS has with regard to diagnoses that are at high risk for being miscoded could be improved. Therefore, contrary to MCS's assertions, we believe that our assessments of this portion of MCS's policies and procedures are appropriate.

## **MCS DID NOT AGREE WITH THE OIG'S RECOMMENDATION TO PERFORM ADDITIONAL REVIEWS BEFORE AND AFTER THE AUDIT PERIOD**

### **MCS Comments**

MCS disagreed with our second recommendation and stated that it is not required to conduct audits of high-risk diagnosis codes to identify similar instances of noncompliance that occurred before or after the audit period and refund any overpayments. MCS stated that "MA regulations do not require MCS to conduct the type of audits that the OIG conducted here; and, therefore, there is no standard for MCS to use to conduct any such audit." Moreover, MCS stated that, if it were to identify unsupported diagnosis codes, these would not necessarily be reflective of "overpayments." According to MCS, it already implements "an effective system for routine monitoring and identification of compliance risks" and promptly and thoroughly corrects any identified problems.

### **OIG Response**

We do not agree with MCS's interpretation of Federal requirements. Contrary to MCS's assertions, we believe that our recommendation for MCS to review whether similar instances of high-risk diagnoses occurred before or after our audit period conforms to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (Appendix E)).

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 MCS'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 addressing potential compliance issues to the MA organizations.

We believe the error rate identified in our audit (183 of 280 sampled enrollee-years) demonstrates that MCS has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope. Accordingly, we maintain our recommendation that MCS review whether similar instances of noncompliance related to high-risk diagnoses occurred before or after our audit period.

**MCS STATED THAT THE OIG DID NOT IDENTIFY SPECIFIC COMPLIANCE PROCEDURES TO IMPROVE AND THAT MCS’S COMPLIANCE PROGRAM WAS ROBUST**

**MCS Comments**

MCS described our third recommendation as vague and stated that we did not identify specific MCS compliance procedures that could be improved. In addition, MCS disagreed that its “compliance procedures to prevent, detect, and correct incorrect high-risk diagnosis codes could be improved.” MCS also stated that it already has a robust compliance program to reduce coding errors and also educates providers. Specifically, MCS stated that its robust policies and procedures were aimed at reducing coding errors and educating providers, which helped ensure that the data submitted to CMS for use in CMS’s risk adjustment program was accurate based on MCS’s “best knowledge, information, and belief,” and, as such, complied with Federal requirements. Finally, MCS stated that its compliance program has been—and continues to be—robust and described several examples of its compliance controls.

**OIG Response**

While we acknowledge that MCS 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, the diagnosis codes for 183 of the 280 sampled enrollee-years were not supported by the medical records. In addition, for 4 of the areas we reviewed (acute heart attack, acute stroke, breast cancer, and colon cancer), the medical records did not validate the HCCs for 108 of the 120 sampled enrollee years (90 percent). Improving compliance program procedures to monitor provider record submissions, with a focus on diagnosis codes at high risk for being miscoded, may have prevented these errors. Accordingly, we maintain that our third recommendation is well-defined and valid.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

CMS paid MCS \$2,993,653,626 to provide coverage to its enrollees for 2016 and 2017. We identified a sampling frame of 20,672 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2015 through 2016 service years. MCS received \$181,724,704 in payments from CMS for these enrollee-years for 2016 and 2017. We selected for audit 280 enrollee-years with payments totaling \$2,698,765.

The 280 enrollee-years included 40 major depressive disorder diagnoses, 30 acute stroke diagnoses, 30 vascular claudication diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, 30 prostate cancer diagnoses, 30 lung cancer diagnoses, 30 acute heart attack diagnoses and 30 embolism diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$402,073 for our sample.

Our audit objective did not require an understanding or assessment of MCS'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 January 2020 to June 2022.

### 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:
  - 29 diagnosis codes for major depressive disorder,
  - 74 diagnosis codes for acute stroke,
  - 4 diagnosis codes for vascular claudication,

- 5 diagnosis codes for breast cancer,
  - 20 diagnosis codes for colon cancer,
  - 2 diagnosis codes for prostate cancer,
  - 24 diagnosis codes for lung cancer,
  - 38 diagnosis codes for acute heart attack, and
  - 85 diagnosis codes for embolism.
- 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;<sup>33</sup>
    - Risk Adjustment System (RAS) to identify enrollees who received an HCC for the high-risk diagnosis codes;<sup>34</sup>
    - Medicare Advantage Prescription Drug System (MARx) to identify enrollees for whom CMS made monthly Medicare payments to MCS, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C);<sup>35</sup>
    - Encounter Data System (EDS) to identify enrollees who received specific procedures;<sup>36</sup> and
    - Prescription Drug Event (PDE) file to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.<sup>37</sup>
  - We interviewed MCS officials to gain an understanding of (1) the policies and procedures that MCS followed to submit diagnosis codes to CMS for use in the risk

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<sup>33</sup> MA organizations use the RAPS to submit diagnosis codes to CMS.

<sup>34</sup> The RAS identifies the HCCs that CMS factors into each enrollee’s risk score calculation.

<sup>35</sup> The MARx identifies the payments made to MA organizations.

<sup>36</sup> The EDS contains information on each item (including procedures) and service provided to an enrollee.

<sup>37</sup> The PDE file contains claims with prescription drugs that have been dispensed to enrollees through the Medicare Part D (prescription drug coverage) program.

adjustment program and (2) MCS's monitoring of those diagnosis codes to identify and correct noncompliance with Federal requirements.

- We selected for audit a stratified random sample of 280 (out of 20,672) enrollee-years.
- We used an independent medical review contractor to perform a coding review for the 262<sup>38</sup> enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.<sup>39</sup>
- 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 for each enrollee-year. Specifically, we calculated:
  - a revised risk score in accordance with CMS's risk adjustment program and

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<sup>38</sup> The independent medical review contractor performed coding reviews for 262 of the 280 enrollee-years in our sample. We did not submit the remaining 18 sampled enrollee-years for coding review. MCS requested and we granted a hardship exception for 5 of these enrollee-years. We considered these enrollee-years to be validated. MCS did not provide medical records to support the remaining 13 enrollee-years. We did not consider these enrollee-years to be validated.

<sup>39</sup> Our independent medical review contractor used senior coders, all of whom possessed one or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS), Certified Coding Specialist – Physician-Based (CCS-P), Certified Professional Coder (CPC), and Certified Risk Adjustment Coder (CRC). RHITs have completed a 2-year degree program and have passed an American Health Information Management Association (AHIMA) certification exam. AHIMA also credentials individuals with CCS and CCS-P certifications, and the American Academy of Professional Coders credentials both CPCs and CRCs.

- the payment that CMS should have made for each enrollee-year.
- We estimated the total net overpayments made to MCS during the audit period.
- We limited the total net overpayment that we recommended for recovery to the sampled enrollee-years.<sup>40</sup>
- We discussed the results of our audit with MCS 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.

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<sup>40</sup> Federal Regulations (42 CFR § 422.311(a)) state, “. . . the Secretary annually conducts RADV audits to ensure risk-adjusted payment integrity and accuracy.” Recovery of improper payments from MA organizations will be conducted in accordance with the Secretary’s payment error extrapolation and recovery methodologies. CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years. 88 Fed. Reg. 6643, 6655 (Feb. 1, 2023)

**APPENDIX B: RELATED OIG REPORTS**

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS</i>	<a href="#"><u>A-09-21-03011</u></a>	3/16/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring of Tennessee, Inc. (Contract H4454) Submitted to CMS</i>	<a href="#"><u>A-07-19-01193</u></a>	12/22/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BCBS of Rhode Island (Contract H4152) Submitted to CMS</i>	<a href="#"><u>A-01-20-00500</u></a>	11/16/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That California Physicians' Service, Inc. (Contract H0504) Submitted to CMS</i>	<a href="#"><u>A-09-19-03001</u></a>	11/10/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (Contract H3916) Submitted to CMS</i>	<a href="#"><u>A-03-19-00001</u></a>	9/29/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS</i>	<a href="#"><u>A-07-19-01195</u></a>	9/29/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS</i>	<a href="#"><u>A-09-20-03009</u></a>	9/13/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc. (Contract H1032) Submitted to CMS</i>	<a href="#"><u>A-04-19-07084</u></a>	8/29/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS</i>	<a href="#"><u>A-02-20-01009</u></a>	7/18/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health Network (Contract H1961) Submitted to CMS</i>	<a href="#"><u>A-06-18-05002</u></a>	5/25/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS</i>	<a href="#"><u>A-01-19-00500</u></a>	2/14/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS</i>	<a href="#"><u>A-02-18-01029</u></a>	1/5/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS</i>	<a href="#"><u>A-07-19-01188</u></a>	11/5/2021

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

## APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

### SAMPLING FRAME

We identified MCS enrollees who (1) were continuously enrolled with MCS throughout all of the 2015 or 2016 service year and January of the following year, (2) were not classified as being enrolled in hospice or end-stage renal disease status at any time during 2015 or 2016 or in January of the following year, (3) received a high-risk diagnosis during 2015 or 2016 that caused an increase payment to MCS for 2016 or 2017, respectively.

We presented the data for these enrollees to MCS for verification and performed an analysis of the data included on CMS's systems to ensure that the high-risk diagnosis codes increased CMS's payments to MCS. After we performed these steps, our finalized sampling frame consisted of 20,672 enrollee-years.

### SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2016 or 2017.

### SAMPLE DESIGN AND SAMPLE SIZE

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

- a major depressive disorder diagnosis (that mapped to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) on only one claim during the service year but did not have an antidepressant medication dispensed on his or her behalf (12,536 enrollee-years);
- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on only one physician claim during the service year but did not have that diagnosis on a corresponding inpatient or outpatient hospital claim (2,673 enrollee-years);
- a diagnosis related to vascular claudication (that mapped to the HCC for Vascular Disease) on only one claim during the service year (a diagnosis that had not been documented during the 2 years that preceded the service year), but had medication for neurogenic claudication dispensed on his or her behalf (2,110 enrollee-years);
- a breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the breast cancer diagnosis administered within a 6-month period before or after the diagnosis (1,074 enrollee-years);

- a colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (481 enrollee-years);
- a prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors), for an individual 74 years old or younger, on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (880 enrollee-years);
- a lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the lung cancer diagnosis administered within a 6-month period before or after the diagnosis (153 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 (472 enrollee-years); or
- a diagnosis (that mapped to an Embolism HCC) on only one claim during the service year but did not have an anticoagulant medication dispensed on his or her behalf (293 enrollee-years).

The specific strata are shown in Table 2.

**Table 2: Sample Design for Statistically Sampled High-Risk Groups**

<b>Stratum (High-Risk Groups)</b>	<b>Frame Count of Enrollee- years</b>	<b>CMS Payment for HCCs in Audited High- Risk Groups</b>	<b>Sample Size</b>
1- Major depressive disorder	12,536	\$17,917,568	40
2- Acute stroke	2,673	3,424,642	30
3- Vascular claudication	2,110	2,619,766	30
4- Breast cancer	1,074	669,739	30
5- Colon cancer	481	660,489	30
6- Prostate cancer	880	584,899	30
7- Lung cancer	153	571,340	30
8- Heart attack	472	568,170	30
9- Embolism	293	397,885	30
<b>Total</b>	<b>20,672</b>	<b>27,414,499*</b>	<b>280</b>

\*Rounded to the nearest whole dollar amount.

#### **SOURCE OF RANDOM NUMBERS**

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

#### **METHOD FOR SELECTING SAMPLE ITEMS**

We sorted the items in each stratum by enrollee identifier and payment year, and then consecutively numbered the items in each stratum in the stratified sampling frame. After generating 280 random numbers according to our sample design, we selected the corresponding frame items for review.

#### **ESTIMATION METHODOLOGY**

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

**APPENDIX D: SAMPLE RESULTS AND ESTIMATES**

**Table 3: Sample Details and Results**

<b>Audited High-Risk Groups</b>	<b>Frame Size</b>	<b>CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)</b>	<b>Sample Size</b>	<b>CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)</b>	<b>Number of Sampled Enrollee-Years With Unvalidated HCCs</b>	<b>Net Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)</b>
1 – Major depressive disorder	12,536	\$17,917,568	40	\$58,454	4	\$6,740
2 – Acute stroke	2,673	3,424,642	30	39,772	28	38,087
3 – Vascular claudication	2,110	2,619,766	30	36,834	6	7,173
4 – Breast cancer	1,074	669,739	30	19,248	25	7,202
5 – Colon cancer	481	660,489	30	35,737	26	29,758
6 – Prostate cancer	880	584,899	30	18,112	21	12,426
7 – Lung cancer	153	571,340	30	121,272	22	66,348
8 – Acute heart attack	472	568,170	30	36,974	29	27,329
9 – Embolism	293	397,885	30	35,670	22	25,515
<b>Totals</b>	<b>20,672</b>	<b>\$27,414,499*</b>	<b>280</b>	<b>\$402,073</b>	<b>183</b>	<b>\$220,577*</b>

\* Difference in total is due to rounding.

**Table 4: Estimated Net Overpayments in the Sampling Frame  
(Limits Calculated for a 90-Percent Confidence Interval)**

Point Estimate	\$8,127,420
Lower Limit	\$6,255,434
Upper Limit	\$9,999,405

**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: MCS COMMENTS

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SINGAPORE  
TOKYO  
TORONTO

August 17, 2022

### VIA HHS/OIG DELIVERY SERVER

Brenda M. Tierney  
Regional Inspector General for Audit Services  
Department of Health and Human Services  
Office of Inspector General  
Office of Audit Services, Region II  
Jacob K. Javits Federal Building  
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RE: MCS Advantage, Inc.'s Response To  
OIG Draft Report Number A-02-20-01008

Dear Ms. Tierney:

I write on behalf of my client, MCS Advantage, Inc. ("MCS"), which arranges for the provision of high quality healthcare services to beneficiaries in Puerto Rico. MCS appreciates the opportunity to respond to the U.S. Department of Health and Human Services ("HHS") Office of Inspector General's ("OIG") Draft Report No. A-02-20-01008 entitled *Medicare Advantage Compliance Audit of*

Brenda M. Tierney  
August 17, 2022  
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*Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS, dated June 2022. (the "OIG Draft Report").*<sup>1</sup>

MCS respectfully requests that OIG update the OIG Draft Report and withdraw its recommendations that MCS (1) refund an extrapolated amount of \$6,385,666 of estimated net overpayments and (2) conduct additional audits before and after the audit period OIG used in the OIG Draft Report and refund any resulting overpayments based on those audits. These recommendations are (i) based on flawed audit sampling and review methodologies, (ii) inconsistent with the Social Security Act's actuarial equivalence mandate and the Center for Medicare and Medicaid's ("CMS") data accuracy and compliance requirements, and (iii) not supported by the factual record.

MCS also disagrees with OIG's assessment that MCS' policies and procedures in place during the audit period were insufficient or unable to detect the alleged diagnosis code errors in the OIG Draft Report or otherwise not compliant with Federal regulations. MCS Advantage prides itself on adhering to its core corporate values -- accountability, compliance, and trust -- and is always working to improve its compliance procedures. As explained more fully below, MCS Advantage has incorporated steps to further enhance its policies to prevent, detect, and correct incorrect high-risk diagnosis codes through: (1) engaging with a third-party healthcare firm to assess and identify opportunities for improvement; (2) expanding its Risk Adjustment Steering Committee; (3) integrating staff from other investigation units into Risk Adjustment Data Validation ("RADV") audit activities and creating a RADV-focused operational unit; (4) revising clauses in provider contracts; (5) instituting new checking and validation activities; (6) implementing educational interventions; (7) reviewing audit documentation; and (8) continually evaluating and conducting reviews of current payment rules, deletions, and potential inaccuracies.

Importantly, as an example of MCS' adherence to compliance, in order to determine the validity of the diagnosis codes identified in the OIG Draft Report, MCS conducted an internal audit, like it would in the ordinary course, and

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<sup>1</sup> MCS would like to notify OIG of a factual inaccuracy in the OIG Draft Report. The OIG Draft Report notes that "As of December 2017, MCS provided coverage under contract H5577 to 191,297 enrollees. For the 2016 and 2017 payment years (audit period), CMS paid approximately \$3 billion to provide coverage to its enrollees." OIG Draft Report at 6. As of December 31, 2017, there were 192,482 enrollees under contract H5577. MCS also received \$2,996,522.264 from CMS for coverage for its enrollees for the 2016 and 2017 payment years.

identified certain diagnoses that it independently identified as not validated. Pursuant to CMS guidelines and its own policies and procedures, MCS will delete those diagnostic codes and submit those deletions to CMS.<sup>2</sup> Similarly, while MCS maintains its objections to OIG's flawed audit methodology, in response to OIG's assertion that MCS received approximately \$227,000 in overpayments,<sup>3</sup> MCS will proceed with submitting those deletions as well.

**I. OIG SHOULD RECALCULATE ITS ESTIMATED REPAYMENT AND EXTRAPOLATION AMOUNTS**

MCS respectfully disagrees with OIG's extrapolated and estimated repayment amount because (a) medical records contradict certain examples of Hierarchical Condition Categories ("HCCs") that OIG purportedly concluded were not validated, and (b) OIG's audit sampling and review methodologies are flawed for several reasons, including because they are (i) biased toward identifying overpayment, (ii) not adjusted to ensure the statutorily required actuarial equivalence between expected costs in Medicare Advantage and Original Medicare, and (iii) generally inconsistent with CMS's own methodologies in conducting ("RADV") audits.

**A. The Samples In The OIG Draft Report Do Not Support OIG's Conclusions That Certain HCCs Were Not Validated Because The Medical Records In Fact Supported The Diagnoses**

As discussed in more detail below, MCS objects generally to OIG's sampling and review methodology. In addition, MCS has identified a subset of examples in which the medical record examples highlighted in the OIG Draft Report do not support OIG's conclusions. MCS requests that OIG reconsider the specific coding conclusions made with respect to the HCCs listed in the chart below and

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<sup>2</sup> Dep't of Health & Human Servs. Ctrs. for Medicare & Medicaid Servs., CMS Manual System, Pub. 100-16 Medicare Managed Care, *CMS Medicare Managed Care Manual*, Chap. 7 at 40 (Sept. 19, 2014) ("If upon conducting an internal review of submitted diagnosis codes, the plan sponsor 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.").

<sup>3</sup> See OIG Draft Report at 10-16. As discussed in Section I.A., MCS maintains that certain cases should have been excluded from the overpayment estimate and, therefore, will not be submitting deletions for those specific cases.

exclude them from the overpayment estimate in the OIG Draft Report.<sup>4</sup> Importantly, the examples provided below are not exhaustive of MCS' objections, but these particular cases are strongly supported by the medical record and, at the very least, OIG should revise the OIG Draft Report in light of this information.<sup>5</sup>

Based on MCS' review, the following cases should have been excluded from OIG's overpayment estimate for the HCC's below:

HCC	The Medical Records Support The Diagnosis Code
Vascular Claudication	For Sample No. 95, the patient was referred to a cardiologist and the diagnosis PVI (Peripheral Vascular Insufficiency - I73.9) is documented in the referral form, which was completed by the cardiologist. The patient was assessed and, as part of the treatment plan, the patient is being treated with Aspirin. The documentation by the cardiologist complies with MEAT <sup>6</sup> requirements and, therefore, supports the vascular claudication HCC.
Breast Cancer	For Sample No. 113, OIG <i>confirmed</i> that the patient had breast cancer, but considered it an "error" because the metastasis resulted in a higher severity (HCC 12 to HCC 8). This is not a case of over-coding, as the higher severity resulted in a higher HCC. MCS does not agree with OIG's classification of non-validated HCC because the documentation sustained that the patient has the condition besides the severity of it and, therefore, should be considered a validated HCC.
Colorectal Cancer	For Sample No. 135, the patient met with a

<sup>4</sup> In addition to this high level summary, MCS will separately submit the medical records previously provided to OIG with annotations to demonstrate support for the original coding decision.

<sup>5</sup> MCS reserves its rights as to these objections with respect to any formal demand for overpayments by CMS.

<sup>6</sup> MEAT stands for (1) "Monitoring signs, symptoms, disease progression, disease regression"; (2) "Evaluating test results, medication effectiveness, response to treatment"; (3) "Assessing/Addressing ordered tests, discussion, review records, counseling"; and (4) "Treating medications, therapies, other modalities." Michelle Dick, *Include MEAT in Your Risk Adjustment Documentation*, AAPC (Mar. 5, 2018), <https://www.aapc.com/blog/41212-include-meat-in-your-risk-adjustment-documentation/>.

HCC	The Medical Records Support The Diagnosis Code
	<p>gastroenterologist, who documented the diagnosis of colon cancer in the progress notes. The medical record also included documentation that the patient presented a positive fecal occult blood test, and documentation of an evaluation and treatment plan for the patient, all of which satisfies the MEAT criteria and, therefore, should be considered a validated HCC.</p> <p>For Sample No. 154, the patient met with a general medicine specialist, who documented the diagnosis of malignant neoplasm of colon in the record and cross-referenced other sections of the record for the diagnosis and treatment plan. In addition, the medical record notes the cancer status as active and classified as Primary Malignancy. Finally, the record includes an evaluation and treatment plan for this encounter, which satisfies the MEAT criteria and, therefore, should be considered a validated HCC.</p>
Lung Cancer	<p>For Sample No. 211, the documentation confirmed that the patient has the condition. This is not a case of over-coding, as the higher severity resulted in a higher HCC. MCS does not agree with OIG's classification of non-validated HCC because the documentation sustained that the patient has the condition besides the severity of it, and therefore should be considered a validated HCC.</p> <p>For Sample No. 191, based on Official ICD-10-CM coding and reporting guidelines, a rule-out diagnosis can be reported during an inpatient encounter, as if the condition were present, as was the case with this sample. Specifically, the official guidelines provide that when coding for "inpatient admissions to short-term, acute, long-term care and psychiatric hospitals . . . [i]f the diagnosis documented at the time of discharge is qualified as 'probable', 'suspected', 'likely', 'questionable', 'possible', or 'still to be ruled out', or other similar terms indicating uncertainty, code the condition as if it existed</p>

HCC	The Medical Records Support The Diagnosis Code
	<p>or was established."<sup>7</sup></p> <p>Additionally, after the audit period, there were seven other instances of treatment for this diagnosis. Merely selecting this one instance in one snapshot in time is not enough to support the conclusion of over-coding, in this instance, let alone extrapolating beyond this specific instance.</p>

OIG should have considered instances where lower hierarchy HCCs were supported by the medical record as validated HCCs, and MCS should not be penalized by OIG counting those HCCs as "non-validated." For example, as reported in the OIG Draft Report, three enrollee-years were found as validating a lower hierarchy HCC for colorectal, bladder, and other cancers resulting in a reduced net overpayment for this HCC.<sup>8</sup> Similarly, seven enrollee-years were found as validating a lower hierarchy HCC for lung cancer, resulting in a reduced net overpayment for this HCC.<sup>9</sup> Not only did these patients have the condition, but OIG's methodology would also result in an underpayment for those patients. These examples are also emblematic of how OIG's audit sampling and methodology inflated the extrapolated payment amount. Consequently, assuming OIG's audit was proper (and MCS disagrees that it was for the reasons in the remaining sections), it should have resulted in *no more than*:

6 out of 30 incorrectly submitted diagnosis codes for vascular claudication;

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<sup>7</sup> Dep't of Health & Human Servs., ICD-10-CM Official Guidelines for Coding and Reporting – FY 2016, § II (2019) (section II titled "Selection of Principal Diagnosis"). By contrast, the guidelines for outpatient services do not permit rule-out diagnoses. *See id.* at § IV (section IV titled "Diagnostic Coding and Reporting Guidelines for Outpatient Services") ("Do not code diagnoses documented as 'probable', 'suspected', 'questionable', 'rule out', or 'working diagnosis' or other similar terms indicating uncertainty. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as symptoms, signs, abnormal test results, or other reason for the visit.").

<sup>8</sup> OIG Draft Report at 12.

<sup>9</sup> *Id.* at 14.

24 out of 30 incorrectly submitted diagnosis codes for breast cancer;

25 out of 30 incorrectly submitted diagnosis codes for colorectal cancer; and

22 out of 31 incorrectly submitted diagnosis codes for lung cancer.

**B. OIG's Audit Sampling And Review Methodology Is Flawed**

OIG's audit departed from established and publicized CMS standards for conducting audits of Medicare Advantage Organizations ("MAOs"). CMS was designated by Congress to administer the MA program. CMS applies a single, consistent RADV audit approach that conforms with written regulations, guidance, and requirements, and is promulgated through a notice and comment rulemaking process.<sup>10</sup> In particular, CMS provides written notice in advance to MAOs about how it will conduct RADV audits. CMS then, adhering to a well-known and publicized methodology, determines any overpayment.

By contrast, OIG's audit process lacks clear parameters and methods, is unaccompanied by any comment and rulemaking procedure,<sup>11</sup> and is retroactive.<sup>12</sup>

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<sup>10</sup> Congress directed HHS "to establish . . . standards" for the MA program on a prospective basis. See 42 U.S.C. § 1395w-26(b)(1), (4) (requiring that regulations imposing "new, significant regulatory requirements" be issued prior to the calendar year in which they take effect). Consequently, CMS provides written notice to MAOs about how it will conduct RADV audits. 42 C.F.R. §422.311; 2021 Program Audit Process Overview Medicare Parts C and D Oversight and Enforcement Group Division of Audit Operations Updated October 2020, <https://www.cms.gov/files/document/2021-program-audit-process-overview.pdf>.

<sup>11</sup> Cf. Memorandum from Kelly M. Cleary, *Impact of Allina on Medicare Payment Rules*, at 3 (Oct. 31, 2019) (advising that "the government generally cannot use" violations of non-regulatory guidance "sett[ing] forth payment rules that are not closely tied to statutory or regulatory standards" in enforcement actions, because "it was not validly issued").

<sup>12</sup> MCS joins other MAOs subject to these audits who have made similar objections. See, e.g., UPMC Response to Medicare Advantage Compliance Audit of Diagnosis Codes that UPMC (Contract H3907) Submitted to CMS, OIG Report No. A-07-19-01188 (Apr. 2021), p. 3; Healthfirst Health Plan, Inc. Response to Medicare

Additionally, as explained below, OIG's sampling and review methodologies not only depart from CMS' standards, but they also are skewed toward identifying overpayments. Because OIG's methods do not follow CMS standards to view a patient's health condition holistically, they are at odds with OIG's objective "to determine whether selected diagnosis codes that MCS submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements."<sup>13</sup>

**1. OIG Did Not Review All Diagnoses  
Or Medical Records From The Sampled Years**

MCS disagrees with OIG's extrapolated repayment amount, because OIG's sampling and review methodologies were biased to identify overpayments. In particular, OIG did not collect and review (i) potential unrelated diagnoses or (ii) an adequate sample size for certain of the HCCs. As a result, OIG inflated the potential extrapolated repayment amount.

*First*, OIG did not collect and review all diagnoses for the enrollees it reviewed. Instead, OIG focused only on enrollees who "received a high-risk diagnosis during [the audit period] that caused an increase payment to MCS."<sup>14</sup> Additionally, OIG did not seek to identify and, as such, did not account for potential, unrelated, HCCs that were not submitted to CMS but were supported by the medical records. Indeed, although OIG recognizes that it "included the financial impact" of *some* "diagnosis codes that should have been submitted to CMS," or that were "mapped to an HCC in the related-disease group," OIG only looked for HCCs that it suspected were potentially mis-keyed diagnosis codes. Consequently, OIG did not holistically review the medical records to add *all* unrelated HCCs that were unreported but supported by the medical records. By ignoring other diagnoses that were or were not submitted to CMS for risk adjustment purposes, OIG's sample did not include potential underpayments.

*Second*, OIG did not explain how it arrived at its sample size for each HCC stratum other than stating that it generated the random numbers using the OIG's Office of Audit Services (OAS) statistical software.<sup>15</sup> CMS uses a "stratification of a

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Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc. (Contract H3359), Submitted to CMS, OIG Report No. A-02-18-01029 (Jan. 2022), at 5.

<sup>13</sup> OIG Draft Report at 1.

<sup>14</sup> OIG Draft Report at 24.

<sup>15</sup> OIG Draft Report at 26.

population prior to sampling and selecting more cases from strata with greater variance," to increase "confidence and precision relative to a simple random sample for which no stratification is performed."<sup>16</sup> There is no apparent explanation for how OIG derived its sample sizes. OIG's sample sizes do not seem to correlate to the frame count of enrollee-years or the CMS payment amounts. Instead, it appears that OIG chose a substantially similar size (of 30 or 40 enrollees per HCC), regardless of the frame count of the enrollee-years. For example, where the frame count for embolism (293) rendered a sample size of 30 enrollees, the frame counts for vascular claudication (2,673), acute stroke (2,673), and major depressive disorder (12,536) -- which range approximately from 10 to 40 times the amount of enrollee years for embolism -- also rendered sample sizes of 30 or 40 enrollees.

This sampling design is flawed for at least two additional reasons. As an initial matter, the sample sizes chosen for each stratum do not vary based on the distribution of enrollee-years or the total of CMS payments at issue between strata. Varying the sample size could have improved precision or accuracy of the sample and would have provided an opportunity to retrieve more accurate and complete medical records. Instead, OIG's method may have resulted in a disproportionate impact from a particular HCC or enrollee year on the total alleged overpayment.<sup>17</sup> In addition, this method undermines OIG's statement in the OIG Draft Report that "[m]ost of the selected high-risk diagnosis codes that MCS submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements."<sup>18</sup> OIG has no support for such a statement based on the small sample populations it reviewed, especially considering that OIG's review of those files were incomplete for the reasons explained above.

OIG's deviations from CMS' RADV audit standards presents additional multiple issues. Because OIG's method was plainly skewed to identify overpayments, OIG's estimated net payment amount is inflated. Moreover, OIG's utilization of a different approach unfairly exposes MCS to potentially paying twice for the same coding error. Because OIG's sampling and methodology differ from

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<sup>16</sup> HHS Risk Adjustment Data Validation (HHS-RADV) White Paper, 32 (Dec. 6, 2019), <https://www.cms.gov/files/document/2019-hhs-risk-adjustment-data-validation-hhs-radv-white-paper.pdf>; *Overview of the 2019 HHS-RADV White Paper*, CMS & HHS (Dec. 2019), <https://www.cms.gov/files/document/2019-hhs-risk-adjustment-data-validation-hhs-radv-white-paper-presentation.pdf>.

<sup>17</sup> *Id.* In fact, in responding to "large issuers' requests for larger sample sizes, HHS is also considering allowing issuers to elect larger sample sizes." *Id.*

<sup>18</sup> OIG Draft Report at 9.

CMS' RADV audit standards, there would be no way to tie OIG's extrapolation to specific HCCs, so MCS could be potentially liable again under a RADV audit for HCCs that fell within OIG's extrapolation. Similarly, OIG -- unlike CMS -- does not apply a coding intensity adjustment to its extrapolation and, therefore, does not account for differences in diagnosis coding patterns against traditional Medicare. These differences are particularly concerning since the OIG Draft Report does not indicate that CMS approves OIG's statements and conclusions. Indeed, based on similar OIG reports that have been finalized, the OIG has admitted that "OIG audit findings and recommendations do not represent final determinations by CMS" and that "CMS will determine whether a potential overpayment exists and will recoup any overpayments consistent with its policies and procedures."<sup>19</sup>

## **2. OIG's Use Of An Independent Reviewer Is Inconsistent With CMS' Approach**

OIG's auditing methodology is also inconsistent with CMS' RADV audit approach because it permits an independent physician to step in and act as a tie breaker to resolve disagreements between senior coders. As OIG acknowledges, CMS requires coding to abide by the International Classification of Diseases (ICD) coding system, including the Official Guidelines for Coding and Reporting (ICD Coding Guidelines).<sup>20</sup> Relying on this guidance, MCS' HCC validation procedures adhere to RADV and ICD Coding Guidelines and, as such, MCS' policies and procedures are based on the ICD Coding Guidelines.

In a RADV audit, where two coders disagree -- *i.e.*, one coder views an HCC as unsubstantiated, escalates the HCC to a second coder for confirmation, and the second coder determines that the medical record substantiates the HCC -- CMS accepts that HCC as substantiated without further analysis. It appears, however, that OIG's medical review followed a different methodology. Where two coders disagreed, OIG's process requires a physician to "independently review[] the medical record to make the final determination."<sup>21</sup> OIG did not identify in how many instances there were disagreements between the coders and on what basis the physician determined which way the tie break should fall. This flawed approach cannot be used to seek repayments from MCS.

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<sup>19</sup> See *e.g.*, <https://oig.hhs.gov/oas/reports/region7/71901187.pdf> at 21 n. 20.

<sup>20</sup> See OIG Draft Report at 1 (observing that the ICD coding system "is used by physicians and other health care providers to classify and code all diagnoses, symptoms, and procedures").

<sup>21</sup> OIG Draft Report, Appendix A, at 21.

**3. OIG Did Not Account For Actuarial  
Equivalence Or Apply The Fee For Service Adjuster**

The fundamental premise of the MA payment system is that CMS pays MAOs an amount that is "actuarially equivalent" to the expected cost that CMS would have otherwise incurred had it provided Medicare benefits directly to the MAO's enrollees on a fee-for-service ("FFS") basis.<sup>22</sup> This mandate led CMS to develop a risk adjustment model that accounts for the expected cost of providing Medicare benefits to beneficiaries with varying health factors. To do so, CMS uses unaudited FFS claims data from the traditional Medicare program in order to account for those traditional Medicare data errors when measuring whether similar erroneous diagnoses for MA enrollees result in overpayment. The same process should have been (but was not) used here.

As OIG is well aware, in 2012, CMS stated that it would calculate recovery amounts for unsupported HCCs identified during its RADV audits by adjusting for error rates in traditional Medicare data.<sup>23</sup> Although CMS attempted to shift away from its previous declaration in 2014, when it implemented the Overpayment Rule,<sup>24</sup> a federal district court held that the Overpayment Rule violated the actuarial equivalence mandate because it did not apply either a FFS adjuster or other mechanism to maintain actuarial equivalence.<sup>25</sup> MCS agrees with this holding, notwithstanding the recent opinion of the U.S. Court of Appeals for the D.C. Circuit, which held that the overpayment rule does not require actuarial equivalence.<sup>26</sup> The D.C. Circuit's holding was narrow as to the Overpayment Rule, and did not find that actuarial equivalence should not apply in the RADV audit context. That conclusion makes sense: the "documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation

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<sup>22</sup> 42 U.S.C. § 1395w-23(a)(3).

<sup>23</sup> CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation for Contract-Level Audits*, at 4 (Feb. 24, 2012).

<sup>24</sup> 42 C.F.R. § 422.326.

<sup>25</sup> *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 187 (D.D.C. 2018).

<sup>26</sup> *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), *cert. denied*, 142 S. Ct. 2851 (2022).

standard used to develop the Part C risk-adjustment model (FFS claims)" and therefore an adjustment for actuarial equivalence is necessary.<sup>27</sup>

Although CMS issued a proposed rule in 2018 suggesting that diagnosis coding errors in unaudited traditional Medicare data do not systematically impact payments to MAOs, many commenters object to the proposed rule, explaining that it does not satisfy the actuarial equivalence requirement. CMS has taken no further action on this rule.

Here, OIG did not apply a FFS adjuster or other mechanism to account for errors in the data when conducting this audit. Other MAOs have observed that this renders OIG's estimated and extrapolated repayment amount "both legally and actuarially unsound," because it not only "violates important principles of administrative law, in particular the requirement for notice and comment rulemaking," but also deviates "from OIG's past audit practices."<sup>28</sup> Consequently, MCS respectfully requests that OIG withdraw its repayment calculation until CMS performs an actuarially sound audit by which it can recalculate any payment that might be due.

#### **4. OIG Inappropriately Applied A Lower Confidence Interval**

In order to determine the lower bound of the alleged payment error, OIG used a confidence interval that was inconsistent with the confidence interval prescribed by CMS for RADV audits. CMS stated that it would calculate its RADV net payment error at the "lower bound of the 99 percent [confidence interval]."<sup>29</sup> Here, however, OIG "recommend[s] recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval."<sup>30</sup> Consequently, OIG's approach results

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<sup>27</sup> CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation for Contract-Level Audits*, at 4 (Feb. 24, 2012).

<sup>28</sup> E.g., Tufts Response to Medicare Advantage Compliance Audit of Diagnosis Codes that Tufts Health Plan (Contract H2256) Submitted to CMS, OIG Report No. A-01-19-00500 (February 2022), at 46.

<sup>29</sup> CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation for Contract-Level Audits*, at 4 (Feb. 24, 2012).

<sup>30</sup> OIG Draft Report at 8 n.16.

in a higher extrapolated overpayment. Importantly, OIG does not provide an explanation for this departure from CMS' practice but, rather, states only that it is taking a "conservative" approach by using the lower limit of the 90 percent confidence interval.

**5. OIG Erroneously Suggests  
That MCS Is Responsible For  
Guaranteeing Complete Accuracy Of The Data It Submits**

OIG acknowledges that MAOs are not expected to submit perfect risk adjustment data.<sup>31</sup> CMS' regulations provide that MAOs must certify that "based on best knowledge, information, and belief" the data they submit is "accurate, complete, and truthful."<sup>32</sup> This "good faith efforts" standard was put in place based on the acknowledgment that data comes "in great volume and from a number of sources, presenting significant verification challenges for the organizations."<sup>33</sup> Moreover, OIG itself has made plain that "[t]he requirement that the CEO or CFO certify as to the accuracy, completeness, and truthfulness of data, based on the best knowledge, information and belief, *does not constitute an absolute guarantee of accuracy*" but, rather, "creates a duty on the Medicare+Choice organization to put in place an information collection and reporting system *reasonably* designed to yield accurate information."<sup>34</sup>

Importantly, HHS and OIG implemented the good faith efforts standard because "the complexity of the data required . . . would [make it] *unfair* and

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<sup>31</sup> See 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999) (noting that "[t]he requirement that the CEO or CFO certify as to the accuracy, completeness, and truthfulness of data, based on the best knowledge, information and belief does not constitute an absolute guarantee of accuracy").

<sup>32</sup> 42 C.F.R. § 422.504(l). CMS reiterated this standard in its April 15, 2022 Memo to MAOs. See *Reminder of Existing Obligation to Submit Accurate Risk Adjustment Data*, CMS (Apr. 15, 2022), <https://www.cms.gov/files/document/obligationtosubmitaccuratedatahpmemo508.pdf>.

<sup>33</sup> 65 Fed. Reg. 40,170, 40,268 (June 29, 2000).

<sup>34</sup> 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999) (emphasis added).

*unrealistic* to hold M+C organizations to a '100 percent accuracy' certification standard," as such a standard would not be "reasonable to enforce."<sup>35</sup>

OIG's Draft Report, however, states only that "MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS," without incorporating the good faith efforts standard.<sup>36</sup> Absent more specific mandates, OIG's statements in the OIG Draft Report appear as an attempt to not only expand the MA compliance program requirements, but also alter the guidance that MCS has relied upon in reviewing diagnosis code submissions, such as the HCCs OIG audited here. Risk adjustment data is submitted to MCS from numerous sources, including healthcare providers. Collecting information in this way presents the potential for coding errors or incomplete provider generated data and, as such, presents significant verification challenges.<sup>37</sup> To combat these potential inaccuracies, MCS implements robust policies and procedures that both detect and correct discrepancies between provider coding and CMS coding standards. MCS also offers education and provides guidance to providers about proper documentation and coding rules for high-risk diagnosis codes. A detailed description of these efforts is explained in Part IV.

Additionally, MCS continuously implements new processes to enhance its prevention, detection, and correction of diagnosis coding errors. For example, MCS' risk adjustment program aligns its operational procedures with changing CMS guidance concerning diagnosis coding and submissions in order to prevent noncompliance, identify errors, and correct any errors that are identified. Similarly, MCS undertakes audit processes to address different targets of high-risk diagnoses in order to identify coding errors and areas of opportunities for educating our providers.

Consequently, MCS respectfully requests that OIG adjust its report to reflect the appropriate good faith efforts standard and to remove any suggestion that MCS failed to meet this good faith standard with respect to the audited HCCs.

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<sup>35</sup> 65 Fed. Reg. 40,170, 40,250 (June 29, 2000) (emphasis added).

<sup>36</sup> OIG Draft Report at 8.

<sup>37</sup> For this reason, CMS includes in the revenue calculation the coding intensity factor to account for the potential coding errors. Richard Kronick & W. Pete Welch, *Measuring Coding Intensity in the Medicare Advantage Program*, 4 Medicare & Medicaid Research Rev. 2, E4 (2014), [https://www.cms.gov/mmrr/downloads/mmrr2014\\_004\\_02\\_a06.pdf](https://www.cms.gov/mmrr/downloads/mmrr2014_004_02_a06.pdf).

**II. MCS ADVANTAGE RESPECTFULLY  
SUBMITS THAT IT IS NOT OBLIGATED  
TO CONDUCT AUDITS FOR OTHER PAYMENT YEARS**

MCS respectfully requests that OIG remove its recommendation that MCS "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."<sup>38</sup> The MA regulations do not require MCS to conduct the type of audit that the OIG conducted here; and, therefore, there is no standard for MCS to use to conduct any such audit. This is especially salient, because OIG has neither provided MCS with an underlying algorithm nor details about how it identified mis-keyed diagnoses, in order for MCS to identify "similar instances of noncompliance."<sup>39</sup> Moreover, even if MCS were able to identify unsupported diagnosis codes in a similar manner to OIG, potentially unsupported diagnosis codes are not necessarily reflective of an overpayment. Rather, the audit recommended here by OIG would require MCS to apply a FFS adjuster to ensure actuarial equivalence.

Additionally, for the reasons discussed below, MCS already implements "an effective system for routine monitoring and identification of compliance risks," including "internal monitoring audits and, as appropriate, external audits to evaluate . . . compliance with CMS requirements and the overall effectiveness of the compliance program."<sup>40</sup> Likewise, MCS corrects problems that it identifies "promptly and thoroughly to reduce the potential for recurrence."<sup>41</sup> Indeed, and as demonstrated more fully below, since the audit period, MCS has bolstered its already robust policies and procedures in both regards.

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<sup>38</sup> OIG Draft Report at 18.

<sup>39</sup> *Id.*

<sup>40</sup> 42 CFR § 422.503(b)(4)(vi) (Appendix D).

<sup>41</sup> *Id.*

**III. MCS ADVANTAGE'S EXISTING COMPLIANCE PROGRAM IS ROBUST, EFFECTIVE AND MEETS OR EXCEEDS REGULATORY REQUIREMENTS**

**A. OIG Has Not Identified Specific Compliance Procedures That Could Be Improved**

OIG's vague recommendation that "MCS's compliance procedures to prevent, detect, and correct incorrect high-risk diagnosis codes could be improved," because "they did not include steps to identify the root cause of the errors or to detect and correct systemic errors," is unfounded.<sup>42</sup> MCS already has a robust compliance program to reduce coding errors and also educate providers. OIG's recommendation is particularly inaccurate considering its own admission that MCS' "procedures included preventative measures (e.g., MCS educated providers on several topics, including the quality of the medical record documentation and guidance on listing accurate diagnosis codes on claims) . . . educated its providers to actively monitor, evaluate, assess, and treat conditions related to diagnoses during face-to-face encounters . . . [implemented] detective and corrective measures such as internal audits of the diagnosis codes that its providers submitted . . . conducted specific review of certain high-risk diagnosis codes that it had identified as being at higher risk for being miscoded . . . [and] provided guidance to coders on how to review diagnoses that MCS had designated as high risk."<sup>43</sup>

**B. MCS Advantage's Compliance Program Has Been -- And Continues To Be -- Robust**

MCS disagrees that its "compliance procedures to prevent, detect, and correct incorrect high-risk diagnosis codes could be improved."<sup>44</sup> MCS has consistently implemented compliance policies and procedures to prevent, detect, and correct risk adjustment errors. These policies and procedures aim to both reduce coding errors and also educate providers, which helps to ensure that the data submitted to CMS for determination of the risk adjustment is accurate based on MCS' "best knowledge, information, and belief," and, as such, compliant with Federal requirements. For example, MCS has implemented Quality Assurance coding and medical records review since 2010 and targeted data checking validation activities since 2013. Indeed, given the flaws in OIG's sampling and methodology,

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<sup>42</sup> OIG Draft Report at 17.

<sup>43</sup> OIG Draft Report at 17.

<sup>44</sup> OIG Draft Report at 17.

MCS does not agree that OIG's overpayment estimate reflects the opposite conclusion.

As demonstrated in the chart below, MCS' compliance program has been -- and continues to be -- robust. Notwithstanding MCS' already comprehensive program, MCS has also already implemented additional processes to enhance its policies and procedures to prevent, detect, and correct potential coding errors in the diagnosis codes received from providers and/or submitted to CMS for use in its risk adjustment program. Moreover, in furtherance of MCS' commitment to continuous improvement in all of its processes and to increase quality and efficiency, MCS is currently implementing additional projects and initiatives that are aimed at expanding and improving its data checking and validation audits.

MCS implemented and continues to implement the following measures and initiatives to best identify incorrect coding practices and reduce payment errors resulting from unsupported documentation:

Compliance Control	Robust Practices In 2015-2016	Robust Practices & Enhancements Today
Unit Structure	MCS' Pre-Audit Unit handled (1) internal and external coding and RADV audits, and (2) conducted educational interventions with providers and internal coders.	<p>The Pre-Audit Unit remains in place and is responsible for internal coding audits. The team monitors diagnosis coding audits for in-house and outsourced coders, identifies risks and educational opportunities, and establishes the coding accuracy rate. The Pre-Audit Unit also ensures correction plans are completed and deletions are performed as needed.</p> <p>Between August 2021 and July 2022, MCS created and instituted a RADV Focused Unit, which is responsible for CMS RADV activities and internal risk adjustment targeted audits. The team is responsible for completing targeted risk adjustment and external coding</p>

Compliance Control	Robust Practices In 2015-2016	Robust Practices & Enhancements Today
		audits to identify risks, increasing efficiency in obtaining clinical information and reducing negative findings in RADV audits. The team also ensures required interventions with providers regarding coding errors or non-validated chronic conditions are completed.
Committees and Work Groups	MCS' Risk Adjustment Steering Committee met annually to review the RAPS data collection logic and identify risk prevention opportunities.	Between November 2020 and March 2021, MCS expanded the roles and responsibilities of its Risk Adjustment Steering Committee, which is composed of employees with responsibilities that directly impact the risk adjustment process. The committee was expanded to provide support, guidance, and oversight of risk adjustment functions, strategies, and decision-making to ensure accurate submissions of HCCs.  MCS' Risk Adjustment Working Group meets annually to review the RAPS and EDS data collection requirements.
Provider Contracts	MCS' contracts included a clause to address the provider's responsibility to cooperate in any audit by providing the necessary information (the "RADV clause").	Between March 2021 and December 2022, MCS revised its RADV clause in its provider contracts to emphasize provider compliance with CMS requirements for accurate submission of risk adjustment data, including provider adherence to correct coding and billing guidelines through completeness of medical

Compliance Control	Robust Practices In 2015-2016	Robust Practices & Enhancements Today
		records documentation. MCS completed this update to the specialists' contracts and is in the process of updating the contracts for the PCP network.
Integration	Premium Management Department led the activities focused on RADV.	<p>Between March 2021 and June 2021, MCS integrated staff from the Special Investigation Unit into the RADV audit activities, in order to take advantage of their knowledge and skills and to improve the prevention, detection, and correction of coding errors.</p> <p>Between December 2020 and December 2021, MCS engaged with a reputable healthcare consulting firm that has been dedicated to improving healthcare for more than twenty years, to assess and identify opportunities of improvement with respect to MCS' risk adjustment program and to increase efficiency and reduce risk related to audits. The consulting firm's assessment included five areas of review, and its recommendations were discussed and implemented by MCS.</p>
Policies and Procedures	MCS had policies and procedures in place that were focused on detecting coding errors and correcting coding errors, including:	MCS annually reviews the relevant policies and has made changes to them as follows: STRFIN-PM-05: coding accuracy threshold increased to 95%

Compliance Control	Robust Practices In 2015-2016	Robust Practices & Enhancements Today
	<p>STRFIN-PM-05: Quality assurance of outsourced coding vendor</p> <p>STRFIN-PM-09: Quality assurance review of in-house coding</p> <p>STRFIN-PM-22: Risk Adjustment Data Validation-National Sample and Contract Level Audits</p> <p>MCS followed the following operational guidelines:</p> <ul style="list-style-type: none"> <li>Delete Indicator</li> <li>Overpayment process</li> <li>Data Collection</li> <li>Audit Program</li> </ul> <p>The RADV targets were based on criteria such as: one instance HCC reporting and target high risk HCCs (e.g., HCCs with 0.8 and greater risk coefficient, inpatient HCCs reported in outpatient setting, potential high risk coding error HCCs, and HCCs for artificial opening) based on previous RADV and quality findings.</p>	<p>STRFIN-PM-09: coding accuracy threshold increased to 94%, which is now used when identifying the impact of coding errors on the risk score as critical or non-critical</p> <p>STRFIN-PM-22: updated to include procedure to reconcile CMS responses to CMS RADV audit reports and procedures for medical record exceptions (e.g., hardships) and when medical records are not available.</p> <p>Between June 2021 and July 2021, MCS instituted a new operational guideline to formalize year-round data checking and validation activities, which MCS utilizes to perform efficiently targeted audits of HCCs. In particular, MCS identifies HCCs with unsubstantiated documentation that will need to be deleted from the CMS EDS and RAPS databases. The high-risk HCC targeted list is then periodically reviewed.</p> <p>Between August 2021 and September 2021, MCS reviewed the medical record documentation audit based on the Accreditation Association for Ambulatory Health Care guidelines. These audits are</p>

Compliance Control	Robust Practices In 2015-2016	Robust Practices & Enhancements Today
		<p>executed by an MCS Clinical Review Specialist, who is a Registered Nurse, at primary care physician offices, in order to identify patterns of noncompliance and provide one-on-one education to providers presenting noncompliance issues. In particular, the Clinical Review Specialist takes a sample of existing and suspect HCCs and verifies them using medical record documentation. The Clinical Review Specialist then identifies and discusses any issues of noncompliance with the provider and refers any incorrect diagnoses to the RADV Focused Unit for deletion.</p> <p>MCS is conducting a review of current payment rules in order to continue to ensure prevention and/or rejection of potential billing or coding errors at the pre-payment level, and to request additional supportive documentation from providers, where necessary.</p> <p>MCS is reviewing the deletions operational guidelines in order to expand the scope of deletions for claims identified with incorrect ICD-10 billing codes that were submitted to CMS.</p>

Compliance Control	Robust Practices In 2015-2016	Robust Practices & Enhancements Today
		MCS monitors specialties with high risk of coding inaccuracies to carry out targeted audits, and has expanded its high risk HCC target list.
Interventions	<p>The Provider Network Education Unit provided education to physicians using different approaches, such as distributing educational material to providers and internal coding staff through emails, letters, in-person meetings, and trainings focused on Risk Adjustment Models 101 and 102; providing e-learning training for providers and medical office staff about coding guidelines, clinical documentation rules, and HCC validation; providing educational information to address specific HCCs, such as CKD, major depression, malnutrition, neoplasm. MCS also conducted Risk Adjustment workshops with different medical groups to promote best practices of coding and documentation.</p> <p>The Pre-Audit Unit also discussed internal HCC</p>	Between June 2021 and the present, MCS expanded educational interventions concerning RADV requirements, in order to support providers with clinical documentation, validation, and coding opportunities. Prior to this enhancement, MCS performed audits to validate HCCs, the results of which were discussed with providers, and educational material and trainings were distributed to prevent HCC coding errors. As a part of this project, MCS developed a RADV physician profiling in order to identify the education intensity level. The interventions are offered by the Physician Services Education Unit and the trainings are provided at the individual provider level, as well as, the IPA and general provider network levels. The trainings concern RADV audits and compliance medical documentation and coding practices. MCS intends for these interventions to improve the documentation and coding of the diagnoses reported to CMS.

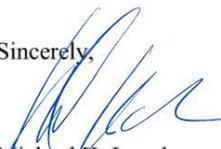
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Compliance Control	Robust Practices In 2015-2016	Robust Practices & Enhancements Today
	audits with selected providers and submitted deletions to CMS.	MCS has instituted new methods of facilitating education, including virtual meetings, online education, medical group round tables and inclusion of risk adjustment topics in clinical symposiums.
Operational Efficiency	MCS documented coding audits in Excel and manually reported and analyzed all its procedures.	MCS now uses an in-house electronic tool, which has enhanced its data entry and reporting capabilities during the audit process and continues to assess additional enhancements, including automatic hand-offs.

**IV. CONCLUSION**

For the reasons described in this letter, MCS respectfully requests that OIG update the OIG Draft Report and withdraw its recommendations that MCS (1) refund an extrapolated amount of \$6,385,666 of estimated net overpayments, (2) conduct additional audits beyond OIG's sample and make repayments based on those audits, and (3) examine existing compliance procedures to identify areas of improvement.

Sincerely,



Michael K. Loucks

cc: Alexandra M. Gorman  
 James P. O'Drobinak  
 Maite Morales Martinez  
 Dr. Ines Hernandez Roses