

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE COMPLIANCE
AUDIT OF SPECIFIC DIAGNOSIS CODES
THAT GEISINGER HEALTH PLAN
(CONTRACT H3954) 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

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Office of Inspector General

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Report in Brief

Date: March 2023

Report No. A-09-21-03011

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, Geisinger Health Plan (Geisinger), and focused on nine groups of high-risk diagnosis codes. Our objective was to determine whether selected diagnosis codes that Geisinger submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

How OIG Did This Audit

We sampled 270 unique enrollee-years with the high-risk diagnosis codes for which Geisinger received higher payments for 2016 and 2017. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$706,678.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS

What OIG Found

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Geisinger submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 224 of the 270 sampled enrollee-years, either the medical records that Geisinger provided did not support the diagnosis codes or Geisinger could not locate the medical records to support the diagnosis codes, resulting in \$566,476 of net overpayments. As demonstrated by the errors found in our sample, Geisinger's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements could be improved. On the basis of our sample results, we estimated that Geisinger received at least \$6.5 million of net overpayments for 2016 and 2017.

What OIG Recommends and Geisinger Comments

We recommend that Geisinger: (1) refund to the Federal Government the \$566,476 of net overpayments; (2) identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before and 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 and take the necessary steps to enhance those procedures.

Geisinger disagreed with all of our findings and recommendations. Specifically, Geisinger disagreed with our first recommendation in the draft report that it should refund \$6.5 million in estimated net overpayments and disagreed with our second and third recommendations. However, Geisinger did not specifically disagree with any of the findings for the sampled enrollee-years identified in our draft report as not having medical records to support the associated diagnosis codes. Geisinger stated that it would delete unsupported codes found for the 224 sampled enrollee-years during our audit.

After reviewing Geisinger's comments, we maintain that our findings are valid. After we had issued our draft report, CMS updated regulations for audits in its risk adjustment program to specify that extrapolated overpayments could only be recouped beginning with payment year 2018. Because our audit period covered payment years 2016 and 2017, we changed our first recommendation to specify a refund of only the net overpayments for the sampled enrollee-years. We made no changes to our second and third recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations based in part on the characteristics of the enrollees being covered. Using a system of risk adjustment, CMS pays MA organizations the anticipated cost of providing Medicare benefits to a given enrollee, depending on such risk factors as the age, gender, and health status of that individual. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources relative to healthier enrollees, who would be expected to require fewer health care resources. To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS.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 29 major depressive disorder diagnoses into 1 group.) This audit covered Geisinger Health Plan (Geisinger) for contract number H3954 and focused on nine groups of high-risk diagnosis codes for payment years 2016 and 2017.² (See Appendix B for a list of related Office of Inspector General (OIG) reports on MA organizations.)

OBJECTIVE

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

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

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 All subsequent references to "Geisinger" in this report refer solely to contract number H3954.

fee-for-service (FFS) program.³ Beneficiaries who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

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

For 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.⁴

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

- *Base rate:* Before the start of each year, each MA organization submits bids to CMS that reflect the MA organization's estimate of the monthly revenue required to cover an enrollee with an average risk profile.⁵ CMS compares each bid to a specific benchmark amount for each geographic area to determine the base rate that an MA organization is paid for each of its enrollees.⁶
- *Risk score:* A risk score is a relative measure that reflects the additional or reduced costs that each enrollee is expected to incur compared with the costs incurred by enrollees on average. CMS calculates risk scores based on an enrollee's health status (discussed below) and demographic characteristics (such as the enrollee's age and gender). This

³ The Balanced Budget Act of 1997, P.L. No. 105-33, as modified by section 201 of the Medicare Prescription Drug, Improvement, and Modernization Act, P.L. No. 108-173, established the MA program.

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

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

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

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

To determine an enrollee's health status for purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from acceptable data sources, including certain physicians and hospitals. MA organizations collect the diagnosis codes from providers based on information documented in the medical records and submit these codes to CMS. CMS then maps certain diagnosis codes, on the basis of similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs).⁷ Each HCC has a factor (which is a numerical value) assigned to it for use in each enrollee's risk score.

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

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

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

CMS multiplies the risk scores by the base rates to calculate the total monthly Medicare payment that an MA organization receives for each enrollee before applying the budget sequestration reduction.⁸ 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

⁷ During our audit period, CMS calculated risk scores based on the Version 22 CMS-HCC model.

⁸ Budget sequestration refers to automatic spending cuts that occurred through the withdrawal of funding for certain Federal programs, including the MA program, as provided in the Budget Control Act of 2011 (BCA) (P.L. No. 112-25 (Aug. 2, 2011)). Under the BCA, the sequestration of mandatory spending began in April 2013.

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.⁹ 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 nine high-risk groups:

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

⁹ 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.

neurogenic claudication.¹⁰ 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.
- *Lung cancer:* An enrollee received one lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period either before or after the diagnosis. In these instances, a diagnosis of history of lung cancer (which does not map to an HCC) typically should have been used.
- *Breast cancer:* An enrollee received one breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of breast cancer (which does not map to an HCC) typically should have been used.
- *Colon cancer:* An enrollee received one colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of colon cancer (which does not map to an HCC) typically should have been used.
- *Prostate cancer:* An enrollee 74 years old or younger received one prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of prostate cancer (which does not map to an HCC) typically should have been used.

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

¹⁰ Vascular claudication and neurogenic claudication are different diagnoses. Vascular claudication is a condition that can result in leg pain while walking and is caused by insufficient blood flow. Neurogenic claudication is a condition that can also result in leg pain but is caused by damage to the neurological system, namely the spinal cord and nerves.

Geisinger Health Plan

Geisinger is an MA organization based in Danville, Pennsylvania. As of December 31, 2017, Geisinger provided coverage under contract number H3954 to 69,233 enrollees. For the 2016 and 2017 payment years (audit period), CMS paid Geisinger approximately \$1.4 billion to provide coverage to its enrollees.^{11, 12}

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of the nine high-risk groups during the 2015 and 2016 service years, for which Geisinger received increased risk-adjusted payments for payment years 2016 and 2017, respectively. Because enrollees could be classified into more than one high-risk group or could have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment year, which we refer to as “enrollee-years.”

We identified 3,734 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$7,960,011). We selected for audit a stratified random sample of 270 enrollee-years as shown in Table 1.

Table 1: Sampled Enrollee-Years

High-Risk Group	Number of Sampled Enrollee-Years
1. Acute stroke	30
2. Acute heart attack	30
3. Embolism	30
4. Vascular claudication	30
5. Major depressive disorder	30
6. Lung cancer	30
7. Breast cancer	30
8. Colon cancer	30
9. Prostate cancer	30
Total for All High-Risk Groups	270

¹¹ The 2016 and 2017 payment year data were the most recent data available at the start of the audit.

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

Geisinger provided medical records as support for the selected diagnosis codes associated with 245 of the 270 sampled enrollee-years.¹³ 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, Appendix D contains our sample results and estimates, and Appendix E contains the Federal regulations regarding MA organizations' compliance programs.

FINDINGS

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Geisinger submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 46 of the 270 sampled enrollee-years, the medical records validated the reviewed HCCs. However, for the remaining 224 enrollee-years, either the medical records that Geisinger provided did not support the diagnosis codes or Geisinger could not locate the medical records to support the diagnosis codes, and the associated HCCs were therefore not validated. As a result, Geisinger received \$566,476 in net overpayments.

As demonstrated by the errors found in our sample, Geisinger's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that Geisinger received at least \$6.5 million of net overpayments for 2016 and 2017.¹⁴

FEDERAL REQUIREMENTS

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

¹³ At the time of our audit, Geisinger had not provided medical records for the remaining 25 sampled enrollee-years.

¹⁴ Specifically, we estimated that Geisinger received at least \$6,523,543 of net overpayments. To be conservative, we estimate net overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

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

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

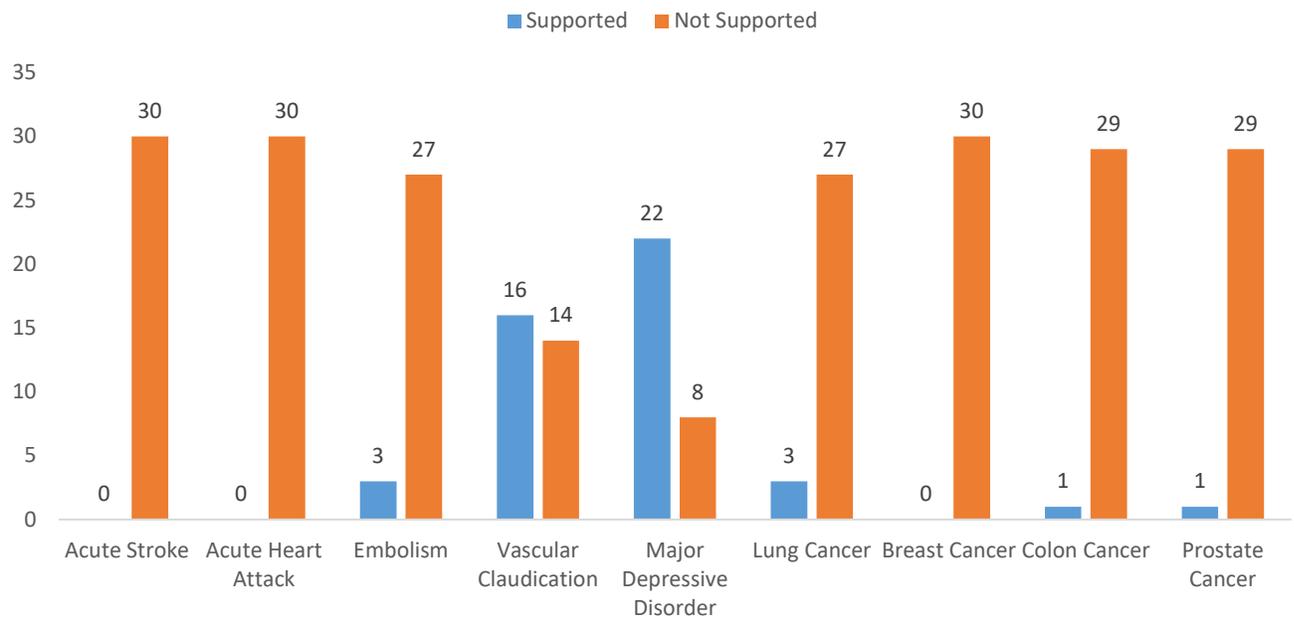
CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap. 7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face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

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

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

Most of the selected high-risk diagnosis codes that Geisinger submitted to CMS for use in CMS’s risk adjustment program did not comply with Federal requirements. As shown in the figure on the following page, the medical records for 224 of the 270 sampled enrollee-years did not support the diagnosis codes. In these instances, Geisinger 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

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

- For 21 enrollee-years, the medical records indicated in each case that the individual had previously had a stroke, but the records did not justify an acute stroke diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC [for Ischemic or Unspecified Stroke] or a related HCC. There is mention of a history of a stroke [diagnosis] . . .” The history of stroke diagnosis code does not map to an HCC.

- For 5 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC [for Ischemic or Unspecified Stroke] or a related HCC. It is noted in the Chief Complaint/[history of present illness] section that the patient’s family requested tests for a possible stroke. The diagnosis was not confirmed on this date of service.”

- For 2 enrollee-years, the medical records that Geisinger provided to support the acute stroke diagnosis were not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner).¹⁵ The data sources provided were a CT (computed tomography) scan and a Minimum Data Set nursing home resident assessment and care-screening report; therefore, the HCC for Ischemic or Unspecified Stroke was not validated.
- For 1 enrollee-year, Geisinger submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiparesis (which was supported in the medical records).¹⁶ The independent medical review contractor noted that “there is no evidence of an acute stroke, however the patient has left hemiparesis from an old stroke that should be coded with [a diagnosis] and would result in the assignment of [a Hemiplegia/Hemiparesis] HCC.” This error caused an underpayment.
- For the remaining 1 enrollee-year, Geisinger could not locate any medical records to support the acute stroke diagnosis; therefore, the HCC for Ischemic or Unspecified Stroke was not validated.

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and Geisinger received \$66,787 of net overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Heart Attack

Geisinger incorrectly submitted diagnosis codes for acute heart attack for all 30 sampled enrollee-years. Specifically:

- For 18 enrollee-years, the medical records indicated in each case that the individual had an old myocardial infarction diagnosis, but the records did not justify a diagnosis that mapped to an Acute Heart Attack HCC at the time of the physician’s service.¹⁷

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Acute Myocardial Infarction]. There is documentation of a past medical history of myocardial infarction [diagnosis] which does not result in an HCC.”

¹⁵ 42 CFR § 422.310(d)(3); the Manual, chap. 7, §§ 40 and 120.1.

¹⁶ Hemiparesis is weakness of one side of the body that results from disease of or injury to the motor centers of the brain.

¹⁷ An “old myocardial infarction” is a distinct diagnosis that represents a myocardial infarction that occurred more than 4 weeks previously, has no current symptoms directly associated with that myocardial infarction, and requires no current care.

- For 6 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Acute Heart Attack HCC.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Acute Myocardial Infarction]. Per physician review, test results of EKG performed did not show signs of change from baseline which did not confirm an acute myocardial infarction.”¹⁸

- For 3 enrollee-years, the medical records in each case did not support the submitted diagnosis that mapped to an Acute Heart Attack HCC. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to the HCC for Angina Pectoris, which is a less severe manifestation of the related-disease group.¹⁹ Accordingly, Geisinger should not have received an increased payment for the submitted diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.
- For the remaining 3 enrollee-years, Geisinger could not locate any medical records to support a diagnosis that mapped to an Acute Heart Attack HCC; therefore, the HCC for Acute Heart Attack was not validated.

As a result of these errors, the Acute Heart Attack HCCs were not validated, and Geisinger received \$57,607 of overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

Geisinger incorrectly submitted diagnosis codes for embolism for 27 of 30 sampled enrollee-years. Specifically:

- For 13 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not justify a diagnosis that mapped to an Embolism HCC at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the]

¹⁸ An electrocardiogram (EKG) is a test that measures the electrical activity of the heart and is used to determine whether a heart attack is developing or has occurred.

¹⁹ 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.

HCC [for Embolism]. There is documentation of a past medical history of deep vein thrombosis [diagnosis] that does not result in an HCC.”²⁰

- For 10 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Embolism HCC.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Embolism]. There is documentation in the findings and conclusions of the sonogram of the lower extremities stating no evidence of deep venous thrombosis or venous obstruction in the lower extremities bilaterally. Condition was ruled out by the test.”

- For 2 enrollee-years, the medical records that Geisinger provided to support an Embolism HCC were not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner). The data sources provided were vascular laboratory results; therefore, the Embolism HCCs were not validated.
- For the remaining 2 enrollee-years, Geisinger could not locate any medical records to support a diagnosis that mapped to an Embolism HCC; therefore, an Embolism HCC was not validated.

As a result of these errors, the Embolism HCCs were not validated, and Geisinger received \$68,232 of overpayments for these 27 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Vascular Claudication

Geisinger incorrectly submitted diagnosis codes for vascular claudication for 14 of 30 sampled enrollee-years. Specifically:

- For 10 enrollee-years, the medical records in each case did not support a diagnosis related to vascular claudication.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Vascular Disease]. Doppler test results of the bilateral lower extremities show no evidence of arterial occlusive disease. Condition was ruled out by the test performed.”

²⁰ Deep vein thrombosis occurs when a blood clot forms in one or more of the deep veins in the body, usually in the legs.

- For the remaining 4 enrollee-years, Geisinger could not locate any medical records to support the vascular claudication diagnosis; therefore, the HCC for Vascular Disease was not validated.

As a result of these errors, the HCC for Vascular Disease was not validated, and Geisinger received \$33,759 of overpayments for these 14 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder

Geisinger incorrectly submitted diagnosis codes for major depressive disorder for 8 of 30 sampled enrollee-years. Specifically:

- For 4 enrollee-years, the medical records in each case did not support a major depressive disorder diagnosis.²¹

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Major Depressive, Bipolar, and Paranoid Disorders]. There is documentation of adjustment disorder with depressed mood [diagnosis] that does not result in an HCC.”

- For the remaining 4 enrollee-years, Geisinger could not locate any medical records to support the major depressive disorder diagnosis; therefore, the HCC for Major Depressive, Bipolar, and Paranoid Disorders was not validated.

As a result of these errors, the HCC for Major Depressive, Bipolar, and Paranoid Disorders was not validated, and Geisinger received \$20,646 of overpayments for these 8 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

Geisinger incorrectly submitted diagnosis codes for lung cancer for 27 of 30 sampled enrollee-years. Specifically:

- For 12 enrollee-years, the medical records in each case indicated that the individual had previously had lung cancer, but the records did not justify a lung cancer diagnosis at the time of the physician’s service.

²¹ For 1 of these enrollee-years, the submitted medical record did not meet Medicare signature requirements. For purposes of medical review, services provided or ordered must be authenticated by a signature in accordance with CMS’s policies (*Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance*). MA organizations may submit attestations for eligible medical records with missing or illegible signatures or credentials (42 CFR § 422.2). Geisinger was not able to obtain an attestation from the associated provider.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Lung and Other Severe Cancers]. There is documentation of a past medical history of lung cancer [diagnosis] that does not result in an HCC.”

- For 9 enrollee-years, the medical records in each case did not support either a lung cancer diagnosis or a diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Lung and Other Severe Cancers]. There is documentation of a right upper lobe mass [diagnosis] that does not result in an HCC.”

- For 4 enrollee-years, the medical records in each case did not support the submitted lung cancer diagnoses.²² However, for each of these enrollee-years, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Specifically, for 2 enrollee-years, we identified support for a diagnosis that mapped to the HCC for Colorectal, Bladder, and Other Cancers; and for 2 enrollee-years, we identified support for a diagnosis that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors. Accordingly, Geisinger should not have received an increased payment for the submitted lung cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.
- For the remaining 2 enrollee-years, Geisinger could not locate any medical records to support the lung cancer diagnosis; therefore, the HCC for Lung and Other Severe Cancers was not validated.

As a result of these errors, the HCC for Lung and Other Severe Cancers was not validated, and Geisinger received \$181,092 of overpayments for these 27 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

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

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

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the]

²² Geisinger could not locate any medical records for 1 of these enrollee-years.

HCC [for Breast, Prostate, and Other Cancers and Tumors]. There is documentation of a past medical history of breast cancer [diagnosis] that does not result in an HCC.”

- For 3 enrollee-years, the medical records in each case did not support a breast cancer diagnosis.²³

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors].”

- For the remaining 2 enrollee-years, Geisinger could not locate any medical records to support the breast cancer diagnosis; therefore, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated.

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Geisinger received \$34,379 of overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

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

- For 20 enrollee-years, the medical records in each case indicated that the individual had previously had colon cancer, but the records did not justify a colon cancer diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no information in the medical record to substantiate an active neoplasm of the large intestine. Patient was seen for an unrelated condition. A past medical history of a malignant neoplasm of the large intestine [diagnosis] should be assigned which does not result in an HCC.”

- For 5 enrollee-years, Geisinger could not locate any medical records to support the colon cancer diagnosis; therefore, the HCC for Colorectal, Bladder, and Other Cancers was not validated.
- For 3 enrollee-years, the medical records in each case did not support either a colon cancer diagnosis or a diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group.

²³ For 1 of these enrollee-years, the medical record that Geisinger provided to support the reviewed HCC was a radiology laboratory result. 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 example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Colorectal, Bladder, and Other Cancers]. There is documentation of colon polyp [diagnosis] which does not result in an HCC.”

- For the remaining 1 enrollee-year, the medical records did not support the submitted colon cancer diagnosis. However, we identified support for another diagnosis that mapped to the HCC for Breast, Prostate and Other Cancers and Tumors, which is a less severe manifestation of the related-disease group. Accordingly, Geisinger should not have received an increased payment for the submitted colon cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and Geisinger received \$69,571 of overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

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

- For 26 enrollee-years, the medical records indicated in each case that the individual had previously had prostate cancer, but the records did not justify a prostate cancer diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors]. There is documentation of a past medical history of prostate cancer [diagnosis] that does not result in an HCC.”

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

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors].”

- For the remaining 1 enrollee-year, Geisinger could not locate any medical records to support the prostate cancer diagnosis; therefore, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated.

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Geisinger received \$34,403 of overpayments for these 29 sampled enrollee-years.

Summary of Net Overpayments for Incorrectly Submitted Diagnosis Codes

In summary and with respect to the 9 high-risk groups covered by our audit, Geisinger received \$566,476 in net overpayments for the 224 sampled enrollee-years.

THE POLICIES AND PROCEDURES THAT GEISINGER HAD TO PREVENT, DETECT, AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS COULD BE IMPROVED

As demonstrated by the errors found in our sample, the policies and procedures that Geisinger 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.

Geisinger had compliance procedures that were designed to prevent providers from submitting incorrect diagnosis codes. These procedures included educating providers to document and code all active conditions at the time of the visit that required or affected patient care or treatment. (An active condition means that the patient is being monitored, evaluated, assessed, or treated for that condition.) In addition, Geisinger's educational material for providers included explanations that supporting documentation needs to represent a face-to-face encounter and must contain a provider signature.

Geisinger also had compliance procedures that were designed to determine whether the diagnosis codes that it submitted to CMS for use in CMS's risk adjustment program were correct. These procedures included conducting routine audits using a random sample of diagnosis codes to ensure that the codes were documented in the associated medical records. However, these audits did not focus on specific high-risk diagnosis codes, including those codes we identified as being at a higher risk for being incorrect.

Furthermore, Geisinger's compliance procedures included conducting a review of 100 sampled claims to evaluate the accuracy and completeness of diagnosis codes for the HCC for Vascular Disease that was included in our audit. However, Geisinger suspended its review after validating the HCC for Vascular Disease for 24 sample claims. By reviewing only these 24 sample claims, Geisinger did not conduct a comprehensive review for the HCC for Vascular Disease.

Although Geisinger had these compliance procedures, 224 of the 270 sampled enrollee-years were not supported by the medical records. For the 25 sampled enrollee-years for which Geisinger had not provided medical records at the time of our audit, Geisinger noted that, in some instances, providers had retired at the time of our request for the medical records or providers did not respond to the request. Geisinger stated that, in other instances, medical records were missing or could not be located for the appropriate time period. Therefore, we concluded that Geisinger's compliance procedures to prevent, detect, and correct miscoded high-risk diagnoses during our audit period could be improved.

GEISINGER 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 Geisinger received at least \$6.5 million of net overpayments for 2016 and 2017.²⁴ (See Appendix D for sample results and estimates.)

Because of Federal regulations that limit the use of extrapolation in Risk Adjustment Data Validation (RADV) audits for recovery purposes, we are reporting the estimated net overpayment amount but are recommending a refund of only the \$566,476 in net overpayments that Geisinger received for the 224 sampled enrollee-years.²⁵

RECOMMENDATIONS

We recommend that Geisinger Health Plan:

- refund to the Federal Government the \$566,476 of net overpayments;
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before and 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.

GEISINGER COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Geisinger disagreed with all of our findings and recommendations. Specifically, Geisinger disagreed with our recommendation in the draft report that it should refund the \$6.5 million in estimated net overpayments. Furthermore, Geisinger disagreed with our recommendations that it should conduct additional audits (to identify similar instances of noncompliance) and that it should examine its compliance procedures. However, Geisinger did not specifically disagree with any of the findings for the sampled enrollee-years identified in our draft report as not having medical records to support

²⁴ Specifically, we estimated that Geisinger received at least \$6,523,543 of net overpayments. To be conservative, we estimate net overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

²⁵ After we had issued our draft report, CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643, (Feb. 1, 2023)).

the associated diagnosis codes. In addition, Geisinger stated that it would delete unsupported codes found for the 224 sampled enrollee-years during our audit.

After reviewing Geisinger's comments and for the reasons detailed below, we maintain that our findings are valid. After we had issued our draft report, CMS updated Federal regulations for RADV audits to specify that extrapolated overpayments could only be recouped beginning with payment year 2018. Because our audit period covered payment years 2016 and 2017, we changed our first recommendation to specify a refund of only the net overpayments of \$566,476 that Geisinger received for the 224 sampled enrollee-years. We made no changes to our second and third recommendations.

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

GEISINGER DISAGREED WITH OUR RECOMMENDATION TO REFUND \$6.5 MILLION OF ESTIMATED OVERPAYMENTS BECAUSE THE OFFICE OF INSPECTOR GENERAL DOES NOT HAVE RULEMAKING AUTHORITY

Geisinger Comments

Geisinger stated that our recommendation that Geisinger refund \$6.5 million to the Federal Government has the effect of creating a rule requiring 100-percent accuracy in MA risk adjustment submission and a retroactive payment adjustment. Specifically, Geisinger commented that our MA audit activities have the effect of creating a new payment rule that, among other things, requires MA organizations to be 100-percent accurate based on medical record review in their risk adjustment submissions. Geisinger further stated that this requirement was created without the requisite authority and did not go through the required Administrative Procedures Act rulemaking procedures.

Geisinger also stated that we lack rulemaking authority under Federal regulations (42 CFR § 422.311) and the Inspector General Act of 1978 (IG Act) and that OIG is prohibited from assuming program operating responsibilities. Geisinger stated that although we cite 42 CFR § 422.311 as one source of authority for our actions, this regulation governs the CMS "RADV Audit Dispute and Appeal Process" and "does not govern or inform OIG's actions." Geisinger concluded that suggesting that 42 § CFR 422.311 gives us the authority to engage in actions that amount to MA payment rulemaking "is a mischaracterization of the regulation." In its comments on the IG Act, Geisinger noted that we identified the IG Act as support for our authority to conduct our actions "in at least five other reviews of [MA organizations]." Geisinger commented that the IG Act does not give us the authority to "effectively create a new rule under the wrappings of an audit."

Lastly, Geisinger stated that Congress intended risk adjustment audits "to be performed by CMS, not OIG . . ." Geisinger quoted CMS's statement that "[t]he RADV program is a corrective audit activity developed by CMS to address provisions included in [Federal statutes] These

statutes require that government agencies annually estimate and report improper payments.” Geisinger noted that the role of the Inspector General in these statutes is limited to agency oversight and reporting and that “[i]n contrast, Congress asks the agencies to identify and recover improper payments.”

Office of Inspector General Response

Although we reduced our recommended refund amount (as discussed above), we disagree with Geisinger’s comments. Our application of the statutory and regulatory requirements does not constitute creation of a new payment rule requiring 100-percent accuracy in MA risk adjustment submissions. Rather, we designed our audit to determine whether Geisinger adhered to those statutory and regulatory requirements and when we identified errors, we recommended that those errors be corrected. The IG Act provides OIG with independent authority to provide oversight of the Department of Health and Human Services’ (HHS’s) programs and operations through audits and investigations. We conduct our audits in accordance with generally accepted government auditing standards, which require that audits be planned and performed so as to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions. As a result, OIG’s audits do not represent the creation of “a new rule under the wrappings of an audit.”

We are authorized to perform audits of the risk adjustment data that MA organizations, like Geisinger, submit to CMS. This audit represents OIG’s exercise of its central statutory authorities under the IG Act as an independent oversight entity. In this respect, we recognize that CMS is responsible for making operational and program payment determinations for the MA program and that action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures.

GEISINGER DISAGREED WITH OUR USE OF STATISTICAL SAMPLING AND EXTRAPOLATION

Geisinger Comments

Geisinger stated that when Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, it authorized CMS to use contractors to perform reviews to determine whether Medicare had overpaid for services. Geisinger further commented on the limits that it stated Congress placed on Medicare contractors: “A Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise, unless the Secretary [of HHS] determines that (A) there is a sustained or high level of payment error; or (B) documented educational intervention has failed to correct the payment error.”²⁶ Geisinger stated that CMS, in developing the *Medicare Program Integrity Manual*, “explicitly recognized Congressional concerns by establishing very clear criteria around a Medicare contractor’s use of statistical sampling and extrapolation” and noted that CMS included these limits in the *Medicare Program Integrity Manual*. While Geisinger

²⁶ 42 U.S.C. § 1395ddd(f)(3).

acknowledged that we are not a Medicare contractor, it stated that we have not indicated why different criteria for the use of extrapolation would apply to this review.

Geisinger noted that CMS has yet to impose extrapolation in its RADV audits and that CMS has proposed but did not implement the use of extrapolation. Geisinger quoted CMS as saying in 2018 that its proposed rule would “*establish* that extrapolation would be utilized as a valid part of audit authority in [Medicare] Part C, as it has been historically a normal part of auditing practice throughout the Medicare program.” According to Geisinger, with this statement, “CMS in effect acknowledged that it had no clear authority to extrapolate under MA.”

Officer of Inspector General Response

We do not fully agree with Geisinger’s statements regarding the use of statistical sampling and extrapolation. Specifically, regarding Geisinger’s comment that CMS has yet to impose extrapolation in its RADV audits and that we have not indicated why different criteria for the use of extrapolation would apply to this audit, we discuss above that: (1) CMS updated, after we had issued our draft report, the Federal regulations for extrapolations in RADV audits and (2) we, accordingly, changed our first recommendation for this final report. However, we maintain that the use of sampling and extrapolation is an acceptable approach to identifying overpayments. Our approach does not always mirror CMS’s approach, nor does it have to. In accordance with the IG Act, 5 U.S.C. App., our audits are intended to provide an independent assessment of HHS programs and operations.

As stated in our report, we conduct our audits in accordance with generally accepted government auditing standards, which require that audits be planned and performed so as to obtain sufficient, appropriate evidence to provide a reasonable basis for the findings and conclusions. Our objective was to determine whether selected high-risk diagnosis codes that Geisinger submitted to CMS for use in CMS’s risk adjustment program complied with Federal requirements. The use of statistical sampling was appropriate to accomplish our objective.

Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.²⁷ 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.²⁸ We properly executed our statistical sampling methodology in

²⁷ 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).

²⁸ See *John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at *34-35 (W.D. Pa. 2012), *aff’d* 555 F. App’x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff’d*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

We note that, as Geisinger did in its comments, the requirement that a determination of a sustained or high level of payment error must be made before extrapolation applies only to Medicare contractors.²⁹ Nevertheless, we believe that the error rate (224 of 270 sampled enrollee-years with unsupported diagnosis codes (Appendix D)) identified in our audit demonstrates that Geisinger has compliance issues that need to be addressed.

Thus, we believe that the steps that we followed for this audit provide a reasonable basis for our findings and recommendations, including our estimation of net overpayments.

GEISINGER DISAGREED THAT OUR AUDIT MET GENERALLY ACCEPTED GOVERNMENT AUDITING STANDARDS

Geisinger Comments

Geisinger questioned whether generally accepted government auditing standards (GAGAS) constitute the appropriate standard to use for this audit. Geisinger further stated that, even if GAGAS was applicable, our audit does not meet the requirements of GAGAS and therefore “the findings and conclusions . . . are not supported.”

Specifically, Geisinger stated that we failed to document our methodology and procedures for sampling and extrapolation in accordance with GAGAS. For example, Geisinger stated that we “failed to provide specific details of [our] methodology in numerous critical areas” and also that we “failed to document or otherwise communicate [our] sampling methodology as required by [GAGAS].” Geisinger proposed sampling and estimation steps that it deduced we performed, then commented on those steps:³⁰ “However, based on information and belief, it appears that OIG implemented steps 1, 4, and 5 utilizing approaches and/or assumptions that are not statistically valid.” Furthermore, Geisinger made inferences and conclusions about our sampling and estimation methodology concerning the consideration of different diagnoses during sample evaluation, inferring that we utilized all-or-nothing evaluation, as well as deducing that we used incorrect formulas to compute the overpayment point estimate and

²⁹ The Act § 1893(f)(3) and CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 8, § 8.4 (effective Jan. 2, 2019).

³⁰ Geisinger stated the following in describing the methodology steps that it assumed we followed: “(1) OIG identified a sample of 30 individual life-years within each group in the frame; (2) OIG reviewed charts to determine the number of claims with unvalidated diagnosis indicators; (3) OIG determined the amount of unvalidated HCC dollars attributable to the unvalidated indicators, accounting for any offsetting conditions; (4) OIG scaled the unvalidated HCC dollars to the entire universe to determine a point estimate of the overall error; and (5) OIG used a common approximation of a commonly used distribution to estimate a 90% confidence interval for the sample error rate to determine lower and upper bounds for the payment error.”

confidence interval. Specifically, Geisinger stated “. . . OIG’s calculations are wrong because the total payment OIG identified as [Geisinger’s] payment for Acute Stroke in the [sampling] frame is [greater than] OIG’s calculated point estimate of the overpayment . . .” and that “[t]he result is impossible, since [Geisinger’s payment for Acute Stroke in the sampling frame] is greater than [OIG’s calculated point estimate of the overpayment].” Geisinger added: “OIG has, in the past, summarily dismissed objections to statistical validity in other [MA organization] audits, stating that it is only required to follow GAGAS, and that such audits merely need be ‘planned and performed so as to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions.’”³¹

In addition, Geisinger questioned our documentation and choice of sample size by stating that we “did not communicate to [Geisinger], or document, how it determined that a sample size of 30 enrollee-years per [high-risk group] was an appropriate sample size in the first place . . . OIG’s use of the sample size of 30, without more analysis, is insufficient to assure that the sample is representative, as required by GAGAS . . .”

Finally, Geisinger questioned whether our sample was representative of the population because “OIG has not provided any information regarding what efforts it made, if any, to ensure that each sample was representative of the universe from which it was drawn.” Geisinger commented that, as a result, “the evidence OIG relied on in its conclusions and findings is not reliable as required by GAGAS . . .” Geisinger suggested that tests should be performed to demonstrate that “a sample of 30 diagnoses will produce a statistically valid confidence interval.” Geisinger continued by questioning the randomness of our sample selection process and stated: “[It] is unclear if the sampling methodology is sufficiently random. The generation of random numbers via computerized software is typically not random.” Geisinger stated that we did not provide sufficient information to evaluate the random number generator, “which . . . poses reliability issues under GAGAS . . .”

Geisinger concluded that “[t]he above makes it clear that OIG’s methodology is not a methodology designed in a manner intended to obtain sufficient and appropriate evidence that provides a reasonable basis for OIG’s findings and conclusions” and that our methodology “contravenes GAGAS Standards . . .”

Office of Inspector General Response

We note that Geisinger commented on how it believed our sampling and estimation techniques did not comply with GAGAS and how it believed we could not use these techniques to support our findings and conclusions. As stated above, our recommendation to refund overpayments is no longer based on an estimation and is now limited to the net overpayments associated with the sampled enrollee-years. However, we believe that our sample results continue to show

³¹ *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS (A-02-20-01009)*, issued July 18, 2022.

that Geisinger has compliance issues that need to be addressed and provide a reasonable basis for our findings and conclusions.

Accordingly, we disagree with Geisinger’s comments that our methodology did not meet GAGAS and that GAGAS was not appropriate for this audit. Specifically, we followed GAGAS in that we communicated to Geisinger the objective, scope, and methodology of our audit multiple times throughout the engagement. We answered Geisinger officials’ questions and confirmed our audit approach and results at an exit conference. We also included in our draft report the details of the audit scope and methodology (Appendix A), statistical sampling methodology (Appendix C), and sample results and estimates (Appendix D). Furthermore, GAGAS is appropriate for this audit because the IG Act requires that we “comply with standards established by the Comptroller General of the United States for audits of Federal establishments, organizations, programs, activities, and functions . . .” Thus, during our audit we followed GAGAS—a set of standards implemented by the Comptroller General of the United States.

We also disagree with Geisinger that we utilized “approaches and/or assumptions that are not statistically valid.” First, the sampling and estimation methodology that Geisinger described in its comments is not the methodology that we used, documented, and communicated to Geisinger throughout the audit. During the entrance conference and throughout our audit fieldwork, we communicated our intent to use statistical sampling as well as our selection criteria for the sampling frame. In addition, we worked with Geisinger to verify the sampling frame. In the exit conference, we again provided Geisinger with the sampling frame selection criteria. We also provided the total dollar amounts for the final sampling frame and the details for the selected sample items, including the total overpayments for the sample items and the estimated overpayment amount for the sampling frame. In the report, we described our sampling and estimation methodology and our calculation of the overpayment amounts (Appendices A, C, and D). Second, our sampling and estimation methodology followed the design-based methods for stratified random sampling outlined in textbooks on finite sampling, e.g., Cochran’s *Sampling Techniques*.³² Lastly, the point estimate and confidence interval computations in RAT-STATS that we used for this audit follow the formulas provided in *Sampling Techniques*.

More specifically, Geisinger is incorrect in its assumption that we used an all-or-nothing sample evaluation. 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 used the overpayments and underpayments (if any) identified for each enrollee-year to determine our estimated net overpayment amount. In addition, we used the correct formulas to compute the point estimate and 90-percent confidence interval of net

³² William G. Cochran, *Sampling Techniques*: 3rd edition, Wiley, New York, 1977. This textbook provides the detailed proofs underlying design-based sampling and estimation methods for stratified and simple random sampling used by OIG.

overpayments.³³ The proofs for the unbiased nature of our point estimate³⁴ and the conservative nature of the lower limit require random selection of the sample units from each stratum. We performed this selection using a valid random number generator.³⁵ In addition, we believe that the normal distribution is appropriate for calculation of the 90-percent confidence interval when stratum sizes are sufficiently large.³⁶ For this audit, the sample sizes were 30 per stratum, which indicates that the normal distribution was appropriate to use when computing the confidence interval.

We disagree with Geisinger's comment that "OIG's calculations are wrong" because the point estimate of net overpayments in the Acute Stroke stratum is larger than the stratum total. Geisinger's comment has the appearance that we asked Geisinger in our draft report to return more than what it was paid. Although we have limited the recommended recovery in this final report to the overpayments associated with the sampled enrollee-years, we did not recommend recovery in the draft report at the stratum point estimate or the overall point estimate, but at the lower limit of the two-sided 90-percent confidence interval for the overall net overpayment amount. We believe this was a reasonably conservative estimate of overall net overpayments in the sampling frame. Furthermore, as noted previously, the estimates were computed using RAT-STATS, which utilizes the correct formulas from Cochran's *Sampling Techniques* (footnotes 32 and 33). In addition, the fact that the point estimate of stratum overpayments is higher than the stratum total does not indicate the calculations are wrong. Because of the nature of random sampling and estimation, it is possible for the point estimate of an overpayment amount to be smaller or larger than the stratum total (footnotes 32 and 33). The chance that the point estimate is larger than the stratum total increases as the error rate in the stratum increases. (Note that the error rate for the stratum in question was found to be 100 percent.) In fact, limiting the stratum point estimate to the stratum total would be an incorrect calculation and would lead to a biased estimate of net overpayments (footnote 34).

Therefore, we believe that our sampling and estimation methodology is statistically valid for the technical reasons provided, and we note that we have not dismissed objections to statistical validity simply because we adhere to GAGAS.

Furthermore, Geisinger's statement that our "use of the sample size of 30, without more analysis, is insufficient to assure that the sample is representative" and hence may not produce a statistically valid confidence interval for total overpayment, is not correct. First, the overall sample size of our stratified random sampling design was 270 enrollee-years, all of which were used to compute the 90-percent confidence interval estimate for total overpayment. Second, small sample sizes, e.g., smaller than 100, have routinely been upheld by the Departmental

³³ See *Sampling Techniques*, equations 5.1 and 5.15.

³⁴ See theorem 5.1 of *Sampling Techniques*.

³⁵ See *New York State Department of Social Services*, Departmental Appeals Board (DAB) No. 1531 (1995).

³⁶ See discussion in section 5.4 of *Sampling Techniques*.

Appeals Board and Federal courts.³⁷ The legal standard for a sample size is that it must be sufficient to be statistically valid, not that it be the most precise methodology.³⁸ Because absolute precision is not required, any imprecision in the sample may be remedied by recommending recovery at the lower limit, which was done in this audit.³⁹ This approach results in an estimate that is lower than the actual overpayment amount 95 percent of the time, and thus it generally favors the provider.⁴⁰

Finally, we disagree with Geisinger's implication that we did not "ensure that each sample was representative of the universe from which it was drawn." Our sample is representative because it was drawn at random from the sampling frame. No other definition of "representative" is required by the methods outlined in Cochran's *Sampling Techniques*. In addition, the sampling and estimation methodology described in that textbook does not require or recommend the type of representative testing performed by Geisinger. As stated previously, in accordance with our objective and as detailed in Appendices A, C, and D, we properly executed a statistically valid sampling and estimation methodology: We defined our sampling frame and sample unit, randomly selected our sample (using a valid random number generator), applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

Accordingly, we maintain that our sampling and estimation methodology was well-founded and statistically valid, well-executed, and sufficiently documented and communicated to allow Geisinger to reproduce our sample and estimates.

GEISINGER DISAGREED WITH OUR METHODOLOGY BECAUSE GEISINGER BELIEVED THAT THE METHODOLOGY DID NOT CONSIDER ACTUARIAL EQUIVALENCE AND THAT PORTIONS OF IT WERE ARBITRARY AND CAPRICIOUS

Geisinger Comments

Geisinger stated that our audit methodology violated the requirement for actuarial equivalence, mandated by the Social Security Act. According to Geisinger, our audit violated this requirement because: (1) we reviewed medical records when the CMS risk adjustment model is based on claims data and (2) our methodology did not consider overcoding and undercoding of claims, which CMS considers in its calculation of risk-adjusted payments.

³⁷ See *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012) (upholding a sample size of 95 claims); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 (S.D. Tex. 2012) (upholding a sample size of 30 claims).

³⁸ 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); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012).

³⁹ See *Pruchniewski v. Leavitt*, 2006 U.S. Dist. LEXIS 101218 at *51-52 (M.D. Fla. 2006).

⁴⁰ See *Puerto Rico Dep't of Health*, DAB No. 2385, at 10-11 (2011); *Oklahoma Dep't of Human Servs.*, DAB No. 1436, at 8 (1993) (stating that the calculation of the disallowance using the lower limit of the confidence interval gave the State the "benefit of any doubt" raised by use of a smaller sample size).

Geisinger commented that because we are “auditing medical record sourced diagnoses in a payment system that is designed, created, and intended to use diagnoses from claim records, OIG is substituting one data source for another in a way that is outside of the intended use of the risk adjustment model.” According to Geisinger, our methodology would need to consider: “1) an adjustment to the model that accounts for substituting claims-based data with medical record-based data, e.g. an adjustment for differences in the diagnoses on FFS claims and diagnoses on FFS medical records; and 2) undercoding and overcoding.” Geisinger concluded that without application of these principles to reconcile the disparate data sources, our audit results are not reliable.

Regarding the consideration of undercoding and overcoding, Geisinger stated that our refusal to consider underpayments is “arbitrary and capricious” and commented that our approach focuses only on “so-called high-risk codes, which have been datamined to find only ‘overpayments . . .’” Geisinger further stated: “CMS, when conducting its RADV audits, takes into consideration diagnosis codes that are supported but not previously submitted (underpayments) in determining net overpayment amounts.” Geisinger commented: “In contrast, OIG’s approach . . . is without precedent, runs counter to the way CMS has administered its responsibilities under the RADV audits, is fundamentally unfair, and punitive.” Geisinger stated that we may argue that some of the codes selected in the audit demonstrate a high rate of error. Geisinger concluded: “Assuming . . . this was the case, such error rate would be attributed only to the highly targeted and selective nature of the audit itself.”

Office of Inspector General Response

Our audit methodology correctly applied CMS requirements to properly identify the overpayment amount associated with unsubstantiated HCCs for each sample item. We used the results of 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. To this point, we note that CMS stated (after we had issued our draft report) that it “will not apply an adjustment factor (known as an FFS Adjuster) in RADV audits.”⁴¹ Thus, our audit methodology was not arbitrary and capricious, because we used the overpayments and underpayments (if any) identified for each enrollee-year to determine our estimated net overpayment amount. However, it was beyond the scope of our audit to identify all possible diagnosis codes that Geisinger could have submitted beyond the audited HCCs for the sampled enrollee-years.

⁴¹ 88 Fed. Reg. 6643 (Feb. 1, 2023).

GEISINGER DISAGREED WITH OUR RECOMMENDATION TO CONDUCT FURTHER AUDITS AND REFUND ANY OVERPAYMENTS

Geisinger Comments

Geisinger disagreed with our second recommendation—that it identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before and after our audit period and refund any resulting overpayments. According to Geisinger, “OIG is, in effect retroactively adjusting the payment terms of MA Contract H3954, which has already inherently taken into consideration the overpayments OIG is alleging, and, again, implementing a ‘rule’ that did not go through appropriate rulemaking.” Geisinger commented that this is “inconsistent with the [Social Security Act’s] prohibition against retroactive application of rules absent a significant public safety concern or other critical need.”

Geisinger stated that CMS does not currently have a mechanism in place to refund monies that resulted from an extrapolation. Geisinger noted that MA organizations submit “delete files” for diagnoses codes but cannot refund extrapolated amounts via those files. Geisinger commented: “Additionally, simply refunding an extrapolated amount in a lump sum would provide no assurance to [Geisinger] that those same codes would not subsequently be pulled into another internal or external audit or investigation for which [Geisinger] would again be responsible because they were not removed from CMS data via the appropriate delete file submission process.”

Office of Inspector General Response

We maintain that our second recommendation—that Geisinger identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before and after our audit period and refund any resulting overpayments—is valid. Because we are not recommending the application of any new statutory or regulatory requirements, Geisinger’s citing of the Social Security Act’s prohibition of retroactive application of rules is not applicable to this audit.

We recognize that OIG audit findings and recommendations do not represent final determinations by CMS, so we will provide CMS with our independent medical review contractor’s results for its consideration. Geisinger should work with CMS officials on its data corrections.

GEISINGER DISAGREED WITH OUR RECOMMENDATION TO EXAMINE ITS EXISTING COMPLIANCE PROCEDURES AND TAKE NECESSARY STEPS TO ENHANCE THEM

Geisinger Comments

Geisinger disagreed with our third recommendation—that it 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 and take the necessary steps to enhance those procedures. Geisinger stated that it conducts regular and targeted monitoring and auditing of risk adjustment data both before and after submission to CMS. Further, Geisinger stated that it is confident that it is making good-faith efforts to ensure that the data submitted to CMS are accurate, complete, and truthful and that its compliance activities are otherwise effective. In addition, Geisinger commented that our audit was an audit of exceptions that “specifically targeted codes and patterns in a manner designed for [MA organizations] to fail.” Finally, Geisinger commented: “With every review, OIG’s focus shifts, making it challenging for [MA organizations] to consider where to focus efforts. . . . OIG’s constantly shifting focus makes these efforts even more difficult and frustrates the compliance process.”

Office of Inspector General Response

Regarding Geisinger’s comment that our audit was an audit of exceptions that specifically targeted codes and patterns in a manner designed for MA organizations to fail, we did not opine on the entirety of Geisinger’s compliance with Federal requirements. We limited our audit and recommendations to certain diagnosis codes that we determined to be at high risk for being miscoded.

Federal regulations (42 CFR § 422.503(b)) require MA organizations like Geisinger to establish and implement an effective system for routine monitoring and the identification of compliance risks. This regulation further explains that a compliance system should consider both internal monitoring and external audits. Accordingly, based on the materiality of our findings—estimated overpayments of at least \$6.5 million out of a \$7.9 million sampling frame and an error rate of 224 out of 270 sampled enrollee-years with unsupported diagnosis codes (Appendix D)—we believe that Geisinger has compliance issues that need to be addressed. Therefore, we maintain that our recommendation that Geisinger examine and enhance its existing compliance procedures is valid. The continued improvement of procedures will assist Geisinger in attaining better assurance with regard to the “accuracy, completeness, and truthfulness” of the risk adjustment data that it submits in the future.

Regarding Geisinger’s comment that our focus shifts with every review, using data mining techniques, discussions with medical professionals, and the results of our audits that reviewed the accuracy of diagnosis codes that MA organizations submitted to CMS, we may uncover additional high-risk groups of diagnosis codes for our audits. Not all MA organizations are the same, and we reviewed the high-risk groups applicable for the MA organizations during the time of the audits.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid Geisinger \$1,430,289,637 to provide coverage to its enrollees for 2016 and 2017. We identified a sampling frame of 3,734 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2015 and 2016 service years. Geisinger received \$56,248,782 in payments from CMS for these enrollee-years for 2016 and 2017. We selected for audit 270 enrollee-years with payments totaling \$4,219,452.

The 270 enrollee-years included 30 acute stroke diagnoses, 30 acute heart attack diagnoses, 30 major depressive disorder diagnoses, 30 embolism diagnoses, 30 vascular claudication diagnoses, 30 lung cancer diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, and 30 prostate cancer diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$706,678 for our sample.

Our audit objective did not require an understanding or assessment of Geisinger'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 February 2020 to July 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:
 - 74 diagnosis codes for acute stroke,
 - 38 diagnosis codes for acute heart attack,
 - 29 diagnosis codes for major depressive disorder,
 - 85 diagnosis codes for embolism,
 - 4 diagnosis codes for vascular claudication,

- 24 diagnosis codes for lung cancer,
 - 65 diagnosis codes for breast cancer,
 - 20 diagnosis codes for colon cancer, and
 - 2 diagnosis codes for prostate cancer.
- 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;⁴²
 - Risk Adjustment System (RAS) to identify enrollees who received an HCC for the high-risk diagnosis codes;⁴³
 - Medicare Advantage Prescription Drug System (MARx) to identify enrollees for whom CMS made monthly Medicare payments to Geisinger, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C);⁴⁴
 - Encounter Data System (EDS) to identify enrollees who received specific procedures;⁴⁵ and
 - Prescription Drug Event (PDE) file to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.⁴⁶
 - We interviewed Geisinger officials to gain an understanding of: (1) the policies and procedures that Geisinger followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Geisinger’s monitoring of those diagnosis codes to prevent, detect, and correct noncompliance with Federal requirements.
 - We selected for audit a stratified random sample of 270 enrollee-years (Appendix C).

⁴² MA organizations use the RAPS to submit diagnosis codes to CMS.

⁴³ The RAS identifies the HCCs that CMS factors into each enrollee’s risk score calculation.

⁴⁴ The MARx identifies the payments made to MA organizations.

⁴⁵ The EDS contains information on each item (including procedures) and service provided to an enrollee.

⁴⁶ 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 270 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.⁴⁷
- 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 Geisinger during the audit period.

⁴⁷ Our independent medical review contractor used senior coders, all of whom possessed one or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS), Certified Coding Specialist–Physician-Based (CCS-P), Certified Professional Coder (CPC), and Certified Risk Adjustment Coder (CRC). RHITs have completed a 2-year degree program and have passed an American Health Information Management Association (AHIMA) certification exam. AHIMA also credentials individuals with CCS and CCS-P certifications, and the American Academy of Professional Coders credentials both CPCs and CRCs.

- We limited the total net overpayment that we recommended for recovery to the sampled enrollee-years.⁴⁸
- We discussed the results of our audit with Geisinger officials.

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

⁴⁸ Federal regulations (42 CFR § 422.311(a)) state: “. . . the Secretary annually conducts RADV audits to ensure risk-adjusted payment integrity and accuracy.” Recovery of improper payments from MA organizations will be conducted in accordance with the Secretary’s payment error extrapolation and recovery methodologies. CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years. 88 Fed. Reg. 6643, 6655 (Feb. 1, 2023).

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring of Tennessee, Inc. (Contract H4454) Submitted to CMS</i>	<u>A-07-19-01193</u>	12/22/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BCBS of Rhode Island (Contract H5412) Submitted to CMS</i>	<u>A-01-20-00500</u>	11/16/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That California Physicians' Service, Inc. (Contract H0504) Submitted to CMS</i>	<u>A-09-19-03001</u>	11/10/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract 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 (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 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 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 Specific Diagnosis Codes That Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS</i>	<u>A-02-18-01029</u>	1/5/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS</i>	<u>A-07-19-01188</u>	11/5/2021

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (H3954) Submitted to CMS (A-09-21-03011)

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

We presented the data for these enrollees to Geisinger for verification and performed an analysis of the data included on CMS's systems to ensure that the high-risk diagnosis codes increased CMS's payments to Geisinger. After we performed these steps, our finalized sampling frame consisted of 3,734 enrollee-years.

SAMPLE UNIT

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

SAMPLE DESIGN AND SAMPLE SIZE

The design for our statistical sample comprised nine 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 (774 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 claim or outpatient claim (1,007 enrollee-years);
- a diagnosis (that mapped to an Embolism HCC) on only one claim during the service year but did not have an anticoagulant medication dispensed on his or her behalf (273 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 (174 enrollee-years);

- 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 (281 enrollee-years);
- a lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the lung cancer diagnosis administered within a 6-month period before or after the diagnosis (102 enrollee-years);
- a breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the breast cancer diagnosis administered within a 6-month period before or after the diagnosis (563 enrollee-years);
- a colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (260 enrollee-years); or
- a prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors), for an individual 74 years old or younger, on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (300 enrollee-years).

The specific strata are shown in Table 2.

Table 2: 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	774	\$1,709,510	30
2 – Acute heart attack	1,007	1,950,983	30
3 – Embolism	273	689,845	30
4 – Vascular claudication	174	387,317	30
5 – Major depressive disorder	281	744,850	30
6 – Lung cancer	102	707,470	30
7 – Breast cancer	563	746,363	30
8 – Colon cancer	260	666,541	30
9 – Prostate cancer	300	357,132	30
Total	3,734	\$7,960,011	270

SOURCE OF RANDOM NUMBERS

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

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 270 random numbers according to our sample design, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

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

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 3: Sample Details and Results

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	774	\$1,709,510	30	\$71,487	30	\$66,787
2 – Acute heart attack	1,007	1,950,983	30	59,912	30	57,607
3 – Embolism	273	689,845	30	76,348	27	68,232
4 – Vascular claudication	174	387,317	30	69,848	14	33,759
5 – Major depressive disorder	281	744,850	30	77,068	8	20,646
6 – Lung cancer	102	707,470	30	209,293	27	181,092
7 – Breast cancer	563	746,363	30	34,379	30	34,379
8 – Colon cancer	260	666,541	30	72,606	29	69,571
9 – Prostate cancer	300	357,132	30	35,737	29	34,403
Total	3,734	\$7,960,011	270	\$706,678	224	\$566,476

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

Point estimate	\$6,874,765
Lower limit	6,523,543
Upper limit	7,225,988

**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: GEISINGER COMMENTS

Geisinger Health Plan
Legal & Regulatory Affairs
100 N. Academy Ave.
Danville, PA 17822-3220



Phone: 570-271-6836
GeisingerHealthPlan.com

VIA EMAIL

September 16, 2022

Lori A. Ahlstrand
Regional Inspector General for Audit Services
Office of Audit Services, Region IX
90 7th Street, Suite 3-650
San Francisco, CA 94103

Re: **Geisinger Health Plan H3954 Response to OIG Draft Report No. A-09-21-03011**

Dear Ms. Ahlstrand:

This letter responds to the Office of Inspector General (“OIG”) draft report, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Geisinger Health Plan (Contract H3954) Submitted to CMS*, dated July 19, 2022 (the “Draft Report”).

The Draft Report states that the Geisinger Health Plan (“GHP”) review was conducted by OIG as part of a series of audits¹ undertaken to review the accuracy of diagnosis codes that MA organizations submitted to the Centers for Medicare and Medicaid Services (“CMS”) with respect to the Medicare Advantage (“MA”) program (the “Audit”).² The Audit methodology involves a review of a selected subset of codes that OIG has determined “are at higher risk for being miscoded.” OIG’s stated objective was “to determine whether selected diagnosis codes that GHP submitted to CMS for use in CMS’s risk adjustment program complied with Federal requirements.”

The Audit involved MA claims submitted over a two-year period from January 1, 2015, through December 31, 2016 for payment years (“PYs”) 2016 and 2017 (the “Audit Period”). The Audit was limited to medical records of enrollees on whose behalf providers documented diagnosis codes that mapped to one of OIG’s so-called high-risk groups (“HRGs”), a limited and datamined subset of GHP data, during the Audit Period. Because enrollees could be classified into more than one HRG or could have high-risk diagnosis codes (“HRDCs”) documented in more than one year, OIG classified these individuals according to the condition and the PY (referred to as “enrollee-years”). This yielded 3,734 enrollee-years from which OIG selected a “stratified random sample” of 270 enrollee-years, and a sample size of 30 enrollee-years per HRG.³

¹ Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN. at 1 (July 2022).

² *Id.*

³ *Id.* at 20 (See also, [Appendix C](#)).

OIG concluded that 46 out of the 270 GHP enrollee-years complied with Federal requirements. OIG found that for the remaining 224 enrollee-years either: (1) the medical records that GHP provided did not support the diagnosis codes, or (2) GHP could not locate the medical records – and as a result the Hierarchical Condition Codes (“HCCs”), triggered by one or more of the nine HRDCs, were not validated. As a final step, “using statistical software to estimate the total amount of net overpayments,”⁷⁴ OIG extrapolated that result over the universe of enrollee-years and its audit findings include an estimate that GHP received “at least \$6.5 million of net overpayments”⁷⁵ for the Audit Period which OIG recommends be “refunded to the Federal Government.”⁷⁶ OIG also recommends that GHP: (1) identify, for the HRDCs included in the report, similar instances of noncompliance that occurred before and after the Audit Period and refund any resulting overpayments to the Federal Government and (2) 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 and take necessary steps to enhance those procedures.⁷

For the reasons that follow, GHP does not agree with the findings and conclusions, or the recommendations. However, GHP will, consistent with its obligations under the Medicare Advantage (“MA”) Program, delete codes in OIG’s sample found to be not supported during OIG’s Audit.

I. OIG’s Recommendation That GHP Return \$6.5 Million to the Federal Government Amounts to Improper Implementation of a Rule Requiring 100% Accuracy in MA Risk Adjustment Submission and a Retroactive Payment Adjustment

OIG arrives at the \$6.5 million dollar figure using methods, processes and assumptions that are, as discussed below, problematic in several areas. In addition, OIG has not fully communicated those methods, processes, and assumptions to GHP or the industry at large that would allow for independent validation.

Although GHP believes it is an unintended consequence, OIG’s MA audit activities have the effect of creating a new payment rule that, among other things, requires MA Organizations (“MAOs”) to be **100% accurate** based on medical record review in their risk adjustment submissions. In addition to imposing material administrative costs on MAOs, GHP respectfully believes that OIG’s implementation of this requirement is improper for several reasons. First, the Administrative Procedures Act (“APA”) prohibits an agency from implementing a substantive legal standard without following the appropriate procedures, importantly, providing affected parties notice and an opportunity for comment. Second, OIG has not provided sufficient authority to support OIG’s MA audit activities (the “Audit Activities”). The only statutory authority OIG has cited are: 1) conclusory references to the authority granted to it under the Inspector General Act of 1978, as amended (the “IG Act”⁸); and 2) 42 CFR § 422.311. For reasons that follow, GHP respectfully submits, neither provides authority for the OIG’s Audit Activities.

A. The Adoption of a Requirement by an Agency That Establishes or Changes a Substantive Legal Standard Must be Done Through APA Rulemaking

The APA provides that when federal agencies establish a substantive legal standard, they must go through the notice and comment rulemaking process. These notice and comment requirements did not originally apply to MA, but in the 1980s, Congress adopted a Medicare-specific statute requiring notice and comment.⁹ As the Supreme Court noted in *Azar v. Allina Health Services*:

⁴ *Id.*

⁵ *Id.* at 7.

⁶ *Id.* at 18.

⁷ *Id.*

⁸ Inspector General Act of 1978, P.L. 95-452, 92 STAT. 1101.

⁹ See *Azar v. Allina Health Services*, 139 S.Ct. 1804, 1809 (2019).

“One way or another, Medicare touches the lives of nearly all Americans. Recognizing this reality, Congress has told the government that, when it wishes to establish or change a ‘substantive legal standard’ affecting Medicare benefits, it must first afford the public notice and a chance to comment.

“Congress chose to write a new, Medicare-specific statute. The new statute required the government to provide public notice and a *60-day* comment period (twice the APA minimum of 30 days) for any rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [Medicare].”¹⁰

The purpose of the notice and comment requirement is to “give[] affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes—and it affords [CMS or any other agency] a chance to avoid errors and make a more informed decision.”¹¹ OIG’s actions have a direct impact on payments to MAOs, like GHP, who should have been provided notice and an opportunity to comment and, as discussed below, OIG would have benefitted from notice and comment on the actuarial implications of its methodologies.

B. OIG’s Audit Activities Have the Effect of Creating a Requirement for Plans to be 100% Accurate Through Costly and Inefficient Medical Records Review in MA Risk Adjustment Submissions Without the Requisite Authority and Without Going Through Required APA Rulemaking Procedures

OIG states in its draft Report that:

“Federal regulations... state that MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes and that such data must conform to all relevant national standards (42 CFR §§ 422.504(l) and 422.310(d)(1)).”¹²

OIG also notes:

“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)).... 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).”¹³

¹⁰ *Id.* at 1808-09 (quoting 42 U. S. C. §1395hh(a)(2)) (emphasis added).

¹¹ *Id.* at 1816.

¹² Draft Report at 8 (quoting 42 CFR §§ 422.504(l) and 422.310(d)(1)).

¹³ *Id.*

OIG then states that “[m]ost of the selected high-risk diagnosis codes that GHP submitted to CMS for use in CMS’s risk adjustment program did not comply with Federal requirements,” and that “GHP should not have submitted the diagnosis codes to CMS and received the resulting net [\$6.5 million] overpayment....”¹⁴

MAOs like GHP receive enumerable claims for services that include risk adjusted codes. It is impossible for MAOs to cull through and review encounter data and their corresponding medical records, which need to be individually retrieved from providers, and locate all instances of coding errors. This has never been a requirement of payment. The risk model created by CMS is a “claim-based” model not a “medical chart review-based” model. Certain assumptions related to fee-for-service (“FFS”) errors are calibrated in payment. CMS has never required that MAOs review medical records as a necessary step to submission of risk adjustment data because this would create untenable administrative inefficiencies that would threaten the operation of the MA program. Moreover, the OIG targeted codes for which the Federal Government would only have payment adjustments in the Government’s favor while ignoring similar analogs of codes that were likely underpaid. This type of retrospective one-way payment adjustment has the effect of creating a payment rule and policy that: (1) requires MAOs to transmit only 100% accurate risk adjustment data to CMS, but only when it is in the Government’s favor; and, (2) in order to meet this obligation, effectively requires MAOs to police their risk adjustment universe by reviewing all medical records or be subject to future audits with retroactive payment adjustments.

The OIG Audit Activities have resulted in the imposition of a substantive change to the requirements applicable to risk adjustment validation and payment process by implementing the substantive requirements (hereinafter referred to as the “OIG Rule”). OIG does not have the authority to implement the OIG Rule, but even if it did, OIG is required to abide by the APA notice-and-comment rulemaking requirements.

1. OIG’s Lacks Rulemaking Authority Under 42 CFR § 422.311

One source of authority OIG has cited for its actions is 42 CFR § 422.311:¹⁵

(a) **Risk adjustment data validation (RADV) audits.** In accordance with § 422.2 and § 422.310(e), *the Secretary* annually conducts RADV audits to ensure risk adjusted payment integrity and accuracy.

(b) **RADV audit results.**

(1) MA organizations that undergo RADV audits will be issued an audit report post medical record review that describes the results of the RADV audit as follows:

- (i) Detailed enrollee-level information relating to confirmed enrollee HCC discrepancies;
- (ii) The contract-level RADV payment error estimate in dollars;
- (iii) The *contract-level payment adjustment* amount to be made in dollars;
- (iv) An approximate timeframe for the payment adjustment; and

¹⁴ *Id.* at 8-9.

¹⁵ See, e.g., Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Cariten Health Plan Inc. Submitted to CMS, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., page 21 n.30 (Jul. 2022) (noting, in connection with its conclusion that that its audit methodology provided a “reasonable basis” for its “findings and recommendations, including [its] estimation of net overpayments: “[i]n accordance with 42 CFR § 422.311, which addresses audits conducted by the Secretary (*including those conducted by the OIG*), if a disallowance is taken, MA organizations have the right to appeal the determination that an overpayment occurred through the Secretary’s RADV appeals process.”) (emphasis added) (hereinafter the “Cariten Report”).

(v) A description of the MA organization's RADV audit appeal rights

First, this regulation governs the CMS “RADV Audit Dispute and Appeal Process.” This regulation does not govern or inform OIG’s actions. The RADV process is CMS’s program administration responsibility, which is undergoing formal rulemaking unlike OIG’s audit. Second, the above regulation *expressly* states: 1) the “Secretary” of Health and Human Services (“HHS”) (*not* the OIG) is authorized to conduct a RADV audit; 2) the RADV audit report must specify the contract-level payment error estimate in dollars; and 3) changes to the payments as a result of a RADV audit are contract-level “payment adjustments.” Payment adjustments are a marker of agency program administration, for which CMS, not OIG, is responsible. To summarily suggest, as OIG has, that *this* regulation gives OIG the authority to engage in actions that amount to MA payment rulemaking is a mischaracterization of the regulation. GHP also notes that in CMS’s RADV proposed rule, the OIG appears to have declined any public notice or formal rulemaking stating that “[OIG] *does not seek comment on its methodology for risk adjustment audit work that may lead to overpayment recoveries from MA organizations.*”¹⁶

2. The IG Act Does Not Provide OIG with Rulemaking Authority

OIG has, in at least five other reviews of other MAOs, identified the IG Act as support for its authority to conduct its actions. For example, in an audit of Humana’s risk adjustment program, OIG noted, “In accordance with the Inspector General Act of 1978, 5 U.S.C. App., our audits are intended to provide an independent assessment of HHS programs and operations.”¹⁷ OIG made the exact same comment in published reports of its reviews for four other MAOs: Cariten Health Plan, UPMC, Tufts, and PacifiCare.¹⁸ GHP respectfully submits that the IG Act does not provide OIG with the authority to effectively create a new rule under the wrappings of an audit.

a) The IG Act Prohibits Inspector Generals from Assuming Program Operational Responsibilities

The IG Act was initially signed into law on October 12, 1978.¹⁹ The purpose of the IG Act was to “increase the economy and efficiency of the Executive Branch,”²⁰ and specifically, “to consolidate existing auditing and investigative resources to more effectively combat fraud, abuse, waste and mismanagement in the programs and operations of [various executive] departments and agencies.”²¹

Congress intended Inspectors General (“IGs”) to be akin to internal auditors of their affiliated “establishments”:

In order to create *independent and objective units* to conduct and supervise audits and investigations relating to the programs and operations *of the establishments* listed in section

¹⁶ Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54982, 55039.

¹⁷ Medicare Advantage Compliance Audit of Diagnosis Codes that Humana, Inc. Submitted to CMS, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., page 13 (Apr. 2021).

¹⁸ Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Cariten Health Plan Inc. Submitted to CMS, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., pages 19, 23 (Jul. 2022); Medicare Advantage Compliance Audit of Specific Diagnosis Codes that UPMC Health Plan Inc. Submitted to CMS, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., pages 23, 26 (Nov. 2021); Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Tufts Health Plan Submitted to CMS, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., page 16 (Feb. 2022); Risk Adjustment Data Validation of Payments Made to PacifiCare of Texas for Calendar Year 2007, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., pages 9, 12, 14 (May 2012).

¹⁹ Inspector General Act of 1978, P.L. 95-452, 92 STAT. 1101.

²⁰ *Id.*

²¹ S.REP. No. 1071, 95th Cong., 2d Sess. 1 (1978), *reprinted in* 1978 U.S.C.C.A.N. 2676, 2676 (emphasis added).

12(2)... there is established...in each of *such establishments* an office of Inspector General....²²

Congress also intended to give IGs broad authority. However, the plain language of the IG Act makes it clear that Congress intended that the IGs' authority be limited to oversight of the IG affiliated *establishments*. The IG Act is replete with examples:

- (1) In addition to the authority otherwise provided by this Act, each Inspector General, in carrying out the provisions of this Act, is authorized—
 - (A) to have timely access to all records, reports, audits, reviews, documents, papers, recommendations, or other materials available to the applicable establishment *which relate to the programs and operations with respect to which that Inspector General has responsibilities under this Act* ...
- (2) to make such investigations and reports relating to the administration of the programs and operations *of the applicable establishment* as are, in the judgment of the Inspector General, necessary or desirable ...
- (4) to require by subpoena the production of all information, documents, reports, answers, records, accounts, papers, and other data in any medium (including electronically stored information), as well as any tangible thing and documentary *evidence necessary in the performance of the functions assigned by this Act*, which subpoena, in the case of contumacy or refusal to obey, shall be enforceable by order of any appropriate United States district court: Provided, That procedures other than subpoenas shall be used by the Inspector General to obtain documents and information from Federal agencies...²³

Phrases like “*under this Act*,” “*applicable establishments*” and “*assigned by this Act*” are intended to restrict the scope of each IG’s authority to the oversight of the “establishment” with which each IG is associated – in this case, the HHS. Further, so that there is a clear demarcation of responsibilities between each agency and the associated IG, 5 U.S.C. App. 3 § 9(a)(2) provides that the head of an establishment may *transfer* to an IG functions, powers, and duties that he determines “are properly related to the functions of the [OIG] and would, if so transferred, further the purposes of this Act, *except that there shall not be transferred to an Inspector General ... program operating responsibilities.*”²⁴

Courts have recognized that Congress granted IGs broad authority under the IG Act.²⁵ However, they have, likewise, determined Congress did not intend that authority to be unlimited. For example, in *Burlington Northern R. Co. v. Office of Inspector General, R.R. Retirement Bd.*,²⁶ a Fifth Circuit case involving the enforceability of a

²² 5a U.S. Code § 2 (1)(A) (emphasis added). 5 U.S. Code § 12(2) defines the term “establishment” to include a number of specified federal agencies, including, specifically, the Department of Health and Human Services (“HHS”).

²³ 5 U.S.C. Appendix (IG Act) § 6 (emphasis added).

²⁴ 5 U.S.C. App. 3 § 9(a)(2) (emphasis added); *see also* Congressional Research Service, *Statutory Inspectors General in the Federal Government: A Primer* (updated May 12, 2022) at 26, n.136 (“The IG Act prohibits IGs from undertaking ‘program operating responsibilities,’ which includes enforcement of recommendations.”); 5 U.S.C. Appendix (IG Act), §§8G(b) and 9(a)(2) (available at <https://crsreports.congress.gov/product/pdf/R/R45450>).

²⁵ *United States v. Newport News Shipbuilding & Dry Dock Co.*, 837 F.2d 162, 170 (4th Cir. 1988) (“[W]here the interests of the government require *broad investigations* into the efficiency and honesty of a defense contractor, the Inspector General is equipped for this task.”) (emphasis added); *United States v. Blue Cross & Blue Shield of Michigan*, 726 F. Supp. 1523, 1525 (E.D. Mich. 1989) (recognizing that Inspectors General are given broad statutory powers to conduct audits and investigations of the programs and operations of their respective agencies).

²⁶ *Burlington N. R. Co. v. Off. of Inspector Gen., R.R. Ret. Bd.*, 983 F.2d 631 (5th Cir. 1993).

subpoena issued by the IG for the Railroad Retirement Board (“RRB”) to Burlington Northern Railroad Company (“Burlington”), the court discussed the limitations on the RRB IG’s authority to conduct audits:²⁷

“[A]s a general rule, when a regulatory statute makes a federal agency responsible for ensuring compliance with its provisions, the Inspector General of that agency will lack the authority to make investigations or conduct audits *which are designed to carry out that function directly*...Our holding recognizing this limit to the authority of Inspectors General is supported by the language and purpose of the Inspector General Act of 1978. The purpose of the Act, as we have already stated...was to create *independent and objective* units that would be responsible for combatting fraud, abuse, waste, and mismanagement *in federal agencies and departments*. If an Inspector General were to assume an agency’s regulatory compliance function, his independence and objectiveness—qualities that Congress has expressly recognized are essential to the function of combatting fraud, abuse, waste, and mismanagement—would, in our view, be compromised. In addition, although Congress granted Inspectors General broad investigative and subpoena authority, Congress also expressed its intent that Inspectors General should not be allowed to conduct “program operating responsibilities” of an agency. *See* 5 U.S.C. App. 3 § 9(a)(2) (head of an agency may transfer to an Inspector General other functions, powers, and duties that he determines “are properly related to the functions of the [OIG] and would, if so transferred, further the purposes of this Act, *except that there shall not be transferred to an Inspector General ... program operating responsibilities.*)”²⁸

b) Adoption of the OIG Rule is Beyond OIG’s Authority Because it Subsumes CMS Program Operating Responsibilities

GHP concedes that OIG has broad authority delegated by Congress to conduct audits pertaining to fraud, waste and abuse pursuant to 42 U.S.C. § 1320a-7c. The statute directs the Secretary, acting through OIG and the Attorney General to establish a program “to conduct investigations, audits, evaluations, and inspections relating to the delivery of and payment for health care in the United States.” Congress has expressly allowed the HHS Secretary to delegate to OIG the administrative authority to adopt rules for the exclusion of entities under the Anti-Kickback Statute and the Civil Monetary Penalties of the Social Security Act.²⁹ OIG clearly has the authority to adopt, and has adopted, rules and other interpretative guidance with respect to these statutes. In the backdrop of these explicit and broad grants of authority, in its numerous reviews of MAOs’ risk adjustment submissions, OIG, curiously, has not cited any statutory authority in support of its ability to conduct risk adjustment audits in MA and implement, what is effectively, rulemaking, *other than* the IG Act.

As the U.S. Supreme Court has noted, an agency’s power to promulgate regulations is limited to the authority delegated by Congress.³⁰ Congress assigned CMS responsibility for compliance with the risk adjustment provisions of Medicare pursuant to the Improper Payments Information Act (“IPIA”) of 2002.³¹ Congress

²⁷ *Id.* at 636 (“Specifically, Burlington Northern expressed its concern that the audit program being conducted by the Inspector General was “a classic exercise of regulatory authority rather than oversight authority” and was “not within the statutory authority of the Office of Inspector General.”)

²⁸ *Id.* at 642-43 (emphasis added). *See also Truckers United for Safety v. Mead* 251 F.3d 183 (D.D.C. 2001) (“discretionary transfers of authority only can be made if the duties are properly related to the functions of the IG, further the purpose of the Act, and do not constitute program operating responsibilities.”)

²⁹ See, e.g., 42 U.S.C. §1320a-7(a)(j)(1) and (2) and 42 C.F.R. pts. 1001, 1003 (2002) (governing OIG exclusion process and assessment of civil monetary penalties).

³⁰ *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988).

³¹ Pub. L. No. 107-300, 116 Stat. 2350 (Nov. 26, 2002), as amended by the Improper Payments Elimination and Recovery Act of 2010 and the Improper Payments Elimination and Improvement Recovery Act of 2012.

intended risk adjustment audits to be performed by CMS, not OIG.³² Subsequent regulations confirm that it is the responsibility of CMS to conduct risk adjustment audits, while it is the responsibility of OIG to remain independent.³³

It follows that OIG does not have the authority to promulgate rules relating to areas which are operating responsibility of CMS. The language in the regulations applicable to RADV audits and adjustments to payments provides further clear support that CMS, not OIG, is the agency with operational responsibility for adoption of rules applicable to RADV audits and changes or adjustments to MAO risk adjusted payments. For example:

42 CFR § 422.2 (“Definitions”) contains the following definition of a risk adjustment data validation (RADV) audit (emphasis added):

“Risk adjustment data validation (RADV) audit means a payment audit of a MA organization administered by the Secretary that ensures the integrity and accuracy of risk adjustment payment data.”

42 CFR § 422.308 addresses adjustments to capitation rates, benchmarks, bids, and payments in the MA program. Known as the “risk adjustment rule,” the Secretary of HHS has clearly designated CMS as the MA operational program administrator under 42 CFR § 422.308 (emphasis added):

c) Risk adjustment -

(1) General rule. *CMS will adjust the payment amounts* under § 422.304(a)(1), (a)(2), and (a)(3) for age, gender, disability status, institutional status, and other factors *CMS determines* to be appropriate, including health status, in order to ensure actuarial equivalence. *CMS may add to, modify, or substitute for risk adjustment factors* if those changes will improve the determination of actuarial equivalence.

The regulations also contemplate CMS as the agency establishing operational audit parameters relating to the validation of risk adjustment data. For example, 42 CFR § 310 (e) (“Validation of Risk Adjustment Data”) provides that MA organizations and their providers and practitioners “will be required to submit a sample of medical records for the validation of risk adjustment data, *as required by CMS...*” (emphasis added).

Moreover, OIG *itself* has recognized that CMS retains program operational authority for the promulgation of rules pertaining to Medicare risk adjustments:

³² Per CMS’s own admission, “The RADV program is a corrective audit activity developed by CMS to address provisions included in the IPIA of 2002, as amended by the IPERA of 2010, and further amended by IPERIA. These statutes require that government agencies annually estimate and report improper payments” (Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54982, 55039). The role of the Inspector General in each of these statutes is limited to agency oversight and reporting. In contrast, Congress asks the agencies to identify and recover improper payments. (*See e.g.*, Improper Payments Information Act of 2002, P.L. 107-300, 116 STAT. 2350; Improper Payments Elimination and Recovery Act of 2010, P.L. 111-204, 124 STAT. 2224; Improper Payments Elimination and Recovery Improvement Act of 2012, P.L. 112-248; 126 Stat. 2390.)

³³ *See* OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, Appendix C of OMB Circular A-123 (2010) (implementing Executive Order 13520 and explaining that “because the recovery audit program required by this Guidance is an integral part of the agency’s internal control over contract payments, and therefore a management function, independence considerations would normally preclude the Inspector General and other agency external auditors from carrying out management’s recovery audit program”). *See also* 42 CFR 422.2; 42 CFR § 422.308(c)(1); 42 CFR § 310(e); 42 CFR § 422.311 (describing risk adjustment audit actions to be taken by the Secretary, with no mention of OIG).

“The Office of the Inspector General, which is required by law to conduct audits and follow generally accepted government auditing standards, does not seek comment on its methodology for risk adjustment audit work that may lead to overpayment recoveries from MA organizations.”³⁴

Moreover, in responding to MAO assertions that implementation of the OIG Rule violated the “actuarial equivalence” payment principle (discussed more fully below), OIG has responded:

“Regarding Cariten’s statement that we did not consider “actuarial equivalence” in our overpayment calculations, *we recognize that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program, including the application of any FFSA.* Moreover, CMS has not issued any requirements that compel us to reduce our net overpayment calculations.²⁹ If CMS deems it appropriate to apply an FFSA, it will adjust our overpayment finding by whatever amount it determines necessary. Thus, we believe that our audit methodology provides a reasonable basis for our findings and recommendations, including our estimation of net overpayments....”³⁵

In fact, OIG has acknowledged that CMS is responsible for making operational and program payment determinations for the MA Program in at least *six separate MAO Audit Reports*.³⁶

There is little conceptual distinction between CMS’s operational authority to decide whether to apply a FFS adjuster to achieve actuarial equivalence, and CMS’s operational authority to determine whether different standards should apply to risk adjustment payments or risk adjustment submissions by an MAO. Both amount to program operational decisions which require APA rulemaking, and CMS, not OIG, implementation.

Moreover, the OIG’s actions change a standard CMS has set for payment accuracy that is based on a MAO’s “best knowledge, information, and belief.”³⁷ CMS set the “best knowledge, information and belief” standard with the intention that the annual attestation an MAO signs when it submit its risk-adjustment data not be a “legal trap.”³⁸ CMS specifically recognized that requiring MAOs to ensure 100% accuracy in the codes they submit, as

³⁴ See, Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54982, 55039.

³⁵ Cariten Report at 21.

³⁶ Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Cariten Health Plan Inc. Submitted to CMS, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., page 21 (Jul. 2022) (Overpayment amount: \$557,250; Extrapolated amount: \$9.2 million); Medicare Advantage Compliance Audit of Specific Diagnosis Codes that HealthFirst Health Plan Inc. Submitted to CMS, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., page 17 (Jan. 2022) (Overpayment amount: \$516,509; Extrapolated amount: \$5,221,852 million); Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Coventry Health Care of Missouri, Inc., Submitted to CMS, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., page 22 (Oct. 2021) (Overpayment amount: \$548,852; No extrapolated amount); Medicare Advantage Compliance Audit of Specific Diagnosis Codes that UPMC Health Plan Inc. Submitted to CMS, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., page 28 (Nov. 2021) (Overpayment amount: \$681,099; Extrapolated amount: \$6.4 million); Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Tufts Health Plan Submitted to CMS, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., page 21 (Feb. 2022)(Overpayment amount: \$536,085; Extrapolated amount: \$3,758,335); Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Anthem Community Insurance Company, Inc., Submitted to CMS, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., page 21 (May 2021) (Overpayment amount: \$354,016; Extrapolated amount: \$3,468,954).³⁷ See 42 C.F.R. § 422.504(l).

³⁷ See 42 C.F.R. § 422.504(l).

³⁸ 65 Fed. Reg. 40,170, 40,250 (June 29, 2000).

the OIG audits require (with the hammer of contract payment adjustment through extrapolation), is not possible.³⁹ In fact, CMS, the agency responsible for ensuring MAO compliance with the risk adjustment process, assured industry participants that MAOs “cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that HCFA, OIG, and DOJ believe *is reasonable to enforce*.”⁴⁰

The financial and operational implications of the OIG Rule to MAOs like GHP are of staggering economic and programmatic significance. The proposed overpayment amounts attributable to the OIG Rule (including the \$6.4 million extrapolated for GHP) total approximately \$30,980,236 thus far.⁴¹ Despite this, OIG offers *no authority*, other than references to the IG Act, to support implementation of the OIG Rule.

The Supreme Court has stated several times, “[w]e expect Congress to speak clearly when authorizing an agency to exercise powers of vast economic... significance.”⁴² In the present situation, there is no “clear Congressional authorization” giving OIG the power to implement substantive payment rules affecting MA risk adjustment payments to the tune of millions of dollars.⁴³ As the U.S. Supreme Court noted in *West Virginia et al. v. Environmental Protection Agency, et al.*, “Congress could not have intended to delegate” such a sweeping and consequential authority “in so cryptic a fashion.”⁴⁴ The IG Act is a “wafer-thin reed” on which to rely, given the sheer scope of OIG’s claimed authority.⁴⁵

We anticipate that OIG may take the position, as it has in past reports, that it has not undertaken an agency action and its audits are just that, audits. OIG has maintained in the past that it only makes “recommendations” in its report, and that the findings and recommendations do not represent final determinations by CMS.⁴⁶ However, as noted by the U.S. Supreme Court in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019):

“[C]ourts have long looked to the *contents* of the agency’s action, not the agency’s self-serving *label*, when deciding whether statutory notice-and-comment demands apply.”⁴⁷

The effect of what OIG has done was to implement a payment rule it is not authorized to implement in a manner that is not legally allowed under the APA. As discussed in detail below, the methodology associated with OIG’s

³⁹ *Id.* at 40268.

⁴⁰ *Id.* (emphasis added).

⁴¹ *Supra* n. 30.

⁴² *See, e.g., National Federation of Independent Businesses et al., v. Department of Labor, Occupational Safety Health Administration, et al.*, 142 S. Ct. 661, 665 (2022) (quoting *Alabama Assn. of Realtors v. Department of Health and Human Servs.*, 141 S. Ct. 2485, 2489 (2021) (*per curiam*) (slip op., at 6) (internal quotation marks omitted).

⁴³ *West Virginia v. EPA*, 142 S. Ct. at 2595 (quoting *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 324) (“the agency must point to ‘clear congressional authorization’ for the authority it claims”).

⁴⁴ *West Virginia v. EPA*, 597 U.S. ___, 17 (2022) (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000)).

⁴⁵ *Id.* (citing *Alabama Assn. of Realtors v. Department of Health and Human Servs.*, 594 U.S. ___ (2021) (*per curiam*) (slip op., at 6-8)).

⁴⁶ *See, e.g., Medicare Advantage Compliance Audit of Diagnosis Codes that Humana, Inc.*, Submitted to CMS, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., page 18, n.18 (Apr. 2021) (“... OIG audit findings and recommendations do not represent final determinations by CMS. Action officials at CMS will determine whether a potential overpayment exists and will recoup any overpayments consistent with its policies and procedures. If a disallowance is taken, MA organizations have the right to appeal the determination that an overpayment occurred through the CMS RADV appeals process); *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that UPMC Health Plan Inc.* Submitted to CMS, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., pages 23, n. 26 (Nov. 2021); *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Tufts Health Plan Submitted to CMS*, DEP’T. OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., page 21, n. 27 (Feb. 2022).

⁴⁷ *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1812 (2019); *see also, e.g., General Motors Corp. v. Ruckelshaus*, 742 F. 2d 1561, 1565 (D.C. Cir. 1984) (“[T]he agency’s own label, while relevant, is not dispositive”).

implementation of this rule is also materially flawed and does not comport with recognized and applicable audit and actuarial practice standards. GHP respectfully requests OIG reconsider implementation of the OIG Rule.

II. The Use of Statistical Sampling and Extrapolation Is Not Allowed Without a Finding of a Sustained or High Level of Payment Error

In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act, also known as the Medicare Modernization Act (“MMA”). In passing the MMA, Congress authorized CMS to use contractors to perform reviews to determine if the Medicare program had overpaid for services. As part of that authorization, Congress placed limits on the ability of a Medicare contractor to use extrapolation to determine overpayment amounts. Specifically:

“A Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise, *unless the Secretary determines that-*

- (A) there is a sustained or high level of payment error; or
- (B) documented educational intervention has failed to correct the payment error.”⁴⁸

The legislative history makes it clear that Congress was concerned about the fairness of the process involved in CMS’s determination of provider overpayments.⁴⁹ CMS, in developing the Medicare Program Integrity Manual (“MPIM”), explicitly recognized Congressional concerns by establishing very clear criteria around a Medicare contractor’s use of statistical sampling and extrapolation:

“The contractor shall use statistical sampling when it has been determined that a sustained or high level of payment error exists. The use of statistical sampling may be used *after documented educational intervention has failed* to correct the payment error.”⁵⁰

“The [MMA], mandates that before using extrapolation (i.e., projection, extension, or expansion of known data) to determine overpayment amounts to be recovered by recoupment, offset, or otherwise, there must be a determination of sustained or high level of payment error, or documentation that educational intervention has failed to correct the payment error.”⁵¹

CMS has yet to impose extrapolation in its own RADV audits. In 2012, CMS indicated through the HPMS process that it intended to incorporate extrapolation into its methodology for payment recoveries related to RADV audits, but it never implemented the change. In 2018, CMS more officially proposed to use extrapolation as part of a

⁴⁸ 42 U.S.C. §1395ddd(f)(3) (emphasis added).

⁴⁹ See, e.g., *Statements on Introduced Bills and Joint Resolutions*, Congressional Record Vol. 147, No. 162 (Senate - November 28, 2001) (Statements of Mr. Kerry pertaining to the Medicare Appeals, Regulatory and Contracting Improvement Act which was the precursor to the MMA, which contained identical language: “it makes the Medicare overpayment collection and extrapolation process more fair” and statements of Mr. Murkowski: “To bring additional fairness to the system..., the bill...requires the Medicare administrative contractors and CMS to place a greater emphasis on provider education and outreach. And most importantly, it reforms the Medicare overpayment collection and extrapolation process.” (emphasis added)).

⁵⁰ *Id.* at 8.4.1.4.

⁵¹ MPIM (Pub. 100-08), Ch. 8, § 8.4.1.2 (emphasis added).

revised RADV audit methodology, this time through notice and comment via the Federal Register.⁵² In so doing, CMS in effect acknowledged that it had no clear authority to extrapolate under MA:

“In this proposed rule, we would, based on longstanding case law and best practice from HHS and other federal agencies, *establish* that extrapolation would be utilized as a valid part of audit authority in Part C, as it has been historically a normal part of auditing practice throughout the Medicare program.”⁵³

OIG may take the position that it is not a Medicare contractor and therefore the guardrails established by CMS do not apply. While we agree that OIG is not a Medicare contractor, OIG has not articulated why different criteria for the use of extrapolation would apply to this review. OIG may also argue that some of the codes selected in the audit demonstrate a high rate of error. Assuming, *arguendo*, this was the case, such error rate would be attributed only to the highly targeted and selective nature of the audit itself. OIG targets only codes that have been purposefully datamined so as to demonstrate failure, through use of multiple qualifying narrow conditions, while ignoring other factors such as similar inaccuracies in the FFS data that drives payment, accounting for underpayments, or comparing those targeted conditions to the universe of all payments for a given HCC.

III. OIG’s Audit Does Not Meet the Generally Accepted Government Auditing Standards

The Draft Report states that OIG used Generally Accepted Government Accounting Standards (“GAGAS”):

“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.”⁵⁴

As a threshold matter, we question whether GAGAS is the appropriate standard to use for an audit of MAO risk adjustment submissions such as the audit OIG conducted of GHP.⁵⁵ We also note that, in other audits of MAOs, OIG has consistently dismissed objections to its audit results based on, e.g., actuarial considerations by responding that it follows GAGAS.⁵⁶ For reasons detailed below, this dismissal overlooks that risk adjustment is based on actuarial science, and failure to follow actuarial standards yields inaccurate findings. Even assuming GAGAS is applicable: a) OIG’s Audit does not meet the requirements of GAGAS; and b) the inability to meet actuarial standards of practice notwithstanding use of GAGAS results in findings and conclusions that are not supported.

⁵² HHS, CMS, Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54,982 (Nov. 1, 2018).

⁵³ *Id.* at 54,984 (emphasis added).

⁵⁴ Draft Report at 7.

⁵⁵ Pursuant to the Single Audit Act Amendments of 1996 (Public Law 104-156), use of GAGAS is limited to audits of state and local governments and nonprofit entities that received federal awards. If OIG were auditing another government program within its scope of its authority under the IG Act, this would be an appropriate standard.

⁵⁶ See, e.g., the Cariten Report at 18 (responding to Cariten’s objections that OIG’s estimate of overpayments significantly devalued underpayments and is statistically unsupported, OIG states: “We disagree with Cariten’s statements regarding underpayments. In accordance with the Inspector General Act of 1978, 5 U.S.C. App., our audits are intended to provide an independent assessment of Department of Health and Human Services (HHS) programs and operations. We conduct our audits in accordance with generally accepted government auditing standards, which require that audits be planned and performed so as to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions.”)

A. GAGAS Standards for Performance Audits Applicable to the GHP Audit

GAGAS, also known as “Yellow Book,” are promulgated and updated by the U.S. Comptroller General. According to the 2018 GAGAS, updated by the Comptroller General in 2021 (emphasis added):

“The professional standards presented in this 2018 revision of *Government Auditing Standards* (known as the Yellow Book) provide a framework for performing high-quality audit work with competence, integrity, objectivity, and independence to provide accountability and to help improve government operations and services. These standards, commonly referred to as generally accepted government auditing standards (GAGAS), provide the foundation for government auditors *to lead by example in the areas of independence, transparency, accountability, and quality through the audit process.*”

Chapter 8 of GAGAS contains Fieldwork Standards for Performance Audits. The following GAGAS Fieldwork Standards, *at a minimum*, apply to the GHP Audit:

“**8.06** Auditors should design the methodology⁵⁷ to obtain sufficient, appropriate evidence that provides a reasonable basis for findings and conclusions based on the audit objectives and to reduce audit risk to an acceptably low level.”

“**8.20** Auditors should communicate an overview of the objectives, scope, and methodology and the timing of the performance audit and planned reporting (including any potential restrictions on the report), unless doing so could significantly impair the auditors’ ability to obtain sufficient, appropriate evidence to address the audit objectives.”

The Application Guidance Section for Evidence discusses appropriateness of evidence used in the audit:

“**8.102** Appropriateness is the measure of the quality of evidence that encompasses the relevance, validity, and reliability of evidence used for addressing the audit objectives and supporting findings and conclusions.

a. **Relevance** refers to the extent to which evidence has a logical relationship with, and importance to, the issue being addressed.

b. **Validity** refers to the extent to which evidence is a meaningful or reasonable basis for measuring what is being evaluated. In other words, validity refers to the extent to which evidence represents what it is purported to represent.

c. **Reliability** refers to the consistency of results when information is measured or tested and includes the concepts of being verifiable or supported. For example, in establishing the appropriateness of evidence, auditors may test its reliability by obtaining supporting evidence, using statistical testing, or obtaining corroborating evidence.”

⁵⁷ Pursuant to GAGAS 8.11, the methodology describes the nature and extent of audit procedures for gathering and analyzing evidence to address the audit objectives. Audit procedures are the specific steps and tests auditors perform to address the audit objectives.

“8.103 The degree of assurance associated with a performance audit is strongly associated with the appropriateness of evidence in relation to the audit objectives”

“8.107 When sampling is used, the appropriate selection method will depend on the audit objectives. When a representative sample is needed, the use of statistical sampling approaches generally results in stronger evidence than that obtained from nonstatistical techniques. When a representative sample is not needed, a targeted selection may be effective if the auditors have isolated risk factors or other criteria to target the selection.”

Finally, with respect to audit Documentation, GAGAS provides:

“8.132 Auditors must prepare audit documentation related to planning, conducting, and reporting for each audit. Auditors should prepare audit documentation in sufficient detail to enable an experienced auditor, having no previous connection to the audit, to understand from the audit documentation the nature, timing, extent, and results of audit procedures performed; the evidence obtained; and its source and the conclusions reached, including evidence that supports the auditors’ significant judgments and conclusions.”

“8.135 Auditors should document the following:

a) the objectives, scope and methodology of the audit.”

As discussed below, a review of the methodology and information provided by OIG to support its conclusions against applicable GAGAS Standards demonstrates that OIG materially did not adhere to GAGAS. OIG’s lack of supporting documentation and transparency about its assumptions and methodology, and refusal to consider applicable actuarial standards not only contravenes GAGAS, but it also makes the audit findings and conclusions invalid and unreliable.

B. OIG Failed to Document Its Methodology and Procedures for Sampling and Extrapolation in Accordance with the Requirements of GAGAS 8.132 and 8.135

OIG has not provided sufficient information to allow an independent third party to understand the methodology that it followed to arrive at its conclusions. As discussed in greater detail below, based on GHP’s review, there are a number of gaps and deficiencies with the methodology OIG used, particularly with the method of sampling and extrapolation, that make OIG’s findings and conclusions unreliable. If anything, OIG has discovered potential issues with the current risk adjustment model and what diagnosis codes and conditions should not trigger a payment, not an error in the data GHP submitted, nor the payments GHP received five years ago. Indeed, GHP provided the data that it received from providers to CMS.

OIG has failed to provide specific details of its methodology in numerous critical areas. However, based on GHP’s review of OIG’s results and accompanying descriptions, it appears that OIG performed separate calculations for each distinct condition, and then added the resulting values to determine key parameters identified in the report. For each condition, OIG appears to have used the following methodology:

1. OIG identified a sample of 30 individual life-years within each group in the frame;
2. OIG reviewed charts to determine the number of claims with unvalidated diagnosis indicators;
3. OIG determined the amount of unvalidated HCC dollars attributable to the unvalidated indicators, accounting for any offsetting conditions;
4. OIG scaled the unvalidated HCC dollars to the entire universe to determine a point estimate of the overall error; and

5. OIG used a common approximation of a commonly used distribution to estimate a 90% confidence interval for the sample error rate to determine lower and upper bounds for the payment error.

Assuming this was the methodology OIG used (and GHP respectfully requests OIG provide details about its methodology if different from the above), on a purely superficial level, this would be a standard approach to this type of audit. However, based on information and belief, it appears that OIG implemented steps 1, 4, and 5 utilizing approaches and/or assumptions that are not statistically valid. OIG has, in the past, summarily dismissed objections to statistical validity in other MAO audits, stating that it is only required to follow GAGAS, and that such audits merely need be “planned and performed so as to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions.”⁵⁸ For the reasons that follow, we believe that OIG has conducted the audit inconsistent with the provisions of GAGAS 8.132 and 8.135.

1. OIG Provided Insufficient Information Regarding its Estimation Methodology

In the Draft Report, the only information provided to GHP regarding its “Estimation Methodology” is:

“We used the OIG, OAS statistical software to estimate the total amount of net overpayments to GHP 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.”

This statement does not describe the statistical “Estimation Methodology” in sufficient detail to evaluate the reasonableness or applicability of OIG’s approach. What is clear is that OIG’s calculations are wrong because the total payment OIG identified as GHP’s payment for Acute Stroke in the frame is \$1,709,510, while the OIG’s calculated point estimate of the overpayment would be \$1,723,105 (see further discussion of this figure below). In other words, OIG’s extrapolated overpayment for Acute Stroke is *greater than the total payment to GHP for the entire Acute Stroke population in the frame*. The result is impossible, since \$1,723,105 is greater than \$1,709,510.

Based on this statement, OIG asserts it has calculated the lower limit/range of an overpayment amount range that is less than the actual overpayment 95% of the time. OIG says this has been achieved with a 90% confidence interval. Often, a 90% confidence interval has 5% of possible outcomes below the lower end of the range and 5% above the upper end of the range. However, confidence intervals are not required to have equal amounts of possible outcomes above and below the range. When probability distributions are highly skewed, it is more likely that confidence intervals are imbalanced.

Put differently, it does not automatically follow from using a 90% confidence interval that an estimated lower overpayment amount range is less than the actual overpayment 95% of the time. Without knowing what methods were used to produce the lower and upper bounds of the confidence interval, it is not possible to support a 90% confidence interval.⁵⁹ OIG has not provided sufficient information to make this determination conclusively. However, as stated above, we can ascertain from the information OIG provided that OIG’s results are not just improbable, but impossible.

⁵⁸ See, e.g., Cariten Report at 19.

⁵⁹ What does appear to be clear, however, is that OIG-generated confidence intervals are symmetrical around the point estimate of overpayment. This suggests that OIG is assuming the underlying sample distribution is symmetric. From casual observation, the underlying sample distribution appears skewed, which, if true, would invalidate OIG’s statistical approach. However, we do not know the underlying distribution of errors in the entire sample frame, hence, another reason why the accuracy of OIG’s statement is not supported.

2. OIG Has Not Provided Documentation that Demonstrates that the Samples Used to Calculate the Overpayment are Representative as Required by GAGAS 8.107, and Has Failed to Demonstrate They Meet the Appropriateness Requirements of GAGAS 8.102

In an audit of alleged overpayments in a risk adjustment context, where the payment amount depends on the amount of overpayments *and* underpayments and other variables discussed below, obtaining a representative sample that reflects the distribution of the sampling frame and that is truly random is critical to arriving at a sample universe representing the basis upon which an MAO was paid, because *that is the basis from which OIG is determining the “overpayment” amount*. OIG has failed to document or otherwise communicate its sampling methodology as required by 8.120 and 8.135.

OIG did not communicate to GHP, or document, how it determined that a sample size of 30 enrollee-years per HRG was an appropriate sample size in the first place. Notably, the same sample size of 30 enrollee-years was used for each HRG, regardless of the number of enrollee-years within each frame size. For instance, the frame size was 102 enrollee-years in the lung cancer HRG and 1,007 enrollee-years in the heart attack HRG, but OIG used a sample size of 30 for both (and for all of the other individual HRGs). While this does not automatically render OIG’s analysis statistically invalid, as discussed more fully below, the choice of sample sizes has distinct implications for any confidence intervals produced, which then has implications for the validity of the audit findings and conclusions.

Based on OIG’s statement that it used a “90 percent confidence interval,” and upon analysis of OIG’s audit conclusions and its finding that GHP was overpaid \$6.5 million dollars, GHP believes that OIG relied on the Central Limit Theorem (“CLT”). According to CLT, for its resulting conclusion to be valid, sample sizes must be “large enough.” A sample size of 30 is frequently cited as a common rule-of-thumb value for “large enough.” Implicit in CLT is the concept that, when the sample size is large enough, the sum of the sample distribution is likewise normalized.^{60,61}

A normal distribution does have the desired symmetric properties, such that a 90% confidence interval for a normally distributed variable would support the proposition that 95% of the expected values are above the lower range of that confidence interval (as OIG’s Draft Report appears to suggest). However, OIG’s use of the sample size of 30, without more analysis, is insufficient to assure that the sample is representative, as required by GAGAS 8.107. For a sample of 30 to be “representative” within the meaning of GAGAS 8.107, the properties reflected in the 30 sampled diagnosis must be statistically consistent with the population from which the sample is drawn. In discrete probability scenarios (such as estimating the expected value of a fixed number of samples as OIG did here), there are two additional common tests that should be applied to ensure that the selection method is appropriate as required by GAGAS 8.107 so that a sample of 30 diagnoses will produce a statistically valid confidence interval:

Test A:
both

$Sample\ Size \cdot Probability_{Error}$

⁶⁰ Boston University School of Public Health. Wayne W. LaMorte, MD, PhD, MPH. July 24, 2016. Retrieved 9/9/2022 from https://sphweb.bumc.bu.edu/otlt/mph-modules/bs/bs704_probability/BS704_Probability12.html

⁶¹ Note that the normal distribution is a common statistical distribution with several highly desirable properties. Throughout this section, we use the word “normal” to refer to this specific mathematical item. When referencing typicality or common nature, we explicitly avoid the word “normal” to avoid confusion between the mathematical concept and the word’s alternative definitions.

and
 $Sample\ Size \cdot (1 - Probability_{Error})$
are individually greater than 5

Test B:

The entire 99% confidence interval lies between 0 and 1.

OIG does not provide enough information about its methodology to determine which, if either, of these tests were applied to ensure the distribution was reflected in the sample, or whether any normal distribution-based approximations were used. This impairs the validity and supportability of OIG's stated confidence interval. OIG's audit findings and conclusions appear to be based on the CLT's assumption. GHP has determined that the error rates identified by OIG (both in terms of the count of HCCs that are not validated and the percentage of dollars that are not validated) fail to pass Test A for all but two of the sampling frames. If a sample fails to satisfy either of the above tests, it is not possible to determine whether the normal approximation required to achieve the 90% confidence interval has occurred, or whether a larger sample is required. As a result, the CLT-derived estimates of the confidence interval are invalid. OIG has failed to demonstrate that evidence used in its audit as indicative of the extrapolated overpayment amount is appropriate within the meaning of GAGAS 8.102.

Second, it is unclear if the sampling methodology is sufficiently random. The generation of random numbers via computerized software is typically not random. Numbers generated in this manner rely on either pseudorandom number generators based on algorithms that will reproduce the same results when run with the same initial conditions. This may be preferable in some situations, such as when it is preferable to independently replicate the sequence of random numbers. However, the numbers generated by such approaches are not truly random. OIG does not provide sufficient information to evaluate the effectiveness of the random number generator utilized, which also poses reliability issues under GAGAS 8.102.

Third, OIG has not provided any information regarding what efforts it made, if any, to ensure that each sample was representative of the universe from which it was drawn. Two of the HRGs (heart attack and embolism) include two HCCs each. Further, all of the HCCs in all of the HRGs consist of numerous diagnoses that roll up into one HCC. For example, HCC 59 (Major depressive, bipolar and paranoid disorders) includes a vast number of ICD-10-CM codes, including codes for delusional disorders; shared psychotic disorder; numerous types of manic episode; bipolar disorder; numerous types of depressive disorder; persistent mood disorders; numerous types of self-harm events (including numerous types of self-harm by poisoning, as well as intentional harm by smoke, fire and flames; and intentional self-harm by jumping from a high place). It is not clear that OIG did anything to ensure that the 30 samples drawn from the Major Depressive Disorder HCC were representative of the array of ICD-10-DM codes within the universe from which the sample was drawn, and as a result, the evidence OIG relied on in its conclusions and findings is not reliable as required by GAGAS 8.102.

C. The Inappropriateness of the Evidence OIG Used Provides No Assurance That OIG's Audit Objectives Were Achieved as Contemplated by GAGAS 8.103

With regards to step 4, the method of extrapolation appears to be inappropriate for the data. In Table 3 of Appendix D of the Draft Report, OIG shows key metrics and results. The information OIG provided does not specify how OIG determined the point estimate. Based on GHP's analysis, in attempting to recreate the estimate using the Table 3 data, it appears that OIG estimated the extrapolated overpayment for each sampling frame using the following formula:

$$Frame\ Overpayment = Sample\ Overpayment \left(\frac{Items\ in\ Frame}{Items\ in\ Sample} \right)$$

The total overpayment then appears to have been determined using the sum of the overpayments across all 9 frames. In undertaking this approach, it appears OIG has "mixed and matched" statistical concepts based on a

count of HCCs with statistical concepts based on dollar impacts. These are separate and distinct concepts. Combining them in this fashion is inappropriate and provides no degree of assurance that the evidence is appropriate in relation to the audit objective as contemplated by GAGAS 8.102.

Based on the information contained in OIG’s report, a review of OIG’s presumed calculation methodology for the extrapolated error for Acute Stroke provides an illustrative example, as mentioned previously. Specifically, the total payment OIG identified as GHP’s payment for Acute Stroke is \$1,709,510, while the OIG’s calculated point estimate of the overpayment using the formula above would be \$1,723,105. In other words, OIG’s extrapolated overpayment using the formula above for Acute Stroke is **greater than the total payment to GHP for the entire Acute Stroke population**. The result is impossible, since \$1,723,105 is greater than \$1,709,510.⁶²

OIG further misapplies the risk score model to MA revenue mechanics. Specifically, risk scores are multiplied by the 1.0 risk adjusted bid amount for each member to calculate revenue to MAOs. It is inappropriate to calculate dollar impacts on one set of beneficiaries and extrapolate those dollar impacts to other beneficiaries who have different 1.0 risk adjusted bid amounts, without any additional adjustments. Continuing with the example of the Acute Stroke HCC, the average value of the Acute Stroke HCC for the 30 sampled enrollee-years is \$2,382.90 while the value of the Acute Stroke HCC for unsampled members is only \$2,201.64, meaning that the Acute Stroke HCC sample is 8.2% more expensive than the unsampled population. This error by itself is worth more than \$100,000. The above demonstrates that the quality of the evidence used by OIG to formulate its overpayment calculations fails the reliability requirements of GAGAS 8.102.

With regards to step 5, we note that OIG appears to have used the CLT, and then accounted for the finite population through use of a T-score instead of the standard Z-score that is applied when the population is very large. Specifically, the confidence interval provided by OIG suggests it is based on the following formula:

$$\text{Point Estimate} - T_{0.95} \cdot \sqrt{\frac{\text{Confidence Interval Lower Bound}}{\frac{\text{Sample Size}}{\text{Sample Size} - 1} \cdot \frac{\text{Validated Samples}}{\text{Sample Size}} \cdot \frac{\text{Unvalidated Samples}}{\text{Sample Size}}}}$$

In a situation where the samples used by OIG met the requirements for the production of confidence intervals based on the CLT, use of a T-score in lieu of a Z-score could be an appropriate choice. However, the samples OIG used do not meet the basic tests required for the production of confidence intervals based on the CLT as noted earlier. The error rates identified by OIG (both in terms of the count of HCCs that are not validated and the percentage of dollars that are not validated) fail to pass Test A for all but two of the sampling frames, and so CLT-derived estimates of the confidence interval are invalid.

In addition, OIG appears to have estimated the upper and lower bound by treating each sampled life year as an all-or-nothing value – a sampled enrollee’s HCC was either validated or not validated. This approach does not take into account the fact that some enrollees had offsetting diagnoses identified, so that only some of the HCC dollars in question were validated. As was the case with the point estimate, this is both inconsistent with the measurement used for determining the sample overpayment before extrapolation and with MA revenue mechanics. Further, it also mixes an error value calculated using dollars with a variation calculated using validation counts, a comparison of two completely different things which contravenes GAGAS 8.102. Assuming the approach was statistically valid, this would produce narrower confidence intervals than an approach that considers validation offsets. For example, the lower range of the confidence interval for Acute Stroke appears to be equal to the point estimate for Acute Stroke, which we note is higher than the actual total payments received

⁶² We believe this conclusion is supported since our replication using the formula above with the values in Table 3 produces a value that is within \$20 of total extrapolated overpayment, or less than \$0.01 for each member in the overall population.

by GHP for Acute Stroke. This amount clearly cannot be less than the actual payment amount with 95% probability.

The above makes it clear that OIG's methodology is not a methodology designed in a manner intended to obtain sufficient and appropriate evidence that provides a reasonable basis for OIG's findings and conclusions. It is not designed so that it uses an appropriate representative sample. It is not properly documented in sufficient detail so that an experienced third party can understand the procedures performed, the results and conclusions obtained, and the source of those conclusions. This contravenes GAGAS Standards 8.06, 8.20, 8.102, 8.107, 8.132 and 8.135.

IV. OIG's Approach Does Not Comport with GAGAS 8.102 Because it Disregards the Inherent Netting Out that Occurs in the Overall Risk Adjusted Payment to a MAO and Other Risk Adjustment Considerations, Resulting in a Violation of the Legal Requirement for Actuarial Equivalence

The Social Security Act ("SSA") provides that a MAO must be compensated in a manner that is the "actuarially-equivalent" amount of what CMS would pay to provide care to identical beneficiaries under traditional Medicare.⁶³ Actuarial equivalence, as required by statute, requires actuarial concepts to apply so that determinations of payment amounts are supportable. In fact, Congress was clear with its intent to emphasize actuarial equivalence when it granted the HHS Secretary the authority to "modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence."⁶⁴

The MA program uses a global capitated payment model developed by CMS. FFS data from the traditional Medicare program is used to calculate the value of coefficients used to calculate payment. The model is population-based. CMS guidelines have required plans to submit claims-based risk adjustment data through the Risk Adjustment Processing System ("RAPS") and the Encounter Data Processing System ("EDPS"). Plans may supplement those claims-based diagnoses through the same systems. While CMS requires reasonable efforts to ensure the submitted diagnoses are supported by an underlying medical record, CMS does not require submission or review of medical records. CMS does not use diagnoses from medical records when it creates the risk adjustment model and the coefficients for each HCC. Instead, CMS uses diagnoses from claims and considers coding differences between FFS and MA in setting the coefficients and the total payment level for the MA population as a whole. Because OIG is auditing medical record sourced diagnoses in a payment system that is designed, created, and intended to use diagnoses from claim records, OIG is substituting one data source for another in a way that is outside of the intended use of the risk adjustment model. The comparison is not "apples to apples" and an additional adjustment is necessary to produce meaningful and relevant audit results.

These nuances are inextricable from the risk adjustment process, which, as specified by the SSA, is an actuarial science. As such, instead of, or at least in addition to, GAGAS, OIG should minimally follow

⁶³ 42 U.S.C. § 1395w-23(a)(1)(C)(i) ("[T]he Secretary shall adjust the payment amount [of fixed monthly payments to Medicare Advantage insurers] for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status ..., *so as to ensure actuarial equivalence.*") (emphasis added).

⁶⁴ *Id.*

Actuarial Standard of Practice (“ASOP”) 45⁶⁵ and ASOP 56.⁶⁶ Failure to follow these standards of practices makes the results of OIG’s audit unreliable and result in violation of the actuarial equivalence requirement in the SSA. ASOP 45 must be followed when actuaries quantifying differences in morbidity across organizations, populations, programs and time periods using commercial, publicly available, or other health status based risk adjustment models or software products, and if it is not followed, the actuary deviating from the standard is required to document the reason the standard is not being followed.⁶⁷ ASOP 56 should be used when, in the actuary’s professional judgment, reliance by the intended user on the model output has a material effect for the intended user,⁶⁸ and requires the actuary to confirm that, in the actuary’s professional judgment, the model reasonably meets the intended purpose.⁶⁹

For example, ASOP No. 45, Section 3.1.1: Intended use, states that “[t]he actuary should consider whether the model was designed to estimate what the actuary is trying to estimate.” The OIG audit methodology does not appropriately consider the intended use of the CMS-HCC Risk Adjustment model. Specifically, the CMS-HCC Risk Adjustment Model was designed to predict the cost of providing care to beneficiaries who have *claims payment data* indicating the presence or absence of certain health conditions. OIG’s use of diagnoses on medical records rather than claim payment records conflicts with the intended use of the model. The risk adjustment model was designed and implemented in a manner that recognizes and accounts for differences in claims-based coding practices *between providers coding for FFS and providers coding for MA*. The risk model has no facility to handle diagnoses from medical records and so, in accordance with ASOP 45 Section 3.1.4, an adjustment must be made to the model.

Specifically, ASOP No. 45, Section 3.1.4 (Population and Program / Section 3.2 Input Data) requires:

“The actuary should consider whether the population and program to which the model is being applied is reasonably consistent with those used to develop the model. . . . The input data that is used in the application of risk adjustment *should be reasonably consistent with the data used to develop the model, unless circumstances dictate that a model be modified to utilize other than originally intended data sources.*”⁷⁰

OIG’s audit methodology compares disparate sources of data. As a result, any inquiry into whether an *improper* payment occurred must **take into consideration both**: 1) an adjustment to the model that accounts for substituting claims-based data with medical record-based data, e.g. an adjustment for differences in the diagnoses on FFS claims and diagnoses on FFS medical records; and 2) undercoding and overcoding. CMS’s assignment of value to coefficients and ultimate overall payment to an MAO takes both over- and under-coding into consideration and also maintains consistency with the intended use of the risk adjustment model, but OIG’s Rule requiring repayment *from* an MAO does not. The use of medical records as the only form of validation for diagnoses in the manner OIG appears to have used it compromises the integrity of the HCC Model and violates ASOP 45, which requires the risk adjustment model to be modified when a different data source is used. Without application of these principles to reconcile the disparate data sources, OIG’s audit results are not reliable

⁶⁵ Actuarial Standard of Practice No. 45, The Use of Health Status Based Risk Adjustment Methodologies (Jan., 2012), located at http://www.actuarialstandardsboard.org/wp-content/uploads/2014/02/asop045_164.pdf. ASOP 45 provides guidance to actuaries applying health status based risk adjustment methodologies to quantify differences in relative healthcare resource use due to differences in health status.

⁶⁶ Actuarial Standard of Practice No. 56, Modeling (Jan., 2012), located at <http://www.actuarialstandardsboard.org/asops/modeling-3/>. ASOP 56 provides guidance to actuaries when performing actuarial services with respect to designing, developing, selecting, modifying, using, reviewing, or evaluating models.

⁶⁷ *Id.*, at 1.

⁶⁸ ASOP No. 56 at 1.2.

⁶⁹ *Id.* at 3.1.3

⁷⁰ ASOP No. 45, Section 3.1.4 (Population and Program / Section 3.2 Input Data) (emphasis added).

(which violates the requirements of the GAGAS sections discussed above) and further violates a legal requirement that OIG has no authority to disregard (see above). GHP respectfully suggests OIG reconsider its position with regard to the actuarial equivalence requirement.

If OIG's audit were scoped to include only a verification of the data required by CMS to be submitted for payment under the MA program, OIG's findings might, setting aside the above issues, be supportable. This did not happen with the OIG Audit and the failure to do so violates the reliability requirement for evidence in GAGAS 8.102, and the legal requirement that MAOs be compensated in a manner that is the actuarial equivalent to what they would be compensated to provide care to identical beneficiaries under traditional Medicare. Geisinger respectfully requests OIG reconsider the actuarial implications of its approach.

A. OIG's Refusal to Consider Underpayments Is Arbitrary and Capricious

OIG, in seeking to determine if GHP received improper payments, indicates that its review objective "was to determine whether *selected* diagnosis codes that GHP submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements."⁷¹ The focus of this OIG objective is improper. A valid review seeking to determine whether an MAO was *improperly paid* must determine whether, on average, across all codes for all members, the MAO was appropriately paid. The Draft Report notes:

"[I]f 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. 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."⁷²

CMS, when conducting its RADV audits, takes into consideration diagnosis codes that are supported but not previously submitted (underpayments) in determining net overpayment amounts. Such an approach is designed to attempt to ensure a more fair and balanced approach to audits, which other federal agencies have also recognized is fair and appropriate.⁷³ In contrast, OIG's approach, which focuses only on so-called high-risk codes, which have been datamined to find only "overpayments," is without precedent, runs counter to the way CMS has administered its responsibilities under the RADV audits, is fundamentally unfair, and punitive. This refusal is without basis and is arbitrary and capricious.

V. OIG's Recommendation to Conduct Further Auditing and to "Refund" The Alleged Overpayments Retroactively is Inappropriate

Among OIG's recommendations is that GHP review the instances of noncompliance that occurred before and after OIG's review using these procedures and refund any overpayments (including those in the extrapolated overpayment calculations) to the Federal Government. As discussed above, OIG is, in effect, retroactively adjusting the payment terms of MA Contract H3954, which has already inherently taken into consideration the overpayments OIG is alleging, and, again, implementing a "rule" that did not go through appropriate rulemaking. This is inconsistent with the SSA's prohibition against retroactive application of rules absent a significant public safety concern or other critical need:

"A substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date

⁷¹ Draft Report at 1.

⁷² *Id.* at 4 (footnote omitted).

⁷³ *See, e.g.*, IRS, TAXPAYER BILL OF RIGHTS, (2017), found at <https://www.irs.gov/pub/irs-pdf/p1.pdf> (allowing, as part of its examination, appeals and collection process, taxpayers to be able to submit refunds for overpaid taxes).

of the change, unless the Secretary determines that (i) such retroactive application is necessary to comply with statutory requirements; or (ii) failure to apply the change retroactively would be contrary to the public interest.”⁷⁴

Moreover, even if OIG could require GHP to retroactively “refund” monies to the government that resulted from the extrapolation, CMS does not currently have a mechanism in place by which to do so. MAOs submit delete files containing various data points including the diagnostic codes via HPMS. Extrapolated amounts cannot just be “refunded” to CMS via delete files. Additionally, simply refunding an extrapolated amount in a lump sum would provide no assurance to GHP that those same codes would not subsequently be pulled into another internal or external audit or investigation for which GHP would again be responsible because they were not removed from CMS data via the appropriate delete file submission process. Even if GHP agreed with OIG, CMS has not created a pathway that allows an extrapolated overpayment to be refunded.

VI. GHP Does Not Agree That the OIG’s Audit Findings Require Identification and Enhancement of GHP’s Existing Compliance Procedures

OIG’s recommended that GHP 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, and for GHP to take the necessary steps to enhance those procedures. First and foremost, if it is OIG’s position that the unsupported provider charts in the audit were caused by an act or omission of GHP’s compliance function, GHP disagrees. OIG’s audit was an audit of exceptions that specifically targeted codes and patterns in a manner designed for MAOs to fail. The OIG’s selection criteria were not random or representative of the GHP member population data at large, which would have provided a far more accurate vantage point of errors in GHP’s risk adjustment data.

GHP’s compliance program and associated procedures to ensure the appropriateness of the risk adjustment data are robust and GHP is proactive in managing the risks surrounding risk adjustment. GHP conducts regular and targeted monitoring and auditing of risk adjustment data ingested through claims both prior to and after submission to CMS. In fact, as referenced in the Draft Report, GHP initiated a review of HCC 108, found 100% compliance after reviewing a subset of records, and made the decision, given the results, to focus on other areas. GHP is confident that it is making good faith efforts to ensure the data submitted to CMS is accurate, complete, and truthful and that its compliance activities are otherwise effective.

OIG’s review methodology (with its constantly shifting focus⁷⁵ and unworkable insistence on 100% accuracy) does not encourage or facilitate greater compliance and, in fact, results in a distraction from MAO routine compliance programs. With every review, OIG’s focus shifts, making it challenging for MAOs to consider where to focus efforts. For instance, the GHP audit focused on nine different “high risk codes” – which is more diagnosis codes than many of the previous audits. An MAO cannot just flip a switch to address each new issue being targeted in OIG audits. Targeting new coding patterns requires intense administrative time and expense to run analytics, request and obtain charts, review medical records, create guidance, and train physicians (who may or may not be receptive) and staff, among other things. OIG’s constantly shifting focus makes these efforts even more difficult and frustrates the compliance process.

⁷⁴ 42 U.S.C. §139hh(e)(1)(A).

⁷⁵ OIG has, in the series of published reports of MAOs (see n. 36, above), targeted a changing mix of codes it considers to be at “high-risk” of being miscoded. In addition, these audits contained a multitude of differing approaches to scope and calculation methods.

VII. GHP Urges OIG to Direct Certain Recommendations to CMS Rather Than MAOs

As noted, OIG, particularly regarding two HCCs (Acute MI and Acute CVA), has identified an issue with the CMS-created risk adjustment model rather than an issue with the payments made to GHP. It would behoove OIG to make specific recommendations to CMS rather than the MAOs that have been subjected to the OIG audits.

Filtering logic has historically been applied by MAOs and CMS to identify those encounters acceptable for risk adjustment purposes. MAOs previously filtered encounters submitted through RAPS while CMS filtered encounters submitted through EDPS. Beginning with 2021 dates of service (corresponding to PY 2022), CMS phased out the use of RAPS, and now solely uses EDPS. Since filtering logic is now a solely a function of CMS, we urge OIG to recommend that CMS amend its filtering logic. For example, CMS could filter out certain coding patterns that OIG believes are almost always wrong (e.g., Acute MI from the in-office setting with no accompanying hospital admission within a certain time frame). Providers will inevitably continue to make these coding errors and plans cannot possibly verify all inaccuracies in data it receives from providers. It seems highly likely, if not nearly certain, that the Acute MI and CVA issue exists, in its same erroneous form, in FFS. This erroneous data was used to calculate MA payment. This is therefore not a MA plan compliance failure; it is an endemic provider coding error assumed by the CMS risk adjustment model.

Accordingly, we urge OIG to include a recommendation to CMS to apply and adopt new filtering rules to both the Original FFS data used by CMS to calibrate the risk adjustment model and to the MAO data used to calculate risk scores and payments, as would be required to maintain actuarial equivalence. As an oversight agency, OIG can, and appropriately should, make these types of recommendations to CMS.

VIII. Conclusion

For all the foregoing reasons, GHP objects to OIG's conclusions and requests that it withdraw all of its recommendations. GHP reserves the right to raise these and other challenges to OIG's findings in the future.

Sincerely,



David J. Weader
Associate Chief Legal Officer and Regulatory Affairs Officer
Geisinger Health Plan

cc: Stacey Benseler, Chief Compliance Officer – Geisinger Health Plan
Mark McCullough, Chief Financial Officer/Chief Operating Officer – Geisinger Health Plan