

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE
COMPLIANCE AUDIT OF
SPECIFIC DIAGNOSIS CODES THAT
CALIFORNIA PHYSICIANS' SERVICE, INC.
(CONTRACT H0504)
SUBMITTED TO CMS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



Amy J. Frontz
Deputy Inspector General
for Audit Services

November 2022
A-09-19-03001

Office of Inspector General

<https://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <https://oig.hhs.gov>

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: November 2022

Report No. A-09-19-03001

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



Why OIG Did This Audit

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

To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS. Some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.

For this audit, we reviewed one MA organization, California Physicians' Service, Inc. (CPS), and focused on seven groups of high-risk diagnosis codes. Our objective was to determine whether selected diagnosis codes that CPS submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

How OIG Did This Audit

We sampled 196 unique enrollee-years with the high-risk diagnosis codes for which CPS received higher payments for 2015 and 2016. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$523,340.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That California Physicians' Service, Inc. (Contract H0504) Submitted to CMS

What OIG Found

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that CPS submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, for 117 of the 196 sampled enrollee-years, the diagnosis codes that CPS submitted to CMS were not supported in the medical records and resulted in net overpayments of \$319,945. As demonstrated by the errors in our sample, the policies and procedures that CPS used to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that CPS received at least \$2 million of net overpayments for these high-risk diagnosis codes for 2015 and 2016.

What OIG Recommends and CPS Comments

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

CPS disagreed with our findings and recommendations. Specifically, CPS disagreed with our findings for 5 sampled enrollee-years and provided additional explanations of why it believed that the medical records validated the diagnosis codes. CPS also disagreed with the methodologies that we used to review the selected diagnoses and to calculate net overpayments. Furthermore, CPS disagreed that it should conduct additional audits (to identify similar instances of noncompliance) and that it should examine its compliance procedures.

After consideration of CPS's comments, we revised our finding for 1 sampled enrollee-year and reduced the refund amount in our first recommendation from \$2,045,043 to \$2,033,039. We maintain that our findings and recommendations, as revised, are valid.

TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objective.....	1
Background.....	2
Medicare Advantage Program.....	2
Risk Adjustment Program.....	2
High-Risk Groups of Diagnoses.....	4
California Physicians’ Service, Inc.	6
How We Conducted This Audit.....	6
FINDINGS.....	7
Federal Requirements.....	8
Most of the Selected High-Risk Diagnosis Codes That California Physicians’ Service Submitted to CMS Did Not Comply With Federal Requirements.....	9
Incorrectly Submitted Diagnosis Codes for Acute Stroke.....	9
Incorrectly Submitted Diagnosis Codes for Acute Heart Attack.....	10
Incorrectly Submitted Diagnosis Codes for Acute Stroke and Acute Heart Attack Combination.....	12
Incorrectly Submitted Diagnosis Codes for Embolism.....	13
Incorrectly Submitted Diagnosis Codes for Vascular Claudication.....	14
Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder.....	14
Potentially Mis-keyed Diagnosis Codes.....	15
The Policies and Procedures That California Physicians’ Service Used To Prevent, Detect, and Correct Noncompliance With Federal Requirements Could Be Improved.....	16
California Physicians’ Service Received Net Overpayments.....	16
RECOMMENDATIONS.....	17
CALIFORNIA PHYSICIANS’ SERVICE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE.....	17

CPS Disagreed With Our Finding for 5 Enrollee-Years	18
CPS Comments	18
OIG Response	19
CPS Disagreed With Our Sampling and Review Methodologies Used To Identify Overpayments	20
CPS Comments	20
OIG Response	20
CPS Stated That We Did Not Adequately Identify the Coding and Documentation Standards Used in Our Audit	22
CPS Comments	22
OIG Response	22
CPS Disagreed With Our Application of CMS Requirements for the Calculation of Overpayments	23
CPS Comments	23
OIG Response	24
CPS Disagreed With the Extrapolation Methodology Used To Calculate the Recommended Net Overpayment Refund Amount	25
CPS Comments	25
OIG Response	25
CPS Disagreed With Our Recommendation To Perform Additional Reviews Before and After Our Audit Period	25
CPS Comments	25
OIG Response	26
CPS Disagreed With Our Recommendation To Examine and Enhance Its Existing Compliance Procedures	27
CPS Comments	27
OIG Response	28

APPENDICES

A: Audit Scope and Methodology	29
B: Related Office of Inspector General Reports	33
C: Statistical Sampling Methodology	35
D: Sample Results and Estimates	38

E: Federal Regulations Regarding Compliance Programs That Medicare Advantage Organizations Must Follow	40
F: Details of Potentially Mis-keyed Diagnosis Codes	42
G: California Physicians' Service Comments.....	45

INTRODUCTION

WHY WE DID THIS AUDIT

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

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS. 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 27 major depressive disorder diagnoses into 1 group.) This audit covered California Physicians' Service, Inc. (CPS),² for contract number H0504 and focused on seven groups of high-risk diagnosis codes for payment years 2015 and 2016.³ (See Appendix B for a list of related Office of Inspector General (OIG) reports on MA organizations.)

OBJECTIVE

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

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

² CPS does business as Blue Shield of California.

³ All subsequent references to "CPS" in this report refer solely to contract number H0504.

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 2020, CMS paid MA organizations \$317.1 billion, which represented 34 percent of all Medicare payments for that year.

Risk Adjustment Program

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

CMS uses two principal components to calculate the risk-adjusted payment that it will make to an MA organization for an enrollee: (1) a base rate that CMS sets using bid amounts received from the MA organization and (2) the risk score for that enrollee. These are described as follows:

- *Base rate*: Before the start of each year, each MA organization submits bids to CMS that reflect the MA organization's estimate of the monthly revenue required to cover an enrollee with an average risk profile.⁶ CMS compares each bid to a specific benchmark

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.*

amount for each geographic area to determine the base rate that an MA organization is paid for each of its enrollees.⁷

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

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

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

For enrollees who have certain combinations of HCCs (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; CMS uses the diagnosis codes that the enrollee received for 1 calendar year (known as the service year) to determine HCCs and calculate risk

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.

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 based on the Version 22 model.

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

CMS multiplies the risk scores by the base rates to calculate the total monthly Medicare payment that an MA organization receives for each enrollee before applying the budget sequestration reduction.⁹ Thus, if the factors used to determine an enrollee's risk score are incorrect, CMS will make an improper payment to an MA organization. Specifically, if medical records do not support the diagnosis codes that an MA organization submitted to CMS, the HCCs are unvalidated, which causes overstated enrollee risk scores and overpayments from CMS.¹⁰ Conversely, if medical records support the diagnosis codes that an MA organization did not submit to CMS, validated HCCs may not have been included in enrollees' risk scores, which may cause those risk scores to be understated and may result in underpayments.

High-Risk Groups of Diagnoses

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

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

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

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

¹¹ Unless otherwise specified, the HCCs described in this report have the same name under both the Version 12 and Version 22 models.

Ischemic Heart Disease (Acute Heart Attack HCCs) on only one physician or outpatient claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician's claim). In these instances, a diagnosis indicating a history of a myocardial infarction 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.¹²
- *Embolism:* An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or the HCC for Vascular Disease With Complications (Embolism HCCs) during the service year but did not have an anticoagulant medication dispensed on his or her behalf. An anticoagulant medication is typically used to treat an embolism. In these instances, a diagnosis of history of embolism (an indication that the provider is evaluating a prior acute embolism diagnosis, which does not map to an HCC) typically should have been used.
- *Vascular claudication:* An enrollee received one diagnosis related to vascular claudication (that mapped to the HCC for Vascular Disease) during the service year, but had not received one of these diagnoses during the 2 preceding years and had medication dispensed on his or her behalf that is frequently dispensed for a diagnosis of neurogenic claudication.¹³ In these instances, the diagnosis related to vascular claudication may not be supported in the medical records.
- *Major depressive disorder:* An enrollee received one major depressive disorder diagnosis (that mapped to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) during the service year but did not have an antidepressant medication dispensed on his or her behalf. In these instances, the major depressive disorder diagnoses may not be supported in the medical records.
- *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

¹² 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).

¹³ Vascular claudication and neurogenic claudication are different diagnoses. Vascular claudication is a condition that can result in leg pain while an individual is 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.

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 could have been mis-keyed because numbers were transposed or other data-entry errors occurred that could have resulted in the assignment of an unvalidated HCC.

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

California Physicians’ Service, Inc.

CPS is a nonprofit MA organization based in Oakland, California. As of December 31, 2016, CPS provided coverage under contract number H0504 to 93,740 enrollees. For the 2015 and 2016 payment years (audit period), CMS paid CPS approximately \$1.8 billion to provide coverage to its enrollees.^{14, 15}

HOW WE CONDUCTED THIS AUDIT

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

We identified 4,314 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$9,984,571). We selected for audit a sample of 196 enrollee-years, which comprised: (1) a stratified random sample of 170 (out of 4,288) enrollee-years for the first 6 high-risk groups and (2) a nonstatistical sample of 26 enrollee-years for the remaining high-risk group.

Table 1 on the following page details the number of sampled enrollee-years (of the 196) for each of the 7 high-risk groups.

¹⁴ The 2015 and 2016 payment year data were the most recent data available at the start of the audit.

¹⁵ All of the payment amounts that CMS made to CPS and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

Table 1: Sampled Enrollee-Years for High-Risk Groups

High-Risk Group	Number of Sampled Enrollee-Years
1. Acute stroke	30
2. Acute heart attack	30
3. Acute stroke/acute heart attack combination	9
4. Embolism	30
5. Vascular claudication	30
6. Major depressive disorder	41
Total for Stratified Random Sample	170
7. Potentially mis-keyed diagnosis codes	26
Total for All High-Risk Groups	196

CPS provided medical records as support for the selected diagnosis codes associated with 192 of the 196 enrollee-years.¹⁶ We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. If the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

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

FINDINGS

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that CPS submitted to CMS for use in CMS’s risk adjustment program did not comply with Federal requirements. For 79 of the 196 sampled enrollee-years, the medical record validated the reviewed HCC, or we identified another diagnosis code (on CMS’s systems) that mapped to the HCC under review. However, for the remaining 117 enrollee-years, the diagnosis codes were not supported and the associated HCCs were therefore not validated.

¹⁶ CPS did not provide medical records for the 4 remaining sampled enrollee-years.

As demonstrated by the errors found in our sample, the policies and procedures that CPS used to prevent, detect, and correct noncompliance 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 CPS received at least \$2 million of net overpayments for these high-risk diagnosis codes for 2015 and 2016.¹⁷

FEDERAL REQUIREMENTS

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

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)).

CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap. 7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7, § 40). The diagnosis must be coded according to the International Classification of Diseases, Clinical Modification, *Official Guidelines for Coding and Reporting* (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

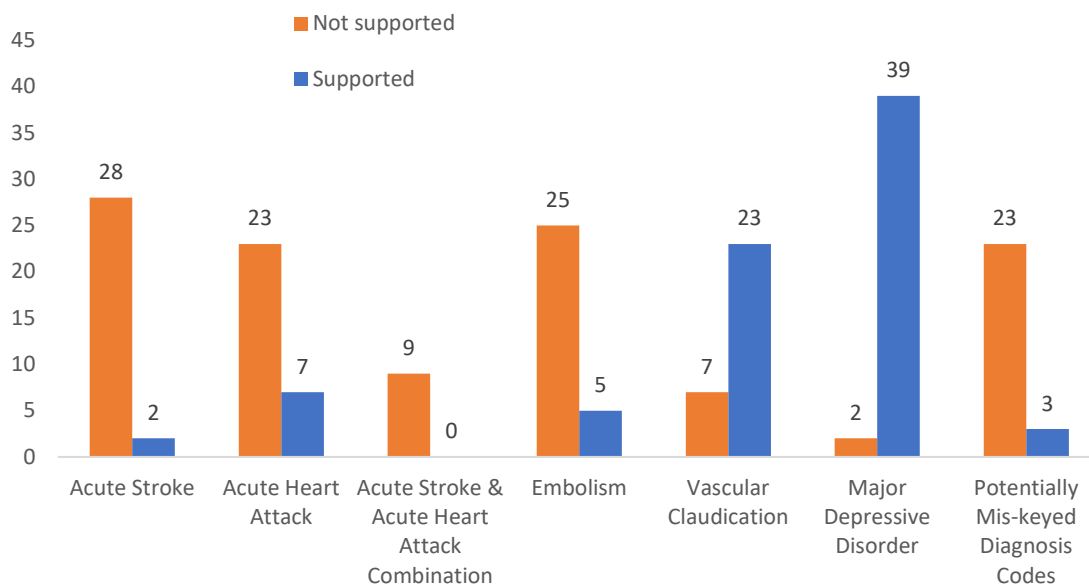
¹⁷ Specifically, we estimated that CPS received at least \$2,033,039 (\$1,920,066 for the statistically sampled groups plus \$112,973 for the group of potentially mis-keyed diagnosis codes) of net overpayments. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 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.

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)). (See Appendix E.)

MOST OF THE SELECTED HIGH-RISK DIAGNOSIS CODES THAT CALIFORNIA PHYSICIANS’ SERVICE SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Most of the selected high-risk diagnosis codes that CPS 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 117 of the 196 sampled enrollee-years did not support the diagnosis codes. In these instances, CPS 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

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

- For 17 enrollee-years, the medical records in each case 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 the submitted HCC or a related HCC. There is mention of a history of a stroke [diagnosis] but no description of residuals or sequelae that should be coded.¹⁸ Patient is seen for a preop evaluation for upcoming blepharoplasty.”¹⁹

- For 9 enrollee-years, the medical records in each case did not contain sufficient information to support an acute stroke diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that the medical records had “no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of HCC [Ischemic or Unspecified Stroke]. Patient presented with left-sided numbness and chest pain and was evaluated for risk of ischemia, as well as [the] possibility of [a] neurological deficit.²⁰ Extensive workup and studies performed were all negative.”

- For the 2 remaining enrollee-years, CPS submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiplegia (which was supported in the medical records).²¹ For the 2 enrollee-years, the independent medical review contractor noted that the patient either had “left sided weakness and numbness” or “right dominant side hemiparesis” from a previous stroke. The contractor noted that, for both instances, the correct diagnoses should have been hemiplegia or hemiparesis, which results in the HCC for Hemiplegia/Hemiparesis. These errors caused underpayments.

As a result of these errors, the HCCs for Ischemic or Unspecified Stroke were not validated, and CPS received \$58,475 of net overpayments for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Heart Attack

CPS incorrectly submitted diagnosis codes for acute heart attack for 23 of 30 sampled enrollee-years. Specifically:

- For 10 enrollee-years, the medical records in each case did not support an acute myocardial infarction diagnosis. However, we identified support for another diagnosis

¹⁸ Residuals or sequelae are lasting effects after the acute phase of an illness or injury has ended.

¹⁹ Blepharoplasty is surgery to repair droopy eyelids.

²⁰ Ischemia is an inadequate blood supply to an organ or a part of the body, especially to the heart muscles.

²¹ Hemiparesis is mild or partial paralysis, while hemiplegia is partial or total paralysis of one side of the body. Both conditions result from disease of or injury to the motor centers of the brain. The difference between the two conditions primarily lies in severity.

that should have been included in the enrollee-years' risk scores. In some instances, the diagnosis mapped to a less severe manifestation of the related-disease group as detailed below:

- For 5 enrollee-years, which occurred in payment year 2015, the old myocardial infarction diagnosis mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, CPS 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 will result in assignment of [a diagnosis] code that translates to the assignment of HCC [Acute Myocardial Infarction]; however, there is documentation of a history of myocardial infarction [diagnosis] which results in HCC [Old Myocardial Infarction].”

- For 3 enrollee-years, which occurred in payment year 2016, the old myocardial infarction diagnosis did not map to an HCC.²² Accordingly, CPS should not have received an increased payment for acute myocardial infarction.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of HCC [Unstable Angina and Other Acute Ischemic Heart Disease]. The medical record mentions an old [myocardial infarction] . . . and does not result in the assignment of an HCC for this case.”

- For 2 enrollee-years, which occurred in either payment year 2015 or 2016, we identified support for the diagnosis of other and unspecified angina pectoris, which mapped to an HCC for a less severe manifestation of the related-disease group.²³ Accordingly, CPS should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the less severe diagnoses.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of HCC

²² 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).

²³ Angina pectoris is a disease marked by brief sudden attacks of chest pain or discomfort caused by deficient oxygenation of the heart muscles, usually due to impaired blood flow to the heart.

[Unstable Angina and Other Acute Ischemic Heart Disease]. The correct diagnosis should have been angina . . . resulting in HCC [Angina Pectoris/Old Myocardial Infarction] instead of the submitted HCC.”

- For 11 enrollee-years, the medical records in each case did not support either an acute myocardial infarction diagnosis or a diagnosis of a less severe manifestation of the related-disease group.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of HCC [Acute Myocardial Infarction]. The medical record states that [a myocardial infarction] was suspected and ruled out.”

- For the 2 remaining enrollee-years, CPS could not locate any medical records to support the acute myocardial infarction diagnoses; therefore, the HCCs for Myocardial Infarction were not validated.

As a result of these errors, the Acute Heart Attack HCCs were not validated, and CPS received \$36,180 of overpayments for these 23 sampled enrollee-years.

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

CPS incorrectly submitted diagnosis codes for all 9 of the sampled enrollee-years for which the physicians had documented conditions for both the acute stroke and acute heart attack high-risk groups in the same year (footnote 11).

Table 2 on the following page details the findings for the 9 enrollee-years for which the medical records did not support the submitted diagnosis codes.

Table 2: Acute Stroke and Acute Heart Attack Combination Findings

Count of Enrollee-Years	Acute Stroke HCC		Acute Heart Attack HCC	
	Medical Record Validated HCC	Support for Different HCC Found	Medical Record Validated HCC	Support for Different HCC Found
4	No	No	No	No
3*	No	No	No	Yes – Old Myocardial Infarction
1*	Yes	No	No	Yes – Old Myocardial Infarction
1	No	No	Yes	No

* For these enrollee-years, CPS submitted a diagnosis code that mapped to the HCC for Unstable Angina and Other Acute Ischemic Heart Disease (one of the Acute Heart Attack HCCs), which was not validated in the medical record. However, we found support for a diagnosis code that mapped to the HCC for Angina Pectoris/Old Myocardial Infarction, which is a less severe manifestation of the related-disease group. Accordingly, CPS should not have received an increased payment for the unstable angina and other acute ischemic heart disease diagnosis but should have received a lesser increased payment for the angina pectoris/old myocardial infarction diagnosis.

As a result of these errors, the HCCs for either Ischemic or Unspecified Stroke or Acute Heart Attack, or both, were not validated, and CPS received \$27,279 of overpayments for these 9 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

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

- For 16 enrollee-years, the medical records in each case did not support an embolism diagnosis.²⁴

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of [the] HCC [for Vascular Disease with Complications]. This is a follow up visit for surveillance of a personal history of uterine cancer. . . .”

²⁴ For one of the enrollee-years, the medical record that CPS provided to support the reviewed HCC was a visit summary recorded by a medical assistant. This record was not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner). (42 CFR § 422.310(d)(3); the Manual, chap. 7, §§ 40 and 120.1.)

- For 8 enrollee-years, the medical records in each case 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 that “there is no documentation of any condition that . . . translates to the assignment of [the] HCC [for Vascular Disease]. The record states that there is a history of [deep vein thrombosis] with no recurrence.”²⁵

- For the 1 remaining enrollee-year, CPS 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 CPS received \$65,317 of overpayments for these 25 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Vascular Claudication

CPS incorrectly submitted diagnosis codes for vascular claudication for 7 of 30 sampled enrollee-years. Specifically, for these 7 enrollee-years, the medical records in each case did not support a vascular claudication diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of HCC [Vascular Disease]. The patient was treated for Bradycardia which does not result in [an] HCC.”²⁶

As a result of these errors, the HCCs for Vascular Disease were not validated, and CPS received \$15,068 of overpayments for these 7 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder

CPS incorrectly submitted diagnosis codes for major depressive disorder for 2 of 41 sampled enrollee-years. Specifically, for each of the 2 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 will result in assignment of [a diagnosis] code that translates to the assignment of [the] HCC [for Major Depressive, Bipolar, and Paranoid Disorders].”

²⁵ Deep vein thrombosis is a blood clot that occurs in a vein.

²⁶ Bradycardia is a slower than normal heart rate.

As a result of these errors, the HCCs for Major Depressive, Bipolar, and Paranoid Disorders were not validated, and CPS received \$4,653 of overpayments for these 2 sampled enrollees-years.

Potentially Mis-keyed Diagnosis Codes

CPS submitted potentially mis-keyed diagnosis codes for 23 of 26 sampled 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. Specifically:

- For 20 enrollee-years, the medical records did not support the diagnosis for the unrelated condition.²⁷ Because of these errors, CPS submitted to CMS unsupported diagnosis codes that mapped to unvalidated HCCs.

For example, for 1 enrollee-year, CPS submitted 47 diagnosis codes for ductal carcinoma of the breast (174.9)²⁸ and only 1 diagnosis code for rheumatoid arthritis (714.9).²⁹ The independent medical review contractor limited its review to the rheumatoid arthritis diagnosis, for which it did not find support.

- For 2 enrollee-years, the medical records did not support the diagnosis for the unrelated condition. However, we identified support for another diagnosis, which mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, CPS received an overpayment, in that it should not have received an increased payment for the submitted diagnosis but should have received a lesser increased payment for the other diagnosis identified.

For example, for 1 enrollee-year, CPS submitted a diagnosis code for unstable angina and other acute ischemic heart disease. 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 [Unstable Angina and Other Acute Ischemic Heart Disease]. There is documentation of [a] stable angina [diagnosis] resulting in HCC [Angina Pectoris] which should have been assigned instead of the submitted HCC.” Accordingly, CPS should not have received an increased payment for the Unstable Angina and Other Acute Ischemic Heart Disease HCC but should have received a lesser increased payment for the Angina Pectoris HCC.

²⁷ For one of the enrollee-years, the medical record that CPS provided to support the reviewed HCC was a pathology report. This record was not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner) and did not support that a face-to-face encounter had occurred (42 CFR § 422.310(d)(3); the Manual, chap. 7, §§ 40 and 120.1).

²⁸ Ductal carcinoma of the breast is a cancer that forms in the milk ducts of the breast.

²⁹ Rheumatoid arthritis is a chronic autoimmune disease that causes inflammation and deformity of the joints.

- For the 1 remaining enrollee-year, CPS could not locate any medical records to support the potentially mis-keyed diagnosis code; therefore, the HCC associated with the potentially mis-keyed diagnosis code was not validated.

Appendix F contains the HCCs that were not validated for the 23 enrollee-years (Table 6) and the HCCs for the less severe manifestation of the related-disease group that were supported for the 2 enrollee-years (Table 7).

As a result of these errors, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated, and CPS received \$112,973 of overpayments for these 23 sampled enrollee-years.

THE POLICIES AND PROCEDURES THAT CALIFORNIA PHYSICIANS' SERVICE USED TO PREVENT, DETECT, AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS COULD BE IMPROVED

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

As a part of its preventive measures, CPS's compliance procedures included outreach by its clinical staff to provide field-based training and to help educate its providers on various topics, including guidance on coding claims. CPS also had compliance procedures to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. CPS contracted with a health care technology company to compare diagnosis codes from specific claims with the diagnoses that were documented in the associated medical records, and to remove any incorrect diagnosis codes from CMS's risk-adjustment system. On a monthly basis, CPS reviewed the contractor's work to ensure the accuracy of the coding.

Although CPS had policies and procedures that addressed some incorrect diagnosis codes, CPS did not have specific procedures to identify a high-risk diagnosis code as problematic unless that diagnosis code appeared on a specific claim that was selected for review. For this reason, we believe that CPS's policies and procedures, with regard to high-risk diagnosis codes, could be improved.

CALIFORNIA PHYSICIANS' SERVICE RECEIVED NET OVERPAYMENTS

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that CPS received at least \$2,033,039 of net overpayments (\$1,920,066 for the statistically sampled high-risk groups plus \$112,973 for the high-risk group with the potentially mis-keyed diagnosis codes) for 2015 and 2016. (See Appendix D for sample results and estimates.)

RECOMMENDATIONS

We recommend that California Physicians' Service, Inc.:

- refund to the Federal Government the \$2,033,039 of estimated net overpayments;
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
- examine its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

CALIFORNIA PHYSICIANS' SERVICE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CPS disagreed with our findings and recommendations. Specifically, CPS disagreed with our findings for 5 sampled enrollee-years and provided additional explanations of why it believed that the medical records validated the HCCs. CPS did not specifically comment on the errors associated with the other 113 sampled enrollee-years identified in the draft report. CPS also disagreed with our audit sampling and review methodologies and stated that our calculations of net overpayments were not consistent with certain Federal requirements. Moreover, CPS said that our recommendations are "not consistent with the Social Security Act's . . . actuarial equivalence mandate and with CMS data accuracy and compliance requirements." Lastly, CPS disagreed that it should conduct additional audits (to identify similar instances of noncompliance) and that it should examine its compliance procedures. Accordingly, CPS requested that we withdraw all of our recommendations.

After reviewing CPS's comments and the information that CPS provided on the 5 sampled enrollee-years, we revised our finding for 1 enrollee-year and reduced the refund amount in our first recommendation from \$2,045,043 to \$2,033,039 for our final report. We maintain that our findings and recommendations, as revised, are valid.

A summary of CPS's comments and our responses follows. CPS's comments are included in their entirety as Appendix G.

CPS DISAGREED WITH OUR FINDINGS FOR 5 ENROLLEE-YEARS

CPS Comments

CPS disagreed with our findings for 5 sampled enrollee-years (in the acute stroke, vascular claudication, and acute heart attack high-risk groups) because it said that it found supporting clinical data in the medical records for these 5 enrollee-years based on its own review. CPS provided the following explanations of why it believed the medical records supported the HCCs for the high-risk diagnosis codes we reviewed:

- For the first enrollee-year (with an Acute Stroke HCC), CPS stated that according to the medical student's progress note (which was reviewed and cosigned by the attending physician), the patient did have a stroke. CPS stated that the patient had symptoms of a stroke, neurological deficits based on an exam (decreased sensation to light touch on the left upper arm, leg, and face), and a magnetic resonance imaging (MRI) scan of the head, which confirmed a right thalamus infarction.³⁰
- For the second enrollee-year (with an Acute Stroke HCC), CPS stated that there was sufficient documentation of an acute stroke. According to CPS, the patient was 82 years old with ataxia, known coronary artery disease, 100-percent left carotid artery occlusion, and cerebellar findings only on the exam, which are listed as a cerebrovascular accident (CVA).³¹ CPS stated there was no action to be taken for the stroke, because the patient's condition did not meet acute anticoagulant guidelines, just watchful waiting by a physician.
- For the third enrollee-year (with a Vascular Claudication HCC), CPS stated that according to the clinical note, there was support for a hip vascular claudication diagnosis (which can present as hip muscle pain, which is aggravated by activity). CPS stated that the patient had worsening hip pain, with one side worse than the other, and an MRI scan of the hip showed moderate arthritis, a bilateral tear of the labrum, gluteus maximus tendonitis, and right trochanteric bursitis.³² CPS added that the MRI findings may not entirely explain the patient's hip pain. CPS stated that the doctor was unclear on the etiology (i.e., cause) of the hip pain and therefore made a referral to a vascular surgeon to assess and screen for hip claudication.

³⁰ A right thalamus infarction is caused by a disruption of blood flow to the right side of the thalamus, which is a part of the brain.

³¹ Ataxia describes poor muscle control that causes clumsy voluntary movements. A CVA is also known as a stroke.

³² A bilateral tear of the labrum is an injury to the tissue that holds the hip ball and socket together, affecting both sides of the hip. Gluteus maximus tendonitis is an inflammation or irritation of the tendon that holds the outer gluteal (buttock) muscle to the hip bone. Right trochanteric bursitis is an inflammation of the right bursa, a fluid-filled sac, at the outside point of the hip.

- For the fourth enrollee-year (with an Acute Heart Attack HCC), CPS stated that based on a review of the emergency room notes, the patient had a past medical history of coronary artery disease, developed a chest pain that was relieved by nitroglycerin, and had an initial Troponin level of 0.03 micrograms per liter, which then increased to 0.05 micrograms per liter.³³ CPS stated that the electrocardiogram (EKG) showed a normal sinus rhythm and possible inferior infarction when compared with another EKG. According to CPS, because of the elevated Troponin level and abnormal EKG, the emergency room physician appropriately diagnosed the patient with non-ST-elevation myocardial infarction (NSTEMI), admitted the patient to the hospital, and consulted cardiology.³⁴
- For the fifth enrollee-year (with an Acute Heart Attack HCC), CPS stated that the emergency room notes supported the diagnosis of acute myocardial infarction because the patient had chest pressure, an abnormal EKG, and an abnormal and rising Troponin level. CPS also stated that the ER physician recommended an inpatient admission, and the admitting diagnosis was NSTEMI.

OIG Response

Our independent medical review contractor reviewed the explanations that CPS provided and re-reviewed the medical records for these 5 enrollee-years. Based on that review, the contractor reconfirmed that the HCCs remained unvalidated for 4 enrollee-years and determined that the HCC was validated for 1 enrollee-year.

For the unvalidated HCCs for the first, second, third, and fifth enrollee-years, the independent medical review contractor found the following:

- For the first enrollee-year, the independent medical review contractor did not find support for the Acute Stroke HCC. Specifically, the contractor stated: “The document was submitted as a physician record where the provider has documented ‘likely CVA’ in the note. As per outpatient coding guidelines, ‘likely’ diagnoses are unconfirmed diagnoses which cannot be assigned as established conditions.”
- For the second enrollee-year, the independent medical review contractor did not find support for the Acute Stroke HCC. Specifically, the contractor stated: “The medical record does not support an acute CVA which is an urgent condition requiring emergency care and/or hospital admission. The discharge disposition indicates that the patient went home and was not admitted. Per outpatient coding guidelines, only confirmed and established diagnoses can be assigned.”

³³ Nitroglycerin is a drug that helps to relieve chest pain by relaxing the blood vessels, which increases the blood and oxygen supply to the heart. Troponin is a protein needed for the contraction of heart and skeletal muscles and appears in the blood only when the heart muscle is damaged.

³⁴ An NSTEMI is a type of heart attack that happens when a part of the heart is not getting enough oxygen.

- For the third enrollee-year, the independent medical review contractor did not find support for the Vascular Claudication HCC. Specifically, the contractor stated: “Even though ‘Claudication’ is listed in the assessment, it is documented as contradictory and questionable. The provider states this as a musculoskeletal issue and the patient was referred to vascular surgery for further testing. The diagnosis was a working diagnosis and should not be coded as confirmed based on outpatient coding guidelines.”
- For the fifth enrollee-year, the independent medical review contractor did not find support for an Acute Heart Attack HCC. Specifically, the contractor stated: “The record was submitted as a physician (outpatient) medical record. The record included several inconsistencies. [An NSTEMI] was listed as a working diagnosis along with the Supraventricular tachycardia (SVT)³⁵ The SVT was noted to be the cause of the patient’s palpitations. Per outpatient coding guidelines the NSTEMI was not a confirmed diagnosis.”

For the fourth enrollee-year, the independent medical review contractor agreed with CPS on its conclusions and validated the Acute Heart Attack HCC. Accordingly, we revised our findings for the Acute Heart Attack high-risk group and reduced the refund amount in our first recommendation from \$2,045,043 to \$2,033,039.

CPS DISAGREED WITH OUR SAMPLING AND REVIEW METHODOLOGIES USED TO IDENTIFY OVERPAYMENTS

CPS Comments

CPS stated that our sampling and review methodologies were “improperly skewed towards identifying overpayments.” Specifically, CPS said that our methodologies were designed to identify “overpayments,” without review or acknowledgment of all diagnoses or medical records from the sampled enrollee-years. CPS also said that our sample “targeted diagnoses that OIG already suspected would not be supported by the underlying medical record.” Further, CPS said that our review methodology “was not designed to include, identify, or acknowledge potential unrelated diagnoses that were not previously submitted to CMS” and “goes beyond assessing coding and questioned the clinical validity of providers’ diagnostic statements.” Finally, CPS requested that we revise our repayment calculations to address what it stated was the bias inherent in our sampling and review methodologies.

OIG Response

We disagree with CPS’s statements regarding our sampling and review methodologies. Specifically, it was beyond the scope of our audit to identify: (1) all possible diagnosis codes

³⁵ SVT is an abnormally fast heart rhythm caused by abnormalities of the cardiac electrical impulses from the top chambers of the heart.

that CPS could have submitted on behalf of the sampled enrollee-years and (2) enrollees for whom CPS did not submit any risk-adjusted diagnosis codes.

For this audit, our objective was to determine whether selected high-risk diagnosis codes that CPS submitted to CMS for use in CMS’s risk adjustment program complied with Federal requirements. For each of the sampled enrollee-years, CPS had previously submitted to CMS only one claim with a high-risk diagnosis code that mapped to the reviewed HCC. We asked CPS to provide a copy of that related medical record for review. We also informed CPS 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 CPS’s 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 the medical records that CPS submitted to determine whether the documentation supported any diagnosis codes that mapped to the reviewed HCCs. 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. In this regard, we considered instances in which the medical review contractor found support for a diagnosis code that should have been used instead of the diagnosis code that was submitted to CMS.

In addition, CPS’s description of our net overpayment calculations as skewed and biased is not accurate. 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 HCCs that were beyond the scope of our audit. Further, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.³⁶ The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.³⁷ In accordance with our objective and as detailed in Appendices A and C, we properly executed a statistically valid sampling methodology in that we defined our sampling frame (CPS 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

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

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

to apply the correct formulas to estimate the net overpayments made to CPS. Accordingly, we did not revise our estimate of net overpayments as a result of CPS's specific comment.

CPS STATED THAT WE DID NOT ADEQUATELY IDENTIFY THE CODING AND DOCUMENTATION STANDARDS USED IN OUR AUDIT

CPS Comments

CPS requested that we provide additional information regarding the coding and documentation standards applied during the audit and stated that it was not made aware of the standards that our independent medical review contractor used during its review. CPS stated that CMS has directed providers and plans to rely on coding and documentation guidance from industry experts, such as the American Health Information Management Association; it stated, however, that "the scope of these resources is quite broad, and they are not always consistent with one another." CPS further stated that "[w]hen applied during an audit process, the coding and documentation standards essentially determine what is a valid risk adjustment payment and what is an 'overpayment.'"

OIG Response

We disagree with CPS that it was not made aware of the coding or documentation standards that the independent medical review contractor used in its review. Our independent medical review contractor performed its review to determine whether the diagnoses in the medical records associated with the sampled enrollee-years were coded according to the ICD Coding Guidelines. 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).³⁸ 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 CPS with the results of our independent medical review contractor's determinations and the reasons for those determinations, including any applicable coding and documentation standards. We also provided CPS with the procedures that the contractor followed to make its determinations (Appendix A).

³⁸ Our independent medical review contractor used senior coders, all of whom possessed one or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS), Certified Coding Specialist – Physician-Based (CCS-P), Certified Professional Coder (CPC), and Certified Risk Coder (CRC). RHITs have completed a 2-year degree program and have passed an AHIMA certification exam. AHIMA also credentials individuals with CCS and CCS-P certifications, and AAPC credentials both CPCs and CRCs.

CPS DISAGREED WITH OUR APPLICATION OF CMS REQUIREMENTS FOR THE CALCULATION OF OVERPAYMENTS

CPS Comments

CPS said that our estimated and extrapolated repayment amount is both legally and actuarially unsound. Specifically, CPS stated that we did not apply a Fee-for-Service (FFS) Adjuster to account for errors in the data used to create the risk adjustment model.

CPS cited the provision of the Act that requires CMS to pay MA organizations 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 MA organizations’ enrollees. CPS stated: “CMS developed the [Medicare Advantage] risk adjustment model using [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.” CPS said that in 2012 CMS published a notice stating 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 . . . amount as an offset to the preliminary recovery amount.’”

CPS also stated that CMS “tried 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 to CMS that is not sufficiently supported by underlying medical records, without adjusting for error rates in traditional Medicare data.” CPS stated that “[t]his rule was struck down when a federal district court found that it violated the actuarial equivalence mandate by defining ‘overpayment’ as the payment of funds to [MA organizations] based on unsupported diagnosis codes without applying a[n] FFS Adjuster or other mechanism to maintain actuarial equivalence.” According to CPS, the U.S. Court of Appeals for the D.C. Circuit (the Circuit) “held that the overpayment rule applies to a diagnosis that an [MA organization] knows lack support in the beneficiary’s medical record and as such, does not require a[n] FFS adjuster or other correction.” CPS further stated that “. . . RADV audits, which are designed to require repayment for all unsupported diagnosis codes, would require a correction for actuarial equivalence.” CPS then stated that it agrees with the Circuit’s statements on RADV audits but does not agree with the decision on the overpayment rule because actuarial equivalence in the MA risk adjustment system is statutorily required.

CPS noted that “CMS issued a proposed rule in 2018 suggesting that diagnosis coding errors in unaudited traditional Medicare data do not systematically impact payments to [MA organizations].” CPS added that CMS was required to take action on this rule in November 2021 but instead granted itself a year extension to November 2022.

In addition, CPS stated that we departed from a report that we issued in 2012 in which we, according to CPS, “acknowledged that the actuarial equivalence requirement made it

inappropriate to estimate an extrapolated audit liability in the absence of a[n] FFS Adjuster.” CPS stated that “it is not possible for OIG to determine whether CPS received an overpayment without establishing an actuarially sound overpayment methodology that takes into account diagnosis coding errors in the FFS data.” Further, CPS stated that “OIG’s estimated and extrapolated repayment amount is both legally and actuarially unsound.” CPS requested that we withdraw our repayment calculation “until such time as CMS issues a legally and actuarially sound methodology that includes a[n] FFS Adjuster. At that time, OIG should apply that actuarially sound methodology to this audit to calculate any repayment that might be due.”

OIG 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 the independent medical review contractor’s coding review to determine which high-risk HCCs were not substantiated and, in some instances, to identify HCCs that should have been used but were not used in the risk score calculations of the sampled enrollee-years. 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.

CPS stated that we did not consider “actuarial equivalence” in our overpayment calculations and that we departed from prior statements that we made on actuarial equivalence. To these points, we recognize that CMS was responsible in 2012 and is responsible now 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.³⁹ If CMS deems it appropriate to apply an FFS Adjuster, it will adjust our overpayment finding by whatever amount it determines necessary. Regarding CPS’s statement that RADV audits are designed to require repayment for all unsupported diagnosis codes and would require a correction for actuarial equivalence, the Circuit did not make such a statement and instead chose not to rule on this issue. Thus, we believe that the steps that we followed for this audit provided reasonable assurance with regard to the findings and recommendations, including our estimation of net overpayments.⁴⁰

³⁹ 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).

⁴⁰ 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 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.

CPS DISAGREED WITH THE EXTRAPOLATION METHODOLOGY USED TO CALCULATE THE RECOMMENDED NET OVERPAYMENT REFUND AMOUNT

CPS Comments

CPS disagreed with the methodology that we used to calculate the estimated net overpayment refund amount. Specifically, CPS stated that our use of the lower limit of a 90-percent confidence interval was not as robust as the use of the lower limit of a 95-percent or 99-percent confidence interval. CPS requested that we use the lower limit of a 99-percent confidence interval, as CMS does for RADV audits.⁴¹

OIG Response

OIG is an independent oversight agency, and therefore we do not need to mirror CMS's estimation methodology. As detailed in Appendices A and C, and as stated previously, we properly executed a statistically valid sampling and estimation methodology. Our policy is to recommend recovery at the lower limit of a two-sided 90-percent confidence interval. The lower limit of a two-sided 90-percent confidence interval provided a reasonably conservative estimate of the total amount of net overpayments to CPS for the enrollee-years and time period covered in our sampling frame. This approach, which is routinely used by the Department of Health and Human Services (HHS) for recovery calculations, 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.⁴² For this reason, we maintain that our use of the lower limit of the two-sided 90-percent confidence interval is valid.

CPS DISAGREED WITH OUR RECOMMENDATION TO PERFORM ADDITIONAL REVIEWS BEFORE AND AFTER OUR AUDIT PERIOD

CPS Comments

CPS disagreed with our second recommendation—that it 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—because, according to CPS, “MA

⁴¹ CMS RADV audits consist of reviews of medical record documentation that audited MA organizations provide to substantiate the diagnosis codes that MA organizations submit to CMS. RADV audits are the primary tools that CMS uses to identify improper payments made to MA organizations.

⁴² HHS has used the two-sided 90-percent confidence interval when calculating recoveries in both the Administration for Children and Families and Medicaid programs. See, for example, *New York State Department of Social Services*, DAB No. 1358, 13 (1992); *Arizona Health Care Cost Containment System*, DAB No. 2981, 4–5 (2019). In addition, HHS contractors rely on the one-sided 90-percent confidence interval, which is less conservative than the two-sided interval, for recoveries arising from Medicare FFS overpayments. See, 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).

regulations do not require the sort of audits that OIG recommends and do not require data perfection.”

CPS stated that our report “appears to expect perfect data . . . which is inconsistent with CMS regulations.” CPS further stated that 42 CFR § 422.504(l) requires MA organizations to attest to the accuracy of the data based on “best knowledge, information and belief.” CPS also stated that CMS said that it 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 . . . believe[s] is reasonable to enforce.” In addition, CPS stated that CMS said that “it would be unfair and unrealistic to hold [MA organizations] to a ‘100 percent accuracy’ certification standard.” Lastly, CPS stated that if it undertook an audit similar to ours, it would not be permitted to submit diagnosis codes that it determined were supported but not previously submitted because all plan years other than 2020, 2021, and 2022 are closed for resubmissions.

Regarding the identified mis-keyed diagnosis codes, CPS stated that it does not have the information needed, i.e., the “underlying algorithm,” to identify potentially mis-keyed diagnoses similar to those within the scope of our audit.

OIG Response

We recognize that CMS applies a “best knowledge, information, and belief” standard when MA organizations certify the great volume of data that they submit to CMS for use in the risk adjustment program. However, we do not agree with CPS’s interpretation of the Federal requirements. In this regard, we believe that our second recommendation conforms to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (Appendix E)).

These Federal regulations state that MA organizations must “implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS’ program requirements.” Furthermore, these regulations specify that CPS’s compliance plan “must, at a minimum, include [certain] core requirements,” which include “an effective system for routine monitoring and identification of compliance risks . . . [including] internal monitoring and audits and, as appropriate, external audits to evaluate . . . compliance with CMS requirements and the overall effectiveness of the compliance program.”

These regulations also require MA organizations to implement procedures and a system for investigating “potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence.” Relatedly, MA organizations must exercise due diligence and good faith in ensuring data accuracy (42 CFR § 422.504(l)) and exercise a duty to detect and correct noncompliance with CMS’s program requirements (42 CFR § 422.503(b)(4)(vi)). Thus, CMS has, through the issuance of these Federal regulations, assigned to the MA organizations the responsibility for dealing with potential compliance issues.

We believe that the error rate identified in our audit (117 of 196 sampled enrollee-years with unsupported diagnosis codes) (Appendix D) demonstrates that CPS has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope. Accordingly, we maintain the validity of our recommendation that CPS 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.

Regarding the algorithm for the mis-keyed diagnoses, during our audit, we explained to CPS officials how we selected each target area, including the mis-keyed diagnoses. Additionally, after issuance of our draft report, we provided CPS with a spreadsheet detailing the 811 scenarios that we identified in which diagnosis codes could have been mis-keyed. Therefore, CPS has the information necessary to identify additional mis-keyed diagnosis codes similar to those we identified.

CPS DISAGREED WITH OUR RECOMMENDATION TO EXAMINE AND ENHANCE ITS EXISTING COMPLIANCE PROCEDURES

CPS Comments

CPS stated that our third recommendation—that CPS examine and enhance its existing compliance procedures—was based on our belief that its compliance policies and procedures must not have been effective. CPS noted that our review was limited to 2014 and 2015 dates of service and the compliance functions in place to monitor claims data for those years and thus there is no basis for findings related to CPS’s current compliance program. CPS stated that it is beyond the scope of our audit to make recommendations related to CPS’s current compliance activities.

In addition, CPS 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 before submission to CMS, CPS 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, CPS said that we failed “to account for the qualified attestation standard that CMS explicitly adopted.”⁴³

CPS stated that its Medicare Compliance Committee provides guidance and oversight for the plan’s compliance program policies and procedures. CPS also stated that it has established the Encounters Performance Organization team, whose goal is to deliver reliable, complete, and

⁴³ The “qualified attestation standard” that CPS referred to in its comments is CMS’s requirement that the MA organizations attest to the completeness of the data and accuracy of the coding submitted for payment purposes (65 Fed. Reg. 40170, 40250 (June 29, 2000)).

compliant encounter data. CPS stated that the team focuses on provider engagement, transactional controls, quality oversight, and system enhancements to drive compliance on encounter data.

OIG Response

CPS's response implied that we opined on the effectiveness of its entire compliance program. That was not our intention or our focus for this audit. Rather, we limited our audit to selected diagnoses that we had determined to be at higher risk of being miscoded. Our audit revealed a significant error rate for some of these areas. Moreover, in its comments on our draft report, CPS did not specify any current practices that it had implemented that would prevent the errors we identified. Thus, we continue to believe that CPS can make improvements by enhancing its compliance procedures to focus on diagnosis codes that are at high risk for being miscoded.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid CPS \$1,848,432,580 to provide coverage to its enrollees for 2015 and 2016. We identified a sampling frame of 4,314 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2014 and 2015 service years. CPS received \$65,065,266 in payments from CMS for these enrollee-years for 2015 and 2016. We selected for audit 196 enrollee-years with payments totaling \$3,338,062.

The 196 enrollee-years included 30 acute stroke diagnoses, 30 acute heart attack diagnoses, 9 acute stroke diagnosis and acute heart attack diagnosis combinations, 30 embolism diagnoses, 30 vascular claudication diagnoses, 41 major depressive disorder diagnoses, and 26 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 \$523,340 for our sample.

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

We performed audit work from December 2018 to February 2022.

METHODOLOGY

To accomplish our objective, we performed the following steps:

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

- We developed an analytical tool that identified 811 scenarios in which either ICD-9 or ICD-10 diagnosis codes, when mis-keyed into an electronic claim because of a data transposition or other data-entry error, could result in the assignment of an incorrect HCC to an enrollee’s risk score. For each of the 811 occurrences, the tool identified a potentially mis-keyed diagnosis code and the likely correct diagnosis code. Accordingly, we considered the potentially mis-keyed diagnosis codes to be high risk.
- We used CMS’s systems to identify the enrollee-years on whose behalf providers documented the high-risk diagnosis codes. Specifically, we used extracts from CMS’s:
 - Risk Adjustment Processing System (RAPS) to identify enrollees who received high-risk diagnosis codes from a physician during the service years;⁴⁴
 - Risk Adjustment System (RAS) to identify enrollees who received an HCC for the high-risk diagnosis codes;⁴⁵
 - Medicare Advantage Prescription Drug system (MARx) to identify the total Medicare payments that CMS calculated, before applying the budget sequestration reduction, for CPS for the payment years;⁴⁶
 - Encounter Data System (EDS) to identify enrollees who received specific procedures;⁴⁷ and
 - Prescription Drug Event (PDE) file to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.⁴⁸
- We interviewed CPS officials to gain an understanding of: (1) the policies and procedures that CPS followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) CPS’s monitoring of those diagnosis codes to prevent, detect, and correct noncompliance with Federal requirements.
- We selected for audit a sample of 196 enrollee-years, which consisted of: (1) a stratified random sample of 170 (out of 4,288) enrollee-years and (2) a nonstatistical sample of the remaining 26 enrollee-years.

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

⁴⁵ The RAS identifies the HCCs that CMS factors into each enrollee’s risk score calculation.

⁴⁶ The MARx identifies the payments made to MA organizations.

⁴⁷ The EDS contains information on each item (including procedures) and service provided to an enrollee.

⁴⁸ 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 196 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.⁴⁹
- The independent medical review contractor’s coding review followed a specific process to determine whether there was support for a diagnosis code and the associated HCC:
 - If the first senior coder found support for the diagnosis code on the medical record, the HCC was considered validated.
 - If the first senior coder did not find support on the medical record, a second senior coder performed a separate review of the same medical record:
 - If the second senior coder also did not find support, the HCC was considered to be not validated.
 - If the second senior coder found support, a physician independently reviewed the medical record to make the final determination.
 - If either the first or second senior coder asked a physician for assistance, the physician’s decision became the final determination.
- We used the results of the independent medical review contractor to calculate overpayments or underpayments (if any) for each enrollee-year. Specifically, we calculated:
 - a revised risk score in accordance with CMS’s risk adjustment program and
 - the payment that CMS should have made for each enrollee-year.
- We estimated the total net overpayment made to CPS during the audit period.
- We discussed the results of our audit with CPS 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

⁴⁹ Our independent medical review contractor used senior coders, all of whom possessed one or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS), Certified Coding Specialist – Physician-Based (CCS-P), Certified Professional Coder (CPC), and Certified Risk Coder (CRC). RHITs have completed a 2-year degree program and have passed an AHIMA certification exam. AHIMA also credentials individuals with CCS and CCS-P certifications, and AAPC credentials both CPCs and CRCs.

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

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contact R5826) Submitted to CMS</i>	<u>A-05-19-00039</u>	9/30/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (Contact H3916) Submitted to CMS</i>	<u>A-03-19-00001</u>	9/29/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS</i>	<u>A-07-19-01195</u>	9/29/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Inter Valley Health Plan, Inc. (Contract H0545), Submitted to CMS</i>	<u>A-05-18-00020</u>	9/26/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS</i>	<u>A-09-20-03009</u>	9/13/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc., (Contract H1032) Submitted to CMS</i>	<u>A-04-19-07084</u>	8/29/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS</i>	<u>A-03-18-00002</u>	8/19/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS</i>	<u>A-02-20-01009</u>	7/18/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health Network (Contract H1961) Submitted to CMS</i>	<u>A-06-18-05002</u>	5/25/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS</i>	<u>A-01-19-00500</u>	2/14/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS</i>	<u>A-07-17-01169</u>	2/3/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS</i>	<u>A-02-18-10129</u>	1/5/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS</i>	<u>A-07-19-01188</u>	11/5/2021

Report Title	Report Number	Date Issued
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS</i>	A-07-17-01173	10/28/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS</i>	A-07-19-01187	5/21/2021
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS</i>	A-07-16-01165	4/19/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS</i>	A-02-18-01028	2/24/2021
<i>Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements</i>	A-07-17-01170	4/30/2019

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified CPS enrollees who: (1) were continuously enrolled in CPS 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 CPS for 2015 or 2016, respectively.

We presented the data for these enrollees to CPS for verification and performed an analysis of the data included in CMS's systems to determine whether the high-risk diagnosis codes increased CMS's payments to CPS. We removed any enrollees whose data could not be verified, and we classified these individuals according to the condition and the payment year (enrollee-years). Our final sampling frame consisted of 4,314 enrollee-years.

SAMPLE UNIT

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

SAMPLE DESIGN AND SAMPLE SIZE

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

- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on only one physician claim during the service year but did not have that diagnosis on a corresponding inpatient or outpatient hospital claim (550 enrollee-years);
- a diagnosis (that mapped to an Acute Heart Attack HCC) on only one physician or outpatient claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician or outpatient claim (354 enrollee-years);
- an acute stroke diagnosis and a diagnosis (that mapped to an Acute Heart Attack HCC) in the same year and that met the criteria mentioned in the previous two bullets (9 enrollee-years);
- a diagnosis that mapped to an Embolism HCC during the service year but for which an anticoagulant medication was not dispensed (187 enrollee-years);

- a diagnosis related to vascular claudication (that mapped to the HCC for Vascular Disease) on only one claim during the service year (a diagnosis that had not been documented during the 2 years that preceded the service year), but had medication for neurogenic claudication dispensed on his or her behalf (218 enrollee-years); and
- a major depressive disorder diagnosis (that mapped to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) on only one claim during the service year but did not have an antidepressant medication dispensed on his or her behalf (2,970 enrollee-years).

The specific strata are shown 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	550	\$1,210,154	30
2 – Acute heart attack	354	653,950	30
3 – Acute stroke/acute heart attack combination	9	34,287	9
4 – Embolism	187	450,894	30
5 – Vascular claudication	218	450,177	30
6 – Major depressive disorder	2,970	7,059,804	41
Total – First Six Strata	4,288	\$9,859,266	170

* Rounded to the nearest whole dollar amount.

After we selected the 170 enrollee-years, we identified an additional group of 26 enrollee-years that represented individuals who received 1 of the 811 potentially mis-keyed diagnosis codes (each of which mapped to a potentially unvalidated HCC) and multiple instances of diagnosis codes that were likely keyed correctly.⁵⁰ Thus, we selected for audit a total of 196 enrollee-years.

SOURCE OF RANDOM NUMBERS

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

⁵⁰ The entire group of 23 enrollee-years was reviewed.

METHOD OF SELECTING SAMPLE ITEMS

We sorted the items in each stratum by beneficiary identification number and payment year, then consecutively numbered the items in each stratum in the stratified sampling frame. After generating 170 random numbers according to our sample design, we selected the corresponding frame items for review. We also selected all 26 nonstatistical sample items from the potentially mis-keyed group.

ESTIMATION METHODOLOGY

We used the OIG-OAS statistical software to estimate the total amount of net overpayments to CPS at the lower limit of the two-sided 90-percent confidence interval (Appendix D). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time. We also identified the overpayments from the nonstatistical sample of 26 items for the potentially mis-keyed diagnosis codes and added that amount to the estimate for the statistical sample to obtain the total net overpayments.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Details and Results

Audited High-Risk Groups	Frame Size	CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With Unvalidated HCCs	Net Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)
1 – Acute stroke	550	\$1,210,154	30	\$74,039	28	\$58,475
2 – Acute heart attack	354	653,950	30	58,350	23	36,180
3 – Acute stroke/acute heart attack combination	9	34,287	9	34,287	9	27,279
4 – Embolism	187	450,894	30	77,399	25	65,317
5 – Vascular claudication	218	450,177	30	58,112	7	15,068
6 – Major depressive disorder	2,970	7,059,804	41	95,848	2	4,653
Totals for Statistical Sample	4,288	\$9,859,266	170	\$398,035	94	\$206,972
7 – Potentially mis-keyed diagnoses	26	\$125,305	26	\$125,305	23	\$112,973
Totals – All	4,314	\$9,984,571	196	\$523,340	117	\$319,945

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

	Estimated Net Overpayment for Statistically Sampled High-Risk Groups	Overpayment for High-Risk Group With Potentially Mis-keyed Diagnosis Codes	Total Estimated Net Overpayments
Point estimate	\$2,379,942	\$112,973	\$2,492,915
Lower limit	1,920,066	112,973	2,033,039
Upper limit	2,839,817	112,973	2,952,790

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

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

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

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

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

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

(1) Articulate the organization's commitment to comply with all applicable Federal and State standards;

(2) Describe compliance expectations as embodied in the standards of conduct;

(3) Implement the operation of the compliance program;

(4) Provide guidance to employees and others on dealing with potential compliance issues;

(5) Identify how to communicate compliance issues to appropriate compliance personnel;

(6) Describe how potential compliance issues are investigated and resolved by the organization; and

(7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials. . . .

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The

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

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

APPENDIX F: DETAILS OF POTENTIALLY MIS-KEYED DIAGNOSIS CODES

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

Number of Sampled Enrollee-Years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
5	714.9	Unspecified inflammatory polyarthropathy	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	174.9	Malignant neoplasm of breast (female), unspecified	\$12,531
3	482.0	Pneumonia due to klebsiella pneumoniae	Aspiration and Specified Bacterial Pneumonias	428.0	Congestive heart failure, unspecified	11,873
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	30,694
2	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	28,251
2	174.0	Malignant neoplasm of nipple and areola of female breast	Breast, Prostate, Colorectal and Other Cancers and Tumors (Version 12 model); and Breast, Prostate, and Other Cancers and Tumors (Version 22 model)	714.0	Rheumatoid arthritis	2,904
1	205.80	Other myeloid leukemia, without mention of having achieved remission	Lung, Upper Digestive Tract, and Other Severe Cancers (Version 12 model) and Lung and Other Severe Cancers (Version 22 model)	250.80	Diabetes with other specified manifestations, type II or unspecified type, not stated as uncontrolled	6,350
1	205.90	Unspecified myeloid leukemia, without mention of having achieved remission	Lung, Upper Digestive Tract, and Other Severe Cancers (Version 12 model) and Lung and Other	250.90	Diabetes with unspecified complications type II or unspecified	6,232

Number of Sampled Enrollee-Years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Overpayment
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
			Severe Cancers (Version 22 model)		type, not stated as uncontrolled	
1	402.01	Malignant hypertensive heart disease with heart failure	Congestive Heart Failure	402.10	Benign hypertensive heart disease without heart failure	4,233
1	250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled	Diabetes With Acute Complications	205.10	Chronic myeloid leukemia, without mention of having achieved remission	2,650
1	493.20	Chronic obstructive asthma, unspecified	Chronic Obstructive Pulmonary Disease	493.02	Extrinsic asthma with (acute) exacerbation	2,160
1	441.00	Dissection of aorta, unspecified site	Vascular Disease With Complications	414.00	Coronary atherosclerosis of unspecified type of vessel, native or graft	2,054
1	174.9	Malignant neoplasm of breast (female), unspecified	Breast, Prostate, Colorectal and Other Cancers and Tumors (Version 12 model); and Breast, Prostate, and Other Cancers and Tumors (Version 22 model)	714.9	Unspecified inflammatory polyarthropathy	1,250
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	969
1	I24.9	Acute ischemic heart disease, unspecified	Unstable Angina and Other Acute Ischemic Heart Disease	I42.9	Cardiomyopathy, unspecified	822
23						\$112,973

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

Count of Sampled Enrollee-Years	More Severe Hierarchical Condition Category That Was Not Validated	Less Severe Hierarchical Condition Category That Was Supported
1	Unstable Angina and Other Acute Ischemic Heart Disease	Angina Pectoris
1	Vascular Disease With Complications	Vascular Disease

APPENDIX G: CALIFORNIA PHYSICIANS' SERVICE COMMENTS



April 19, 2022

U.S. Department of Health & Human Services
Office of Inspector General
Office of Audit Services, Region IX
Attn: Lori A. Ahlstrand
Regional Inspector General for Audit Services

Re: Response to Draft Report Number: A-09-19-03001

First, we would like to thank you for your review of 206 targeted diagnoses from 2014 and 2015. We appreciate your commitment to oversight, in our common vision to deliver care worthy of our family and friends.

California Physicians' Service d/b/a Blue Shield of California ("CPS") respectfully submits these comments in response to the Draft Report provided by the U.S. Department of Health and Human Services 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 the Centers for Medicare & Medicare Services ("CMS") under contract H0504 (the "Draft Report"). CPS is a nonprofit health plan that offers high quality health care services to Medicare beneficiaries through contract H0504.

OIG's recommendations are not consistent with the Social Security Act's ("SSA's") actuarial equivalence mandate and with CMS data accuracy and compliance requirements. As we describe in detail below, CPS requests that OIG revise its Draft Report and withdraw its recommendations that CPS (I) refund to the Federal Government \$2,000,000 of estimated new overpayments, (II) identify similar instances of noncompliance outside of the audit period and refund any resulting overpayments, and (III) examine existing compliance procedures to identify where improvements can be made to ensure diagnosis codes that are at high risk for being miscoded comply with Federal requirements.

I. CPS Does Not Agree with OIG's Estimated and Extrapolated Repayment Amount and Respectfully Requests OIG Recalculate to Address Errors in OIG's Analysis of Certain Enrollee-Years, Remove The Impact of Underlying Biases and Ensure Actuarial Equivalence

CPS respectfully requests OIG withdraw its recommended repayment amount and recalculate it, when possible, to account for (a) errors in OIG's analysis of certain enrollee-years; (b) inherent bias in an audit sampling and review methodology that is designed to identify "overpayments"; (c) a review methodology that did not identify the standards of review; (d) the statutorily required actuarial equivalence between expected costs in MA and traditional Medicare; and (e) statistical bias from an insufficiently robust confidence interval inconsistent with CMS RADV audits.

blueshieldca.com

601 12th Street | Oakland, CA 94607

Blue Shield of California is an independent member of the Blue Shield Association. LS2000-W (1/20)

a. OIG's Recommended Repayment Amount is Incorrect Because Certain Sample Enrollee-years Found Unsupported are Supported by Documentation in the Relevant Medical Records

CPS disagrees with OIG's findings related to five enrollee-years. Our team reviewed all samples identified as not having supporting documentation and we found five samples as having supporting clinical data. We respectfully request that OIG review the records listed in Attachment A and revise its findings related to these enrollee-years.

b. OIG's Sampling and Review Methodology was Improperly Skewed Towards Identifying "Overpayments"

The MA RADV regulations state that such audits will be conducted "to ensure risk adjustment payment integrity and accuracy."^{1/} OIG's underlying sampling and review methodologies were designed to identify "overpayments," without review or acknowledgement of all diagnoses or medical records from the sampled enrollee years, and as such, were not designed or implemented to "ensure risk adjustment payment integrity and accuracy." As a result, OIG's estimated and extrapolated repayment amount is incorrect and inconsistent with the regulation. To conduct this audit, OIG collected and reviewed certain medical records, based on data obtained from CMS systems, and narrowed its review to high-risk diagnoses. OIG designed the audit not to look for unreported unrelated diagnoses, which skewed any calculation of a potential "overpayment" and related extrapolation.

OIG's audit sample targeted diagnoses that OIG already suspected would not be supported by the underlying medical record. The data mining techniques OIG used to identify its audit sample skew any potential extrapolation towards being over-inclusive by focusing only on high-risk diagnoses. Such a sampling methodology cannot be used to extrapolate because it ignores all other diagnoses CPS 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."

Further, OIG's review methodology was not designed to include, identify, or acknowledge potential unrelated diagnoses that were 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 "if medical records support diagnosis codes the MA organizations do not to submit to CMS, enrollee risk scores may be understated, which may also result in... (underpayments)."^{2/}

Finally, it appears OIG's review methodology goes 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

^{1/} 42 C.F.R. §422.311(a).

^{2/} Draft Report at 4.

^{3/} Draft Report at 20.

physician likely would not be limiting their analysis to issues of coding and documentation and would ultimately skew results towards identifying overpayments.

For these reasons, CPS respectfully requests that OIG revise its repayment calculations to address the bias inherent in an audit sampling and review methodology that is skewed towards identifying “overpayments.”

c. In Addition to Being Skewed Towards Identifying “Overpayments,” OIG Did Not Adequately Identify the Coding and Documentation Standards Applied During The Medical Record Review and OIG Should Update its Draft Report to Include Additional Information Regarding its Medical Record Review.

CPS respectfully requests that OIG provide additional information regarding the coding and documentation standards applied during the review. CPS was not 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. CPS 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.

When applied during an 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 payment standard until notice and comment rulemaking is complete.^{5/}

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

^{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).

The SSA requires CMS to 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/} 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 published a notice stating that it would incorporate this into 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 tried 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 it 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 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

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

^{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).

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

equivalence. While CPS agrees with the Circuit’s statements regarding RADV audits, we do not agree with the decision regarding the overpayment rule because actuarial equivalence in the MA 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 was required to take action on this rule in November 2021 but instead granted itself a year extension to November 2022 as it continues to contemplate how to handle this significant issue.^{15/} As a result, the proposed rule 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 a 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.^{16/}

Considering this history, it is not possible for OIG to determine whether CPS received an overpayment without establishing an actuarially sound overpayment methodology 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. CPS respectfully requests that OIG withdraw its repayment calculation until such time as CMS issues a legally and 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.

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

^{15/} See CMS, *Extension of Timeline To Finalize a Rulemaking*, 86 Fed. Reg. 58,245.

^{16/} 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).

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.^{17/} OIG provides no explanation for its decision to do so, which is unusual because CMS uses the lower limit of a 99-percent confidence interval when calculating extrapolated repayment amounts for its Medicare Advantage RADV audits. CPS 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 Medicare Advantage RADV audits.

II. CPS Does Not Agree and Respectfully Requests that OIG Withdraw its Recommendation that CPS Conduct Additional Auditing Related to the High-Risk Diagnoses Included in the Audit

OIG recommends that CPS “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[.]”^{18/} However, MA regulations do not require the sort of audits that OIG recommends and do not require data perfection. An overpayment based on the audit OIG recommends CPS undertake can only be calculated by applying a FFS Adjuster to ensure actuarial equivalence. Not to mention that CPS 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. By making this recommendation, OIG is holding MAOs to standards that are unknown, vague, and nonexistent.

In addition, if CPS undertook an audit similar to that of OIG, it could not result in “risk adjustment payment integrity and accuracy”^{19/} because CPS would not be permitted to submit diagnosis codes that CPS determined were supported but not previously submitted because all plan years other than 2020, 2021, and 2022 are closed for resubmissions.

OIG’s Draft Report appears to expect perfect data from CPS, 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.”^{20/} 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”^{21/} 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

^{17/} Draft Report at 8.

^{18/} Draft Report at 17.

^{19/} See 42 C.F.R. §422.311(a).

^{20/} Draft Report at 8.

^{21/} 65 Fed. Reg. 40170, 40250 (June 29, 2000).

reasonable to enforce.”^{22/} CMS further stated that “it would be unfair and unrealistic to hold [MAOs] to a ‘100 percent accuracy’ certification standard.”^{23/}

A perfection standard is inconsistent with the “actuarial equivalence” requirement and, as discussed above, potentially unsupported diagnosis codes are not, by default, reflective of an overpayment. CPS respectfully requests OIG revise its Draft Report to recognize that MAOs are not required to have perfect data and that not all potentially unsupported diagnoses correlate to an overpayment.

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

III. CPS Does Not Agree and Respectfully Requests that OIG Withdraw its Recommendation that CPS Examine Existing Compliance Procedures and Requests

OIG recommends that CPS “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 take the necessary steps to enhance those procedures.”^{24/} However, CPS has a strong and effective compliance program that is designed to comply with all relevant legal and regulatory requirements. OIG’s audit was limited to 2014 and 2015 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 CPS’ current compliance program. It is beyond the scope of OIG’s audit to make recommendations related to CPS’ 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 data submitted to CMS for

^{22/} *Id.* at 40268.

^{23/} *Id.*

^{24/} Draft Report at 17.

^{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% accuracy in order for a compliance program to be effective.

^{27/} Draft Report at 8.

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. Nevertheless, 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.

It also seems that, simply by virtue of the fact that it discovered unsupported diagnosis codes through its audit, OIG believes CPS’ compliance policies and procedures must not have been effective. But as we’ve discussed throughout our comments, perfection is not the standard that CMS imposes and OIG has long recognized that. The fact that OIG identified unsupported diagnoses, through its skewed audit sampling and review methodology, does not indicate that CPS’ compliance program is ineffective, particularly when measured by MA program guidance. CPS’s Medicare Compliance Committee provides guidance and oversight for the plan’s compliance program policies and procedures. In addition, CPS has established the Encounters Performance Organization team to drive end-to-end performance for encounters. The goal of the team is to deliver reliable, complete, and compliant encounter data. The team focuses on provider engagement, transactional controls, quality oversight, and system enhancements to drive compliance on encounter data. Because of these reasons, CPS respectfully requests that OIG withdraw its recommendation that CPS examine existing compliance procedures as it is inconsistent with existing MA guidance.

IV. Conclusion

For the reasons described, CPS requests that OIG revise its Draft Report and withdraw its recommendations that CPS (I) refund to the Federal Government \$2,000,000 of estimated new overpayments, (II) identify similar instances of noncompliance outside of the audit period and refund any resulting overpayments, (III) examine existing compliance procedures to identify where improvements can be made to ensure diagnosis codes that are at high risk for being miscoded comply with Federal requirements.

^{28/} Draft Report at 8.

Attachment A

Enrollee-Year	Category	HCC	Diagnosis Code	\$ Disputed	Dispute Rationale
1	Acute Stroke	HCC 096 (v12) 100 (v22)	43491	\$454.20	According to the medical student's progress note (reviewed and co-signed by the attending physician), the patient did have a stroke. The patient had symptoms of stroke (Left-sided weakness and numbness), neurological deficits on the exam (decreased sensation to light touch on Left upper arm, leg, and face), and the MRI head confirmed Right thalamus infarct. The diagnosis code for the Thalamus Infarction is 434.91, which is HCC 96 & 100. For these reasons, HCC 096 (v12) & 100 (v22) is validated.
2	Acute Stroke	HCC 100 (v22)	43491	\$2048.64	The patient does indeed have sufficient documentation of an acute stroke. 82 y/o with ataxia, known coronary artery disease (CABG), 100% left carotid artery occlusion, and cerebellar findings only on the exam. They are listed as CVA. There was no action to be taken for the stroke, since patient's condition did not meet acute anticoagulant guidelines, just watchful waiting by a physician. The diagnosis code for the CVA is 434.91, which is V22 HCC 100. For these reasons, HCC 100 (v22) is validated.
3	Vascular Claudication	HCC 105 (v12) 108 (v22)	4439	\$2400.60	As per the clinical note, there is support for hip vascular claudication diagnosis (which can present as hip muscle pain which is aggravated by activity). <ul style="list-style-type: none"> • Patient has worsening hip pain (Right side worse than Left side); not able to walk to the gym • MRI of the hip showed moderate arthritis, bilateral tear of labrum, glut maximus (buttock muscle) tendonitis, Rt trochanteric bursitis (these MRI findings may not entirely explain the patient's hip pain) The doctor was unclear on etiology of the hip pain, and therefore made a referral to a vascular surgeon to assess and screen for hip claudication. The diagnosis code for claudication is 443.9, which is V12 HCC 105 and V22 HCC 108. For these reasons, HCC 105 (v12) & 108 (v22) is validated.

Attachment A

Enrollee-Year	Category	HCC	Diagnosis Code	\$ Disputed	Dispute Rationale
4	Acute MI	HCC 087 (v22)	41070	\$990.00	<p>Reviewing the ER notes:</p> <ul style="list-style-type: none"> The patient has past medical history of CAD. The patient developed chest pain which was relieved by NTG. The patient initial Troponin was 0.03ug/L and a repeat Troponin was 0.05 ug/L (borderline high). EKG showed normal sinus rhythm, possible inferior infarction when compared to other EKG. <p>Given the elevating Troponin and abnormal EKG, the ER physician appropriately diagnosed the patient with NSTEMI, admitted the patient to the hospital, and consulted cardiology. The diagnosis code for the NSTEMI is 410.71, which is V22 HCC 86. This is a higher HCC than the reported HCC 87, which would validate the reported HCC. For these reasons, HCC 087 (v22) is validated.</p>
5	Acute MI	HCC 086	41071	\$2068.68	<p>The patient's ER notes support the diagnosis of Acute MI:</p> <ul style="list-style-type: none"> The patient has symptoms of Acute MI (chest pressure). The patient has abnormal EKG. The patient has abnormal and rising Troponin level. The ER physician's recommended inpatient admission and admitting diagnosis was Non-ST elevation MI. <p>The diagnosis code for the NSTEMI is 410.71, which is V22 HCC 86. For these reasons, HCC 086 is validated.</p>
Total Disputed				\$7,962.12	

124094053v.2

blueshieldca.com

10