

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE
COMPLIANCE AUDIT OF SPECIFIC
DIAGNOSIS CODES THAT TUFTS
HEALTH PLAN (CONTRACT H2256)
SUBMITTED TO CMS**

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Office of Inspector General

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Report in Brief

Date: February 2022

Report No. A-01-19-00500

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



Why OIG Did This Audit

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations according to a system of risk adjustment that depends on the health status of each enrollee. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources than to healthier enrollees, who would be expected to require fewer health care resources. To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS. For this audit, we reviewed one MA organization, Tufts Health Plan, Inc. (Tufts), and focused on seven groups of high-risk diagnosis codes.

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

How OIG Did This Audit

We sampled 212 unique enrollee-years with the high-risk diagnosis codes for which Tufts received higher payments for 2015 through 2016. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$746,427.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS

What OIG Found

Most of the selected diagnosis codes that Tufts submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 58 of the 212 sampled enrollee-years, the medical records validated the reviewed Hierarchical Condition Categories (HCCs). However, for the remaining 154 enrollee-years, the diagnosis codes were not supported in the medical records. These errors occurred because the policies and procedures that Tufts had to ensure compliance with CMS's program requirements, as mandated by Federal regulations, could be improved. As a result, the HCCs for some of the high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Tufts received at least \$3.7 million of net overpayments for these high-risk diagnosis codes in 2015 and 2016.

What OIG Recommends

We recommend that Tufts: (1) refund to the Federal Government the \$3.7 million 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 to improve its existing compliance procedures to identify areas where improvements can be made to ensure 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.

Tufts did not concur with our findings and recommendations. Tufts stated that we should not have included the errors associated with 5 enrollee-years in our calculation of total net overpayments because, according to Tufts, it had already submitted corrections to CMS. Tufts did not specifically comment on the errors associated with the other 154 enrollee-years. Tufts disagreed with our sampling and review methodologies and stated that our report reflected misunderstandings of legal and regulatory requirements underlying the MA program.

After consideration of Tufts' comments, we maintain that our findings and recommendations are valid. However, we revised our findings for the 5 enrollee-years and considered the impact of the budget sequestration reduction; therefore, we reduced our first recommendation from \$4,013,034 to \$3,758,335 for our final report. We also revised the beginning of our third recommendation in recognition of Tuft's past efforts to improve its compliance program.

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INTRODUCTION

WHY WE DID THIS AUDIT

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

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS.² Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 28 major depressive disorder diagnoses into 1 group.) This audit covered Tufts Health Plan (Tufts) for contract number H2256³ and focused on seven groups of high-risk diagnosis codes for payment years 2015 and 2016.

OBJECTIVE

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

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

² Two reports in this series of audits have been issued, *Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements* ([A-07-17-01170](#)), Apr. 30, 2019, and *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (H9572) Submitted to CMS* ([A-02-18-01028](#)), Feb. 24, 2021.

³ All subsequent references to "Tufts" in this report refer solely to contract number H2256.

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.⁴ Beneficiaries who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

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

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

Risk Adjustment Program

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

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

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

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

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

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

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

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

To determine an enrollee's health status for the 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, based on similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs).⁸ Each HCC has a factor (which is a numerical value) assigned to it for use in each enrollee's risk score.

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

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

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

⁸ CMS transitioned from one HCC payment model to another during our audit period. As part of this transition, for 2015, CMS calculated risk scores based on both payment models. CMS refers to these models as the Version 12 model and the Version 22 model, each of which has unique HCCs. CMS blended the two separate risk scores into a single risk score that it used to calculate a risk-adjusted payment. Accordingly, for 2015, an enrollee's blended risk score is based on the HCCs from both payment models. For 2016, CMS calculated risk scores on the Version 22 model.

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

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

High-Risk Groups of Diagnoses

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

- *Acute Stroke*: An enrollee received one acute stroke diagnosis (which maps to the HCC for Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim. A diagnosis of history of stroke (which does not map to an HCC) typically should have been used.
- *Acute Heart Attack*: An enrollee received one diagnosis that mapped to either the HCC for Acute Myocardial Infarction or to the HCC for Unstable Angina and Other Acute Ischemic Heart Disease (Acute Heart Attack HCCs) on only one physician claim but did not have that diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician's claim). A diagnosis for a less severe manifestation of a disease in the related-disease group typically should have been used.
- *Acute Stroke and Acute Heart Attack Combination*: An enrollee met the conditions of both the acute stroke and acute heart attack high-risk groups in the same year.¹⁰
- *Embolism*: An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease with Complications (Embolism HCCs) but did not have an anticoagulant medication dispensed on his or her behalf. An anticoagulant medication is typically used to treat an embolism. A diagnosis of history

⁹ 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 (8-2-2011)). Under the BCA, the sequestration of mandatory spending began in Apr. 2013.

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

of embolism (an indication that the provider is evaluating a prior acute embolism diagnosis, which does not map to an HCC) typically should have been used.

- *Vascular Claudication*: An enrollee received one diagnosis related to vascular claudication (which maps to the HCC for Vascular Disease) but had medication dispensed on his or her behalf that is frequently dispensed for a diagnosis of neurogenic claudication.¹¹ In these instances, the vascular claudication diagnoses may not be supported in the medical records.
- *Major Depressive Disorder*: An enrollee received a major depressive disorder diagnosis (which maps to the HCC entitled Major Depressive, Bipolar, and Paranoid Disorders) on one claim during the service year but did not have an antidepressant medication dispensed on his or her behalf. In these instances, the major depressive disorder diagnoses may not be supported in the medical records.
- *Potentially Mis-keyed Diagnosis codes*: An enrollee received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition (which mapped to a possibly unvalidated HCC). For example, ICD-9 diagnosis code 250.00 (which maps to the HCC for Diabetes Without Complication) could be transposed as diagnosis code 205.00 (which maps to the HCC for Metastatic Cancer and Acute Leukemia and in this example would be unvalidated). Using an analytical tool that we developed, we identified 811 scenarios in which diagnosis codes mis-keyed because of data transposition or other data entry errors could have resulted in the assignment of an unvalidated HCC.

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

Tufts Health Plan

Tufts is an MA organization based in Watertown, Massachusetts. As of December 31, 2016, Tufts provided coverage under contract number H2256 to approximately 107,000 enrollees. For the 2015 through 2016 payment years (audit period), CMS paid Tufts approximately \$2.3 billion to provide coverage to its enrollees.¹²

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

¹² All of the payment amounts that CMS made to Tufts and the adjustment amounts that we identified in this report reflect the budget sequestration reduction.

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of the seven high-risk groups during the 2014 through 2015 service years, for which Tufts received increased risk-adjusted payments for payment years 2015 through 2016, respectively. Because enrollees could be classified in more than one high-risk group or have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment year, which we refer to as “enrollee-years.” We identified 2,704 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$7,081,740). We selected for audit a sample of 212 enrollee-years, which comprised: (1) a stratified random sample of 154 (out of 2,646) enrollee-years for the first 6 high-risk groups and (2) all 58 enrollee-years for the remaining high-risk group.

Table 1 breaks out the 212 sampled enrollee-years associated with each of the 7 high-risk groups.

Table 1: Sampled Enrollee-Years

High-Risk Group	Number of Sampled Enrollee-Years
1. Acute Stroke	30
2. Acute Heart Attack	30
3. Acute Stroke/Acute Heart Attack Combination	4
4. Embolism	30
5. Vascular Claudication	30
6. Major Depressive Disorder	30
Total for Stratified Random Sample	154
7. Potentially Mis-keyed Diagnosis Codes	58
Total for All High-Risk Groups	212

Tufts provided medical records as support for the selected diagnosis codes associated with 201 of the 212 enrollee-years.¹³ We used an independent medical review contractor to review the medical records to determine whether the selected diagnosis codes that Tufts submitted to CMS were supported. If the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

¹³ Tufts did not provide any medical records for 11 enrollee-years.

based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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

FINDINGS

With respect to the seven groups of high-risk diagnosis codes covered by our audit, most of the selected diagnosis codes that Tufts submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 58 of the 212 sampled enrollee-years, the medical records validated the reviewed HCCs. However, for the remaining 154 enrollee-years, the diagnosis codes were not supported in the medical records.

These errors occurred because the policies and procedures that Tufts had to ensure compliance with CMS's program requirements, as mandated by Federal regulations, could be improved. As a result, the HCCs for some of the high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Tufts received at least \$3.7 million of net overpayments for these high-risk diagnosis codes in 2015 and 2016.¹⁴

FEDERAL REQUIREMENTS

Payments to MA organizations are adjusted for risk factors, including the health status of each enrollee (the 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)).

¹⁴ Specifically, we estimated that Tufts received at least \$3,758,335 (\$3,466,463 for the statistically sampled high-risk groups plus \$291,872 for the group of potentially mis-keyed diagnosis codes) of net overpayments. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

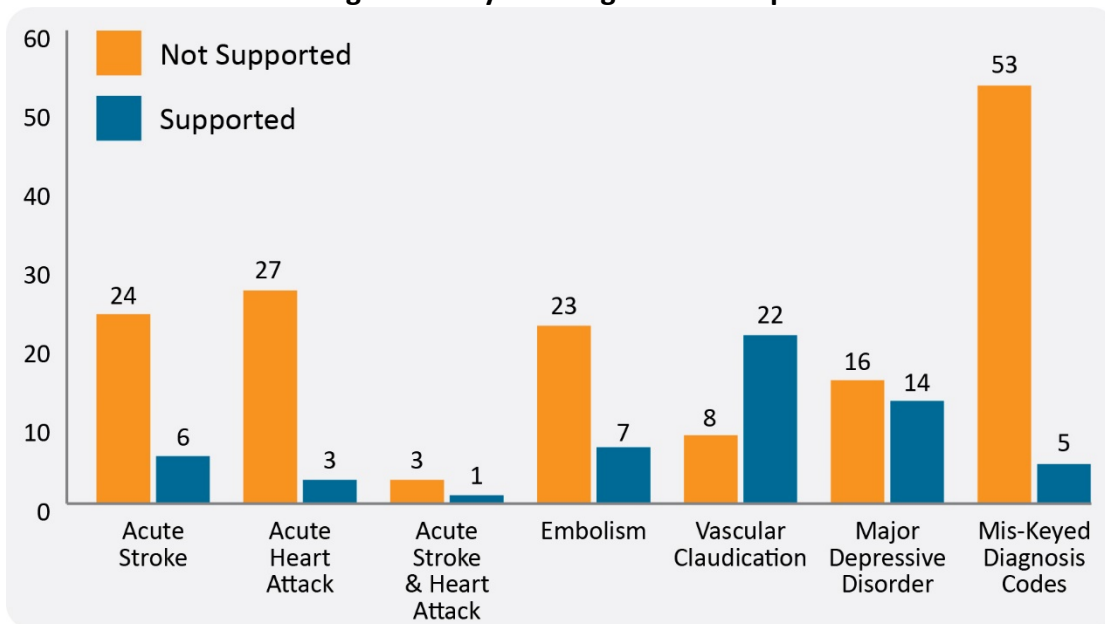
CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap. 7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face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

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

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

Most of the selected high-risk diagnosis codes that Tufts submitted to CMS for use in CMS’s risk adjustment program did not comply with Federal requirements. As shown in the figure below, the medical records for 154 of the 212 sampled enrollee-years did not support the diagnosis codes. In these instances, Tufts should not have submitted the diagnosis codes to CMS and received the resulting net overpayments.

Figure: Analysis of High-Risk Groups



Incorrectly Submitted Diagnosis Codes for Acute Stroke

Tufts incorrectly submitted diagnosis codes for acute stroke for 24 of the 30 sampled enrollee-years. Specifically:

- For 12 enrollee-years, the medical records indicated that the individual had previously had a stroke, but the records did not justify an acute stroke diagnosis at the time of the physician's service.

For example, for 1 enrollee-year, the independent medical review contractor noted that "there is no evidence of an acute stroke or any related condition that would result in an assignment of an [Ischemic or Unspecified Stroke] HCC. There is mention of a history of a stroke but no description of residuals or sequelae that should be coded."

- For 12 enrollee-years, the medical records did not contain sufficient information to support an acute stroke diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no evidence of an acute stroke or any related condition that would result in an assignment of an [Ischemic or Unspecified Stroke] HCC or a related HCC. The consultation report describes multiple symptoms and test results; however, an acute stroke is not confirmed."

As a result of these errors, the HCCs for Ischemic or Unspecified Stroke were not validated, and Tufts received \$61,047 of overpayments for these 24 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Heart Attack

Tufts incorrectly submitted diagnosis codes for acute heart attack for 27 of 30 sampled enrollee-years. Specifically:

- For 18 enrollee-years, the medical records did not support an acute myocardial infarction diagnosis. However, we identified support for a diagnosis of a less severe manifestation of the related-disease group:
 - For 17 enrollee-years, we identified support for an old myocardial infarction diagnosis.
 - For 10 enrollee-years, which occurred in 2015, we identified support for an old myocardial infarction diagnosis, which mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Tufts should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the old myocardial infarction diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that . . . translates to the assignment of [an Acute Heart Attack] HCC. The medical documentation states a medical history of a myocardial infarction which results in the HCC for Angina Pectoris/Old Myocardial Infarction.”

- For 7 enrollee-years, which occurred in 2016, we identified support for an Old Myocardial Infarction diagnosis, which did not map to an HCC.¹⁵ Accordingly, Tufts should not have received an increased payment for acute myocardial infarction.
 - For the 1 remaining enrollee-year, we identified support for a diagnosis of demand ischemia,¹⁶ which mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Tufts should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the demand ischemia diagnosis.
- For 8 enrollee-years, the medical records did not support either an acute myocardial infarction diagnosis or an old acute myocardial infarction diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no evidence of any condition that . . . translates to the assignment of [an Acute Heart Attack] HCC. This observation stay addressed nontraumatic shoulder pain, which does not result in HCC. There is no documentation of an acute myocardial infarction [diagnosis] or an old acute myocardial infarction [diagnosis] that can be assigned.”

- For the 1 remaining enrollee-year, the medical record did not support an acute myocardial infarction diagnosis. However, we identified support for a diagnosis of moderate diastolic dysfunction¹⁷ resulting in a congestive heart failure HCC which should have been coded instead of [the Acute Heart Attack] HCC. This error resulted in an underpayment for this enrollee year.

¹⁵ In contrast to the enrollee-years that occurred in 2015 (for which CMS used the Version 12 model), for 2016, CMS used only the Version 22 model, which did not include an HCC for Old Myocardial Infarction, to calculate risk scores (footnote 8).

¹⁶ Demand ischemia is defined as a type of heart attack for which blockages in the arteries may not be present. It occurs when a patient’s heart needs more oxygen than is available in the body’s supply. It may occur in patients with infection, anemia, or tachyarrhythmias (abnormally fast heart rates).

¹⁷ Diastolic dysfunction is a cardiac condition caused by a “stiffening” of the heart’s ventricles (the major pumping chambers). This relative stiffness restricts the heart’s ability to fill up with blood in between heart beats.

As a result of these errors, the Acute Heart Attack HCCs were not validated, and Tufts received \$38,009 of net overpayments for these 27 sampled enrollee-years.

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

Tufts incorrectly submitted diagnosis codes for 3 of 4 sampled enrollee-years for which the physicians had documented conditions for both the acute stroke and acute heart attack high-risk groups in the same year (footnote 9).

For 2 of the enrollee-years, the medical records did not support both the acute stroke and acute myocardial infarction diagnoses. For the 1 remaining enrollee-year, the medical records did not support the acute stroke diagnosis and Tufts did not provide a legible copy of a medical record to support the acute myocardial infarction diagnosis.

As a result of these errors, the HCCs for Acute Stroke and Acute Heart Attack were not validated, and Tufts received \$5,659 of overpayments for these 3 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

Tufts incorrectly submitted diagnosis codes for embolism for 23 of 30 sampled enrollee-years. The medical records did not support these diagnosis codes. Specifically:

- For 13 enrollee-years, the medical records indicated 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 "there is no documentation of any condition that . . . translates to the assignment of a Vascular Disease with Complications HCC; however, there is documentation of a history of [postoperative] pulmonary embolism in 2005, which does not result in an HCC."

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

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that . . . translates to the assignment of [the Vascular Disease HCCs]."

- For the 1 remaining enrollee-year, Tufts could not locate any medical records to support the embolism diagnosis; therefore, the Embolism HCC was not validated.

As a result of these errors, the Embolism HCCs were not validated, and Tufts received \$74,552 of overpayments for these 23 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Vascular Claudication

Tufts incorrectly submitted diagnosis codes for vascular claudication for 8 of 30 sampled enrollee-years. Specifically:

- For 7 enrollee-years, the medical records did not contain documentation to support a vascular claudication diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that . . . translates to the assignment of [the Vascular Disease HCCs].”

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

As a result of these errors, the HCCs for Vascular Claudication were not validated, and Tufts received \$17,781 of overpayments for these 8 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder

Tufts incorrectly submitted diagnosis codes for major depressive disorder for 16 of 30 sampled enrollee-years. Specifically:

- For 11 enrollee-years, the medical records did not support a major depressive disorder diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that . . . translates to the assignment of [the Major Depressive, Bipolar, and Paranoid Disorders HCCs].”

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

As a result of these errors, the HCCs for Major Depressive, Bipolar, and Paranoid Disorders were not validated, and Tufts received \$47,165 of overpayments for these 16 sampled enrollee-years.

Potentially Mis-keyed Diagnosis Codes

Tufts submitted potentially mis-keyed diagnosis codes for 53 of 58 enrollee-years. In each of these cases, the beneficiaries associated with the enrollee-years received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated

condition. Appendix E contains the potentially mis-keyed diagnosis codes that we identified for the 53 enrollee-years.

Specifically:

- For 49 enrollee-years, the medical records did not support the diagnosis for the unrelated condition. Because of these errors, Tufts submitted unsupported diagnosis codes that mapped to unvalidated HCCs to CMS.

For example, for 1 enrollee-year, Tufts submitted 30 diagnosis codes for diabetes mellitus (250.00) and only 1 diagnosis code for metastatic cancer and acute leukemia (205.00) to CMS. The independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of HCC [Metastatic Cancer and Acute Leukemia]. There is documentation of type 2 diabetes (250.00) that maps to HCC [Diabetes without Complication] which should have been coded instead of a diagnosis that maps to the submitted HCC [Metastatic Cancer and Acute Leukemia].” Thus, we concluded that the 205.00 diagnosis code was mis-keyed and incorrectly submitted to CMS and that the HCC for metastatic cancer and acute leukemia was therefore not validated.

- For the remaining 4 enrollee-years, Tufts could not locate any medical records to support the potentially mis-keyed diagnosis code; therefore, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated.

As a result of these errors, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated, and Tufts received \$291,872 of overpayments for these 53 sampled enrollee-years.

THE POLICIES AND PROCEDURES THAT TUFTS USED TO ENSURE COMPLIANCE WITH FEDERAL REQUIREMENTS COULD BE IMPROVED

As demonstrated by the errors found in our sample, the policies and procedures that Tufts used to ensure compliance with CMS’s program requirements, as mandated by Federal regulations (42 CFR § 422.503(b)(4)(vi) (Appendix D)), could be improved.

Tufts had compliance procedures to determine whether the diagnosis codes that it submitted to CMS for use in CMS’s risk adjustment program were correct. These procedures included steps to identify (through computer algorithms) and review diagnosis codes that were at risk for being miscoded. The risk areas identified using the computer algorithms included acute stroke and acute myocardial infarction diagnoses. We note that these procedures resulted in Tufts taking corrective action for more than 1,200 instances of incorrect acute stroke diagnosis

codes that should not have been submitted to CMS.¹⁸ Tufts initiated its corrective actions for these diagnosis codes before we started our audit; however, Tufts informed us that this process is ongoing.

One of Tufts compliance procedures included audits of selected risk areas on claims that Tufts received from its providers to ensure that the diagnosis codes that Tufts submitted to CMS were supported in the medical records. For these audits, Tufts issued reports to the providers that indicated the diagnoses that were not supported and explanations as to why they were not supported. However, these compliance procedures were not designed to identify systematic errors or to target specific diagnosis codes. Therefore, Tufts' compliance procedures to prevent and detect incorrect high-risk diagnosis during our audit period could be improved.

Furthermore, Tufts' compliance procedures also included outreach to educate providers on accurately identifying, coding, and submitting diagnoses. The outreach included: (1) risk adjustment education to new providers, (2) opportunities that focused on ensuring diagnosis and suspected conditions were properly coded and submitted, and (3) coder education regarding identification of codes based on CMS HCC methodology.

Although Tufts had these compliance procedures in place, we identified additional high-risk claims and determined that 154 of the 212 sampled enrollee-years were not supported by the medical records; therefore, we believe Tufts' policies and procedures used to ensure compliance with the Federal requirements could be improved.

TUFTS RECEIVED NET OVERPAYMENTS

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. Based on our sample results, we estimated that Tufts received at least \$3,758,335 of net overpayments (\$3,466,463 for the statistically sampled high-risk groups plus \$291,872 for the potentially mis-keyed diagnosis group) in 2015 and 2016 (see Appendix C for Sample Results and Estimates).

RECOMMENDATIONS

We recommend that Tufts Health Plan:

- refund to the Federal Government the \$3,758,335 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

¹⁸ These 1,200 claims were not included in our sampling frame.

- continue to improve its existing compliance procedures to identify areas where improvements can be made to ensure 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.

TUFTS HEALTH PLAN COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Tufts did not concur with our findings and recommendations.

Tufts stated that we should not have included the errors associated with 5 enrollee-years in our calculation of total net overpayments because, according to Tufts, it had already submitted corrections to CMS. Tufts did not specifically comment on the errors associated with the other 154 enrollee-years. Tufts also stated that our sampling and review methodologies had a bias that was improperly skewed towards identifying overpayments. Further, Tufts stated that our report reflected misunderstandings of legal and regulatory requirements underlying the MA program and that our recommendations are inconsistent with mandates of the Social Security Act and with the Department of Health and Human Services (HHS) and CMS’s data accuracy and compliance requirements. Tufts requested that we update our report and withdraw our recommendations.

We reviewed Tufts’ comments and followed up with officials from Tufts regarding the 5 enrollee-years and, accordingly, revised our findings and our calculation of net overpayments. In addition, we did not consider the impact of the budget sequestration reduction in our draft report. After consideration of Tuft’s comments and budget sequestration, we reduced our first recommendation from \$4,013,034 to \$3,758,335 for our final report. We also revised the beginning of our third recommendation in recognition of Tufts’ past efforts (described below and in Appendix F) to improve its compliance program.

A summary of Tufts’ comments and our responses follows. Tufts’ comments appear in their entirety as Appendix F.

TUFTS DID NOT AGREE WITH THE SAMPLING AND REVIEW METHODOLOGIES THAT THE OFFICE OF INSPECTOR GENERAL USED TO IDENTIFY OVERPAYMENTS

Tufts Comments

Tufts stated that our sampling and review methodologies were “improperly skewed toward identifying overpayments.”

Specifically, Tufts stated that our sampling methodology:

- did not include a review of all diagnoses or records from the sampled enrollee years. Instead, our audit sample “targeted diagnoses OIG already suspected would not be supported by the underlying medical record” and
- excluded enrollees for whom no risk adjustment data was submitted to CMS and created an additional systematic bias toward identifying overpayments.

In addition, Tufts stated that our review methodology is different from CMS’s review methodology and does not account for the value of other supported diagnoses that are not included in the sample submission. Tufts noted that at “OIG’s request, [Tufts] submitted only one record to OIG for the majority of the sampled members and two records for a very small subset of those members.” Tufts also stated that our review methodology was not designed to capture potential unrelated and unsubmitted diagnoses that were supported by the medical records that Tufts provided.

Tufts stated that as a result of our sampling and review methodologies, “OIG’s actual and extrapolated repayment calculations are inflated, and its extrapolated repayment calculation is statistically unsupported.” Accordingly, Tufts contested our monetary recommendation and requested that we recalculate our repayment calculations to address these biases.

Office of Inspector General Response

We disagree with Tufts’ statements regarding our sampling methodology. Specifically, it was beyond the scope of our audit to identify: (1) all possible diagnosis codes that Tufts could have submitted on behalf of the sampled enrollee-years and (2) enrollees for whom Tufts did not submit any risk-adjusted diagnosis codes.

We agree with Tufts that our review methodology is different than CMS risk-adjusted data validation (RADV) review methodology. Although our approach for reviewing the medical records was generally consistent with the methodology used by CMS in its RADV audits, it did not mirror CMS’s approach in all aspects, nor did it have to. Our audits are intended to provide an independent assessment of HHS programs and operations in accordance with the Inspector General Act of 1978, 5 U.S.C. App.

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

records (up to four) to submit to us for review. We asked our independent medical review contractor to review all of the medical records that Tufts submitted to determine whether the documentation supported any diagnosis codes that mapped to the reviewed HCCs. In this regard, we considered instances in which the medical review contractor found support for a diagnosis that should have been used instead of the diagnosis that was submitted to CMS.

Accordingly, we believe that our sampling and review methodologies allowed us to calculate correctly the net overpayment amounts relevant to our objective. A valid estimate of net overpayments does not need to take into consideration all potential HCCs or underpayments within the audit period. Our estimate of net overpayments addresses only the portion of the payments related to the reviewed HCCs and does not extend to the HCCs that were beyond the scope of our audit. In accordance with our objective, and as detailed in Appendices B and C, we properly executed a statistically valid sampling methodology in that we defined our sampling frame (Tufts' enrollee-years 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 Tufts.

TUFTS DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S DECISION TO INCLUDE THE RESULTS OF 5 ENROLLEE-YEARS IN THE CALCULATION OF NET OVERPAYMENTS

Tufts Comments

Tufts disagreed with our decision to include the results of 5 enrollee-years in the calculation of net overpayments. For these enrollee-years, Tufts stated that its quality assurance process had identified these errors and that it had already submitted to CMS diagnosis code deletions in December 2018, March 2019, and July 2019: 2 enrollee-years for acute stroke, 1 enrollee-year for embolism, 1 enrollee-year for acute stroke and acute heart attack combination, and 1 enrollee-year for major depressive disorder.¹⁹ Tufts stated that the inclusion of these five overpayments inaccurately inflated our calculation of net overpayment amounts to refund to the Federal government.

Office of Inspector General Response

We agree with Tufts that we should not include the financial impact associated with these 5 enrollee-years in our net overpayment calculations. Before we selected our sample, we worked with Tufts to verify the accuracy of our sampling frame and to remove any enrollee-years for which Tufts had taken corrective action (diagnosis code deletions). Based on the information that Tufts provided, we removed approximately 1,200 enrollee-years from our sampling frame. However, Tufts did not inform us of the deletions associated with the 5 enrollee-years until

¹⁹ CMS uses diagnosis codes to determine HCCs and calculate payments to MA organizations. CMS pays MA organizations a higher payment if an enrollee has more HCCs. Consequently, the deletion of diagnoses may result in the removal of HCCs, which would result in a reduction in payments to MA organizations.

after we issued our draft report. Through subsequent discussions, Tufts demonstrated that it had initiated its review before we selected our sample. Accordingly, we have, for this final report, classified these 5 enrollee-years as non-errors in our sample results and net overpayment calculations.

As a result, we reduced the number of sampled enrollee-years in error from 159 (in our draft report) to 154, and removed the associated overpayments from our calculations for this final report.

TUFTS QUESTIONED THE QUALIFICATIONS OF THE INDEPENDENT MEDICAL REVIEW CONTRACTOR AND THE OFFICE OF INSPECTOR GENERAL’S MEDICAL REVIEW PROCESS

Tufts Comments

Tufts questioned the qualifications of our independent medical review contractor and our medical record review process. Specifically:

- Tufts stated that OIG should identify our independent medical review contractor so Tufts can assess: “(1) whether there is a conflict of interest, (2) the contractor’s credentials, coding policies, procedures, training, and (3) evaluations and audits of specific reviewers, including accuracy rate and inter-rater reliability scores.” Tufts further stated that “the methodology indicates that most records received two levels of review” and Tufts “should be able to evaluate the results at each level” which is a standard practice in CMS audits.
- In addition, Tufts stated that it was not “made aware of the coding or documentation standards used by the independent medical review contractor in its review.” Tufts requested that we update our report “to identify the specific coding and documentation standards that were used to evaluate the high-risk diagnoses, as required by relevant auditing standards.”

To this point, Tufts stated: “Even if the OIG identified the coding and documentation standards used during the review, the standards were not validly established.” Tufts also stated: “As used in the audit process, the coding and documentation standards essentially determine what is a valid risk adjustment payment and what is an ‘overpayment.’ In other words, the coding and documentation standards are, in effect, establishing a payment standard.” Tufts acknowledged CMS’s proposed rule that defines “the payment standard” for MA risk-adjustment payments, but maintained that, since CMS has not taken further action on the proposed rule since 2018, there is no payment standard until notice and comment rulemaking is complete.

- Lastly, Tufts questioned our use of a physician as a “tie-breaker” when the first- and second-level coders disagreed, stating that “the physician likely would not be limiting their analysis to issues of coding and documentation.”

Office of Inspector General Response

We disagree with Tufts comments about the qualifications of our independent medical review contractor and our medical record review process. It is not our practice to name our medical review contractor. The name of the contractor would not provide information about the contractor's qualifications beyond what we state in this audit report. Additionally, part of our audit process is to ensure that there are no conflicts of interest among the parties involved in the audit. Furthermore, during the course of our audit, we informed Tufts that our medical reviews were performed by professional coders credentialed by the American Health Information Management Association (AHIMA) and the American Association of Professional Coders (AAPC).²⁰ These coders were experienced in coding ICD-9-CM and ICD-10-CM diagnosis codes for hospital inpatient, outpatient, and physician medical records. We provided Tufts with the results of our contractor's determinations and the reasons for those determinations, including any coding and documentation standards that applied.

We disagree with Tufts that it was not "made aware of the coding or documentation standards used by the independent medical review contractor in its review." Our independent medical review contractor performed its review to determine whether the diagnoses in the sampled enrollees' medical records were coded according to the ICD Coding Guidelines. We provided Tufts with the procedures that the contractor followed to make its determinations (Appendix A).

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

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

Tufts Comments

Tufts stated that our estimated net overpayment amount is incorrect because it is not adjusted to ensure a payment principle known as "actuarial equivalence" was used to determine it.

Tufts stated that the "MA payment system is based on the requirement that CMS pay [MA organizations] an amount that is 'actuarially equivalent' to the expected costs that CMS would

²⁰ 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), CPC – Instructor, and Certified Risk Coder (CRC). RHITs have completed a 2-year degree program and have passed an AHIMA certification exam. AHIMA also credentials individuals with CCS and CCS-P certifications and the AAPC credentials both CPCs and CRCs.

have otherwise incurred had it provided required Medicare benefits directly to the [MA organizations'] enrollees.”²¹ In this regard, Tufts stated that “CMS developed the MA risk adjustment model using Fee-for-Service (FFS) claims data from the traditional Medicare program. The FFS claims data is unaudited and contains numerous errors.” Accordingly, CMS must, according to Tufts, account for these errors during an audit that determines “whether similar errors for MA enrollees resulted in an overpayment.” Tufts stated that to address this concern, “CMS said that it would first identify a ‘payment recovery amount’ based on the value of supported and unsupported HCCs identified during its review. Then ‘to determine the final payment recovery amount, CMS [would] apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount.’”²²

Tufts also stated that “CMS attempted to shift away from this principle in 2014 when it implemented a rule stating that [MA organizations] receive an ‘overpayment’ when they submit any diagnosis code . . . that is not sufficiently supported by underlying medical records, without adjusting for error rates in traditional Medicare data.”²³ This rule, according to Tufts, applied to occurrences that were not a part of CMS's RADV audits. According to Tufts, a recent court determination upheld CMS's position that an FFS Adjuster does not need to be applied to known errors that occur outside of a RADV audit.²⁴ Although Tufts expressed its disagreement with this decision, Tufts also stated that the same court held that “RADV audits, which are designed to require repayment for all unsupported diagnosis codes, would require a correction for actuarial equivalence.” Further, Tufts stated that CMS proposed another “rule in 2018 suggesting that diagnosis coding errors in unaudited traditional Medicare data do not systematically impact payments to [MA organizations].”²⁵ Tufts also noted that “CMS has taken no further action on this rule; it is not final and remains subject to the administrative rule-making process.”

Tufts asserted that without an FFS Adjuster to account for diagnosis coding errors, our estimated net overpayment amount is “both legally and actuarially unsound.” Tufts requested that we withdraw the repayment calculation until CMS issues an actuarially sound methodology, and “at that time, OIG should apply that actuarially sound methodology to this audit to calculate any repayment that might be due.”

²¹ 42 U.S.C. § 1395w-24(a)(5)(A), (a)(6)(A)(i)-(iii).

²² CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation for Contract-Level Audits* (Feb. 24, 2012).

²³ See 79 Fed. Reg. 29844, 29921 (May 23, 2014), implementing 42 CFR. § 422.326.

²⁴ See *UnitedHealthcare Inc. Co. v. Becerra*, 9 F.4th 868, (D.C. Cir. 2021).

²⁵ 83 Federal Register 54982, 55041 (Nov. 1, 2018).

Office of Inspector General Response

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

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

Tufts stated that we did not consider actuarial equivalence in our overpayment calculations. To this point, and with consideration of Tufts' comments, we recognize that CMS is responsible for making operational and program payment determinations for the MA program, including the application of any FFS Adjuster requirements. Moreover, CMS has not issued any requirements that compel us to reduce our net overpayment calculations.²⁶ If CMS deems it appropriate to apply an FFS Adjuster, it will adjust our overpayment finding by whatever amount it determines necessary. Thus, we believe that the steps we followed in this audit provide a reasonable basis for our findings and conclusions, including our calculation of net overpayments.²⁷

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

Tufts Comments

Tufts disagreed with the methodology that we used to calculate the estimated net overpayments. Specifically, Tufts stated that our use of a 90-percent confidence interval was not as robust as a 95-percent or 99-percent confidence interval. Tufts requested that we use the lower limit of a 99-percent confidence interval as CMS does for RADV audits.

²⁶ We note that in 2018, CMS proposed "not to include an FFS adjuster in any final RADV payment error methodology." (Proposed Rule at 83 Fed. Reg. 54982, 55041.)

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

Office of Inspector General Response

OIG is an independent oversight agency, and as a result we do not need to mirror CMS's estimation methodology. OIG 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 overpaid to Tufts for the enrollee-years and time period covered in our sampling frame. This approach, which is routinely used by HHS for recovery calculations,²⁸ results in a lower limit (the estimated overpayment amount to refund) that is designed to be less than the actual overpayment total 95 percent of the time. For this reason, we maintain that our use of the lower limit of the two-sided 90-percent confidence interval is valid.

TUFTS DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S RECOMMENDATION TO PERFORM ADDITIONAL REVIEWS BEFORE AND AFTER THE AUDIT PERIOD

Tufts Comments

Tufts disagreed with our second recommendation to perform additional reviews to determine whether similar instances of high-risk diagnoses occurred before or after the audit period and to refund any overpayments because, according to Tufts, "MA regulations do not require the sort of audits that OIG recommends and do not require data perfection."

Tufts stated that our report "appears to expect perfect data . . . which is inconsistent with CMS regulations." Tufts further stated that "subsection 422.504(l) requires [MA organizations] to attest to the accuracy of the data based on 'best knowledge, information and belief.'" In addition, Tufts stated that CMS included this limitation to recognize that MA organizations "cannot reasonably be expected to know that every piece of data is correct nor is that the standard that the OIG believes is reasonable to enforce." Lastly, Tufts stated that CMS said that "it would be unfair and unrealistic to hold" MA organizations "to a '100 percent accuracy' certification standard."

Tufts also stated that potentially unsupported diagnosis codes are not indicative of an overpayment. In addition, in regard to the identified mis-keyed diagnosis codes, Tufts stated that it would be unable to replicate our methodology because it does not have all the information needed, such as the "underlying algorithm," to identify potentially mis-keyed diagnoses similar to those within the scope of our audit.

²⁸ For example, HHS has used the two-sided 90-percent percent confidence level when calculating recoveries in both the Administration for Child and Families and Medicaid programs. See, for example, *New York State Department of Social Services*, DAB No. 1358, 13 (1992); and *Arizona Health Care Cost Containment System*, DAB No. 2981, 4-5 (2019). In addition, HHS contractors rely on the one-sided 90-percent confidence interval, which is less conservative than the two-sided interval, for recoveries arising from Medicare FFS overpayments. See, for example, *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); and *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 17-18 (E.D.N.Y. 2012).

Office of Inspector General Response

We do not agree with Tufts' interpretation of the Federal requirements. We also recognize that CMS applies a "good faith attestation" standard when MA organizations certify the great volume of data that they submit to CMS for use in the risk adjustment program. However, contrary to Tufts' assertions, we believe that our recommendation for Tufts 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 D)).

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

We believe the error rate identified in our audit demonstrates that Tufts 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 Tufts review whether similar instances of noncompliance related to high-risk diagnoses occurred before or after our audit period.

With regard to the algorithm for the mis-keyed diagnoses, during the course of our audit, we explained to Tufts officials in detail how we selected each target area, including the mis-keyed diagnoses. We also provided Tufts with additional information about how we identified potentially mis-keyed diagnosis codes. Therefore, Tufts has the information necessary to identify additional mis-keyed diagnosis codes similar to those we identified.

TUFTS DID NOT CONCUR WITH THE OFFICE OF INSPECTOR GENERAL'S RECOMMENDATION TO ENHANCE ITS EXISTING COMPLIANCE PROCEDURES

Tufts Comments

Tufts stated that our recommendation to enhance its existing compliance procedures was based on an incorrect belief that its compliance program was not always effective. In this regard, Tufts said that our draft report was "a surprising mischaracterization of [its] compliance procedures to review diagnosis code at risk for being miscoded."

Tufts noted that our review was limited to 2015 and 2016 dates of service and the compliance functions in place to monitor claims data for those years. Due to the limitation, Tufts stated that making recommendations related to its current compliance activities is beyond the scope of our audit.

In addition, Tufts stated that we made two misleading statements regarding its implementation of an effective compliance program. First, with regard to our statement that MA organizations must monitor the data that they receive from providers prior to submission to CMS, Tufts stated that “CMS gives [MA organizations] broad discretion to design their own compliance and risk adjustment data accuracy programs and has declined to require MA organizations to implement any specific oversight measures.” Second, with regard to our statement that MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS, Tufts said we failed to account for the “qualified attestation standard” that CMS explicitly adopted to ensure that the attestation is “not a legal trap.”²⁹

Tufts stated that it has a “comprehensive compliance program led by the Quality Assurance (QA) unit . . . to address and remediate potential instances of diagnosis coding error that may impact our submissions to CMS.”

“The QA program has consistently evolved and had operational enhancements in order to be compliant with federal and state requirements and guidance,” Tufts stated. “The most recent version of the QA program includes but is not limited to seven (7) algorithms (Breast Cancer, Colon Cancer, Prostate Cancer, Acute MI, Unstable Angina, Acute Stroke, Pathological/Traumatic Fractures, and Claims Validation) with a targeted review of 50,000 to 60,000 unique diagnosis codes per payment year.”

In addition to the use of algorithms, Tufts stated that it has undertaken significant efforts to ensure its provider network is also committed to an effective and comprehensive risk adjustment QA program, engaged a chart retrieval vendor to acquire the medical charts when Tufts does not already have internal access, and offers training to all medical providers and related staff in their network. Tufts stated that this training includes education and training materials on high risk conditions and a review of processes at provider organizations to ensure adherence to the coding guidelines.

Tufts reiterated that we found that its procedures resulted in the correction of more than 1,200 cases of inaccurate diagnosis codes before the audit. Tufts noted that its compliance policies have been examined multiple times by CMS. Tufts stated that its compliance procedures are already “strong and effective” and that its compliance program is “designed to comply with all

²⁹ The “qualified attestation standard” that Tufts’ referred to in its comments is CMS’s requirement of the MA organizations to attest to the completeness of the data and accuracy of the coding submitted for payment purposes (65 Fed. Reg. 40170, 40250 (June 29, 2000)).

relevant legal and regulatory requirements.”

In summary, Tufts stated that we did not identify any specific improvements that it should make to its existing compliance policies and procedures. Tufts requested that we withdraw our third recommendation.

Office of Inspector General Response

We acknowledge that Tufts has taken steps in recent years to improve its policies and procedures. However, based on the materiality of our findings—overpayments of at least \$3.7 million—we do not agree with Tufts that our assessment of its compliance program was unfounded.

Federal regulations at 42 CFR § 422.503(b) require MA organizations like Tufts to establish and implement an effective system for routine monitoring and the identification of compliance risks. This regulation further explains that a compliance system should consider both internal monitoring and external audits. Although we have not reviewed the effectiveness of the improvements that Tufts said it has made to its policies and procedures, we note Tufts’ statement that it made these changes to ensure the accuracy of its risk adjustment submissions to CMS. We also concluded that Tufts could make improvements. Specifically, the number of diagnosis codes that were not supported in the medical records (154 out of 212 enrollee-years or approximately 73 percent according to our findings (Appendix C)) demonstrates that Tufts’ compliance program could be improved. Thus, Tufts should consider the results of this audit to reduce the occurrence of similar errors in subsequent periods and to identify appropriate opportunities for improvement consistent with CMS requirements and expectations.

With respect to Tufts’ statements about its policies and procedures and our audit findings, we changed our description of Tufts’ policies and procedures for preventing, detecting, and correcting noncompliance with CMS’s program requirements from “not always effective” to “could be improved.” Further, we have revised our third recommendation for Tufts to “continue to improve” its policies and procedures.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid Tufts \$2,342,973,171 to provide coverage to its enrollees for 2015 and 2016. We identified a sampling frame of 2,704 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2014 and 2015 service years, for which Tufts received \$49,092,078 in payments from CMS for these enrollee-years for 2015 and 2016. We selected for audit 212 enrollee-years with payments totaling \$4,773,103.

The 212 enrollee-years included 30 acute stroke diagnoses, 30 acute heart attack diagnoses, 4 acute stroke and acute heart attack diagnoses combinations, 30 embolism diagnoses, 30 vascular claudication diagnoses, 30 major depressive disorder diagnoses, and 58 potentially mis-keyed diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$746,427 for our sample.

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

We performed audit work from November 2018 through January 2021.

METHODOLOGY

To accomplish our objective, we performed the following steps:

- We reviewed applicable Federal laws, regulations, and guidance.
- We discussed with CMS program officials the Federal requirements that MA organizations should follow when submitting diagnosis codes to CMS.
- We identified, through data mining and discussions with medical professionals at a Medicare administrative contractor, diagnosis codes and HCCs that were at high risk for noncompliance. We also identified the diagnosis codes that potentially should have been used for cases in which the high-risk diagnoses were miscoded.
- We consolidated the high-risk diagnosis codes into specific groups, which included:
 - 6 diagnosis codes for acute stroke,
 - 35 diagnosis codes for acute heart attack,
 - 57 diagnosis codes for embolism,

- 4 diagnosis codes for vascular claudication, and
- 28 diagnosis codes for major depressive disorder.
- We developed an analytical tool that identified 811 scenarios in which diagnosis codes that, when mis-keyed into an electronic claim because of a data transposition or other data entry error, could result in the assignment of an incorrect HCC to an enrollee's risk score. For each of the occurrences, the tool identified a potentially mis-keyed diagnosis code and the likely correct diagnosis code. Accordingly, we considered the potentially mis-keyed diagnosis codes to be high risk.
- We used CMS's systems to identify the enrollee-years on whose behalf providers documented the high-risk diagnosis codes. Specifically, we used extracts from CMS's:
 - Risk Adjustment Processing System (RAPS)³⁰ to identify enrollees who received high-risk diagnosis codes from a physician during the service years,
 - Risk Adjustment System (RAS)³¹ to identify enrollees who received an HCC for the high-risk diagnosis codes,
 - Medicare Advantage Prescription Drug (MARx)³² to identify the total Medicare payments that CMS calculated, before applying the budget sequestration reduction for Tufts for the payment years,
 - Prescription Drug Event (PDE)³³ to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.
- We interviewed Tufts officials to gain an understanding of: (1) the policies and procedures that Tufts followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Tufts' monitoring of those diagnosis codes to identify and detect noncompliance with Federal requirements.
- We selected for audit a sample of 212 enrollee-years that included: (1) a stratified random sample of 154 enrollee-years and (2) a nonstatistical sample of 58 enrollee-years.

³⁰ MA organizations use the RAPS to submit diagnosis codes to CMS.

³¹ The RAS identifies the HCCs that CMS factors into each enrollee's risk score calculation.

³² The MARx identifies the payments made to MA organizations.

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

- We used an independent medical review contractor to perform a coding review for the 212 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.
- 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
 - the payment that CMS should have made for each enrollee-year.
- We estimated the total net overpayment made to Tufts during the audit period.
- We discussed the results of our audit with Tufts officials.

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

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

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

We presented the data for these enrollees to Tufts 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 Tufts. After we performed these steps, our finalized sampling frame consisted of 2,646 enrollee-years.

SAMPLE UNIT

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

SAMPLE DESIGN

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

- an acute stroke diagnosis (which maps to the HCC Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim (289 enrollee-years),
- a diagnosis that mapped to an acute heart attack HCC on only one physician claim but did not have that diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician claim (873 enrollee-years),
- an acute stroke diagnosis and a diagnosis that mapped to an acute heart attack HCC in the same year and met the criteria mentioned in the previous two bullets (4 enrollee-years),
- a diagnosis that mapped to an embolism HCC but for which an anticoagulant medication was not dispensed (346 enrollee-years),
- a vascular claudication diagnosis (which maps to HCC for Vascular Disease) but for which medication was dispensed for neurogenic claudication (357 enrollee-years), or

- a major depressive disorder diagnosis (which maps to the HCC entitled Major Depressive, Bipolar, and Paranoid Disorders) on one claim during the service year but for which antidepressant medication was not dispensed (777 enrollee-years).

The specific strata are shown below in Table 3.

Table 3: Sample Design for Audited High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee- Years	CMS Payment for HCCs in Audited High- Risk Groups*	Sample Size
1 – Acute Stroke	289	\$722,953	30
2 – Acute Heart Attack	873	1,939,155	30
3 – Acute Stroke / Acute Heart Attack Combination	4	15,298	4
4 – Embolism	346	1,064,368	30
5 – Vascular Claudication	357	860,208	30
6 – Major Depressive Disorder	777	2,146,387	30
Total – First Six Strata	2,646	\$6,748,369	154

*Rounded to the nearest whole dollar amount.

After we selected the 154 enrollee-years, we identified an additional group of 58 enrollee-years, (for a total of 212 sampled enrollee-years) that represented individuals who received 1 of the 811 potentially mis-keyed diagnosis codes (which mapped to a potentially unvalidated HCC) and multiple instances of diagnosis codes that were likely keyed correctly.³⁴

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the items in each stratum in the stratified sampling frame. We generated the random numbers for our sample according to our sample design, and we then selected the corresponding frame items for review. We also non-statistically selected 58 items from the potentially mis-keyed group.

³⁴ The entire group of 58 enrollee-years was reviewed.

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to estimate the total amount of net overpayments to Tufts at the lower limit of the two-sided 90-percent confidence interval (Appendix C). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time. We also identified all net overpayments in the sample of 58 items for the potentially mis-keyed group. The net overpayment for the non-statistical sample was added to the estimate for the statistical sample to obtain the total reported net overpayment amount.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Results

Audited High-Risk Groups	Frame Size	CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)*	Sample Size	CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With Incorrect Diagnosis Codes	Net Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)*
1 – Acute Stroke	289	\$722,953	30	\$80,340	24	\$61,047
2 – Acute Heart Attack	873	1,939,155	30	67,588	27	38,009
3- Acute Stroke/ Acute Heart Attack Combination	4	15,298	4	15,298	3	5,659
4 – Embolism	346	1,064,368	30	93,944	23	74,552
5 – Vascular Claudication	357	860,208	30	69,029	8	17,781
6 – Major Depressive Disorder	777	2,146,387	30	86,858	16	47,165
Totals for Statistical Sample	2,646	\$6,748,369	154	\$413,056	101	\$244,213

7 – Potentially Mis-keyed Diagnoses	58	\$333,371	58	\$333,371	53	\$291,872
Totals – All Strata	2,704	\$7,081,740	212	\$746,427	154	\$536,085

*Rounded to the nearest whole dollar amount

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

	Net Overpayment Estimated from the Statistical Sample	Overpayment for Potentially Mis-keyed Diagnosis Group	Total Estimated Net Overpayments
Point estimate	\$3,992,794	\$291,872	\$4,284,666
Lower limit	\$3,466,463	\$291,872	\$3,758,335
Upper limit	\$4,519,124	\$291,872	\$4,810,996

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

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

Any entity seeking to contract as an MA organization must

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

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

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

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

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

APPENDIX E: DETAILS OF POTENTIALLY MIS-KEYED DIAGNOSIS CODES

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

Number of Enrollee -Years	One Diagnosis for a Condition (Determined to be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment*
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
7	482.0	Pneumonia due to klebsiella pneumoniae	Aspiration and specified bacterial pneumonias	428.0	Congestive heart failure, unspecified	\$38,640
6	205.00	Acute myeloid leukemia, without mention of having achieved remission	Metastatic cancer and acute leukemia	250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled	117,673
6	441.01	Dissection of aorta, thoracic	Vascular disease with complications	414.01	Coronary atherosclerosis of native coronary artery	17,849
4	441.00	Dissection of aorta, unspecified site	Vascular disease with complications	414.00	Coronary atherosclerosis of unspecified type of vessel, native or graft	5,538
3	714.9	Unspecified inflammatory polyarthropathy	Rheumatoid arthritis and inflammatory connective tissue disease	174.9	Malignant neoplasm of breast (female), unspecified	6,569
3	124.9	Acute ischemic heart disease, unspecified	Unstable angina and other acute ischemic heart disease	142.9	Cardiomyopathy, unspecified	6,691
2	205.02	Acute myeloid leukemia, in relapse	Metastatic cancer and acute leukemia	250.02	Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled	32,040

Number of Enrollee -Years	One Diagnosis for a Condition (Determined to be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment*
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
2	249.20	Secondary diabetes mellitus with hyperosmolarity, not stated as uncontrolled, or unspecified	Diabetes with acute complications	294.20	Dementia, unspecified, without behavioral disturbance	6,855
2	250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled	Diabetes with acute complications	205.10	Chronic myeloid leukemia, without mention of having achieved remission	6,306
2	E32.9	Disease of thymus, unspecified	Other significant endocrine and metabolic disorders	F32.9	Major depressive disorder, single episode, unspecified	4,515
2	227.4	Benign neoplasm of pineal gland	Breast, prostate, colorectal and other cancers and tumors (Version 12 model) and Breast, prostate, and other cancers and tumors (Version 22 model)	272.4	Other and unspecified hyperlipidemia	2,832
2	174.9	Malignant neoplasm of breast (female), unspecified	Breast, prostate, colorectal and other cancers and tumors (Version 12 model) and Breast, prostate, and other cancers and tumors (Version 22 model)	714.9	Unspecified inflammatory polyarthropathy	2,368

Number of Enrollee -Years	One Diagnosis for a Condition (Determined to be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment*
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
1	205.20	Subacute myeloid leukemia, without mention of having achieved remission	Lung, upper digestive tract, and other severe cancers (Version 12 model) and Lung and other severe cancers (Version 22 model)	250.20	Diabetes with hyperosmolarity, type II or unspecified type, not stated as uncontrolled	8,291
1	200.60	Anaplastic large cell lymphoma, unspecified site, extranodal and solid organ sites	Lymphatic, head and neck, brain, and other major cancers (Version 12 model) and Lymphoma and other cancers (Version 22 model)	250.60	Diabetes with neurological manifestations, type II or unspecified type, not stated as uncontrolled	6,286
1	482.42	Methicillin resistant pneumonia due to Staphylococcus aureus	Aspiration and specified bacterial pneumonias	428.42	Chronic combined systolic and diastolic heart failure	6,234
1	820.8	Closed fracture of unspecified part of neck of femur	Hip fracture/dislocation	802.8	Closed fracture of other facial bones	3,988
1	433.01	Occlusion and stenosis of basilar artery with cerebral infarction	Ischemic or unspecified stroke	433.10	Occlusion and stenosis of carotid artery without mention of cerebral infarction	3,534
1	250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled	Diabetes without complication	205.00	Acute myeloid leukemia, without mention of having achieved remission	3,413
1	428.41	Acute combined systolic and diastolic heart failure	Congestive heart failure	482.41	Methicillin susceptible pneumonia due to staphylococcus aureus	3,204

Number of Enrollee -Years	One Diagnosis for a Condition (Determined to be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment*
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
1	200.00	Reticulosarcoma, unspecified site, extranodal and solid organ sites	Lymphatic, head and neck, brain, and other major cancers (Version 12 model) and Lymphoma and other cancers (Version 22 model)	250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled	2,812
1	441.02	Dissection of aorta, abdominal	Vascular disease with complications	414.02	Coronary atherosclerosis of autologous vein bypass graft	2,098
1	482.32	Pneumonia due to streptococcus, group B	Pneumococcal pneumonia, emphysema, lung abscess	428.32	Chronic diastolic heart failure	1,852
1	482.30	Pneumonia due to streptococcus, unspecified	Pneumococcal pneumonia, emphysema, lung abscess	428.30	Diastolic heart failure, unspecified	1,818
1	F20.81	Schizophreniform disorder	Schizophrenia	F02.81	Dementia in other diseases classified elsewhere with behavioral disturbance	466
53						\$291,872

*Rounded to the nearest whole dollar amount

September 16, 2021

U.S. Department of Health & Human Services
Office of Inspector General
Office of Audit Services
15 New Sudbury Street
JFK Federal Building - Room 2425
Boston, MA 02203

Attn: Pei Sun, Assistant Regional Inspector General for Audit Services
David Lamir, Regional Inspector General for Audit Services

Re: Response to Draft Report Number: A-01-19-00500

Tufts Associated Health Maintenance Organization, Inc. (“THP”) appreciates the opportunity to respond to the Draft Report provided by the U.S. Department of Health and Human Services (“HHS”) Office of Inspector General (“OIG”) in connection with OIG’s Medicare Advantage (“MA”) risk adjustment data validation (“RADV”) audit of specific diagnosis codes submitted to CMS under contract H2256 (the “Draft Report”). Through contract H2256, THP arranges for the provision of high quality healthcare services to beneficiaries in Massachusetts. THP is one of the highest performing MA contracts in the MA program, routinely achieving 5 star quality ratings. THP is one of only two plans in the country to receive this rating for six years in a row.

For the reasons described below, THP respectfully requests that OIG update its Draft Report and withdraw its recommendations that THP (I) repay an extrapolated amount of \$4,013,034, (II) conduct additional audits beyond OIG’s sample and make repayments based on those audits, and (III) examine its existing compliance procedures. As written, these recommendations are inconsistent with the Social Security Act’s (“SSA’s”) actuarial equivalence mandate and with HHS and Centers for Medicare & Medicaid Services (“CMS”) data accuracy and compliance requirements.

I. THP Does Not Concur with OIG’s Estimated and Extrapolated Repayment Amounts and Respectfully Requests OIG Recalculate its Estimate to Remove Underlying Biases and Ensure Actuarial Equivalence

THP respectfully requests OIG withdraw its recommended repayment amount and recalculate it, when possible, to account for (a) bias stemming from an audit sampling and review methodology that is improperly skewed toward identifying “overpayments”; (b) inclusion of diagnosis that had previously been deleted by THP in the ordinary course of its comprehensive Quality Assurance program; (c) a review methodology that is needlessly opaque; (d) the statutorily required actuarial equivalence between expected costs in MA and traditional Medicare; (e) statistical bias from an insufficiently robust confidence

interval inconsistent with CMS RADV audits; and (f) the long-standing principle that MA organizations (“MAOs”) are not required to have perfect data.

a. OIG’s Sampling and Review Methodology was Improperly Skewed Towards Identifying “Overpayments”

THP disagrees with OIG’s recommended repayment amount because OIG’s sampling and review methodologies were designed to focus on and identify “overpayments,” without review or acknowledgement of all diagnoses or records from the sampled enrollee years. As intended, OIG’s audit sample targeted diagnoses OIG already suspected would not be supported by the underlying medical record and did not involve a review of all diagnoses or records from the sampled years for the enrollees included in the audit sample. Additionally, THP was required to “self-audit” the sampled records. THP was then required to identify specific records and specific page numbers as evidentiary support, with the OIG auditing only THP findings. This review methodology is in contrast to CMS’s review methodology and does not account for the value of other supported diagnosis that are not included in the sample submission. These methodologies, as described in greater detail below, improperly skewed OIG’s recommended repayment amount.

i. Sampling Methodology

The data mining techniques used by OIG to identify its audit sample, by default, skew any potential extrapolation towards being over-inclusive by focusing only on high-risk diagnoses. Such a sampling methodology should not be used to extrapolate because it ignores all other diagnoses THP submitted to CMS for risk adjustment purposes. On top of this, OIG’s audit population overall was skewed because it excluded enrollees for whom no risk adjustment data was submitted to CMS. By doing this, OIG ignored the fact that there may be supported diagnoses not submitted to CMS for those enrollees (i.e., “underpayments”) and created an additional systematic bias toward identifying “overpayments.”

ii. Review Methodology

OIG’s review methodology was not designed to include, identify, or acknowledge potential unrelated diagnoses not previously submitted to CMS but were supported by the medical records OIG reviewed. This is despite the fact that OIG recognizes in the Draft Report that “correctly coded diagnoses that MA organizations do not submit to CMS may lead to . . . (underpayments).”^{1/}

For example, at OIG’s request, THP submitted only one record to OIG for the majority of the sampled members and two records for a very small subset of those members. OIG’s review therefore, by design, included far fewer than the full set of records for each enrollee in the audited years. In some cases where OIG found a diagnosis was not

^{1/} Draft Report at 4.

supported but concluded that a lesser, related diagnosis was supported, OIG included the confirmed diagnosis in its calculation. And in some circumstances in the “potentially mis-keyed diagnosis” category, OIG reviewed and confirmed additional, unrelated diagnoses that were not previously submitted to CMS. But, OIG only included the diagnosis it already suspected was originally miscoded; OIG did not review these records and add all supported diagnoses. And even beyond this category, there was only one instance in which OIG accounted for an additional, related diagnosis supported by the medical record.^{2/}

1. *OIG’s review methodology is not focused on validating diagnosis codes and instead incorporates clinical decision making.*

Similar to the issues related to the scope of OIG’s sampling methodology, it appears that OIG’s independent medical review contractor went beyond assessing coding and questioned the clinical validity of providers’ diagnostic statements. Specifically, the audit methodology required a physician serve as the “tie-breaker” when the first and second level coders disagreed, and, the physician’s decision was to be the final determination any time one of the coders asked for assistance.^{3/} This emphasis on a physician’s determination indicates that the physician likely would not be limiting their analysis to issues of coding and documentation and THP believes this would ultimately skew results towards identifying overpayments.

* * *

To conduct this audit, OIG collected and reviewed certain medical records, based on prescription data obtained from CMS systems, and narrowed its review to high-risk diagnoses. OIG designed the audit to not look for unreported unrelated diagnoses, which skewed any calculation of a potential “overpayment” and related extrapolation. Because OIG’s sampling was skewed toward identifying “overpayments” and because OIG’s review process was structured to avoid considering additional prescription information, diagnoses that had not been previously reported for those enrollees, or that missing records may support the diagnosis under review, OIG’s actual and extrapolated repayment calculations are inflated and its extrapolated repayment calculation is statistically unsupported. THP respectfully requests that OIG revise its repayment calculations to address these biases.

b. OIG Failed to Account for Diagnosis Code Deletions Proactively Submitted Through THP’s Quality Assurance Program in its Estimated and Extrapolated Repayment Amounts.

^{2/} Draft Report at 10.

^{3/} Draft Report at 18.

OIG's estimated and extrapolated repayment should also be recalculated to exclude five (5) diagnosis deletions that THP has already submitted to CMS through its robust Quality Assurance processes, further described below. In December 2018, March 2019, and July 2019, in adhering to CMS requirements, THP submitted diagnosis code deletions for one (1) Embolism, two (2) Acute Stroke, one (1) AS-MI and one (1) Major Depressive Disorder. Inclusion in the alleged overpayment and extrapolation inaccurately inflates the OIG's recommended repayment amount.

c. In Addition to Being Skewed Towards Identifying “Overpayments,” OIG’s Review Methodology is Needlessly Opaque and OIG Should Update its Draft Report to Include Additional Information Regarding its Medical Record Review.

THP respectfully requests that OIG provide additional information regarding its review, including the (i) independent medical review contractor and (ii) coding and documentation standards applied during the review.

i. OIG did not identify its independent medical review contractor or provide their credentials.

OIG did not provide any information regarding its independent medical review contractor. Given the importance of OIG's audit and OIG's broad findings and recommendations, it is critical to identify and establish the credentials of the reviewers conducting the audit. OIG should identify its independent medical review contractor so that THP knows who conducted the review and can assess (1) whether there is a conflict of interest, (2) the contractor's credentials, coding policies, procedures, training, and (3) evaluations and audits of specific reviewers, including accuracy rate and inter-rater reliability scores.

Further to this point, the Draft Report only includes the “final” determination by the medical record review contractor. However, the methodology indicates that most records received two levels of review. Given the subjective nature of coding determinations, THP should be able to evaluate the results at each level. Similarly, THP should be made aware of any inter-rater reliability reviews, which is a standard practice in CMS audits, and be able to evaluate the results of such reviews. THP respectfully requests OIG update its Draft Report to include this information about its independent medical review contractor.

ii. OIG did not adequately identify the coding and documentation standards applied during the medical record review.

In addition, at no point during the audit was THP made aware of the coding or documentation standards used by the independent medical record review contractor in its review. Codes are expected to be submitted in accordance with ICD-10 coding guidelines, but because of the lack of specificity, CMS has directed providers and plans to rely on

coding and documentation guidance from industry experts such as the American Health Information Management Association (AHIMA), the American Medical Association (AMA), and the American Academy of Professional Coders (AAPC). However, the scope of these resources is quite broad and they are not always consistent with one another. THP respectfully requests OIG update its Draft Report to identify the specific coding and documentation standards that were used to evaluate the high-risk diagnoses, as required by relevant auditing standards.

Even if OIG identified the coding and documentation standards used during the review, the standards were not validly established. As used in the audit process, the coding and documentation standards essentially determine what is a valid risk adjustment payment and what is an “overpayment.” In other words, the coding and documentation standards are, in effect, establishing a payment standard. CMS indicated in a recent proposed rule, discussed in greater detail below, that RADV coding and documentation standards define “the payment standard” for MA risk adjustment payments.^{4/} However, CMS has not taken further action on this proposed rule since 2018, and as such, there is no standard until notice and comment rulemaking is complete.^{5/}

* * *

Considering these points, THP believes information regarding the independent medical review contractor and the coding and documentation standards applied during the review is critical to the overall analysis and assessment of OIG’s audit. THP respectfully requests OIG update its Draft Report to include this information.

d. OIG’s Estimated and Extrapolated Repayment Amount is Incorrect Because it is Not Adjusted to Ensure Actuarial Equivalence

The MA payment system is based on the requirement that CMS pay MAOs an amount that is “actuarially equivalent” to the expected cost that CMS would have otherwise incurred had it provided required Medicare benefits directly to the MAOs’ enrollees.^{6/}

^{4/} See 83 Fed. Reg. 54928, 55041 (Nov. 1, 2018) (“If a payment has been made to an [MAO] based on a diagnosis code that is not supported by medical record documentation, that entire payment is in error and should be recovered in full, because the payment standard has not been met.”).

^{5/} For reference, the Medicare Act requires that any “policy that “establishes or changes a substantive legal standard governing ... payment for services” must be established through notice and comment rulemaking. See 42 U.S.C. § 1395hh(a)(2). The Supreme Court has explained that this obligation is likely to encompass policies contained only in the Medicare manuals and is broader than the one set out in the APA. See *Azar v. Allina Health Services*, 139 S. Ct. 1804, 1814 (2019). The coding and documentation standards set by private parties are not even contained in the Medicare manuals. The HHS Office of General Counsel further advised that, when non-regulatory guidance “set[s] forth payment rules that are not closely tied to statutory or regulatory standards, the government generally cannot use violations of that guidance in enforcement actions, because ... it was not validly issued.” Memorandum from Kelly M. Cleary, *Impact of Allina on Medicare Payment Rules*, 2 (Oct. 31, 2019).

^{6/} 42 U.S.C. § 1395w-24(a)(5)(A), (a)(6)(A)(i)-(iii).

CMS does this by making risk-adjusted payments to MAOs that are based on actuarially sound calculations of the expected cost of providing traditional Medicare benefits to enrollees with differing health status.^{7/}

CMS developed the MA risk adjustment model using Fee-for-Service (“FFS”) claims data from the traditional Medicare program. The FFS claims data is unaudited and contains numerous errors that CMS must account for when determining whether similar errors for MA enrollees resulted in an overpayment. In 2012, CMS stated that it would address this concern via its methodology for calculating recovery amounts for unsupported HCCs identified during its RADV audits. CMS said that it would first identify a “payment recovery amount” based on the value of supported and unsupported HCCs identified during its review.^{8/} Then, “to determine the final payment recovery amount, CMS [would] apply a Fee-for-Service Adjuster (“FFS Adjuster”) amount as an offset to the preliminary recovery amount.” The FFS Adjuster would be based “on a RADV-like review of records submitted to support [traditional Medicare] claims data.”^{9/}

CMS attempted to shift away from this principle in 2014 when it implemented a rule stating that MAOs receive an “overpayment” when they submit any diagnosis code to CMS that is not sufficiently supported by underlying medical records, without adjusting for error rates in traditional Medicare data.^{10/} This rule was struck down when a federal district court found that the rule violated the actuarial equivalence mandate by defining “overpayment” as the payment of funds to MAOs based on unsupported diagnosis codes without applying a FFS Adjuster or other mechanism to maintain actuarial equivalence.^{11/} However, the district court’s ruling was recently partially overturned by the U.S. Court of Appeals for the D.C. Circuit when the Circuit found that actuarial equivalence does not apply to the overpayment rule and distinguished the overpayment rule from RADV audits.^{12/} The Circuit held that the overpayment rule applies to a diagnosis that an MAO knows lacks support in the beneficiary’s medical record and as such, does not require a

^{7/} 42 U.S.C. § 1395w-23(b)(4)(C), (D).

^{8/} CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation for Contract-Level Audits*, at 3–4 (Feb. 24, 2012).

^{9/} *Id.*

^{10/} See 79 Fed. Reg. 29844, 29921 (May 23, 2014), implementing 42 C.F.R. § 422.326.

^{11/} *UnitedHealthcare Ins. Co. v. Azar II*, 330 F. Supp. 3d 173, 187–90 (D.D.C. 2018). The court concluded that by measuring overpayments without adjusting for error rates in traditional Medicare, “The consequence is inevitable: while CMS pays for all diagnostic codes, erroneous or not, submitted to traditional Medicare, it will pay less for Medicare Advantage coverage because essentially no errors would be reimbursed.” *Id.* at 187. This position was reaffirmed on January 27, 2020 when the same court denied the government’s request to reconsider the court’s prior holding. *Azar*, Case No. 16-cv-157 (RMC), 2020 WL 417867 (D.D.C. Jan. 27, 2020).

^{12/} See *UnitedHealthcare Inc. Co. v. Becerra*, No. 18-5326, 2021, U.S. App. LEXIS 24241 (D.C. Cir. Aug. 13, 2021).

FFS adjuster or other correction.^{13/} On the other hand, RADV audits, which are designed to require repayment for all unsupported diagnosis codes, would require a correction for actuarial equivalence. While THP agrees with the circuit court’s statements regarding RADV audits, THP does not agree with the decision regarding the overpayment rule because actuarial equivalence in the Medicare Advantage risk adjustment system is statutorily required and cannot be achieved or maintained without it applying to all payment contexts within the risk adjustment system.

Amidst this litigation, CMS issued a proposed rule in 2018 suggesting that diagnosis coding errors in unaudited traditional Medicare data do not systematically impact payments to MAOs.^{14/} Many MAOs and numerous other parties, including actuarial and statistical experts, submitted comments to CMS explaining that the 2018 proposal does not satisfy the actuarial equivalence requirement. CMS has taken no further action on this rule; it is not final and remains subject to the administrative rule-making process.

The actuarial equivalence requirement extends to OIG’s estimation and extrapolation of a potential “overpayment” amount in this audit. OIG did not apply a FFS Adjuster to account for errors in the data used to create the risk adjustment payment model. The lack of FFS Adjuster violates important principles of administrative law, in particular the requirement for notice and comment rulemaking. It also would mark a departure from OIG’s past audit practices. In prior contract-level RADV audits, OIG acknowledged that the actuarial equivalence requirement made it inappropriate to estimate an extrapolated audit liability in the absence of a FFS Adjuster:

Although an analysis to determine the potential impact of error rates inherent in FFS data on MA payments was beyond the scope of our audit, we acknowledge that CMS is studying this issue and its potential impact on audits of [MAOs]. Therefore, because of the potential impact of these error rates on the CMS model that we used to recalculate MA payments for the beneficiaries in our sample, we (1) modified one recommendation to have [the MAO] refund only the overpayments identified for the sampled beneficiaries rather than refund the estimated overpayments and (2) added a recommendation that [the MAO] work with CMS to determine the correct contract-level adjustments for the estimated overpayments.^{15/}

* * *

Considering this history, it is not possible for OIG to determine whether THP has been overpaid without first establishing an actuarially sound overpayment methodology

^{13/} See *id.* at 4 and 48 (D.C. Cir. Aug. 13, 2021).

^{14/} 83 Fed. Reg. 54982, 55041 (Nov. 1, 2018).

^{15/} OIG, Risk Adjustment Data Validation of Payments Made to PacifiCare of California for Calendar Year 2007 (Contract Number H0543), A-09-09-00045, ii-iii (Nov. 2012).

that takes into account diagnosis coding errors in the FFS data. As a result, OIG’s estimated and extrapolated repayment amount is both legally and actuarially unsound. THP respectfully requests that OIG withdraw its repayment calculation until such time as CMS issues an actuarially sound methodology that includes a FFS Adjuster. At that time, OIG should apply that actuarially sound methodology to this audit to calculate any repayment that might be due.

e. OIG’s Extrapolated Repayment Amount Relies on a Confidence Interval that is Too Conservative and Inconsistent with CMS RADV Audit Practice

OIG acknowledged it was taking a conservative position by using the lower limit of a two-sided 90-percent confidence interval to calculate the extrapolated repayment amount, rather than the statistically valid and more robust practice of using the lower limit of a 95-percent or 99-percent confidence interval.^{16/} OIG provides no explanation for its decision to do so, which seem unusual because CMS uses the lower limit of a 99-percent confidence interval when calculating extrapolated repayment amounts for its RADV audits. THP respectfully requests that OIG recalculate the extrapolated “overpayment” amount using the lower bound of the more statistically robust 99-percent confidence interval, consistent with CMS practice for RADV audits.

f. OIG Should Revise its Draft Report to Recognize That MAOs Are Not Required to Have Perfect Data.

OIG’s Draft Report appears to expect perfect data from THP, which is inconsistent with CMS regulations. For example, the Draft Report cites 42 C.F.R. § 422.504(l) stating that MAOs “are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS.”^{17/} However, subsection 422.504(l) requires MAOs to attest to the accuracy of the data based on “best knowledge, information and belief.” CMS included this limitation to ensure that the attestation is “not a legal trap”^{18/} and “in recognition of the fact that [MAOs] cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that...the OIG...believe[s] is reasonable to enforce.”^{19/} CMS further stated that “it would be unfair and unrealistic to hold [MAOs] to a ‘100 percent accuracy’ certification standard.”^{20/}

A perfection standard is also inconsistent with the “actuarial equivalence” requirement as we discussed above. THP respectfully requests OIG revise its Draft Report

^{16/} Draft Report at 7.

^{17/} Draft Report at 7.

^{18/} 65 Fed. Reg. 40170, 40250 (June 29, 2000).

^{19/} *Id.* at 40268.

^{20/} *Id.*

to recognize that MAOs are not required to have perfect data and that not all potentially unsupported diagnosis correlate to an overpayment.

II. THP Does Not Concur With OIG’s Recommendation to Conduct Additional Auditing Related to the High-Risk Diagnoses Included in OIG’s Audit and Requests OIG Withdraw its Recommendation

OIG recommends that THP “identify, for the high-risk diagnoses included in [the Draft Report], similar instances of noncompliance that occurred before or after [the] audit period and refund any resulting overpayments to the Federal Government[.]”^{21/} However, MA regulations do not require the sort of audits that OIG recommends and do not require data perfection. By making this recommendation, OIG is holding MAOs to standards that are unknown, vague, and nonexistent.

Further, as discussed above, potentially unsupported diagnosis codes are not, by default, reflective of an overpayment. An overpayment based on the audit OIG recommends THP undertake can only be calculated by applying a FFS Adjuster to ensure actuarial equivalence. Not to mention that THP does not have the information needed (i.e., the underlying algorithm) to identify “potentially mis-keyed diagnoses” similar to those within the scope of OIG’s audit.

For these reasons, THP respectfully requests OIG withdraw its recommendation for THP to conduct additional audits related to the high-risk diagnoses targeted by OIG’s audit.

III. THP Does Not Concur with OIG’s Recommendation to Examine Existing Compliance Procedures and Requests OIG Withdraw its Recommendation

OIG recommends that THP “examine its existing compliance policies and procedures to identify areas where improvements can be made to ensure diagnosis codes that are at high risk for being miscoded comply with Federal requirements...and that the necessary steps to enhance those procedures.”^{22/} This recommendation is based on OIG’s incorrect belief that even though THP “had compliance procedures to determine whether the diagnosis codes that it submitted to CMS for use in CMS’s risk adjustment program were correct,” the policies and procedures “were not always effective for high-risk diagnosis codes.”^{23/} The Draft Report is a surprising mischaracterization of THP’s compliance procedures to review diagnosis codes at risk for being miscoded. Especially in light of OIG’s note that “these procedures resulted in THP taking correction action for more than 1,200 instances of incorrect acute stroke diagnosis codes that should not have

^{21/} Draft Report at 14.

^{22/} Draft Report at 15.

^{23/} Draft Report at 13 – 14.

been submitted to CMS.”^{24/} And further, that these corrective actions were initiated prior to the audit.

It is also noteworthy that THP’s compliance policies and procedures have been repeatedly examined by CMS. THP participated in CMS Contract 2010 RADV (for 2006 Year-of-Service and Plan Year 2007), Contract 2013 RADV (2012 Year-of-Service and Plan Year 2013) and Contract 2014 RADV (2013 Year-of-Service and Plan Year 2014).

THP respectfully requests that OIG withdraw its recommendation that THP examine its existing compliance procedures in recognition of THP’ strong and effective compliance procedures that are already in place.

a. THP Has a Strong and Effective Compliance Program and the OIG should withdraw its Recommendation.

THP has a strong, robust, and effective compliance program that is designed to comply with all relevant legal and regulatory requirements. OIG’s audit was limited to 2015 and 2016 dates of service and the compliance functions in place to monitor claims data for those years. Thus, there is no basis for findings related to THP’ current compliance program. It is beyond the scope of OIG’s audit to make recommendations related to THP’ current compliance activities.

The Draft Report cites 42 C.F.R. § 422.503(b)(vi), which requires organizations to adopt an “effective” compliance program. But, OIG has “recognize[d that] the implementation of an effective compliance program may not entirely eliminate fraud, abuse and waste from an organization.”^{25/}

OIG’s Draft Report makes two potentially misleading statements in this respect.^{26/} First, the Draft Report states that “[f]ederal regulations state that [MAOs] must monitor the data that they receive from providers and submit to CMS.”^{27/} However, this statement is incomplete. CMS gives MAOs broad discretion to design their own compliance and risk adjustment data accuracy programs and has declined to require MAOs to implement any specific oversight measures. Second, the Draft Report also states that federal regulations “state that [MAOs] are responsible for the accuracy, completeness, and truthfulness of the

^{24/} Draft Report at 13.

^{25/} 64 Fed. Reg. 61894, 61895 (Nov. 15, 1999).

^{26/} 64 Fed. Reg. at 61900. The Draft Report also appears to suggest that perfection is required by 42 C.F.R. § 422.310(d)(1), which states that MA organizations “must submit data that conform to CMS’ requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards.” However, 310(d)(1) does not establish or reference any standards that require 100 percent accuracy in order for a compliance program to be effective.

^{27/} Draft Report at 8.

data submitted to CMS for payment purposes.”^{28/} This statement is again incomplete because it fails to account for the qualified attestation standard that CMS explicitly adopted.

Relying on these misleading broad characterizations of CMS regulations, OIG’s recommendation expands MA compliance program requirements. CMS is undoubtedly aware of industry-wide trends related to the high-risk diagnoses audited by OIG. Yet CMS has not opted to take any action to implement regulations or additional requirements, let alone the broad recommendations OIG makes in its Draft Report. Because of these reasons, THP respectfully requests that OIG withdraw its recommendation that THP examine existing compliance procedures as it is inconsistent with existing MA guidance.

THP has a comprehensive compliance program led by the Quality Assurance (QA) unit within the Enterprise Risk Adjustment Department to address and remediate potential instances of diagnosis coding error that may impact our submissions to CMS. The unit utilizes internally created algorithms based on industry best practices to identify and target potential problem areas in the Medicare Advantage encounter data specific to diagnosis coding (e.g., diagnoses codes on claims that are prone to coding and documentation discrepancies). The QA program is evaluated at least annually to ensure that it remains operationally feasible, maintains or strengthens our risk management for the organization, is still consistent with medical coding and documentation guidance and addresses any evolving federal or state requirements. The program configuration and processes are also fully documented within the QA Policies and Procedure document; acceptable ICD-10 coding standards are documented separately in the THP Coding Policy document.

The THP QA program has consistently evolved and had operational enhancements in order to be compliant with federal and state requirements and guidance. The most recent version of the QA program includes but is not limited to seven (7) algorithms (Breast Cancer, Colon Cancer, Prostate Cancer, Acute MI, Unstable Angina, Acute Stroke, Pathological/Traumatic Fractures, and Claims Validation) with a targeted review of 50,000 to 60,000 unique diagnosis codes per payment year.

In addition to the use of algorithms, THP has undertaken significant efforts to ensure its provider network is also committed to an effective and comprehensive risk adjustment Quality Assurance program. THP has engaged a chart retrieval vendor to acquire the medical charts when THP does not already have internal access. THP also offers training to all medical providers and related staff in our network. This training includes education and training materials on high risk conditions and a review of processes at provider organizations to ensure adherence to the coding guidelines.

b. OIG Has Not Identified Compliance Procedures That Could Be Improved.

^{28/} Draft Report at 8.

OIG seems to infer, simply by virtue of the fact that it discovered unsupported diagnosis codes through its audit, that THP's compliance policies and procedures must not have been effective. But as we've discussed throughout our response, perfection is not the standard that CMS imposes and OIG has long recognized that. The mere fact that OIG identified some unsupported diagnoses, through its skewed audit sampling and review methodology, does not indicate that THP's compliance program is ineffective, particularly when measured by MA program guidance.

OIG did not identify any specific improvements it thinks THP should make to existing compliance policies and procedures. Instead, OIG highlighted THP's effective procedures to identify and review high-risk diagnosis codes and provider outreach and education efforts. THP would be happy to discuss any specific suggestions with OIG, to the extent it offers such suggestions, at OIG's convenience.

* * *

THP existing compliance procedures are robust, effective, and designed to comply with all applicable legal and regulatory requirements. OIG has not identified any material flaws in THP's compliance program. Therefore, THP respectfully requests OIG withdraw its recommendation that THP examine existing compliance procedures.

IV. Conclusion

For the reasons described, THP respectfully requests that OIG update its Draft Report and withdraw its recommendations that THP (I) repay an extrapolated amount of \$4,013,034, (II) conduct additional audits beyond OIG's sample and make repayments based on those audits, and (III) examine its existing compliance procedures. As written, these recommendations are inconsistent with the actuarial equivalence mandate and with CMS data accuracy and compliance requirements.

Sincerely,

/Patty Blake/
President, Senior Products

cc: Tisa Hughes, Chief Legal Officer
Rezarta Molla, Chief Compliance Officer
Serina Barkley, Senior Associate General Counsel