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Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Triple-S Advantage, Inc., (Contract H5774) Submitted to CMS

REPORT HIGHLIGHTS



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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.
- To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from its providers and submit these codes to CMS. Some diagnoses are at a higher risk for being miscoded, which may result in overpayments from CMS.
- For this audit, we reviewed one MA organization, Triple-S Advantage, Inc. (Triple-S), and focused on nine groups of high-risk diagnosis codes. Our objective was to determine whether selected diagnosis codes that Triple-S submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

What OIG Found

- Most of the selected diagnosis codes that were submitted by Triple-S to CMS for use in CMS's risk
 adjustment program did not comply with Federal requirements. For 204 of the 281 sampled enrolleeyears, the diagnosis codes that Triple-S submitted to CMS were not supported by the medical records
 and resulted in \$296,758 in overpayments.
- As demonstrated by the errors in our sample, Triple-S's policies and procedures did not prevent, detect, and correct noncompliance with CMS program requirements as mandated by Federal regulations.

What OIG Recommends

We recommend that Triple-S:

- 1. refund to the Federal Government the \$296,758 in net overpayments;
- 2. identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
- 3. continue to 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.

Triple-S did not concur with all of our recommendations.

TABLE OF CONTENTS

INTRODUCTION	1
Why We Did This Audit	1
Objective	1
Background	
Medicare Advantage Program	2
Risk Adjustment Program	2
High-Risk Groups of Diagnoses	4
Triple-S Advantage, Inc.	6
How We Conducted This Audit	6
FINDINGS	8
Federal Requirements	8
Most of the Selected High-Risk Diagnosis Codes That Triple-S Submitted to CMS Did Not Comply With Federal Requirements	10 11 12 13 13 14
Triple-S Received Net Overpayments	17
RECOMMENDATIONS	17
TRIPLE-S COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE	18
Triple-S Did Not Concur With OIG's First Recommendation To Refund Net Overpayments	18

	Triple-S Did Not Agree With the OIG's Findings for	
	15 Sampled Enrollee-Years	
	Triple-S Stated that Progress Notes Supported Numerous HCCs	20
	Triple-S Stated That OIG's Targeted Sampling and Selective Review Process	
	is Flawed and Leads to Misrepresentative Results	21
	Triple-S Stated That OIG Does Not Appear To Conform With Actuarial	
	Equivalence, While Relying on Data That Requires It	23
	Triple-S Stated That the OIG Effectively Requires Triple-S To Submit Perfect	
	Risk-Adjustment Data	24
	Triple-S Stated That Extrapolation Is Not Appropriate and Is Inconsistent Wit	h
	Current Guidance	25
	Triple-S Did Not Concur With OIG's Second Recommendation To Conduct	
	Similar Reviews for Other Payment Years	26
	Triple-S Did Not Concur With OIG's Third Recommendation To Continue To Examine	
	Its Existing Compliance Procedures and Take Necessary Steps To	
	Enhance Them	27
APPE	NDICES	
		20
	A: Audit Scope and Methodology	29
	D. Dolotod Office of Increator Concret Borowto	22
	B: Related Office of Inspector General Reports	33
	C: Statistical Sampling Methodology	21
,	C. Statistical Sampling Methodology	34
	D: Sample Results and Estimates	27
	D. Sample Nesalts and Estimates	<i>J</i> ,
	E: Federal Regulations Regarding Compliance Programs That Medicare Advantage	
	Organizations Must Follow	38
	- 0	
	F: Triple-S Comments	40

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 of 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.² Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk of being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 29 major depressive disorder diagnoses into 1 group.) This audit covered Triple-S Advantage, Inc. (Triple-S), a subsidiary of GuideWell Mutual Holding Corporation, for contract number H5774 and focused on nine groups of high-risk diagnosis codes for payment years 2016 and 2017.³

OBJECTIVE

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

¹ The providers code diagnoses using the International Classification of Diseases (ICD), Clinical Modification (CM), Official Guidelines for Coding and Reporting (ICD Coding Guidelines). The ICD is a coding system that is used by physicians and other health care providers to classify and code all diagnoses, symptoms, and procedures. Effective Oct. 1, 2015, CMS transitioned from the 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 See Appendix B for related Office of Inspector General reports.

³ All subsequent references to "Triple-S" in this report refer solely to contract number H5774.

BACKGROUND

Medicare Advantage Program

The MA program offers people eligible for Medicare managed care options by allowing them to enroll in private health care plans rather than having their care covered through Medicare's traditional fee-for-service program. Individuals 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 2022, CMS paid MA organizations \$403.3 billion, which represented 45 percent of all Medicare payments for that year.

Risk Adjustment Program

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

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

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

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

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

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

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

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

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

As 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

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Triple-S Advantage, Inc. (H5774) Submitted to CMS (A-04-21-07095)

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

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

High-Risk Groups of Diagnoses

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

- Major depressive disorder—An enrollee received one 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 their behalf. In these instances, the major depressive disorder diagnosis may not be supported in the medical records.
- Vascular claudication—An enrollee received one diagnosis related to vascular claudication (that mapped to the HCC for Vascular Disease) on only one claim during the service year but had not received one of these diagnoses during the 2 preceding years and had medication dispensed on their behalf that is frequently dispensed for a diagnosis of neurogenic claudication.¹¹ In these instances, the diagnosis related to vascular claudication may not be supported in the medical records.
- Acute stroke—An enrollee received one acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on only one physician claim during the service year but did not have an acute stroke diagnosis on a corresponding inpatient or outpatient

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

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

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

hospital claim. In these instances, a diagnosis of history of stroke (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) 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. In these instances, a diagnosis of history of colon 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) 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. In these instances, a diagnosis of history of breast 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) 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. In these instances, a diagnosis of history of prostate cancer (which does not map to an HCC) typically should have been used.
- Acute heart attack—An enrollee received one diagnosis that mapped to either the HCC for Acute Myocardial Infarction or to the HCC for Unstable Angina and Other Acute Ischemic Heart Disease (Acute Heart Attack HCCs) on only one physician or outpatient claim during the service year but did not have an acute heart attack diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician or outpatient claim). In these instances, a diagnosis indicating a history of a myocardial infarction (which does not map to an HCC) typically should have been used.
- Embolism—An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease with Complications (Embolism HCCs) on only one claim during the service year but did not have an anticoagulant medication dispensed on their 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.
- Lung cancer—An enrollee received one 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 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.

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

Triple-S Advantage, Inc.

Triple-S is an MA organization based in San Juan, Puerto Rico. As of December 2017, Triple-S provided coverage under contract number H5774 to 97,158 enrollees. For the 2016 and 2017 payment years (audit period), CMS paid Triple-S approximately \$1.5 billion to provide coverage to its enrollees. 12, 13

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 Triple-S 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 their condition and the payment year, which we refer to as "enrollee-years."

We identified 12,008 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$15,298,962). We selected for audit a stratified random sample of 281 enrollee-years as shown in Table 1 (following page).

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

¹³ All of the payment amounts that CMS made to Triple-S and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

Table 1: Sampled Enrollee-Years

		Number of Sampled
	High-Risk Group	Enrollee-Years
1.	Major depressive disorder	30
2.	Vascular claudication	30
3.	Acute stroke	30
4.	Colon cancer	30
5.	Breast cancer	30
6.	Prostate cancer	30
7.	Acute heart attack	30
8.	Embolism	30
9.	Lung cancer	41
Total for All High-Risk Groups		281

Triple-S provided medical records as support for the selected diagnosis codes associated with 270 of the 281 sampled enrollee-years. We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. For the HCCs that were not validated, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or if we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group, we included the financial effect of the resulting HCC (if any) in our calculation of overpayments.

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

Appendix A contains the details of our audit scope and methodology, Appendix C contains our statistical sampling methodology, and Appendix D contains our sample results and estimates. Appendix E contains Federal regulations regarding MA organizations' compliance programs.

¹⁴ Triple-S could not locate medical records for the remaining 11 sampled enrollee-years. We discuss 4 of these 11 sampled enrollee-years further in footnote 15.

FINDINGS

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Triple-S submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 77 of the 281 sampled enrollee-years, the medical records validated the reviewed HCCs. However, for the remaining 204 enrollee-years, either the medical records that Triple-S provided did not support the diagnosis codes or Triple-S could not locate the medical records to support the diagnosis codes and the associated HCCs were therefore not validated and resulted in \$296,758 in net overpayments.

As demonstrated by the errors found in our sample, Triple-S'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 Triple-S received at least \$2.5 million in net overpayments for 2016 and 2017. Because of Federal regulations that limit the use of extrapolation in Risk Adjustment Data Validation (RADV) audits for recovery purposes to payment years 2018 and forward, we are reporting the overall estimated net overpayment amount but are recommending a refund of \$296,758 in net overpayments for the sampled enrollee-years.

FEDERAL REQUIREMENTS

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

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

¹⁵ For 4 of these enrollee-years, Triple-S informed us that it could not locate the associated medical records because the records had been destroyed in a natural disaster. CMS provides guidance for medical records that are unavailable because of "extraordinary circumstances" (*Contract-Level Risk Adjustment Data Validation CMS Submission Instructions*). As a result of our assessment of the information provided by Triple-S, we determined that an extraordinary circumstance prevented Triple-S from locating the medical records for these enrollee-years, and we treated the sample items as non-errors.

¹⁶ Specifically, we estimated that Triple-S received at least \$2,587,741 in net overpayments. To be conservative, we estimate 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.

¹⁷ Federal regulations limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643 (Feb. 1, 2023)).

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(I) and 42 CFR § 422.310(d)(1)). In addition, MA organizations must contract with CMS and agree to follow CMS's instructions, including the *Medicare Managed Care Manual* (the Manual) (42 CFR § 422.504(a)).

CMS has provided instructions to MA organizations regarding the submission of data for risk-scoring purposes (the Manual, chap. 7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7, § 40). The diagnosis must be coded according to the International Classification of Diseases, Clinical Modification, Official Guidelines for Coding and Reporting (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 them 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 TRIPLE-S SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Most of the selected high-risk diagnosis codes that Triple-S submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. As shown in the figure below, the medical records that Triple-S provided for 204 of the 281 sampled enrollee-years either did not support the diagnosis codes or Triple-S could not locate the medical records to support the diagnosis codes. In these instances, Triple-S should not have submitted the diagnosis codes to CMS and received the resulting net overpayments.

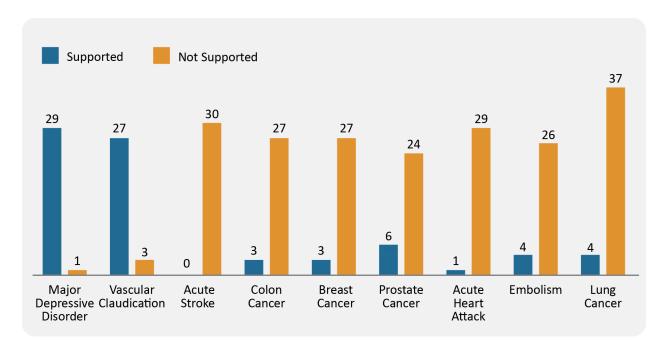


Figure: Analysis of High-Risk Groups

Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder

Triple-S incorrectly submitted diagnosis codes for major depressive disorder for 1 of 30 sampled enrollee-years. Specifically, for the enrollee-year, the medical record in this case did not contain sufficient information to support a major depressive disorder diagnosis. For the enrollee-year, the independent medical review contractor noted 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 depression . . . that does not result in an HCC."

As a result of this error, the HCC for Major Depressive, Bipolar, and Paranoid Disorders was not validated, and Triple-S received \$1,998 in overpayments for the sampled enrollee-year.

Incorrectly Submitted Diagnosis Codes for Vascular Claudication

Triple-S incorrectly submitted diagnosis codes for vascular claudication for 3 of 30 sampled enrollee-years, specifically:

For 3 enrollee-years, the medical records in each case did not support a vascular claudication diagnosis. For example, for 1 enrollee-year, the independent medical review contractor noted that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Vascular Disease]."

As a result of these errors, the HCC for Vascular Disease was not validated, and Triple-S received \$3,739 in overpayments for these 3 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Stroke

Triple-S incorrectly submitted diagnosis codes for acute stroke for all 30 sampled enrollee-years, specifically:

- For 16 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 or a related HCC."
- For 11 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 noted that "there is no evidence of an acute stroke, or any related condition that would result in an assignment of the submitted HCC or a related HCC. There is mention of an old cerebrovascular accident making this a history of a stroke . . . but no description of residuals or sequelae that should be coded." 18
- For 2 enrollee-years, Triple-S could not locate any medical records to support the acute stroke diagnosis; therefore, the HCC for Ischemic or Unspecified Stroke was not validated.
- For the remaining 1 enrollee-year, Triple-S submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiplegia (which was supported in the medical records). ¹⁹ The independent medical review contractor stated that "there is no evidence of an acute stroke, however the patient has left sided hemiparesis from an old stroke . . . [which] would result in the assignment of [the] HCC [for Hemiplegia/Hemiparesis]." This error caused an underpayment.

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and Triple-S received \$38,503 in net overpayments for these 30 sampled enrollee-years.

¹⁸ A cerebrovascular accident is the medical term for a stroke. Residuals or sequelae are the late effects of an injury that can occur only after the acute phase of the injury or illness has passed.

¹⁹ Hemiplegia is defined as complete paralysis or loss of function of one-half of the body, including one leg and arm, because of injury or disease in the motor centers of the brain.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

Triple-S incorrectly submitted diagnosis codes for colon cancer for 27 of 30 sampled enrollee-years, specifically:

- For 14 enrollee-years, the medical records indicated in each case that the individual had previously had colon cancer, but the records did not justify a colon cancer diagnosis at the time of the physician's service. For example, for 1 enrollee-year, the independent medical review contractor noted "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 personal history of colon cancer . . . that does not result in an HCC."
- For 9 enrollee-years, the medical records in each case did not contain sufficient information to support a colon cancer diagnosis. For example, for 1 enrollee-year the independent medical review contractor noted "there is no documentation of any condition that will result in the assignment of [the] HCC [for Colorectal, Bladder, and Other Colon Cancers]."
- For 3 enrollee-years, the medical records in each case did not support a colon cancer diagnosis. However, for each of these enrollee-years, we identified support on CMS's systems for another diagnosis that mapped to an HCC for Breast, Prostate, and Other Cancers and Tumors; a less severe manifestation of the related-disease group. Accordingly, Triple-S should not have received an increased payment for the submitted colon cancer diagnosis but should have received a lesser increased payment for the other diagnosis identified.
- For the remaining 1 enrollee-year, Triple-S could not locate any medical records to support the colon cancer diagnosis; therefore, the Colorectal, Bladder, and Other Cancers HCC was not validated.

As a result of these errors, the Colorectal, Bladder, and Other Cancers HCC was not validated, and Triple-S received \$32,183 in overpayments for these 27 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

Triple-S incorrectly submitted diagnosis codes for breast cancer for 27 of 30 sampled enrolleeyears, specifically:

For 20 enrollee-years, the medical records indicated in each case that the individual had
previously had breast cancer, but the records did not justify a breast cancer diagnosis at
the time of the physician's service. For example, for 1 enrollee-year, the independent
medical review contractor noted 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 personal history of neoplasm of breast . . . that does not result in an HCC."

- For 5 enrollee-years, the medical records in each case did not support a breast cancer diagnosis. For example, for 1 enrollee-year, the independent medical review contractor noted that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors]."
- For the remaining 2 enrollee-years, Triple-S could not locate any medical records to support the breast cancer diagnosis; therefore, the Breast, Prostate, and Other Cancers and Tumors HCC was not validated.

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Triple-S received \$19,622 in overpayments for these 27 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

Triple-S incorrectly submitted diagnosis codes for prostate cancer for 24 of 30 sampled enrollee-years, specifically:

- For 21 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 noted 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 . . . that does not result in an HCC."
- For 3 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 noted 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]."

As a result of these errors, the Breast, Prostate, and Other Cancers and Tumors HCC was not validated, and Triple-S received \$15,316 in overpayments for these 24 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Heart Attack

Triple-S incorrectly submitted diagnosis codes for acute heart attack for 29 of 30 sampled enrollee-years, specifically:

• For 14 enrollee-years, the medical records in each case noted that the individual previously had a myocardial infarction diagnosis, but the records did not justify a myocardial infarction diagnosis at the time of the physician's service. For example, for 1

enrollee-year, the independent medical review contractor noted that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Unstable Angina and Other Acute Ischemic Heart Disease]. There is documentation of a past medical history of myocardial infarction . . . that does not result in an HCC."

- For 8 enrollee-years, the medical records in each case did not support a diagnosis that
 mapped to an Acute Heart Attack HCC. However, for each of these enrollee-years, we
 identified support on CMS's systems for another diagnosis that mapped to an HCC for
 Angina Pectoris; a less severe manifestation of the related-disease group. Accordingly,
 Triple-S should not have received an increased payment for the submitted acute heart
 attack diagnosis but should have received a lesser increased payment for the other
 diagnosis identified.
- 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 noted that "there is no documentation of any condition that will result in assignment of [the] HCC [for Unstable Angina and Other Acute Ischemic Heart Disease]."
- For the remaining 1 enrollee-year, Triple-S could not locate any medical records to support the acute heart attack diagnosis; therefore, the Unstable Angina and Other Acute Ischemic Heart Disease HCC was not validated.

As a result of these errors, the HCC for Acute Heart Attack was not validated, and Triple-S received \$28,080 in overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

Triple-S incorrectly submitted diagnosis codes for embolism for 26 of 30 sampled enrollee-years, specifically:

- For 15 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 noted that "there is no documentation of any condition that
 will result in the assignment of [the] HCC [for Vascular Disease with Complications]."
- For 10 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 noted that "there is no documentation of any condition that will result in the assignment of [the HCC for Embolism]. There is documentation of a past medical history of deep vein thrombosis. . . that does not result in an HCC."

 For the remaining 1 enrollee-year, Triple-S 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 HCC was not validated, and Triple-S received \$40,050 in overpayments for these 26 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

Triple-S incorrectly submitted diagnosis codes for lung cancer for 37 of 41 sampled enrolleeyears, specifically:

 For 17 enrollee-years, the medical records in each case did not support a lung cancer diagnosis. However, for each of these enrollee-years, we identified support on CMS's systems for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Triple-S should not have received an increased payment for the submitted lung cancer diagnosis but should have received a lesser increased payment for the other diagnosis identified.

Table 2 identifies the HCCs for the less severe manifestations of the related-disease groups that were supported for the 17 enrollee-years.

Table 2: HCCs for a Less Severe Manifestation of the Related-Disease Group That Should Have Been Used Instead of the HCC for Lung and Other Severe Cancers

Count of Enrollee-Years	Less Severe Hierarchical Condition Category	
7	Colorectal, Bladder, and Other Cancers	
6	Breast, Prostate, and Other Cancers and Tumors	
4	Lymphoma and Other Cancers	

- For 13 enrollee-years, the medical records in each case did not support a lung cancer diagnosis. For example, for 1 enrollee-year, the independent medical review contractor noted that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Lung and Other Severe Cancers]."
- For 7 enrollee-years, the medical records indicated in each case that the individual had previously had lung cancer, however, the records did not justify a lung cancer diagnosis at the time of the physician's service. For example, for 1 enrollee-year, the independent medical review contractor noted that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Lung and Other Severe Cancers]. There is

documentation of a past medical history of lung cancer . . . that does not result in an HCC."

As a result of these errors, the Lung and Other Severe Cancers HCC was not validated, and Triple-S received \$117,267 in overpayments for these 37 sampled enrollee-years.

Summary of Incorrectly Submitted Diagnosis Codes

In summary and with respect to the nine high-risk groups covered by our audit, Triple-S received \$296,758 in net overpayments for the 281 sampled enrollee-years.

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

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

Triple-S had, for our audit period, compliance procedures to determine whether the diagnosis codes used to calculate risk-adjusted payments were correct. These procedures included preventive measures such as continuous education of its participating providers. Subsequent to our audit period, Triple-S updated its trainings to focus on key conditions that may affect diagnosis codes in medical record documentation, including information from recent Office of Inspector General (OIG) audits addressing relevant conditions, such as acute stroke and acute heart attack. Triple-S designed this program to assist its providers in capturing and documenting chronic conditions in detail.

Triple-S officials stated that they also use a data-driven software platform to prospectively review and analyze patient data in their attempts to improve documentation, coding, and risk score accuracy. Specifically, Triple-S analyzes clinical and claims data for individual enrollees; in turn, the software offers its providers guidance on potential issues and proper documentation for conditions they may encounter. In this regard, Triple-S has contracted with multiple vendors, each of which has a unique compliance program that incorporates quality assurance steps, such as continuously evaluating the accuracy of the coders' performance.

Triple-S's compliance procedures also included detective and corrective measures such as coding pre-submission reviews and internal audits. Triple-S conducted analytical reviews of conditions submitted through its claims system to identify possible trends or increases in diagnoses submitted by its providers. Triple-S reviews a sample of the claims and compares the data to the medical record documentation to validate that they were correctly coded. Any findings are discussed with senior management and referred to its coding contractor for corrections.

Triple-S did have policies and procedures designed to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations. However, with respect to diagnoses that were at high risk of being miscoded, our audit determined that the medical records could not validate the audited HCCs for 204 of the 281 sampled enrollee-years. As a result, we concluded that Triple-S's oversight procedures could be improved.

TRIPLE-S 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 Triple-S received at least \$2.5 million in net overpayments for these high-risk diagnosis codes for 2016 and 2017 (See Appendix D for our sample results and estimates).

Because of Federal regulations that limit the use of extrapolation in RADV audits for recovery purposes to payment year 2018 and forward, we are reporting the estimated net overpayment amount but are recommending a refund of only the \$296,758 in net overpayments that Triple-S received for the 281 sampled enrollee-years. ²⁰

RECOMMENDATIONS

We recommend that Triple-S Advantage, Inc.:

- refund to the Federal Government the \$296,758 in net overpayments;²¹
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
- continue to examine its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk of 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.

²⁰ 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)).

²¹ OIG audit recommendations do not represent final determinations. Action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures. In accordance with 42 CFR § 422.311, which addresses audits conducted by the Secretary (including those conducted by the OIG), if a disallowance is taken, MA organizations have the right to appeal the determination that an overpayment occurred through the Secretary's RADV appeals process.

TRIPLE-S COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Triple-S did not agree with some of our findings and did not concur with all of our recommendations. Specifically, Triple-S did not agree with our findings for 15 of the 209 enrollee-years identified as errors in our draft report and provided additional information for our consideration. Triple-S did not directly agree or disagree with our findings for the remaining 194 enrollee-years.

Triple-S stated that our audit approach was not balanced, was inconsistent with relevant guidance, and resulted in misleading findings and recommendations. Triple-S did not concur with our first recommendation because, according to Triple-S, we selectively identified HCCs that were more likely to be deficient, did not comply with the Federal requirement known as "actuarial equivalence," and required that Triple-S submit perfect risk-adjustment data to CMS. Triple-S also stated that our approach to extrapolating overpayments is inconsistent with current guidance and disagreed with the inclusion of the extrapolated overpayment amount in our report.

Triple-S stated that our second recommendation would result in it performing additional auditing, which is not required by the relevant regulations. With regard to our third recommendation, Triple-S stated that it has "a robust compliance program that meets relevant guidance."

After reviewing Triple-S's comments and the additional information it provided, we reduced the number of enrollee-years in error from 209 (in our draft report) to 204 and adjusted our calculation of overpayments. Accordingly, we reduced the recommended refund in our first recommendation from \$301,018 to \$296,758 for this final report. We maintain that our second and third recommendations remain valid.

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

TRIPLE-S DID NOT CONCUR WITH OIG'S FIRST RECOMMENDATION TO REFUND NET OVERPAYMENTS

Triple-S Did Not Agree With the OIG's Findings for 15 Sampled Enrollee-Years

Triple-S Comments

Triple-S did not agree with our draft report findings for 15 sampled enrollee-years (as shown in Table 3 on the following page) and requested that we reconsider our findings for each of these cases and recalculate any recommended net overpayment. Triple-S also stated "[c]orrecting these issues will increase the rate of HCC substantiation and impact OIG's projections and overpayment calculations."

Table 3: Summary of Enrollee-Years for Which Triple-S Disagreed With Our Findings

High Risk Group	Number of Sampled Enrollee Years
1. Vascular Claudication	1
2. Acute Stroke	1
3. Colon Cancer	1
4. Prostate Cancer	3
5. Acute Heart Attack	3
6. Embolism	3
7. Lung Cancer	3
Total for all High-Risk Groups	15

For 13 of the 15 enrollee-years, Triple-S provided explanations supporting its position that previously submitted medical records validated the audited HCCs. For example, regarding sample number 83, an enrollee-year from the Acute Stroke high-risk group, Triple-S stated the following:

[t]he assessment section lists a cerebrovascular accident evaluated by a cardiologist. The record also listed prescriptions for Cardizem, Plavix, and Diovan. This diagnosis maps to [the HCC for Ischemic or Unspecified Stroke]. The provider also referred the patient to a follow-up visit with a neurologist.

For the remaining 2 enrollee-years, Triple-S provided explanations as to why it believed there was support for a diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. For example, Triple-S provided (for sample number 94, an enrollee-year from the Colon Cancer high-risk group) multiple explanations supporting its position, including the following:

in the progress note following evaluation by a hematologist oncologist, the chief complaint listed is a follow-up visit for prostate cancer. The assessment section documented early-stage prostate cancer, which maps to [the HCC for Breast, Prostate, and Other Cancers and Tumors], a lower-hierarchy [HCC].

Office of Inspector General Response

For the 13 enrollee-years for which Triple-S provided additional documentation, our independent medical review contractor reviewed the documentation and reaffirmed that 8 of the 13 HCCs were not validated. For example, regarding sample number 83, the enrollee-year from the acute stroke high-risk group, our contractor upheld its original decision upon reconsideration and noted that the medical record "supports a past medical history of stroke

which does not result in an HCC . . . there is no documentation of acute stroke symptoms or treatment, and the provider documented '[n]o active health concerns recorded.'"

For the remaining 5 enrollee-years, our contractor reversed its original decision and stated that the HCCs were validated.²² Our contractor also completed a quality review of the enrollee-years for which it reversed its original decision based on Triple-S's explanations of previously submitted medical records and reported that it did not identify any systemic issues. Accordingly, we reduced the number of enrollee-years in error from 209 (as reported in our draft report) to 204. We also revised our findings and reduced the associated monetary recommendation.

With respect to the 2 enrollee-years for which Triple-S asserted that it had support for a diagnosis code that mapped to an HCC for a less severe manifestation of the related-disease group, we agree that the HCCs indicated by Triple-S in its comments were supported. However, we considered the financial effect of these HCCs when we calculated the recommended refund amount included in our draft report.²³ Therefore, we did not need to make any adjustments related to these HCCs for the recommended refund amount included in this final report.

Triple-S Stated that Progress Notes Supported Numerous HCCs

Triple-S Comments

Triple-S stated that it "reviewed the records for the sampled enrollee-years and found 76 samples where an HCC was documented on the assessment portion of the progress note." According to Triple-S, "CMS now recognizes regarding coding, a 'provider's statement that the patient has a particular condition is sufficient.' Although this guidance was not in place at the time, it speaks to the importance of relying on the record as prepared by, and in the judgment of, the treating provider." Triple-S requested that we review and update our findings and repayment amounts for these 76 sampled enrollee-years.

Office of Inspector General Response

Our independent medical review contractor told us that it included the assessment portion of the progress notes as a part of its review process. Because the information that Triple-S commented on had already been considered in our contractor's determinations, we did not ask that the contractor re-review the medical records for the 76 sampled enrollee-years.

²² The 5 enrollee-years were in the following high-risk groups: Prostate Cancer (2 enrollee-years), Embolism (1 enrollee-year), and Lung Cancer (2 enrollee-years).

²³ Specifically, on pages 12 and 15 of this report, we state that, for 20 enrollee-years in the colon cancer (3 enrollee-years) and lung cancer (17 enrollee-years) high-risk groups, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. For these 20 enrollee-years, including the 2 enrollee-years that Triple-S identified in its comments, the associated overpayment amount already reflects the lesser increased payment for the less severe manifestation of the related disease groups.

Triple-S Stated That OIG's Targeted Sampling and Selective Review Process is Flawed and Leads to Misrepresentative Results

Triple-S Comments

Triple-S stated that we took "a singularly targeted audit approach that tilts the results in favor of finding repayment obligations." In doing so, Triple-S stated we did "not conduct an overall assessment of the patient's condition, supporting records, or payment accuracy, which includes underpayments as well as overpayments." Triple-S also stated that our methodology deviated from CMS's audit standards and RADV regulations. In this respect, Triple-S made the following points:

- Triple-S stated that we based our audit entirely on specific groups of high-risk diagnosis codes that we selected precisely for being codes considered to be at a higher risk of being miscoded. Triple-S said that by limiting our audit "to just these select HCCs, OIG ignores the impact of other diagnosis codes or any other issues in the same patient's records or related payments." Triple-S also stated that we only requested documentation targeting the specific HCCs on which we focused and that our independent medical review contractor reviewed "the records with the same narrow focus" by not considering any other HCCs.
- Triple-S also stated that the "sample selections do not appear to correspond to the relevant population, nor do they appear designed for accuracy." Triple-S stated that we did not explain how we "landed on the sample size or other key aspects of [our] approach." To this point, Triple-S said that "[r]elying on an apparently uniform sample size, . . . raises questions about whether these results can be considered a representative sample and about OIG's overall approach and findings"
- Triple-S also stated that our audit approach "is not consistent with well-established CMS audit standards." Specifically, Triple-S stated that CMS promulgates written guidance that describes its approach to RADV audits and that we neither followed this guidance nor offered clear guidance or clarification on our approach for this audit.

Office of Inspector General Response

Our sampling and review methods were not flawed and do not lead to misrepresentative results.

Triple-S is correct in that our audit was not designed to assess the overall medical condition of the enrollee associated with the enrollee-year. Our methodology did, however, identify diagnoses that we determined to be at a higher risk for being miscoded and therefore at a higher risk of resulting in an overpayment. OIG is an independent oversight agency and our audits are intended to provide an independent assessment of HHS programs and operations in accordance with the Inspector General Act of 1978, 5 U.S.C. Ch. 4. Accordingly, we did not

mirror CMS's methodology in all aspects, nor are we required to do so. We conducted our audit in accordance with generally accepted government auditing standards, and our methodology provides a reasonable basis for our findings and conclusions based on our audit objective. Our audit methodology can be found in Appendix A of this report. Below are additional responses to the points that Triple-S made about our audit methodology:

- As stated above, we based our audit—including our request for medical records and our instructions to the independent medical review contractor—entirely on specific groups of selected diagnosis codes that we considered to be at a higher risk of being miscoded. However, we did consider underpayments as they related to our objective. For the HCCs that were not validated, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or if we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group, then we included the financial effect of the resulting HCC (if any) in our calculation of overpayments. A valid calculation of overpayments, given the objective of our audit, does not need to take into consideration all potential HCCs or underpayments within the audit period; this calculation addressed only the accuracy of the portion of payments related to the reviewed HCCs and did not extend to HCCs that were beyond the scope of this audit.
- We disagree with Triple-S that our sample selections did not correspond to the relevant population and were not designed for accuracy. In accordance with our objective and as detailed in Appendix C, we properly executed a statistically valid sampling methodology in that we defined our sampling frame (Triple-S enrollees with a high-risk diagnosis) and sample unit, randomly selected our sample, applied relevant criteria to evaluate the sample, and used statistical sampling software to apply the correct formulas to estimate the net overpayments made to Triple-S. 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.²⁴ Because absolute precision is not required, any imprecision in the sample may be remedied by identifying net overpayments at the lower limit, which was done in this audit.²⁵
- With regard to Triple-S's statement that our audit is not consistent with the guidance that CMS issued for its RADV audits, we note that we did incorporate relevant portions of this guidance into our audit to accomplish our objective. Notably, each of the enrollees associated with the enrollee-years included in our sampling frame were continuously enrolled with Triple-S throughout all of the 2015 or 2016 service year and January of the following year. Thus, Triple-S submitted the diagnoses that were at risk for being miscoded to CMS and for which Triple-S received an increased payment from

²⁴ 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).

²⁵ See Pruchniewski v. Leavitt, 2006 U.S. Dist. LEXIS 101218 at *51-52 (M.D. Fla. 2006).

CMS. With regard to Triple-S's statement that we did not offer clear guidance or clarification on our approach for this audit, we communicated the methodology of the audit multiple times throughout our fieldwork, including during our entrance conference. Further, at the beginning of our audit, to ensure an enrollee-year should be included in our sampling frame, we provided Triple-S with the listing of the enrollee-years in our sampling frame and requested that Triple-S verify certain data elements—including verification that the diagnosis code under review was submitted to CMS for the date of service shown on CMS's systems. During our audit, we informed Triple-S that it could submit up to five medical records for each sampled enrollee-year and provided several extensions for Triple-S to submit the medical records to us. We also provided Triple-S with a document explaining our coding review process along with our independent medical reviewer's determinations, which is explained in our audit methodology. Accordingly, we believe that our audit methodology was designed to provide a reasonable basis for our findings and conclusions based on our audit objective.

Triple-S Stated That the OIG Does Not Appear To Conform With Actuarial Equivalence, While Relying on Data That Requires It

Triple-S Comments

Triple-S stated that our approach does not account for actuarial equivalence, which, according to Triple-S, is a Federal requirement that helps ensure that MA enrollees are treated similarly as those in the traditional Medicare Fee-For-Service (FFS) program. Moreover, Triple-S stated that "Federal regulations mandate that MA plans receive an amount 'actuarially equivalent' to what CMS would have expected to pay to cover the same [individual] under the traditional FFS program."

Triple-S stated that the risk adjustment model was based on "administrative claims [traditional FFS] data, not a review of medical records." Triple-S also stated that FFS providers are paid for "services provided, not diagnosis codes." According to Triple-S, these FFS records are not audited and inherently contain errors. To this point, Triple-S, stated "[i]n now demanding the return of claimed overpayments to an MA plan based on audited records, OIG does not explain or appear to account for these basic differences. OIG's approach therefore appears to violate the actuarial equivalence requirement."

Triple-S also stated that because we did not account for actuarial equivalence, we effectively applied "a new standard of evaluation" and that "it is not possible to accurately calculate financial impact without an actuarially sound approach that considers these data issues." Further, Triple-S stated that, "CMS recognizes Puerto Rico as a unique market and directs adjustments to account for this, it is fundamentally unfair for OIG to now elect not to take these into account for purposes of this audit."

Office of Inspector General Response

Our audit methodology correctly applied CMS requirements to properly identify the overpayment amount associated with the unvalidated HCCs for each sampled enrollee-year. Specifically, we used the results of the independent medical review contractor's review to determine which HCCs were not validated and, in some instances, to identify HCCs that should have been used but were not used in the associated enrollees' risk score calculations. We followed CMS's risk adjustment program requirements as they relate to Triple-S to determine the payment that CMS should have made for each enrollee and to estimate overpayments.

CMS has not issued any requirements that compelled us to reduce our overpayment calculations. In the context of CMS's requirements, CMS stated that it will not make adjustments for actuarial equivalence in RADV audits." We recognize that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program.

Triple-S Stated That the OIG Effectively Requires Triple-S To Submit Perfect Risk-Adjustment Data

Triple-S Comments

Triple-S stated that, "OIG's underlying approach ultimately expects [Triple-S] to submit perfect risk-adjustment data." To this point, Triple-S stated that due to "the large amount of data and number of stakeholders involved in coding certain conditions, [Triple-S] believes this is an unreasonably high standard, one that is unsupported by regulatory guidance." Triple-S added that "[a]lthough OIG points to the general requirement that 'MA organizations are responsible for the accuracy, completeness, and dutifulness of the data submitted to CMS,' OIG does not appear to recognize the well-understood contours of that requirement" Triple-S also stated that our "[d]raft [r]eport and recommendations imply that an [MA organization] must review or monitor every data point it receives. This is not required, nor is it possible."

Office of Inspector General Response

Triple-S's comments regarding "perfect risk-adjustment data" implied that we opined on its responsibilities to ensure accuracy on 100 percent of the data it submitted to CMS. That was not our intention nor our focus for this audit. We limited our audit (including our assessment of Triple-S's compliance program) and recommendations to certain diagnosis codes that we had determined to be at high risk of being miscoded. In this respect, we did not misunderstand CMS's requirement with regard to MA organizations' responsibilities for submitting risk-adjustment data to CMS.²⁷

²⁶ 88 Fed. Reg. 6643 (Feb. 1, 2023).

²⁷ 79 Fed. Reg. 29844, 29926 (May 23, 2014).

Triple-S Stated That Extrapolation Is Not Appropriate and Is Inconsistent With Current Guidance

Triple-S Comments

Triple-S stated that because CMS regulations direct that extrapolated overpayments can only be recouped beginning with audits of payment year 2018, "[t]he extrapolated amount referenced in the [d]raft [r]eport [estimated net overpayment] is therefore inadequately supported . . . " For this reason, Triple-S requested that we "remove this purported amount" from the report.

Triple-S also stated that "even if extrapolation could be applied to any of the years at issue, applying it here would be misplaced. Federal regulations generally reflect that this approach should be rarely used and only where the audit satisfies the appropriate conditions, which OIG has not demonstrated are relevant here." Triple-S noted several disagreements with our audit methodology and gave an example of a difference between our methodology and that of CMS. Specifically, Triple-S disagreed with our use of a 90-percent confidence interval to calculate "extrapolated repayment amounts" because "CMS guidance for RADV uses a 99% confidence interval." According to Triple-S, using "a different confidence interval introduces an arbitrary bias to over-extrapolate findings beyond what CMS defined as appropriate."

Office of Inspector General Response

We disagree with Triple-S that our calculation of net estimated overpayments is inadequately supported. Triple-S is correct in that Federal requirements limit the use of extrapolation in RADV audits for recovery purposes to payment year 2018 and forward. For this reason, we recommended a refund of the net overpayments that Triple-S received for the sampled enrollee-years. However, we disagree with Triple-S that the estimated net overpayments should not be included in this report.

As stated previously, in accordance with the Inspector General Act of 1978, 5 U.S.C. Ch. 4, our audits are intended to provide an independent assessment of HHS programs and operations. Although our approach was generally consistent with the methodology CMS uses in its audits, it did not mirror CMS' approach in all aspects, nor did it have to. We note that the requirement that a determination of a sustained or high level of payment error must be made before extrapolation applies only to Medicare contractors. In addition, we believe the error rates identified in our audit demonstrate that Triple-S has compliance issues that need to be addressed. Finally, Federal courts have consistently upheld statistical sampling and

²⁸ See Social Security Act § 1893(f)(3) and CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 8, §8.4.1.4 (effective June 28, 2011).

extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.²⁹

Regarding our extrapolation of overpayments, longstanding OIG policy is to estimate net overpayments at the lower limit of a two-sided 90-percent confidence interval. We believe that the lower limit of a two-sided 90-percent confidence interval does not introduce an arbitrary bias and provides a reasonably conservative estimate of the total amount overpaid to Triple-S for the enrollee-years and the time period covered in our sampling frame. This approach, which is routinely used by HHS for recovery calculations, results in a lower limit (the estimated overpayment amount) that is designed to be less than the actual overpayment total 95 percent of the time.³⁰

TRIPLE-S DID NOT CONCUR WITH OIG'S SECOND RECOMMENDATION TO CONDUCT SIMILAR REVIEWS FOR OTHER PAYMENT YEARS

Triple-S Comments

Triple-S did not concur with, and requested that we withdraw, our second recommendation—that Triple-S identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government. Triple-S said the recommendation should be withdrawn because "additional auditing is not required by the relevant regulations."

Office of Inspector General Response

We do not agree with Triple-S's interpretation of Federal requirements. We recognize that MA organizations have the latitude to design their own federally mandated compliance programs. We also acknowledge the requirement that MA organizations certify that the data they submit to CMS are based on "best knowledge, information, and belief." However, contrary to Triple-S's statements, our second recommendation conforms to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (Appendix E)). These regulations state that MA

²⁹ 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).

³⁰ For example, HHS has used the two-sided 90-percent confidence interval when calculating recoveries in both the Administration for Child and Families and Medicaid programs. See e.g., *New York State Department of Social Services*, HHS Departmental Appeals Board (DAB) No. 1358, 13 (1992); *Arizona Health Care Cost Containment System*, DAB No. 2981, 4-5 (2019). In addition, HHS contractors rely on the one-sided 90-percent confidence interval, which is less conservative than the two-sided interval, for recoveries arising from Medicare fee-for-service (FFS) overpayments. See e.g., *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 17-18 (E.D.N.Y. 2012).

organizations must "implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements . . ."

Furthermore, these regulations specify that Triple-S's compliance plan "must, at a minimum, include [certain] core requirements" which include "an effective system for routine monitoring and identification of compliance risks . . . [including] internal monitoring and audits and, as appropriate, external audits, to evaluate . . . compliance with CMS requirements and the overall effectiveness of the compliance program." These regulations also require MA organizations to implement procedures and a system for investigating "potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence" (42 CFR § 422.503(b)(4)(vi)(G)). Thus, CMS has, through the issuance of these Federal regulations, assigned the responsibility for dealing with potential compliance issues to the MA organizations.

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

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

We believe that the error rates identified in this report demonstrate that Triple-S has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope. Accordingly, we maintain the validity of our second recommendation.

TRIPLE-S DID NOT CONCUR WITH OIG'S THIRD RECOMMENDATION TO CONTINUE TO EXAMINE ITS EXISTING COMPLIANCE PROCEDURES AND TAKE NECESSARY STEPS TO ENHANCE THEM

Triple-S Comments

Triple-S did not concur with, and requested that we reconsider, our third recommendation—that it continue to examine its existing compliance procedures for diagnoses that are at high risk of being miscoded and enhance those procedures as necessary. Specifically, Triple-S stated that it has "a robust compliance program that meets relevant guidance." Triple-S also said that its compliance program "includes multiple processes and controls designed to prevent, detect, and correct potential concerns, including concerns related to risk adjustment coding."

Triple-S said that we acknowledged that it had compliance procedures in place during our audit period and that it has continued to make enhancements to its policies and procedures since our audit period. However, Triple-S stated that our "audit's misrepresentative results, based on a flawed process, do not reflect the strength of [Triple-S's] policies and procedures." Moreover, Triple-S stated that it has a series of layered controls developed over multiple years, which include continuous education of participating providers and their staff, the use of software tools to assess risk and identify conditions for the plan of care, internal quality reviews, and audits to test and oversee that these processes, to ensure the accuracy of data submitted to CMS, including risk-adjustment data.

Office of Inspector General Response

We do not fully agree with Triple-S's statements. Although we commend Triple-S for its stated improvements to its policies and procedures, we limited our audit—including our assessments of its policies and procedures—to selected diagnoses that we determined to be at high risk of being miscoded. In this respect, our audit revealed a significant error rate for most of the nine audited high-risk groups. Thus, we continue to believe that Triple-S should continue to examine and enhance its compliance procedures with respect to diagnoses that are at high risk of being miscoded. Accordingly, we maintain that our third recommendation remains valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid Triple-S \$1,534,584,077 to provide coverage to its enrollees for 2016 and 2017. We identified a sampling frame of 12,008 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2015 through 2016 service years. Triple-S received \$15,298,962 in payments from CMS for these enrollee-years for 2016 and 2017. We selected for audit 281 enrollee-years with payments totaling \$2,666,617.

The 281 enrollee-years included 30 major depressive disorder diagnoses, 30 vascular claudication diagnoses, 30 acute stroke diagnoses, 30 colon cancer diagnoses, 30 breast cancer diagnoses, 30 prostate cancer diagnoses, 30 acute heart attack diagnoses, 30 embolism diagnoses, and 41 lung cancer diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$394,803 for our sample.

Our audit objective did not require an understanding or assessment of Triple-S'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 March 2021 to December 2024.

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 of noncompliance. We also identified the diagnosis codes that potentially should have been used for cases in which the high-risk diagnoses were miscoded.
- We consolidated the high-risk diagnosis codes into specific groups, which included:
 - 85 diagnosis codes for embolism,
 - 74 diagnosis codes for acute stroke,
 - 65 diagnosis codes for breast cancer,

- 38 diagnosis codes for acute heart attack,
- 29 diagnosis codes for major depressive disorder,
- o 24 diagnosis codes for lung cancer,
- o 20 diagnosis codes for colon cancer
- 4 diagnosis codes for vascular claudication, 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) ³¹ and the Encounter Data System (EDS)³² to identify enrollees who received high-risk diagnosis codes from a physician during the service years;
 - Risk Adjustment System (RAS) to identify enrollees who received an HCC for the high-risk diagnosis codes;³³
 - Medicare Advantage Prescription Drug System (MARx) to identify enrollees for whom CMS made monthly Medicare payments to Triple-S, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C);³⁴
 - o EDS to identify enrollees who received specific procedures;³⁵ and
 - Prescription Drug Event (PDE) file to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.³⁶

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

³² CMS uses the EDS to collect encounter data, including diagnosis codes, from MA organizations.

³³ The RAS identifies the HCCs that CMS factors into each enrollee's risk score calculation.

³⁴ The MARx identifies the payments made to MA organizations.

³⁵ The EDS contains information on each item (including procedures) and service provided to an enrollee.

³⁶ The PDE file contains claims with prescription drugs that have been dispensed to enrollees through the Medicare Part D (prescription drug coverage) program.

- We interviewed Triple-S officials to gain an understanding of (1) the policies and procedures that Triple-S followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Triple-S's monitoring of those diagnosis codes to identify and correct noncompliance with Federal requirements.
- We selected for audit a stratified random sample of 281 (out of 12,008) enrollee-years (Appendix C).
- We used an independent medical review contractor to perform a coding review for the 270³⁷ enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.³⁸
- 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(s), then the HCC was considered validated.
 - o If the first senior coder did not find support on the medical record(s), then a second senior coder performed a separate review of the same medical record:
 - If the second senior coder also did not find support, then the HCC was considered to be not validated.
 - If the second senior coder found support, then the coding supervisor reviewed the medical record(s) to make the final determination.
 - If either the first or second senior coder asked the coding supervisor for assistance, then the coding supervisor's decision became the final determination. In addition, at any point in the review process, a senior coder or coding supervisor may have consulted a physician reviewer for additional clarification.
- We used the results of the independent medical review contractor and CMS's systems to calculate overpayments or underpayments (if any) for each enrollee-year.
 Specifically, we calculated:

³⁷ Triple-S could not locate medical records for the remaining 11 sampled enrollee-years.

³⁸ Our independent medical review contractor used senior coders, all of whom possessed one or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS), Certified Coding Specialist—Physician-Based (CCS-P), Certified Professional Coder (CPC), and Certified Risk 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 CPCs and CRCs.

- o a revised risk score in accordance with CMS's risk adjustment program and
- o the payment that CMS should have made for each enrollee-year.
- We estimated the total net overpayments made to Triple-S during the audit period.
- We limited the total net overpayments that we recommended for recovery to the sampled enrollee-years.³⁹
- We discussed the results of our audit with Triple-S 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.

³⁹ Federal regulations at 42 CFR § 422.311 state: "the Secretary annually conducts RADV audits to ensure riskadjusted 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
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Humana Health Plan, Inc. (Contract	A-02-22-01001	9/23/2024
H2649) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That HealthAssurance, Pennsylvania, Inc.	A-05-22-00020	9/23/2024
(Contract H5522) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Independent Health Association,	A-07-19-01194	6/26/2024
Inc. (Contract H3362) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That MediGold (Contract H3668)	A-07-20-01198	2/16/2024
Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That SelectCare of Texas, Inc. (Contract	A-06-19-05002	11/27/2023
H4506) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Aetna, Inc. (Contract H5521)	A-01-18-00504	10/02/2023
Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Presbyterian Health Plan, Inc.	A-07-20-01197	8/3/2023
(Contract H3204) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Excellus Health Plan, Inc. (Contract	A-07-20-01202	7/10/2023
H3351) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Keystone Health Plan East, Inc.	A-03-20-00001	5/31/2023
(Contract H3952) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That HumanaChoice (Contract H6609)	A-05-19-00013	4/4/2023
Submitted to CMS		

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified Triple-S enrollees who (1) were continuously enrolled with Triple-S 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 Triple-S for 2016 or 2017, respectively.

We presented the data for these enrollees to Triple-S for verification and performed an analysis of the data included in CMS's systems to ensure that the high-risk diagnosis codes increased CMS's payments to Triple-S. After we performed these steps, our finalized sampling frame consisted of 12,008 enrollee-years.

SAMPLE UNIT

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

SAMPLE DESIGN AND SAMPLE SIZE

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

- 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 their behalf (8,040 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 their behalf (1,323 enrollee-years);
- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke)
 on only one physician claim during the service year but did not have that diagnosis on a
 corresponding inpatient or outpatient hospital claim (1,271 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 (248 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 (366 enrollee-years);
- a prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors), for an individual 74 years old or younger, on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (373 enrollee-years);
- a diagnosis (that mapped to an Acute Heart Attack HCC) on only one physician or outpatient claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician or outpatient claim (252 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 their behalf (94 enrollee-years); or
- 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 (41 enrollee-years).

The specific strata are shown in Table 4 on the following page.

Table 4: Sample Design for Statistically Sampled High-Risk Groups

Stratum	Frame Count of Enrollee-	CMS Payment for HCCs in Audited High-	Sample	
(High-Risk Groups)	years	Risk Groups	Size	
1- Major depressive disorder	8,040	\$10,903,439	30	
2- Vascular claudication	1,323	1,569,399	30	
3- Acute stroke	1,271	1,557,725	30	
4- Colon cancer	248	312,565	30	
5- Breast cancer	366	231,966	30	
6- Prostate cancer	373	231,529	30	
7- Heart attack	252	229,899	30	
8- Embolism	94	135,475	30	
9- Lung cancer	41	126,965	41	
Total	12,008	15,298,962*	281	
*Rounded to the nearest whole dollar amount.				

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We sorted the items in each stratum by enrollee identifier and payment year, and then consecutively numbered the items in each stratum in the stratified sampling frame. After generating 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 Triple-S 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 5: 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—Major						
depressive						
disorder	8,040	\$10,903,439	30	\$42,299	1	\$1,998
2—Vascular						
claudication	1,323	1,569,399	30	34,786	3	3,739
3—Acute stroke	1,271	1,557,725	30	40,871	30	38,503
4—Colon cancer	248	312,565	30	35,455	27	32,183
5—Breast cancer	366	231,966	30	21,231	27	19,622
6—Prostate						
cancer	373	231,529	30	18,384	24	15,316
7 —Acute heart						
attack	252	229,899	30	28,406	29	28,080
8—Embolism	94	135,475	30	46,406	26	40,050
9—Lung cancer	41	126,965	41	126,965	37	117,267
Totals	12,008	\$15,298,962	281	\$394,803	204	\$296,758

Table 6: Estimated Net Overpayments in the Sampling Frame (Limits Calculated for a 90-Percent Confidence Interval)

Point Estimate	\$3,506,048
Lower Limit	\$2,587,741
Upper Limit	\$4,424,354

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 selfevaluations, 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: TRIPLE-S COMMENTS



March 28, 2024

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U.S. Department of Health & Human Services Office of Inspector General Office of Audit Services, Region IV Attention: Lori S. Pilcher Regional Inspector General for Audit Services 61 Forsyth Street, SW, Suite 3T41 Atlanta, GA 30303

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Re: Triple-S Advantage, Inc.'s Response to Draft Report Number A-04-21-07095

Dear Ms. Pilcher:

Triple-S Advantage, Inc. ("Triple-S Advantage") appreciates this opportunity to respond to the February 2024 Draft Report No. A-04-21-07095, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Triple-S Submitted to CMS* (the "Draft Report"), by the U.S. Department of Health and Human Services ("HHS") Office of Inspector General ("OIG"). While Triple-S Advantage appreciates the efforts taken by OIG in this audit to protect Medicare Advantage ("MA") funding, it believes that several of the premises on which the Draft Report is based are flawed and that the Draft Report does not accurately reflect the strength of Triple-S Advantage's compliance program. Accordingly, Triple-S Advantage respectfully requests that OIG not finalize the Draft Report, or OIG's draft recommendations based on the Draft Report, in its current state, but modify it to address the concerns discussed below.

As background, Triple-S Advantage is a Medicare Advantage Organization ("MAO") that provides quality health care services to individuals and employers, today covering a total of 124,412 enrollees, across Puerto Rico. Triple-S Advantage is a committed partner of the Centers for Medicare and Medicaid Services ("CMS"), including consistently sharing specifics of its operations and compliance program with CMS over the past 19 years.

EXECUTIVE SUMMARY

Triple-S Advantage believes, for the reasons set forth below, that OIG's approach to the audit is not balanced, is inconsistent with relevant guidance, and results in misleading findings and recommendations. Given these concerns, Triple-S Advantage does not concur with OIG's three recommendations. The summary below addresses each OIG draft recommendation and then briefly outlines the reasons for nonconcurrence, which are discussed in specific detail in the sections referenced.

Triple-S Advantage does not concur with OIG's calculation of the net overpayment amount. OIG concluded that Triple-S Advantage received \$301,018 in net overpayments. Triple-S

Lori S. Pilcher Office of Inspector General March 28, 2024 Page 2 of 19



Advantage does not agree, because: OIG's targeted sampling and selective review process leads to misrepresentative results. OIG selectively identified Hierarchical Condition Category ("HCC") submissions that OIG knew, at the time it selected them, were more likely to be deficient (Section 1). It is Triple-S Advantage's view that OIG's approach does not account for important aspects of the reported data and how it is used in the audit and calculations. Specifically, OIG's audit does not appear to conform with actuarial equivalence, while relying on data that requires it (Section 2). The Draft Report effectively requires perfect data from Medicare Advantage Organizations ("MAOs"), which is not the CMS standard (Section 3). Further, for certain HCCs, the record does not support OIG's conclusions. OIG inaccurately determined that certain samples were unsupported, when the medical documentation previously provided demonstrates otherwise (Section 4). Specifically, Triple-S Advantage respectfully disagrees with OIG's findings as to 15 samples that OIG found "unsupported." Triple-S Advantage therefore respectfully requests that OIG address these issues and then recalculate any recommended net overpayment. Triple-S Advantage maintains its objections to OIG's approach and overall findings, but will submit deletions through appropriate CMS processes for certain samples that OIG asserts were not supported.¹

Triple-S also disagrees with OIG's statement of an extrapolated overpayment amount, as well as the amount itself (Section 5). Federal regulations do not permit the use of extrapolation for the payment years covered by this audit, as OIG recognized in the Draft Report. But OIG nevertheless included this figure. OIG's extrapolation figure therefore has no bearing and should be removed. Furthermore, even if extrapolation could be applied to any of the relevant payment years, OIG's approach to extrapolation is inconsistent with current guidance.

Triple-S Advantage does not concur with OIG's recommendation that it conduct audits for additional years. OIG recommended that Triple-S Advantage "identify, for the high-risk diagnoses included in [the Draft Report], similar instances of noncompliance that occurred before or after [the] audit period and refund any resulting overpayments...." Triple-S Advantage does not agree, because such additional auditing is not required by the relevant regulations. As this letter describes below (see Section 6), the relevant regulations do not provide a standard for such an audit and OIG has not provided basic information about its process that would allow Triple-S Advantage to perform such an audit. Even if Triple-S Advantage were to attempt such an audit, it would not create actionable results, as Triple-S Advantage does not agree with OIG's conclusions based on the information it identified. Therefore, Triple-S Advantage respectfully requests that OIG withdraw this recommendation.

Triple-S Advantage does not concur with OIG's recommendation that it examine its compliance procedures to identify areas for improvement. OIG recommended that Triple-S Advantage "continue to 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

¹ CMS, Pub. 100-16 Medicare Managed Care, CMS Medicare Managed Care Manual (Sept. 19, 2014), Chapter 7, Section 40, *available at*: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c07.pdf.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Triple-S Advantage, Inc. (H5774) Submitted to CMS (A-04-21-07095)

Lori S. Pilcher Office of Inspector General March 28, 2024 Page 3 of 19



comply with Federal requirements . . . and take the necessary steps to enhance those procedures." Triple-S Advantage does not concur, because the Company has a robust compliance program that meets relevant guidance (Section 7). Triple-S Advantage's program includes multiple processes and controls designed to prevent, detect, and correct potential concerns, including concerns related to risk adjustment coding. Given the issues with OIG's audit procedures discussed herein, Triple-S Advantage submits that the results and Draft Report should not be relied upon to assess the strength of its overall compliance program or approach to HCCs.

Moreover, as part of the normal course of its business, Triple S Advantage has continued to make changes to its risk-adjustment-related compliance activities since the audit period. This includes changes to further expand its education program for participating providers and their billing staff focusing on key conditions that may impact diagnosis codes in documentation.² These updates and additional steps are part of Triple-S Advantage's commitment to continuous improvement.

Accordingly, Triple-S Advantage respectfully disagrees with OIG's approach and recommendations in the Draft Report, including the determined repayment amount. Triple-S Advantage therefore respectfully requests that OIG revise its Draft Report and reconsider its draft recommendations. In doing so, Triple-S Advantage would appreciate the opportunity to work with OIG to address each of the concerns with the Draft Report raised below. To that end, Triple-S Advantage is glad to meet or answer any questions at OIG's convenience. While Triple-S Advantage stands by its concerns with the Draft Report, it is committed to compliance and cooperation with OIG and CMS.

DETAILED RESPONSE TO THE DRAFT REPORT

1. OIG's Targeted Sampling and Selective Review Process Is Flawed and Leads to Misrepresentative Results.

OIG's audit takes a singularly targeted approach that tilts the results in favor of finding repayment obligations. In its sampling, document requests, and review, OIG focuses on identifying overpayments. OIG does not conduct an overall assessment of the patient's condition, supporting records, or payment accuracy, which would include underpayments as well as overpayments. OIG's methodology appears to deviate significantly from CMS audit standards and risk adjustment data validation regulations.³ This section outlines how OIG's approach leads to a result that favors finding overpayments, not an overall assessment of the record or Triple-S Advantage's compliance program.

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² Draft Report, p. 16.

³ OIG does not promulgate general guidelines for an audit such as this, it has not provided any full explanation of its process or approach in this instance, and it has not offered relevant detail in its draft response that would explain the same.

Lori S. Pilcher Office of Inspector General March 28, 2024 Page 4 of 19



First, OIG's audit is based entirely on specific groups of "high-risk" diagnosis codes selected by OIG precisely for being codes it considers to be "at a higher risk of being miscoded." That is, OIG leaned on this assumption to produce a desired outcome, ultimately defeating the purpose of the audit, i.e., using this narrow set to find actual errors that lead to undesired outcomes. OIG performed an initial analysis of data from which it selected these HCCs, focusing on enrollees who "received a high-risk diagnosis during 2015 or 2016 that caused an increased payment to Triple-S for 2016 or 2017." A cursory review of recent Medicare Advantage compliance audits shows that OIG routinely selects many of the same HCC codes regardless of the auditee or its patient population. These same HCC codes were reviewed in OIG's audit of Triple-S Advantage.⁶ By limiting its review to just these select HCCs, OIG ignores the impact of other diagnosis codes or any other issues in the same patient's records or related payments. OIG seemingly focuses on the diagnoses it suspected may not be supported. For instance, there may be supported but unrelated HCCs or other diagnoses relating to the same enrollee-year that could have been submitted to CMS, but OIG's review does not appear to consider anything other than the limited "high-risk" HCCs that OIG selected. Nor does OIG's process appear to sample other enrollees, which could indicate potentially underreported diagnoses or underpayments. In practice, OIG appears to focus on diagnoses that it already had reason to believe may be unsupported and then looked for errors in that set.

Second, OIG's sample selections do not appear to correspond to the relevant population, nor do they appear designed for accuracy. OIG selected 30 samples for almost every HCC it targeted for review, and 41 for lung cancer, apparently without regard to how the figure compares to the overall population, total payments, or distribution of enrollee years for the same HCC. OIG does not explain how it landed on the sample size or other key aspects of its approach. Nor does it appear that OIG adjusted the sample sizes during the audit, such as after samples were reviewed and more information was available. Relying on an apparently uniform sample size, regardless of what proportion it represents or the distribution of data, raises questions about whether these results can be considered a representative sample and about OIG's overall approach and findings, as these are based on the same sample set.

Third, OIG requested documentation only targeting the specific HCCs on which it is focused. OIG requested records relevant to the specific "high-risk" HCCs previously submitted, for the selected patient and specific year. The medical records OIG sought are far less than what is available for the same enrollee within the same year. OIG's approach does not appear designed to obtain information that would give it a view into the complete picture of that patient's record, all

⁴ Draft Report at 4; see also Draft Report at 18.

⁵ Draft Report at 23.

⁶ Here, OIG selected "nine high-risk groups." Draft Report at 4. HHS-OIG makes its submission to CMS public via the CMS Office of Audit Services; archive available at https://oig.hhs.gov/reports-and-publications/oas/cms.asp. A brief review of recent reports shows these other MA providers are being targeted with the same conclusions for the same codes.

⁷ Draft Report at 7.

Lori S. Pilcher Office of Inspector General March 28, 2024 Page 5 of 19



submissions, or even all HCCs. For instance, OIG does not consider other potential, unrelated HCCs that may not have been submitted to CMS, even if support exists in the medical record provided. In practical terms, OIG's approach eliminates the possibility of a holistic audit that would more accurately assess the actual amounts owed.⁸

Fourth, OIG's outside contractor reviews the records with the same narrow focus. The reviewer looks at each patient year and assesses the support for this specific HCC within this specific record—but does not consider any other chargeable conditions or HCCs, whether submitted or unsubmitted, even if other HCCs are supported by the record. That is, even if the limited record (as OIG requested it) points to another valid HCC for the specific identified patient and year, it is not considered here. Although OIG has recently asked certain reviewers to reassess the evidence of possible underbilling, the initial focus only on specific HCCs and the related limited records request make it unlikely that the reviewer, even if asked, would be positioned to identify any underpayments.

Rather than credit the record, OIG's approach, and the apparent issues it identifies, appear to assume that a diagnosis or HCC is *de facto* unsupported if the provider is unable to produce all relevant medical records. But the provider's decision to submit a diagnosis code is itself evidence that the same provider diagnosed the relevant condition. That a specific record is now unavailable or incomplete does not show that the submitted diagnosis was originally inaccurate. Rather, it only proves that the records currently available do not meet OIG's review standard.

OIG's approach is not consistent with well-established CMS audit standards. As OIG is aware, CMS promulgates written guidance that sets out its approach to RADV audits, including a description of the process used covering topics such as target precision, confidence interval, and sample size. CMS's approach is also subject to a public review process and shared with the target in advance of any audit. OIG's approach does not follow CMS's clearly established standards. Nor does it offer clear guidance or clarification on its approach to these HCC audits. And while the government also promulgates other audit guidance relating to the review of government programs—

⁸ Note that this does not mean, nor does Triple-S Advantage conclude or argue, that there is no possibility of adverse findings of any type through said approach, but it would allow at least the possibility of OIG taking a balanced view of the patient's record and submissions to CMS.

⁹ 2021 Program Audit Process Overview (updated October 2020), *available at:* https://www.cms.gov/files/document/2021-program-audit-process-overview.pdf; HHS Risk Adjustment Data Validation (HHS-RADV) White Paper, 32 (Dec. 6, 2019), *available at:* https://www.cms.gov/files/document/2019-hhs-risk-adjustment-data-validation-hhs-radv-white-paper.pdf.

¹⁰ The Draft Report states that OIG "conducted this performance audit in accordance with generally accepted government auditing standards," but does not cite any specific standards. Draft Report at 7, 20.

¹¹ The Draft Report notes that it "reviewed applicable Federal laws, regulations, and guidance," in Appendix A, but it does not cite or otherwise specify which such materials. Draft Report at 18.

Lori S. Pilcher Office of Inspector General March 28, 2024 Page 6 of 19



addressing topics such as the need for a systematic or statistically valid sample set—none of those seem to have been relied upon by OIG.¹²

Triple-S Advantage is ready and motivated to work closely with OIG to address the issues raised by the Draft Report and ensure that OIG's audit results reflect the full scope of each patient's conditions and all relevant HCCs.

2. OIG's Audit Does Not Appear to Conform With Actuarial Equivalence, While Relying on Data That Requires It.

To treat MA enrollees fairly, CMS takes steps to account for risk adjustment and makes related supplemental payments to MAOs. These steps help ensure that MA enrollees are treated similarly as those in the traditional Fee-For-Service Medicare ("FFS") program, as required under federal law.¹³ Here, OIG's approach does not appear to account for this basic aspect of using this data.

Federal regulations mandate that MA plans receive an amount "actuarially equivalent" to what CMS would have expected to pay to cover the same beneficiary under the traditional FFS program. For traditional FFS Medicare, CMS pays providers a predetermined rate for services. For MA plans, CMS pays MAOs based on the predicted cost of care and administrative expenses for each enrollee in the local market—that is, an assessment of the amount that CMS would have paid for the enrollee to receive the same health benefits via the FFS program. Within this framework, the risk adjustment methodology is used to adjust payments to MA plans to ensure they fairly account for variations in per capita costs, incorporating disease factors and demographic characteristics. Absent these payments, MA enrollees could be disadvantaged. CMS itself has acknowledged the importance of risk-adjustment payments and offered guidance on when and how these should apply during its audit process, some of which have been subject to litigation. ¹⁶

¹² That guidance, specifically designed for use in financial audits and performance audits of government entities and entities that receive government awards, provides generally applicable points outlined by the GAO. *See, e.g.*, Government Auditing Standards (2018 Revision), *available at:* https://www.gao.gov/assets/gao-21-368g.pdf.

¹³ See 42 U.S.C. § 1395w-23(a)(3). See also UnitedHealthcare Ins. Co. v. Azar, 330 F. Supp. 3d 173, 176, 187-90 (D.D.C. 2018).

¹⁴ 42 U.S.C. § 1395w-23(a)(3).

¹⁵ Id. See, e.g., HHS OIG, Module 1: Risk Adjustment Introduction and Overview.

¹⁶ Compare CMS, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation for Contract-Level Audits, at 4 (Feb. 24, 2012) (stating that CMS would include calculations for unsupported HCCs during RADV audits) with 42 C.F.R. § 422.326 (2014) (implementing the overpayment rule and moving away from the prior approach) and UnitedHealthcare Ins. Co. v. Azar, 330 F. Supp. 3d 173, 187-90 (D.D.C. 2018) (striking down the 2014 approach for violating the actuarial equivalence mandate where it failed to apply an FFS adjustment or alternative). CMS has also issued other statements regarding the risk adjustments in RADV audits, including a 2018 proposal that coding errors in unaudited traditional Medicare data do not systematically impact payments to MAOs, 83 Fed. Reg. 54982, 55041 (Nov. 1, 2018), but that have not been finalized and implemented. More recently, United Healthcare Ins. Co. v. Becerra, 16 F.4th 867 (D.C. Cir. 2021), cert. denied, 142 S. Ct. 2851 (2022) held the

Lori S. Pilcher Office of Inspector General March 28, 2024 Page 7 of 19



But there are meaningful differences between the FFS data relied upon to develop the risk adjustment model and the MA records that OIG audits, including the Triple-S Advantage data at issue here. The risk adjustment model is based on administrative claims data, not a review of medical records. The FFS model pays providers based on services provided, not diagnosis codes. FFS records are not audited and inherently contain errors. And the FFS program experiences cost variations, some of which are associated with issues in the unaudited data, including where unaudited diagnosis codes may be partially unsubstantiated by the supporting record. In now demanding the return of claimed overpayments to an MA plan based on audited records, OIG does not explain or appear to account for these basic differences. OIG's approach therefore appears to violate the actuarial equivalence requirement.

More specifically, OIG's audit of Triple-S Advantage operates within this same framework and appears to rely on the same underlying assumptions. Accordingly, the actuarial equivalence requirement should apply to OIG's calculations regarding Triple-S Advantage, including any calculation of a potential "overpayment" amount, coming out of this audit. In practical terms, OIG cannot assume for purposes of this audit that a purportedly unsubstantiated HCC submission—which is all that OIG claims to have found here—can be automatically equated to a specific risk-adjusted payment value.

These equivalence considerations are particularly important in Puerto Rico, which has the highest proportion of MA enrollees and low rates of FFS enrollment. As most dual-eligible beneficiaries in Puerto Rico, who generally need more expensive services, have opted into the MA program, local FFS per enrollee costs are generally significantly less than MA per enrollee costs. This makes Puerto Rico an outlier for MA payment rates, which are far lower than in most states and U.S. territories.¹⁹ In response, CMS has made several changes, including benchmarking costs for Puerto Rico based on dual eligibles and making a specific local adjustment to reflect the high percentage of beneficiaries with no claims. In other words, because Puerto Rico's FFS population is not representative of the MA population, CMS directs that multiple supplemental adjustments should be made to ensure Puerto Rican MA enrollees are treated fairly.

Based on the limited information it has provided and its own Draft Report, OIG did not apply an FFS adjuster during this audit or take other steps to account for actuarial equivalence, even though it is essential to the payment model. First, as a general matter, by not accounting for these critical adjustments, OIG is effectively applying a new standard of evaluation. It does so without notice or

overpayment rule specifically does not require actuarial equivalence but distinguished this from the broadly applicable actuarial equivalence standard. The D.C. Circuit also did not address audits.

¹⁷ See, e.g., UnitedHealthcare Ins. Co. v. Azar, 330 F. Supp. 3d 173, 179-80 (D.D.C. 2018) (discussing the models and reimbursement codes).

¹⁸ *Id*.

¹⁹ See, e.g., T. Roberts, "Medicare Advantage Financing and Quality in Puerto Rico vs the 50 US States and Washington, DC" JAMA HEALTH FORUM, September 2022; available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9482057/.

Lori S. Pilcher Office of Inspector General March 28, 2024 Page 8 of 19



satisfying other basic procedural requirements. Given the backdrop of how MA plans and cost of care calculations work, it is not possible to accurately calculate financial impact without an actuarially sound approach that considers these data issues. Second, because of the unique aspects of the Puerto Rican market, noted above, OIG's failing to account for or otherwise explain the way it handled these critical local considerations specifically and disproportionately disadvantages Triple-S Advantage and its enrollees. Given that CMS recognizes Puerto Rico as a unique market and directs adjustments to account for this, it is fundamentally unfair for OIG to now elect not to take these into account for purposes of this audit. As the Draft Report does not explain how OIG accounted for these issues, it raises significant questions about the accuracy of OIG's conclusions and the asserted repayment amount. Triple-S Advantage therefore requests that OIG withdraw its current findings and update its approach and calculations to account for this requirement.

3. OIG Effectively Requires Perfect Data, Which Is Not Required.

OIG's underlying approach ultimately expects Triple-S Advantage to submit perfect risk-adjustment data. Given the large amount of data and number of stakeholders involved in coding certain conditions, Triple-S Advantage believes this is an unreasonably high standard, one that is unsupported by regulatory guidance, and that is now being applied to a process that is inherently imperfect.

MAOs rely on coding that is based on the information in a patient's medical record and supported by the description of the patient's status reflected therein. Medical records are based on a medical provider's observations and clinical judgment. A provider prepares the medical record and works with office or billing staff to submit diagnoses and related codes that reflect the patient's conditions. MAOs, in turn, submit the relevant HCCs. But there is no single rule about what a required submission looks like or the format that an appropriately documented medical record should take. CMS does not prescribe a specific diagnostic approach, and the relevant coding guidelines may be ambiguous.

As an MAO, Triple-S Advantage does not, and should not, control providers' submissions.²⁰ It is not possible to proactively audit 100% of medical and claims documentation and some human error is unavoidable—instances where, despite Triple-S Advantage's training and controls designed to minimize such error and ensure proper documentation, the provider may not have properly documented a diagnosis code or the claim submitted was not clearly representative of the documentation on the medical record.²¹ Diagnoses on claims are reported and then submitted based on a provider's assessment of the patient and the patient's condition(s). This is a matter of a treating provider's professional judgment and not a simple check-the-box exercise. Accordingly, CMS

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Triple-S Advantage, Inc. (H5774) Submitted to CMS (A-04-21-07095)

²⁰ Triple-S Advantage provides extensive training to providers, including relating specifically to coding and HCC submissions, as detailed further in Section 7, below.

²¹ The industry has previously provided extensive feedback on the challenges and limitations of the process. *See, e.g.*, 65 Fed. Reg. 40,170, at 40,250, 40,268 (June 29, 2000).

Lori S. Pilcher Office of Inspector General March 28, 2024 Page 9 of 19



requires MAOs to submit accurate data based on "their best knowledge, information, and belief."²² This reflects the reality that MAOs are dealing with large volumes of information from various sources "presenting significant verification challenges for the organization…." MAOs, as CMS has explained, "cannot reasonably be expected to know that every piece of data is correct" nor is this the expectation.²³ OIG guidance has similarly recognized that where an organization certifies as to the "accuracy, completeness and truthfulness of data," this "does not constitute an absolute guarantee of accuracy."²⁴

Here, however, the Draft Report seems to ignore these established principles and instead effectively requires Triple-S Advantage to submit flawless data. Although OIG points to the general requirement that "MA organizations are responsible for the accuracy, completeness, and dutifulness of the data submitted to CMS,"²⁵ OIG does not appear to recognize the well-understood contours of that requirement and the acknowledged challenges, discussed above. Consequently, the Draft Report suggests that because the audit found errors, Triple-S Advantage and its compliance program are at fault. In doing so, the Draft Report and recommendations imply that an MAO must review or monitor every data point it receives. This is not required, nor is it possible.

The Draft Report does not, however, identify relevant guidance that would explain the specific standard that OIG now appears to apply when evaluating the specific "high-risk" codes at issue, nor does CMS issue specific guidance on "high-risk" diagnosis codes or their use by MAOs. ²⁶ In fact, the submission of diagnosis codes itself reflects the providing team's judgment and demonstrates that the provider deemed it appropriate. And the few points of guidance highlighted in the Draft Report are general and were satisfied in cases that OIG still found unsupported. ²⁷ In now deeming some of the submissions unsupported, OIG does not address how it credits the record, which reflects a provider's good-faith effort to evaluate the record and determine that the relevant coding was appropriate. In other words, OIG's audit is not only a retrospective reassessment of the record, it also effectively holds MAOs and providers to a higher standard without notice or articulating what that should look like.

Furthermore, OIG is identifying as "unsupported" certain issues that are likely due to records retention challenges. As Triple-S Advantage previously explained, certain potentially relevant records could not be obtained due to various circumstances beyond those that HHS accepted as

²² CMS, "Reminder of Existing Obligation to Submit Accurate Risk Adjustment Data" (Apr. 15, 2022), *available at:* https://www.cms.gov/files/document/obligationtosubmitaccuratedatahpmsmemo508.pdf.

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

²⁴ 64 Fed. Reg. 61,893, at 61,900 (Nov. 15, 1999).

²⁵ Draft Report at 9.

²⁶ Draft Report at 19-20, describing the process only in terms of sequence and steps, but without description of, or reference to, any specific standards being applied.

²⁷ See, e.g., Draft Report at 9 ("... 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....").

Lori S. Pilcher Office of Inspector General March 28, 2024 Page 10 of 19



hardship waivers. While Triple-S Advantage requires providers maintain these records and share them upon request, there are instances where, despite best efforts, record retrieval is not possible. The frequency of such business disruptions, which could have had a significant impact on obtaining medical records, increased significantly in the aftermath of Hurricane Maria, which significantly impacted records for 2016 and 2017. Triple-S Advantage acknowledges its recordkeeping obligations. It notes that, in such circumstances, an MAO's options for remediating unavailable records may be limited, resource-intensive, and unlikely to prove fruitful.

MAOs are obligated to implement an effective compliance program, but they are not held to the vague standard of perfection the Draft Report suggests. Triple-S Advantage has done exactly that, as detailed below (Section 7). Any suggestion in the Draft Report that the identification of purported issues may evidence broader compliance shortcomings inaccurately characterizes Triple-S Advantage's obligations and misrepresents the strength of its compliance program. For the foregoing reasons, Triple-S Advantage is of the view that OIG should revise its report to reflect the appropriate best-efforts standard for submissions and supporting records, and that Triple-S Advantage's compliance program satisfied these obligations.

4. For Certain HCCs, The Record Does Not Support OIG's Conclusions.

Triple-S Advantage also respectfully disagrees with OIG's assessment in part because the medical record documentation provided does not support OIG's conclusions that certain HCCs were not validated.

First, in at least 13 cases, as outlined below, the documentation provided contradicts OIG's findings. The list below is not a comprehensive list of issues, but rather focuses on the specific instances where Triple-S Advantage found that the existing record—the materials previously submitted to OIG—shows that the HCCs were appropriately supported and therefore appropriately paid. Triple-S Advantage requests that OIG reconsider its draft audit findings for each of these cases and any findings related to the same. Correcting these issues will increase the rate of HCC substantiation and impact OIG's projections and overpayment calculations.

Based on Triple-S Advantage's review, the record provided in this audit in fact supports the HCCs submitted for each of the following enrollee years:

Vascular Claudication

■ Sample No. 34:²⁹ Patient enrollee met with a cardiologist who performed an upper extremity arterial doppler and duplex and detected mild calcification throughout the

²⁸ 42 C.F.R. § 422.503(b)(vi); Draft Report, p. 17.

²⁹ Note that these numbers correspond to the OIG Member ID number used in OIG's audit. For ease of reference, here this letter uses the term "sample" for each.

Lori S. Pilcher Office of Inspector General March 28, 2024 Page 11 of 19



radial and ulna arteries and mild area stenosis detected at the left ulna, approximately 20-30%.³⁰ This study was performed and signed by the cardiologist. Based on the findings on the study, this maps to HCC 108.

Acute Stroke

Sample No. 83: The assessment section lists a cerebrovascular accident evaluated by a cardiologist.³¹ The record also listed prescriptions for Cardizem, Plavix, and Diovan. This diagnosis maps to HCC 100. The provider also referred the patient to a follow-up visit with a neurologist. For reference, see CMS's ICD-10-CM Official Guidelines for Coding and Reporting ("CMS Coding Guidelines").³²

Prostate Cancer

- Sample No. 161: Patient was admitted to the hospital and evaluated by an internal medicine physician and a urologist. The urologist later operated on the patient, performing a transurethral vaporization of the prostate (four quadrants) for prostate cancer, which maps to HCC 12. In short, the patient was treated for prostate cancer by a urologist.³³
- Sample No. 162: Urologic surgeon documented "prostate cancer" in the assessment section, which maps to HCC 12. The physician also discussed with the patient future treatment options for management. The physician recommended that, prior to starting cancer treatment, the patient follow up with a cardiologist.³⁴ The urologic surgeon also requested a needle biopsy of the prostate. The biopsy result confirmed the diagnosis of prostate cancer, which maps to HCC 12. The result was reviewed by pathologists and the diagnosis of prostate cancer was confirmed.³⁵ Per CMS's RADV Medical Record Reviewer Guidance ("CMS Reviewer Guidance"), a pathologist's report is acceptable

³⁰ See Record No. 34-03-PHY, p. 2.

³¹ Record No. 83-01-PHY, p. 8.

³² CMS, *ICD-10-CM Official Guidelines for Coding and Reporting* (FY 2015), p. 104 (Section IV, Part J – "Code all documented conditions that coexist at the time of the encounter/visit, and require or affect patient care treatment or management. Do not code conditions that were previously treated and no longer exist."); *available at*: https://www.cms.gov/medicare/coding/icd10/downloads/icd10cm-guidelines-2015.pdf.

³³ Record No. 161-01-IP, pp. 2-6.

³⁴ Record No. 162-01-PHY, pp. 2-3.

³⁵ Record No. 162-02-PHY, pp. 2-4.



documentation.³⁶ A pathologist is also an acceptable physician specialty type for Risk Adjustment.

Sample No. 175: The patient was evaluated by a urologist for a chief complaint of prostate cancer, which maps to HCC 12. Provider documented the condition as: "Prostate Cancer less than six months ago." Treatment for cancer—external beam radiation therapy (EBRT), which is commonly used for prostate cancer—was documented in the medical record. Under assessment and plan, the provider documented: "continue follow up every four months and physical exam." The provider also documented a conversation with the patient concerning prostate cancer management, including that the patient understood and agreed.³⁷

Acute Heart Attack (Myocardial Infarction)

- Sample No. 197: The physician documented, under the assessment section, the condition subendocardial infarction subsequent, which maps to HCC 87. Under plan, the provider recommended that the patient have a 12-lead-electrocardiogram (EKG) performed. Under medication, the provider documented various medications managing the condition, including clopidogrel, an antiplatelet medication used to prevent blood clots in patients who have had a heart attack, stroke, or circulation problems.³⁸
- Sample No. 206: Under the review and assessment section, the provider documented a diagnosis of acute myocardial infarction of the anterolateral wall. Based on the progress note, the provider found the condition stable and recommended the patient continue present management.³⁹ For reference, see CMS Coding Guidelines.⁴⁰
- Sample No. 207: Under assessment, the record shows the diagnosis to be acute myocardial infarction of the anterolateral wall, subsequent episode of care. Provider ordered laboratory testing for troponin levels and an EKG. In the facility, the patient was placed on three liters of oxygen and cardiac monitoring, administrated nitroglycerine 0.4 q 5 minutes, 325mg of aspirin, and 300mg of Plavix. The provider ordered absolute bed

³⁶See CMS, Contract-Level 15 Risk Adjustment Data Validation Medical Record Reviewer Guidance, Version 2.0 (in effect as of 01/10/2020), p. 37-38; available at https://www.cms.gov/files/document/medical-record-reviewer-guidance-january-2020.pdf.

³⁷ Record No. 175-01-PHY, pp. 2-3.

³⁸ Record No. 197-01-PHY, p. 4

³⁹ Record No. 206-01-PHY, pp. 4, 6.

⁴⁰ CMS, *ICD-10-CM Official Guidelines for Coding and Reporting* (FY 2015), p. 104 (Section IV, Part J – "Code all documented conditions that coexist at the time of the encounter/visit, and require or affect patient care treatment or management. Do not code conditions that were previously treated and no longer exist."); *available at*: https://www.cms.gov/medicare/coding/icd10/downloads/icd10cm-guidelines-2015.pdf.



rest. The provider also educated the patient about the risk of sudden death and referred to a hospital setting immediately, but the patient refused to attend until the morning; the patient was discharged without medical consent.⁴¹ The physician complied with the protocol established for managing this diagnosis according to CMS Coding Guidelines.⁴²

Embolism

- Sample No. 215: The provider evaluated the patient and documented, in the assessment section, the diagnosis of acute venous embolism and thrombosis of unspecified deep vessels of lower extremity. The condition was documented as stable and the patient was to continue present management.⁴³ For reference, see CMS Coding Guidelines.⁴⁴
- Sample No. 231: The neurologist evaluated and documented the patient's condition under the assessment section, and documented, in the subjective section, heaviness in the legs, swelling, and pain. The provider then referred the patient to cardiology due to a leg arterial occlusion. This diagnosis mapped to HCC 107. See CMS Coding Guidelines.
- Sample No. 239: The physician evaluated, confirmed, and documented the diagnosis of acute embolism and thrombosis of unspecified deep veins of the lower extremities, and that the condition was stable and to continue present management.⁴⁷ The patient was on Simvastatin, 40 mg. For reference, see CMS Coding Guidelines.⁴⁸

Lung Cancer

Sample No. 271: In the assessment section, the provider documented a diagnosis of lung cancer, mapping to HCC 9.⁴⁹ The provider also documented referrals to Computer Tomography (CT) for a scan of the lungs and follow-up visits to providers at a cancer center and the pneumology department. See CMS Coding Guidelines.⁵⁰

⁴¹ Record No. 207-01-PHY, p. 5.

⁴² CMS Coding Guidelines, p. 103 (Section IV – "Diagnostic Coding and Reporting Guidelines for Outpatient Service"), 104.

⁴³ Record No. 215-01-PHY, p. 6.

⁴⁴ CMS Coding Guidelines, p. 104 (Section IV, Part J).

⁴⁵ Record No. 231-01-PHY, p. 2.

⁴⁶ CMS Coding Guidelines, p. 104 (Section IV, Part J).

⁴⁷ Record No. 239-01-PHY, p. 7.

⁴⁸ CMS Coding Guidelines, p. 104 (Section IV, Part J).

⁴⁹ Record No. 271-01-PHY, p. 4.

⁵⁰ CMS Coding Guidelines, p. 27-31 (Chapter 2, regarding neoplasm).



Sample No. 275: Throughout the medical record from this hospitalization there is documentation of suspected pulmonary cancer, consistent with HCC 9.⁵¹ There was also a CT scan of the thorax (without contrast) suggesting underlying primary lung neoplasia. Patient was evaluated by hematologist-oncologist who documented, on the assessment, suspected primary lung carcinoma. The patient died during the hospital stay. See CMS Coding Guidelines.⁵²

Second, through this process, Triple-S Advantage identified two instances where lower-hierarchy HCCs were supported by the record as submitted. OIG should have generally considered if a lower-hierarchy HCC was appropriate. In these cases, the record confirms the patient had the relevant condition, but another related HCC code was more appropriate. In these cases, OIG should credit Triple-S Advantage for the lower hierarchy HCC, as this was trumped by the audited HCC.

Colon Cancer

Sample No. 94: The progress note lists, under assessment, prostate cancer, specifically "positive for Prostatic Carcinoma with referral to hematologist-oncologist."⁵³ Refer to the CMS Coding Guidelines.⁵⁴ In addition, in the progress note following evaluation by a hematologist oncologist, the chief complaint listed is a follow-up visit for prostate cancer. The assessment section documented early-stage prostate cancer, which maps to HCC 12, a lower hierarchy code.⁵⁵ Under the plan section, the provider directed the patient "to continue follow up with urologist for further treatment decision." Furthermore, the biopsy performed by the pathologist confirmed prostate cancer, which again maps to the lower-hierarchy HCC 12.⁵⁶ The pathology report mentioned "Positive for Adenocarcinoma of Prostate without perineural invasion." Per CMS Reviewer Guidance, the pathologist's report is acceptable documentation.⁵⁷ In addition, a pathologist is an acceptable physician specialty type for risk adjustment.

⁵¹ Record No. 275-01-IP, pp. 41, 51, 52, 57, 58, 64, 67.

⁵² CMS Coding Guidelines, p. 98 (Chapter 2, Part H "Uncertain Diagnosis – If the diagnosis documented at the time of discharge is qualified as 'probable', 'suspected', 'likely', 'questionable', 'possible', or 'still to be ruled out', or other similar terms indicating uncertainty, code the condition as if it existed or was established. The bases for these guidelines are the diagnostic workup, arrangements for further workup or observation, and initial therapeutic approach that correspond most closely with the established diagnosis.").

⁵³ Record No. 94-01-PHY, p. 2.

⁵⁴ CMS Coding Guidelines, p. 104 (Section IV, Part J).

⁵⁵ Record No. 94-03-PHY, p. 3.

⁵⁶ Record No. 94-04-PHY, p. 3.

⁵⁷ See CMS Reviewer Guidance, p. 37.

Lori S. Pilcher Office of Inspector General March 28, 2024 Page 15 of 19



Lung Cancer

• *Sample No. 268*: The provider documented "Papillary Urothelial Cancer High Grade," in the progress note.⁵⁸ This maps to lower-hierarchy HCC 11. The provider also referred the patient to a follow-up visit with oncology. Refer to CMS Coding Guidelines.⁵⁹

In addition to the two specific records that Triple-S Advantage identified (above), as part of its audit process, OIG should have generally considered if a lower-hierarchy HCC was appropriate in each instance. If such a lower-hierarchy HCC is appropriate, it would be an overstatement for OIG to claim that the record did *not validate* the HCC. The record shows that Triple-S Advantage was entitled to a risk-adjustment payment in connection with this condition, patient, and year—just in a different amount. Failing to account for lower-hierarchy HCCs is yet another instance in which OIG's narrowly focused approach may result in underpayments for Triple-S Advantage.

Third, Triple-S Advantage reviewed the progress notes and found numerous instances where the HCC was in the progress note. Specifically, Triple-S Advantage reviewed the records for the sampled enrollee-years and found 76 samples where an HCC was documented on the assessment portion of the progress note, including at least a half dozen patients/members for every one of the conditions that OIG selected for review. Triple-S Advantage is happy to provide specific detail on this finding and related supporting detail to OIG, if helpful. As the Draft Report directs, Triple-S Advantage and other "MA organizations must obtain risk adjustment data required by CMS from the provider, supplier, physician, or other practitioner that furnished the item or service." And as CMS now recognizes regarding coding, a "provider's statement that the patient has a particular condition is sufficient." Although this guidance was not in place at the time, it speaks to the importance of relying on the record as prepared by, and in the judgment of, the treating provider.

Given the above, Triple-S Advantage respectfully requests that OIG review and update its draft audit findings, estimated repayment amounts, and other recommendations to account for these issues.

5. Extrapolation Is Not Appropriate and Is Inconsistent With Current Guidance.

Extrapolation is only appropriate in specific circumstances, where supported by appropriate and vetted data and consistent with applicable guidance. None of these circumstances apply here.

⁵⁸ Record No. 268-04-PHY, p. 3.

⁵⁹ CMS Coding Guidelines, p. 27-31 (Chapter 2, regarding neoplasm).

⁶⁰ Specifically, reviewing the member sample that OIG selected, Triple-S Advantage's own review found: 8 HCCs documented on the assessment portion of the progress note for acute stroke, 12 for colon cancer, 14 for breast cancer, 16 for prostate cancer, 8 for heart attack, 6 for embolism, and 12 for lung cancer.

⁶¹ Draft Report, p. 8.

⁶² CMS, ICD-10-CM Official Guidelines for Coding and Reporting (FY 2022), p. 12.

Lori S. Pilcher Office of Inspector General March 28, 2024 Page 16 of 19



Critically, such extrapolation cannot be applied for recovery purposes to any of the payment years under audit. As OIG expressly acknowledged, CMS regulations concerning audits direct that extrapolated overpayments can only be recouped beginning with payment year 2018.⁶³ The extrapolated amount referenced in the Draft Report is therefore inadequately supported and not applicable to this review, regardless of how it is framed. Triple-S Advantage requests OIG remove this purported amount from the Draft Report.

In addition, even if extrapolation could be applied to any of the years at issue, applying it here would be misplaced. Federal regulations generally reflect that this approach should be rarely used and only where the audit satisfies the appropriate conditions, which OIG has not demonstrated are relevant here. Rather, as described in the prior sections, the record demonstrates numerous issues in OIG's audit methodology, approach to sampling, assumptions regarding risk adjustment, and basic conclusions as to whether the record supports OIG's findings with respect to certain samples. As one key example, while CMS guidance for RADV audits employs a 99% confidence interval when calculating extrapolated repayment amounts, here OIG used a 90% confidence interval. OIG's selection of a different confidence interval introduces an arbitrary bias to overextrapolate findings beyond what CMS defined as appropriate. No methodological basis has been presented to justify this deviation. That is, OIG does not explain why it would select a different confidence interval, one that differs from CMS's publicized and accepted practice. While OIG is a separate agency, its approach here seems to run counter to its own stated objective of ensuring compliance with federal requirements. Extrapolating from OIG's audit only risks compounding these issues, particularly the shortcomings in methodology that shape the results.

6. Triple-S Advantage Should Not Be Required to Conduct Audits for Additional Years.

Conducting additional audits is not required by governing regulations. But OIG's recommendation to "identify, for the high-risk diagnoses included in [the Draft Report], similar instances of noncompliance that occurred before or after our audit period" seems to require just that. OIG's audit process—starting with the highly targeted sampling through the apparent lack of risk adjuster—appears inconsistent with CMS's processes and guidelines. Even then, Triple-S Advantage submits it would be far more efficient and effective to conduct a broad audit that appropriately considers all types of submission issues, including both under- and overpayments.

⁶³ 88 Fed. Reg. 6643, (Feb. 1, 2023). This current guidance, updated after the audit was conducted but before the draft report, limits the use of extrapolation in RADV audits to payment years 2018 and later.

⁶⁴ See, e.g., 42 U.S.C. § 1395ddd(f)(3) (Medicare statute, Part E), which directs that certain forms of audit "may not use extrapolation ...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."

⁶⁵ Draft Report at 8. Compare with CMS, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation for Contract-Level Audits (Feb. 24, 2012).



7. Triple-S Advantage's Compliance Program Meets Regulatory Requirements.

Triple-S Advantage has a robust compliance program. Consistent with industry standards and applicable regulations, Triple-S Advantage has a series of layered controls developed over multiple years—including continuous education of participating providers and more recently their billing staff, the use of software tools to assess risk and document identified conditions for the plan of care, pre-submission quality review by two industry-leading vendors for its delegated processes, internal quality retrospective reviews by both the Company and an outside team, and multiple layers of auditing and assessment to test and oversee these processes—designed to ensure the accuracy of data submitted to CMS, including risk-adjustment data. The audit's misrepresentative results, based on a flawed process, do not reflect the strength of Triple's policies and procedures. Because the Draft Report's overbroad recommendation—that Triple-S Advantage should "continue to examine its existing compliance procedures to identify areas where improvements can be made . . . and take the necessary steps to enhance those procedures"—is based on these results, it is misplaced.

The audit is industry standards and more recently their billions and more recently their billions for the plan of care, pre-submission quality review by two industry-leading providers and more recently their billions for the plan of care, pre-submission quality review by two industry-leading providers and more recently their billions for the plan of care, pre-submission quality review by two industry-leading providers and more recently their billions for the plan of care, pre-submission quality review by two industry-leading providers and more recently their billions for the plan of care, pre-submission quality review by two industry-leading providers and more recently their billions for the plan of care, pre-submission quality review by two industry-leading providers and more recently their billions for the plan of care, pre-submission quality review by two industry-l

As the record demonstrates, Triple-S Advantage's risk-adjustment compliance program meets relevant federal program requirements and guidance. This was true during the audit period. In fact, the Draft Report itself recognized that Triple-S Advantage had, for the audit period, "compliance procedures to determine whether the diagnosis codes used to calculate risk-adjusted payments were correct." Triple-S Advantage's program has only been strengthened in the years since. And OIG's audit did not assess, nor was it designed to, whether current practices would have addressed the issues identified in the Draft Report. Per governing federal regulations, MAOs must "adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements, including an effective system for routine monitoring and identification of compliance risks." In turn, federal guidance recognizes that the MAO—i.e., Triple-S Advantage—is the entity best situated to develop its own compliance program based on its own needs and processes. Triple-S Advantage's record of strong performances during CMS audits confirms this fact.

As the Draft Report offers only a brief description of Triple-S Advantage's compliance program before saying it could be improved,⁷¹ the Company believes it is important to provide a more detailed picture in this reply.

⁶⁶ Draft Report, p. 16.

⁶⁷ Draft Report, p. 16.

⁶⁸ *Id*.

⁶⁹ 42 C.F.R. § 422.503(b)(4)(vi); see also Draft Report, p. 9.

⁷⁰ See 65 Fed. Reg. at 40,265 ("[O]rganizations and contract applicants have broad discretion under § 422.501(b)(3)(vi) to design their compliance plan structure to meet the unique aspects of each organization. Triple-S Advantage recognizes that there is no one best way for an organization to take steps to ensure that it is operating in compliance with all applicable regulations and requirements.").

⁷¹ Draft Report, p. 16.

Lori S. Pilcher Office of Inspector General March 28, 2024 Page 18 of 19



Overall Compliance Program and Structure. Triple-S Advantage has, both during the audit period and since, maintained a well-developed and effective risk-based compliance program designed to monitor, audit, prevent, detect, report, and respond to a range of compliance concerns. The program is overseen by a Compliance Committee, led by a Compliance Officer with regular reporting to the Board of Directors, and benefits from a strong tone at the top.

Triple-S Advantage engages with two entities to support and expand its compliance controls, documentation, and coding tools, as well as supplement its educational programs. One provides a prospective risk-assessment tool and performs a retrospective chart review, both of which were in place during the audit period. The other provides services and support, including a general quality assurance process and a provider engagement coordination program, for improving the quality and accuracy of submissions.

That the Draft Report identified certain issues in connection with a specific, targeted subset of high-risk HCCs does not disprove this record. That some HCCs may have been unsubstantiated is to be expected given both how MAOs work and the governing best-effort standard for submissions—not the apparent expectation of perfection suggested by OIG in the Draft Report.⁷² In fact, the regulations and guidance acknowledge that inaccuracies are unavoidable, not a de facto sign of a deficient program. The Draft Report's recommendation that Triple-S Advantage should "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," is not supported by the audit record and Triple-S Advantage therefore asks that OIG reconsider this recommendation.

Provider Contracts. Triple-S Advantage ensures that its participating providers are similarly committed to compliance. Providers contractually agree, in relevant part, that they are responsible for proper documentation of all services provided to the members. This includes members' specific diagnosis information, treatment plan, if applicable, laboratory results, and any other relevant health care, chronic condition, or acute condition-related information in their medical records. These requirements are spelled out in the governing Participating Provider Agreement. Triple-S Advantage also regularly reviews, and updates as appropriate, its Participating Provider Agreement, including but not limited to provisions related to its risk adjustment compliance program and processes.

Training and Education for Providers and Their Billing Staff. Triple-S Advantage has developed and maintains a continuous provider education and coding improvement program, which was in place since before the audit period. For newly participating providers, Triple-S Advantage mandates they complete onboarding education and training courses covering a range of compliance topics. Triple-S Advantage participating providers receive a range of continuing education resources

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⁷² Draft Report, p. 9, cites to 42 C.F.R. § 422.504(l), which explains that the MAO's certification should be "based on best knowledge, information, and belief" standard, but the Draft Report then points to the "the errors found in [the audit] sample" as justifying OIG's recommendations.

Lori S. Pilcher Office of Inspector General March 28, 2024 Page 19 of 19



and targeted training, including regularly updated sessions on diagnoses and documentation, and targeted training on HCCs and related ICD-10 codes.

Triple-S Advantage also works with partner entities to provide trainings, guidelines, and other educational materials for providers, with particular attention to billing, coding, and documentation, that complement and strengthen Triple-S Advantage's educational tools for its providers.

Prospective Processes for Preventive/Detective Review. Triple-S Advantage uses multiple, independent review tools and experienced reviewers as part of a comprehensive, data-driven process designed to ensure the accuracy of diagnosis codes submitted to calculate risk-adjusted payments.

Triple-S Advantage also engages a third-party entity to implement a quality assurance ("QA") program that helps ensure HCCs submitted are appropriately documented in the patient's medical record. The third party also minimizes the risk resulting from errors, continuously tracks coding accuracy and completeness, and identifies opportunities for future training. Triple-S Advantage also selectively reviews providers' documentation and provides feedback when documentation does not meet relevant guidelines, including guidelines around coding. In addition, Triple-S Advantage continues to review its organizational structure focusing on quality assurance and updating its risk adjustment processes.

Conclusion

Triple-S Advantage remains committed to both growing and strengthening its compliance program and to working with OIG in this audit process. However, for the reasons outlined above, it respectfully requests that OIG reconsider its recommendations and revise the Draft Report.

Sincerely,

Thora A. Johnson

Thora A. Johnson

Copy to: David E. Rhinesmith

Jenny D. Cárdenas Curbelo, CHC

Thurman Justice

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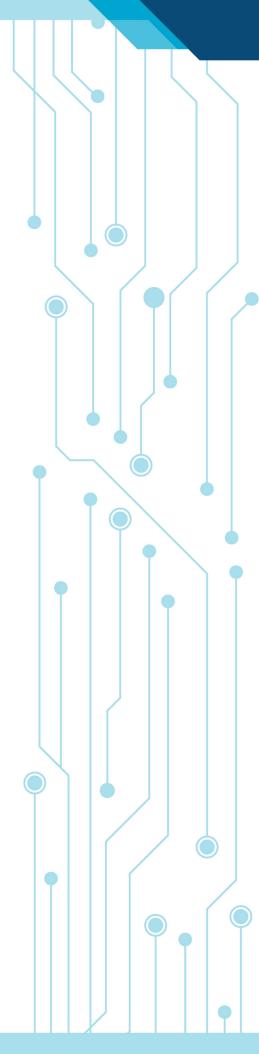
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