Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE ADVANTAGE COMPLIANCE AUDIT OF SPECIFIC DIAGNOSIS CODES THAT BLUE CROSS & BLUE SHIELD OF RHODE ISLAND (H4152) SUBMITTED TO CMS

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

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BCBS of Rhode Island (H4152) Submitted to CMS

Why OIG Did This Audit

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations using a system of risk adjustment that depends on the health status of each enrollee. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources 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. For this audit, we reviewed one MA organization, Blue Cross & Blue Shield of Rhode Island (BCBS RI) and focused on nine groups of high-risk diagnosis codes for payment years 2016 and 2017.

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

How OIG Did This Audit

We sampled 270 unique enrollee-years with the high-risk diagnosis codes for which BCBS RI received higher payments for 2016 through 2017. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $732,418.

What OIG Found

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that BCBS RI submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 58 of the 270 sampled enrollee-years, the medical records validated the reviewed Hierarchical Condition Categories (HCCs). For the remaining 212 enrollee-years, however, either the medical records that BCBS RI provided did not support the diagnosis codes or BCBS RI could not obtain the medical records to support the diagnosis codes and the associated HCCs were therefore not validated. As demonstrated by the errors found in our sample, BCBS RI's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. As a result, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that BCBS RI received at least $4.8 million in net overpayments for 2016 and 2017.

What OIG Recommends and BCBS RI Comments

We recommend that BCBS RI: (1) refund to the Federal Government the $4.8 million of estimated net overpayments; (2) identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and (3) continue its examination of 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.

BCBS RI concurred with our second and third recommendations, but disagreed with our first recommendation. BCBS RI provided additional information that it believed: (1) validated the reviewed HCCs for 27 enrollee-years, and (2) supported that 1 enrollee-year should not be considered a finding because BCBS RI had corrected the overpayment prior to our audit. BCBS RI stated we did not properly conduct statistical sampling or correctly follow established guidelines. After reviewing BCBS RI's comments and additional information, we revised the number of enrollee-years in error from 222 to 212 and the amount of our first recommendation from $5.3 to $4.8 million for this final report. We followed a reasonable audit methodology and correctly applied applicable Federal requirements underlying the MA program.

The full report can be found at https://oig.hhs.gov/oas/reports/region1/12000500.asp.

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INTRODUCTION

WHY WE DID THIS AUDIT

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

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS.[2] Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 29 major depressive disorder diagnoses into 1 group.) This audit covered Blue Cross & Blue Shield of Rhode Island (BCBS RI)[3] for contract number H4152 and focused on nine groups of high-risk diagnosis codes for payment years 2016 and 2017.[4]

OBJECTIVE

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

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[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 October 1, 2015, CMS transitioned from the ninth revision of the ICD Coding Guidelines (ICD-9-CM) to the tenth revision (ICD-10-CM). Each revision includes different diagnosis code sets.

[2] See Appendix B for a list of related Office of Inspector General reports.

[3] BCBS RI is an independent licensee of the Blue Cross Blue Shield Association.

[4] All subsequent references to "BCBS RI" in this report refer solely to contract number H4152.

BACKGROUND

Medicare Advantage Program

The MA program offers people 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.[5] People who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

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

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

Risk Adjustment Program

Federal requirements mandate that payments to MA organizations be based on the anticipated cost of providing Medicare benefits to a given enrollee and, in doing so, also account for variations in the demographic characteristics and health status of each enrollee.[6]

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

- *Base rate*: Before the start of each year, each MA organization submits bids to CMS that reflect the MA organization's estimate of the monthly revenue required to cover an enrollee with an average risk profile.[7] CMS compares each bid to a specific benchmark

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[5] 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.

[6] The Social Security Act §§ 1853(a)(1)(C) and (a)(3); 42 CFR § 422.308(c).

[7] The Social Security Act § 1854(a)(6); 42 CFR § 422.254 *et seq*.

amount for each geographic area to determine the base rate that an MA organization is paid for each of its enrollees.[8]

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

To determine an enrollee's health status for purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from acceptable data sources, including certain physicians and hospitals. MA organizations collect the diagnosis codes from providers based on information documented in the medical records and submit these codes to CMS. CMS then maps certain diagnosis codes, on the basis of similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs).[9] Each HCC has a factor (which is a numerical value) assigned to it for use in each enrollee's risk score.

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

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

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

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

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

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

CMS multiplies the risk scores by the base rates to calculate the total monthly Medicare payment that an MA organization receives for each enrollee before applying the budget sequestration reduction.[10] Thus, if the factors used to determine an enrollee's risk score are incorrect, CMS will make an improper payment to an MA organization. Specifically, if medical records do not support the diagnosis codes that an MA organization submitted to CMS, the HCCs are unvalidated, which causes overstated enrollee risk scores and overpayments from CMS.[11] Conversely, if medical records support the diagnosis codes that an MA organization did not submit to CMS, validated HCCs may not have been included in enrollees' risk scores, which may cause those risk scores to be understated and may result in underpayments.

High-Risk Groups of Diagnoses

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

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

- *Acute heart attack*: An enrollee received one diagnosis that mapped to either the HCC for Acute Myocardial Infarction or to the HCC for Unstable Angina and Other Acute Ischemic Heart Disease (Acute Heart Attack HCCs) on only one physician or outpatient claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician or outpatient claim). In these instances, a diagnosis for a less severe manifestation of a disease in the related-disease group typically should have been used.

- *Major depressive disorder*: An enrollee received one major depressive disorder diagnosis (that mapped to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) during

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

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

the service year but did not have an antidepressant medication dispensed on his or her behalf. In these instances, a major depressive disorder diagnosis may not be supported in the medical records.

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

- *Vascular claudication*: An enrollee received one diagnosis related to vascular claudication (that mapped to the HCC for Vascular Disease) during the service year, but had not received one of these diagnoses during the 2 preceding years and had medication dispensed on his or her behalf that is frequently dispensed for a diagnosis of neurogenic claudication.[12] In these instances, the diagnosis related to vascular claudication may not be supported in the medical records.

- *Lung cancer*: An enrollee received one lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period either before or after the diagnosis. In these instances, a diagnosis of history of lung cancer (which does not map to an HCC) typically should have been used.

- *Breast cancer*: An enrollee received one breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of breast cancer (which does not map to an HCC) typically should have been used.

- *Colon cancer*: An enrollee received one colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of colon cancer (which does not map to an HCC) typically should have been used.

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

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

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

Blue Cross & Blue Shield of Rhode Island

BCBS RI is an MA organization based in Providence, Rhode Island. As of December 2017, BCBS RI provided coverage under contract number H4152 to 53,039 enrollees. For the 2016 and 2017 payment years (audit period), CMS paid BCBS RI approximately $1.1 billion to provide coverage to its enrollees.[13, 14]

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 BCBS RI received increased risk-adjusted payments for payment years 2016 and 2017, respectively. Because enrollees could be classified into more than one high-risk group or could have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment year, which we refer to as "enrollee-years."

We identified 3,037 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes ($6,656,419). We selected for audit a stratified random sample of 270 enrollee-years as shown in Table 1 on the next page.

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

[14] All of the payment amounts that CMS made to BCBS RI and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

Table 1: Sampled Enrollee-Years

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

BCBS RI provided medical records as support for the selected diagnosis codes associated with 250 of the 270 sampled enrollee-years.[15] We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. If the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

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

FINDINGS

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that BCBS RI submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 58 of the 270 sampled enrollee-years, the medical records validated the reviewed HCCs. For the remaining 212 enrollee-years, however, either the medical records that BCBS RI provided did not support the diagnosis codes or BCBS RI could not

[15] BCBS RI could not obtain medical records for the remaining 20 sampled enrollee-years.

obtain the medical records to support the diagnosis codes and the associated HCCs were therefore not validated.

As demonstrated by the errors found in our sample, BCBS RI's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. As a result, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that BCBS RI received at least $4.8 million in net overpayments for 2016 and 2017.[16]

FEDERAL REQUIREMENTS

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

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

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

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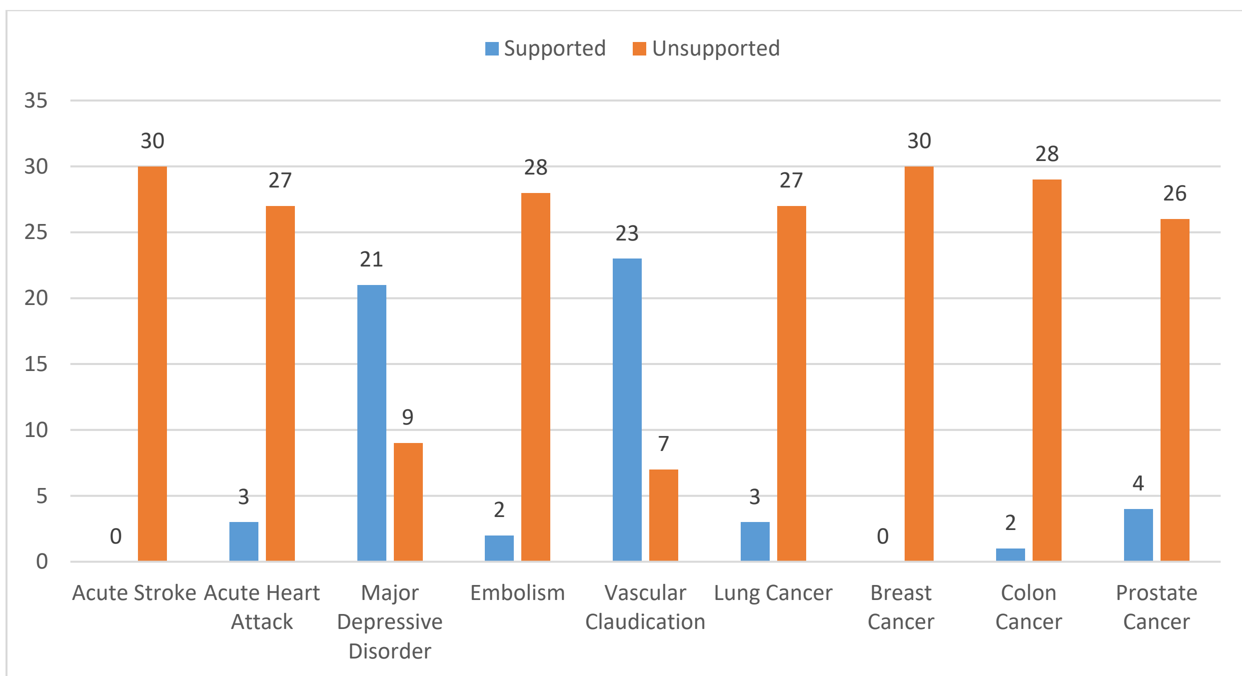
[16] Specifically, we estimated that BCBS RI received at least $4,894,595 in net overpayments. To be conservative, we recommend recovery at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

Federal regulations state that MA organizations must monitor the data that they receive from providers and submit to CMS. Federal regulations also state that MA organizations must "adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS's 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 BLUE CROSS & BLUE SHIELD OF RHODE ISLAND SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Most of the selected high-risk diagnosis codes that BCBS RI submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. As shown in the figure below, the medical records for 212 of the 270 sampled enrollee-years did not support the diagnosis codes. In these instances, BCBS RI should not have submitted the diagnosis codes to CMS and received the resulting net overpayments.

Figure: Analysis of High-Risk Groups According to the Number of Sampled Enrollee-Years



Incorrectly Submitted Diagnosis Codes for Acute Stroke

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

- For 17 enrollee-years, the medical records indicated in each case that the individual had previously had a stroke, but the records did not justify an acute stroke diagnosis at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC [for Ischemic or Unspecified Stroke] or related HCC. There is mention of a history of a stroke [diagnosis] but no description of residuals or sequelae that should be coded."[17] The history of stroke diagnosis code does not map to an HCC.

- For 11 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.[18]

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC [for Ischemic or Unspecified Stroke] or a related HCC."

- For each of the remaining 2 enrollee-years, BCBS RI could not obtain any medical records to support the acute stroke diagnosis; therefore, the HCC for Ischemic or Unspecified Stroke was not validated.

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and BCBS RI received $63,392 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Heart Attack

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

- For 11 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Acute Heart Attack HCC.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [an Acute Heart Attack] HCC."

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[17] Sequelae are residual effects, after the acute phase of an illness or injury has ended.

[18] For 1 of the enrollee-years, the medical record that BCBS RI provided to support the reviewed HCC was a radiology report. This record was not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3) and the Manual, chap. 7, § 120.1).

- For 8 enrollee-years, the medical records indicated in each case that the individual had an old myocardial infarction diagnosis, but the records did not justify a diagnosis that mapped to an Acute Heart Attack HCC at the time of the physician's service.[19]

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

- For 3 enrollee-years, the medical records in each case did not support the submitted diagnosis that mapped to an Acute Heart Attack HCC. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to the HCC for Angina Pectoris, which is a less severe manifestation of the related-disease group.[20] Accordingly, BCBS RI should not have received an increased payment for the submitted acute myocardial infarction diagnosis, but should have received a lesser increased payment for the other identified diagnosis.

- For each of the remaining 5 enrollee-years, BCBS RI could not obtain any medical records to support a diagnosis that mapped to an Acute Heart Attack HCC; therefore, an Acute Heart Attack HCC was not validated.[21]

As a result of these errors, the Acute Heart Attack HCCs were not validated, and BCBS RI received $53,268 in overpayments for these 27 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder

BCBS RI incorrectly submitted diagnosis codes for major depressive disorder for 9 of 30 sampled enrollee-years. Specifically:

- For 5 enrollee-years, the medical records in each case did not support a major depressive disorder diagnosis.

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

[19] An "old myocardial infarction" is a myocardial infarction that occurred more than 4 weeks previously, has no current symptoms directly associated with that myocardial infarction, and requires no current care.

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

[21] For 1 enrollee-year, although BCBS RI did not obtain any medical records for the submitted diagnosis, another diagnosis mapped to the HCC for Angina Pectoris, which is a less severe manifestation of the related-disease group. Accordingly, BCBS RI should not have received an increased payment for the submitted acute myocardial infarction diagnosis but should have received a lesser increased payment for the other identified diagnosis.

HCC [for Major Depressive, Bipolar, and Paranoid Disorders]. There is documentation of [a] depression [diagnosis] that does not result in an HCC."

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

As a result of these errors, the HCC for Major Depressive, Bipolar, and Paranoid Disorders was not validated, and BCBS RI received $25,909 in overpayments for these 9 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

BCBS RI incorrectly submitted diagnosis codes for embolism for 28 of 30 sampled enrollee-years. Specifically:

- For 18 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Embolism HCC.

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

- For 8 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not justify a diagnosis that mapped to an Embolism HCC at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [an Embolism] HCC. There is documentation of a past medical history of [a] deep vein thrombosis [diagnosis] that does not result in an HCC."[22]

- For each of the remaining 2 enrollee-years, BCBS RI could not obtain any medical records to support a diagnosis that mapped to an Embolism HCC; therefore, an Embolism HCC was not validated.

As a result of these errors, the Embolism HCCs were not validated, and BCBS RI received $75,383 in overpayments for these 28 sampled enrollee-years.

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

Incorrectly Submitted Diagnosis Codes for Vascular Claudication

BCBS RI incorrectly submitted diagnosis codes for vascular claudication for 7 of 30 sampled enrollee-years. Specifically:

- For 7 enrollee-years, the medical records in each case did not support a diagnosis related to vascular claudication.

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

As a result of these errors, the HCC for Vascular Disease was not validated, and BCBS RI received $17,025 in overpayments for these 7 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

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

- For 13 enrollee-years, the medical records in each case indicated that the individual had previously had lung cancer, but the records did not justify a lung cancer diagnosis at the time of the physician's service.

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

- For 7 enrollee-years, the medical records in each case did not support a lung cancer diagnosis.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Lung and Other Severe Cancers]. There is documentation of a right upper lobe lung nodule [diagnosis] that does not result in an HCC."[23]

- For 6 enrollee-years, the medical records in each case did not support the submitted lung cancer diagnoses. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, BCBS RI should not have received an increased

[23] A lung nodule is a small single mass in the lungs that is usually benign.

payment for the submitted lung cancer diagnosis, but it 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 6 enrollee-years.

Table 2: Hierarchical Condition Categories (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
2	Colorectal, Bladder, and Other Cancers
2	Lymphoma and Other Cancers
2	Breast, Prostate, and Other Cancers and Tumors

- For the 1 remaining enrollee-year, BCBS RI could not obtain any medical records to support the lung cancer diagnosis; therefore, the HCC for Lung and Other Severe Cancers was not validated.

As a result of these errors, the HCC for Lung and Other Severe Cancers was not validated, and BCBS RI received $187,753 in overpayments for these 27 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

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

- For 25 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 stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors]. There is documentation of a past medical history of breast cancer [diagnosis] that does not result in an HCC."

- For 3 enrollee-years, BCBS RI could not obtain any medical records to support the breast cancer diagnosis; therefore, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated.

- For the remaining 2 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 stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors]."

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and BCBS RI received $36,859 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

BCBS RI incorrectly submitted diagnosis codes for colon cancer for 28 of 30 sampled enrollee-years. Specifically:

- For 23 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 stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Colorectal, Bladder, and Other Cancers]. There is documentation of a past medical history of colon cancer [diagnosis] that does not result in an HCC."

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

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

- For 1 enrollee-year, BCBS RI submitted a colon cancer diagnosis code that would result in the assignment of the HCC for Colorectal, Bladder, and Other Cancers, which was not supported in the medical records, instead of a diagnosis code for metastatic bone cancer that would result in the assignment of the HCC for Metastatic Cancer and Acute Leukemia, which was supported in the medical records.[24] This error caused an underpayment.

- For the 1 remaining enrollee-year, BCBS RI could not obtain any medical records to support the colon cancer diagnosis; therefore, the HCC for Colorectal, Bladder, and Other Cancers was not validated.

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and BCBS RI received $52,477 in net overpayments for these 28 sampled enrollee-years.

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[24] Bone metastasis occurs when cancer cells spread from their original site to a bone.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

BCBS RI incorrectly submitted diagnosis codes for prostate cancer for 26 of 30 sampled enrollee-years. Specifically:

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

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

- For 8 enrollee-years, the medical records in each case did not support a prostate cancer diagnosis.

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

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

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and BCBS RI received $30,665 in overpayments for these 26 sampled enrollee-years.

THE POLICIES AND PROCEDURES THAT BLUE CROSS & BLUE SHIELD OF RHODE ISLAND HAD TO PREVENT, DETECT, AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS COULD BE IMPROVED

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

For the 20 enrollee-years for which BCBS RI was unable to obtain medical records to support the diagnosis codes, BCBS RI officials stated that some providers could not locate medical records, and others would not release medical records without patient consent.

The compliance procedures that BCBS RI had in place during our audit period included preventative measures to ensure that providers submitted accurate diagnosis codes on its claims. BCBS RI also had compliance procedures in place to substantiate some of the diagnosis codes that it had submitted to CMS. Specifically, BCBS RI had internal methodologies to select

certain claims and perform a review of the associated medical records. When BCBS RI detected an unsupported diagnosis, it had procedures to correct that diagnosis code on CMS's risk adjustment system. BCBS RI also had procedures to review the results of its analysis and when it identified improper coding patterns for a provider, it gave those providers additional education material and performed targeted medical record reviews. Although we did not evaluate the overall effectiveness of BCBS RI's policies and procedures, we note that the compliance program in effect during our audit period did not specifically address high-risk diagnosis codes.

BCBS RI officials explained to us that the miscoded diagnoses could have occurred because the providers lacked education on proper coding practices. With regard to reviewing the accuracy of diagnosis codes providers had submitted, BCBS RI officials told us that BCBS RI had been short staffed but emphasized that it had identified and corrected certain diagnoses that did not comply with Federal requirements. However, these diagnoses were not associated with our sampled enrollee-years. Nonetheless, BCBS RI officials informed us that BCBS RI had recently incorporated our high-risk areas into its policies and procedures.

Based on our assessment of the policies and procedures that were in place for our audit period, our discussions with BCBS RI officials and because the diagnosis codes for 212 of the 270 sampled enrollee-years were not supported by the medical records, we believe that BCBS RI's compliance procedures to prevent and detect incorrect high-risk diagnoses could be improved.

BLUE CROSS & BLUE SHIELD OF RHODE ISLAND 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 BCBS RI received at least $4,894,595 in net overpayments for 2016 and 2017. (See Appendix D for sample results and estimates.)

RECOMMENDATIONS

We recommend that Blue Cross & Blue Shield of Rhode Island:

- refund to the Federal Government the $4,894,595 of estimated net overpayments;
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
- continue its examination of 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.

BLUE CROSS & BLUE SHIELD OF RHODE ISLAND COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, BCBS RI concurred with our second and third recommendations and stated that it has already: (1) implemented procedures to ensure high-risk diagnosis codes are correctly billed, (2) expanded its coding quality team to enhance compliance with CMS guidelines, and (3) provided education to physicians, providers, coders, and billers.

However, BCBS RI did not concur with our first recommendation. Although BCBS RI agreed with our findings for 194 of the 222 sampled enrollee-years in error, it did not agree with our findings for the remaining 28 enrollee-years.[25] BCBS RI provided additional information that it believed:
(1) validated the reviewed HCCs for 27 enrollee-years, and (2) supported that 1 enrollee-year should not be considered a finding because BCBS RI had corrected the overpayment prior to our audit.[26] Although BCBS RI stated that it would take corrective actions on the 194 enrollee-years, it also stated that it did not agree that "the extrapolated penalty" (to refund to the Federal Government approximately $5.3 million of estimated overpayments) was appropriate because, according to BCBS RI, we did not properly conduct statistical sampling or correctly follow established guidelines. Therefore, BCBS RI requested that we withdraw our first recommendation.

After reviewing BCBS RI's comments and the additional information it provided, we reduced the number of sampled enrollee-years in error from 222 to 212 and adjusted our calculation of net overpayments. Accordingly, we reduced the estimated net overpayment in our first recommendation from $5,300,482 to $4,894,595 for this final report.

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

BLUE CROSS & BLUE SHIELD OF RHODE ISLAND DISAGREED WITH OUR FINDINGS FOR 28 ENROLLEE-YEARS

BCBS RI Comments

BCBS RI did not agree with our draft report findings for 28 enrollee-years (as shown in the Table 3 on the following page) and requested that we reconsider our findings.

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[25] BCBS RI's comments included statements that it agreed with our findings for 196 enrollee-years and disagreed with our findings for 26 enrollee-years. However, BCBS RI officials clarified (after commenting on our draft report) that it agreed with our findings for 194 enrollee-years and disagreed with the remaining 28 enrollee-years.

[26] Under separate cover, BCBS RI included additional medical records that it had not previously submitted to us for two sampled enrollee-years.

Table 3: Summary of Enrollee-Years for Which BCBS RI Disagreed With Our Findings

High Risk Group	Number of Sampled Enrollee Years
Acute Stroke	4
Acute Heart Attack	4
Embolism	4
Lung Cancer	4
Colon Cancer	3
Prostate Cancer	4
Major Depressive Disorder	2
Vascular Claudication	3
Total	**28**

For 27 of the 28 enrollee-years, BCBS RI provided additional information (including medical records and explanations) that supported its belief that the audited HCCs were validated.

For example, for 1 enrollee-year, BCBS RI provided an inpatient record that it believed would validate an Acute Heart Attack HCC and stated that the "Member was admitted to VA hospital. He transferred from the VA hospital to Nursing and Rehab Center for continuation of care within 4 weeks of diagnosis."

For the remaining 1 enrollee-year, BCBS RI stated that it had already deleted the associated diagnosis "prior to the audit" and that we should remove this enrollee-year from our findings.[27]

Office of Inspector General Response

Our independent medical review contractor reviewed the additional information that BCBS RI provided for the 27 enrollee-years.

- For 18 of the enrollee-years, our contractor reaffirmed its original decision that the HCCs were unvalidated.

  For example, for 1 enrollee-year from the prostate cancer high-risk group, our independent medical review contractor stated: "Decision upheld at reconsideration.

[27] BCBS RI stated that it reviewed the diagnosis codes associated with 7 of the sampled enrollee-years and came to the same conclusions as our independent medical review contractor. Because 6 of these conclusions showed that the audited HCC was validated, no additional adjustments needed to be made to our findings for these enrollee-years.

There is no documentation to support an active prostate cancer [diagnosis]. The patient had prostate surgery to remove the cancer in 2000. Per coding guidelines, a past medical history of prostate cancer [diagnosis] is assigned which does not result in an HCC."

- For 8 enrollee-years, our independent medical review contractor reversed its original decisions and stated that the HCCs were validated.

  For example, for 1 enrollee-year, our independent medical review contractor reversed its original unvalidated decision because the HCC for Breast, Prostate, and Other Cancers and Tumors "was substantiated based on the assessment of prostate cancer [diagnosis] on active surveillance."

- For the remaining 1 enrollee-year, our independent medical review contractor found support for a metastatic bone cancer diagnosis that should have been used instead of the colon cancer diagnosis that was originally submitted. Accordingly, BCBS RI should not have received an increased payment for the HCC for Colorectal, Bladder, and Other Cancers, but should have received a higher increased payment for Metastatic Cancer and Acute Leukemia, resulting in an underpayment.

Our independent medical review contractor confirmed that BCBS RI's written comments had no impact on the decisions that the contractor made for other sampled enrollee-years, and stated that there were no "systemic issues" in its reviews.

For the enrollee-year that BCBS RI stated that it deleted the diagnosis code prior to our audit, we agree with BCBS RI that we should not include the financial impact associated with this enrollee-year in our overpayment calculation. Before we selected our sample, we worked with BCBS RI to verify the accuracy of our sampling frame and remove any enrollee-years for which BCBS RI had taken corrective action (diagnosis code deletions). Based on the information that BCBS RI provided at the time, we were not aware of the corrective action that it had taken until after we issued our draft report. Because BCBS RI demonstrated that it had initiated its review before we selected our sample, we have classified this enrollee-year as a non-error in our sample results and overpayment calculation for this final report.

Accordingly, we revised our findings for Acute Heart Attack, Major Depressive Disorder, Vascular Claudication, Lung Cancer, Colon Cancer, and Prostate Cancer high-risk groups and reduced the total number of enrollee-years in error from 222 (as reported in our draft report) to 212 and reduced the refund amount in our first recommendation from $5,300,482 to $4,894,595.

BLUE CROSS & BLUE SHIELD OF RHODE ISLAND DID NOT AGREE THAT IT SHOULD HAVE TO REFUND AN EXTRAPOLATED AMOUNT TO THE FEDERAL GOVERNMENT

BCBS RI agreed that it should refund the overpayments for the sampled enrollee-years found to be in error, but it disagreed that it should refund an extrapolated amount because, according to BCBS RI, we did not properly conduct statistical sampling and our audit methodology did not correctly follow established guidelines.

Improperly Conducted Statistical Sampling

BCBS RI Comments

BCBS RI disagreed with the sampling and extrapolation methodology that we used to calculate the estimated net overpayments. Specifically:

- BCBS RI stated that our "statistical sampling was not properly conducted to be able to extrapolate data" because "[o]nly 30 cases were sampled per category, and algorithms were employed to ensure discovery of errors." In this regard, BCBS RI stated that it "feels that the findings are legitimate for calculating codes that need to be deleted, but inappropriate for extrapolation."

- BCBS RI stated that "CMS acknowledges a certain error rate" and that "finding a limited number of errors using a specific algorithm does not represent a failure of [BCBS RI's] policies or procedures, but represents an acceptable range of errors."

- BCBS RI stated that "the timeframe of the audit also fails to demonstrate a sustained level of payment error CMS recommends warranting extrapolation. As described in [CMS's *Program Integrity Manual*], it is recommended to give plans the ability to enact preventative measures and education before asserting an extrapolated penalty."

Office of Inspector General Response

We correctly applied a statistically valid sampling methodology and maintain that extrapolation is appropriate for this audit. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.[28] The legal standard for use of sampling and extrapolation is that it must be based

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[28] *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).

on a statistically valid methodology, not the most precise methodology.[29] We properly executed our statistical sampling methodology in that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

More specifically,

- We note that the overall sample size of our stratified random sampling design was 270 enrollee-years. Small sample sizes (for example, fewer than 100 samples) have routinely been upheld by the Departmental Appeals Board and Federal courts.[30] Generally, a smaller sample size leads to worse precision and a smaller lower limit. Because absolute precision is not required, any imprecision in the sample may be remedied by recommending recovery at the lower limit, which we have done in this audit.[31] This approach results in an estimate that is lower than the actual overpayment amount 95 percent of the time, and thus it generally favors the MA organization.[32]

- Further, we disagree with BCBSRI's statement that "algorithms were employed to ensure discovery of errors." A valid estimate of net overpayments does not need to take into consideration all potential HCCs or underpayments within the audit period. Our estimate of net overpayments addresses only the portion of the payments related to the reviewed HCCs and does not extend to the HCCs that were beyond the scope of our audit. In accordance with our objective, and as detailed in Appendices C and D, we properly executed a statistically valid sampling methodology as explained above.

- We also disagree with BCBS RI's statements that CMS acknowledges certain error rates and that finding a limited number of errors using a specific algorithm represents an acceptable range of errors. There is no provision that acknowledges certain error rates

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

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

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

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

and instructs MA organizations to not submit corrections. Furthermore, the methodology that we used to identify diagnosis codes that were at high risk for being miscoded is not a reason in and of itself to not calculate overpayments, including extrapolations to the sampling frame.

- Regarding BCBS RI's comments that the timeframe of our audit also failed to demonstrate a sustained level of payment errors, we note that the requirement that a determination of a sustained or high level of payment error must be made before extrapolation applies to Medicare contractors only.[33] Nonetheless, we disagree that we did not identify a sustained level of payment errors, as evidenced by the number of errors that we identified in our audit (212 of 270 enrollee-years with unsupported diagnosis codes (Appendix D)).

Accordingly, we made no additional changes to our first recommendation in response to BCBS RI's comments concerning our sampling and estimation methodology.

Established Guidelines Not Correctly Followed

BCBS RI Comments

In its disagreement with our recommendation to refund an extrapolated amount, BCBS RI made several related comments about how our audit methodology did not correctly follow established guidelines. Specifically, BCBS RI stated that we:

- should not have used a coder to determine if a diagnosis code is correct for risk adjustment because it is the physician's responsibility to make the correct diagnostic statements in the chart and to clearly document all the conditions a patient has at the time of the visit

- reviewed only a particular date of service to validate a diagnosis code whereas CMS allows (in Chapter; 7 of the Manual) for a diagnosis code to be correctly documented once per year;

- did not follow CMS's Risk Adjustment Data Validation (RADV) methodology[34] because, according to BCBS RI, our coders did not validate all diagnosis codes from acceptable face-to-face visits, allowable providers, and according to ICD Guidelines;

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

[34] RADV methodology identifies discrepancies in payments by comparing risk adjustment diagnosis data submitted by a MA organization for payment against medical record documentation provided by MA organization during contract-level RADV audits.

- estimated overpayments without accounting for HCCs identified within the charts that are below the targeted HCCs in the hierarchy or include additive value for new HCCs identified during the audit.

Office of Inspector General Response

We maintain that our audit methodology was appropriate for the audit objective, and our audit objective and methodology provided a reasonable basis for us to calculate estimated overpayments and recommend that the overpayments be refunded to the Federal Government.

We used the results of the independent medical review contractor's coding review to determine which high-risk HCCs were not substantiated. As shown in Appendix A (and more specifically in footnote 39), the contractor's senior coders and physicians possessed the requisite credentials needed to review the medical records that BCBS RI provided to us and to determine whether the diagnosis codes that BCBS RI submitted to CMS were supported.

Consistent with our audit methodology, if the independent medical review contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments. We followed the requirements of CMS's risk adjustment program to determine the payment that CMS should have made for each sampled enrollee-year. We used the overpayments and underpayments identified for each enrollee-year to determine our estimated net overpayment amount.

Further, although our approach was generally consistent with the methodology CMS uses in its RADV audits, it did not mirror CMS's approach in all aspects, nor did it have to. We also recognize that CMS is responsible for making operations and program payment determinations for the MA program. Thus, we believe that the steps that we followed for this audit provide a reasonable basis for our findings and recommendations, including our estimation of net overpayments.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid BCBS RI $1,057,403,797 to provide coverage to its enrollees for 2016 and 2017. We identified a sampling frame of 3,037 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2015 and 2016 service years. BCBS RI received $42,081,441 in payments from CMS for these enrollee-years for 2016 and 2017. We selected for audit 270 enrollee-years with payments totaling $4,082,900.

The 270 enrollee-years included 30 acute stroke diagnoses, 30 acute heart attack diagnoses, 30 embolism diagnoses, 30 vascular claudication diagnoses, 30 major depressive disorder diagnoses, 30 lung cancer diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, and 30 prostate cancer diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $732,418 for our sample.

Our audit objective did not require an understanding or assessment of BCBS RI'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 October 2019 through April 2022.

METHODOLOGY

To accomplish our objective, we performed the following steps:

- We reviewed applicable Federal laws, regulations, and guidance.

- We discussed with CMS program officials the Federal requirements that MA organizations should follow when submitting diagnosis codes to CMS.

- We identified, through data mining and discussions with medical professionals at a Medicare administrative contractor, diagnosis codes and HCCs that were at high risk for noncompliance. We also identified the diagnosis codes that potentially should have been used for cases in which the high-risk diagnoses were miscoded.

- We consolidated the high-risk diagnosis codes into specific groups, which included:

    - 74 diagnosis codes for acute stroke,
    - 38 diagnosis codes for acute heart attack,
    - 29 diagnosis codes for major depressive disorder,
    - 85 diagnosis codes for embolism,
    - 4 diagnosis codes for vascular claudication,
    - 24 diagnosis codes for lung cancer,

- 65 diagnosis codes for breast cancer,
- 20 diagnosis codes for colon cancer, and
- 2 diagnosis codes for prostate cancer.

- We used CMS's systems to identify the enrollee-years on whose behalf providers documented the high-risk diagnosis codes. Specifically, we used extracts from CMS's:

    - Risk Adjustment Processing System (RAPS) to identify enrollees who received high-risk diagnosis codes from a physician during the service years,[35]

    - Risk Adjustment System (RAS) to identify enrollees who received an HCC for the high-risk diagnosis codes,[36]

    - Medicare Advantage Prescription Drug System (MARx) to identify enrollees for whom CMS made monthly Medicare payments to BCBS RI, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C),[37]

    - Encounter Data System (EDS) to identify enrollees who received specific procedures,[38] and

    - Prescription Drug Event (PDE) file to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.[39]

- We interviewed BCBS RI officials to gain an understanding of: (1) the policies and procedures that BCBS RI followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) BCBS RI's monitoring of those submissions to prevent, detect, and correct noncompliance with Federal requirements.

- We selected for audit a stratified random sample of 270 enrollee-years (Appendix C).

[35] MA organizations use the RAPS to submit diagnosis codes to CMS.

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

[37] The MARx identifies the payments made to MA organizations.

[38] The EDS contains information on each item (including procedures) and service provided to enrollees.

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

- We used an independent medical review contractor to perform a coding review for the 270 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.[40]

- The independent medical review contractor's coding review followed a specific process to determine whether there was support for a diagnosis code and the associated HCC:

  - If the first senior coder found support for the diagnosis code on the medical record, the HCC was considered validated.

  - If the first senior coder did not find support on the medical record, a second senior coder performed a separate review of the same medical record:

    - If the second senior coder also did not find support, the HCC was considered to be not validated.

    - If the second senior coder found support, then a physician independently reviewed the medical record to make the final determination.

  - If either the first or second senior coder asked a physician for assistance, the physician's decision became the final determination.

- We used the results of the independent medical review contractor to calculate overpayments or underpayments (if any) for each enrollee-year. Specifically, we calculated:

  - a revised risk score in accordance with CMS's risk adjustment program and

  - the payment that CMS should have made for each enrollee-year.

- We estimated the total overpayment made to BCBS RI during the audit period.

- We discussed the results of our audit with BCBS RI officials.

[40] 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. The AHIMA also credentials individuals with CCS and CCS-P certifications, and the American Academy of Professional Coders credentials both CPCs and CRCs.

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

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (H3916) Submitted to CMS	A-03-19-00001	9/29/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract (H7917) Submitted to CMS	A-07-19-01195	9/29/2022
Medicare Advantage Compliance Audit of Diagnosis Codes that Inter Valley Health Plan, Inc. (Contract H0545), Submitted to CMS	A-05-18-00020	9/26/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS	A-09-20-03009	9/13/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc., (Contract H1032) Submitted to CMS	A-04-19-07084	8/29/2022
Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS	A-03-18-00002	8/19/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS	A-02-20-01009	7/18/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health Network (Contract H1961) Submitted to CMS	A-06-18-05002	5/25/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS	A-01-19-00500	2/14/2022
Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS	A-07-17-01169	2/3/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS	A-02-18-01029	1/5/2022
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS	A-07-19-01188	11/5/2021
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS	A-07-17-01173	10/28/2021
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS	A-07-19-01187	5/21/2021

Report Title	Report Number	Date Issued
Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS	A-07-16-01165	4/19/2021
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS	A-02-18-01028	2/24/2021
Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements	A-07-17-01170	4/30/2019

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified BCBS RI enrollees who: (1) were continuously enrolled in BCBS RI 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 BCBS RI for 2016 or 2017, respectively.

We presented the data for these enrollees to BCBS RI 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 BCBS RI. After we performed these steps, our finalized sampling frame consisted of 3,037 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 individual received:

- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on only one physician claim during the service year but did not have that diagnosis on a corresponding inpatient or outpatient hospital claim (656 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 (362 enrollee-years);

- a major depressive disorder diagnosis (that mapped to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) on only one claim during the service year but did not have an antidepressant medication dispensed on his or her behalf (321 enrollee-years);

- a diagnosis (that mapped to an Embolism HCC) on only one claim during the service year but did not have an anticoagulant medication dispensed on his or her behalf (169 enrollee-years);

- a diagnosis related to vascular claudication (that mapped to the HCC for Vascular Disease) on only one claim during the service year (a diagnosis that had not been

documented during the 2 years that preceded the service year), but had medication for neurogenic claudication dispensed on his or her behalf (158 enrollee-years);

- a lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the lung cancer diagnosis administered within a 6-month period before or after the diagnosis (131 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 (713 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 (217 enrollee-years); or

- a prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors), for an individual 74 years old or younger, on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (310 enrollee-years).

The specific strata are shown in Table 4.

Table 4: Sample Design for Audited High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee-Years	CMS Payment for HCCs in Audited High-Risk Groups	Sample Size
1 – Acute stroke	656	$1,436,457	30
2 – Acute heart attack	362	750,140	30
3 – Major depressive disorder	321	867,361	30
4 – Embolism	169	444,617	30
5 – Vascular claudication	158	329,791	30
6 – Lung cancer	131	989,309	30
7 – Breast cancer	713	913,240	30
8 – Colon cancer	217	543,654	30
9 – Prostate cancer	310	381,850	30
Total	**3,037**	**$6,656,419**	**270**

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We sorted the items in each stratum by enrollee identification number and then consecutively numbered the items in each stratum in the stratified sampling frame. After generating 270 random numbers according to our sample design, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to estimate the total amount of overpayments to BCBS RI 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	Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)
1 – Acute stroke	656	$1,436,457	30	$63,392	30	$63,392
2 – Acute heart attack	362	750,140	30	64,907	27	53,268
3 – Major depressive disorder	321	867,361	30	85,940	9	25,909
4 – Embolism	169	444,617	30	79,641	28	75,383
5 – Vascular claudication	158	329,791	30	62,262	7	17,025
6 – Lung cancer	131	989,309	30	229,215	27	187,753
7 – Breast cancer	713	913,240	30	36,859	30	36,859
8 – Colon cancer	217	543,654	30	74,567	28	52,477
9 – Prostate cancer	310	381,850	30	35,635	26	30,665
Total	**3,037**	**$6,656,419**	**270**	**$732,418**	**212**	**$542,731**

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

Point Estimate	$5,212,828
Lower Limit	$4,894,595
Upper Limit	$5,531,060

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's program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:
>
> (A) Written policies, procedures, and standards of conduct that—
>
> (1) Articulate the organization's commitment to comply with all applicable Federal and State standards;
>
> (2) Describe compliance expectations as embodied in the standards of conduct;
>
> (3) Implement the operation of the compliance program;
>
> (4) Provide guidance to employees and others on dealing with potential compliance issues;
>
> (5) Identify how to communicate compliance issues to appropriate compliance personnel;
>
> (6) Describe how potential compliance issues are investigated and resolved by the organization; and
>
> (7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials . . .
>
> (F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The

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

(G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

(1) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

(2) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.

(3) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

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Curtis Roy
Regional Inspector General for Audit Service
Department of Health & Human Services
Office of Inspector General
Office of Audit Services, Region 1
JFK Federal Building
15 New Sudbury Street, Room 2425
Boston, MA 02203

Date: July 15, 2022

Re: Report Number 01-20-00500

Blue Cross & Blue Shield of Rhode Island (BCBSRI) is in receipt of your draft audit report dated May 17, 2022, regarding the Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Blue Cross & Blue Shield of Rhode Island (H4152) submitted to CMS. We would like to begin by thanking you for granting an extension to respond to your audit findings. As requested, we have taken the opportunity to address your audit findings by using the requested statement of concurrence or nonconcurrence in response to each recommendation. In addition, for each concurrence, we have included a statement describing the nature of corrective action taken or planned. Where we provide a statement for nonconcurrence, you will find specific reasons for the nonconcurrence, and a statement of any alternative corrective action taken or planned.

For the reasons described below, BCBSRI respectfully requests that The Office of Inspector General (OIG) update its draft report to (I) withdraw its recommendation that BCBSRI repays an extrapolated amount of $5,300,482, and (II) remove the 26 contested samples for which BCBSRI has provided valid justification.

1. *It is recommended BCBSRI refund to the Federal Government $5,300,482 of estimated overpayments.*

BCBSRI does not concur with the OIG recommendation to refund $5,300,482 in estimated overpayments. BCBSRI requests that OIG reconsider its findings for 26 of the 222 samples the OIG reports are invalid. BCBSRI believes it has provided sufficient evidence to support these Hierarchal Condition Categories (HCCs) found in Appendix A. BCBSRI will delete the remaining 196 diagnoses instances where BCBSRI agrees with OIG's categorization that the diagnoses are invalid. BCBSRI does not agree with the OIG's findings that the extrapolated penalty is appropriate for the following reasons:

- A statistical sampling was not properly conducted to be able to extrapolate data. Only 30 cases were sampled per category, and algorithms were employed to ensure discovery of errors. Due to this methodology, BCBSRI feels that the findings are legitimate for calculating codes that need to be deleted, but inappropriate for extrapolation.
- CMS acknowledges a certain error rate and factors this error rate into the risk adjustment model. As such, finding a limited number of errors using a specific algorithm does not represent a failure of our policies or procedures, but represents an acceptable range of errors.
- CMS has passed scenarios in a simultaneous Contract Year 2015 Risk Adjustment Data Validation (CON15 RADV) audit (examples of embolisms and malignancies), which closely match cases of failed validation in the OIG audit as detailed on our spreadsheet. CON15 examples available upon request.

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- The timeframe of the audit also fails to demonstrate a sustained level of payment error CMS recommends warranting extrapolation. As described in CMS guidance,[1] it is recommended to give plans the ability to enact preventative measures and education before asserting an extrapolated penalty.
- CMS does not require 100% chart review. Recognizing the burden 100% chart review would place on Medicare Advantage (MA) plan sponsors, CMS has internal calculations they apply to even out risk scores and as they relate to chart reviews, CMS instructs plan sponsors as follows: "If upon conducting internal review of submitted diagnosis codes that do not meet risk adjustment requirements, delete as soon as possible." Per CMS, requiring 100% coder validation would place an undue burden on the part of the plan sponsor. BCBSRI makes a good faith effort to validate code accuracy, including, but not limited to conducting chart audits and targeted audits on high-risk claims diagnoses. BCBSRI is unable to validate all charts considering we can accept diagnoses from many sources.
- Determining if a diagnosis is correct for risk adjustment is outside a coder's scope of work. Physicians are the diagnosticians and if they make a diagnostic statement in the chart, it must be coded or clarified. Coders then translate the diagnosis into a code set; they do not perform clinical validation. Clinical validation is beyond the scope of DRG validation. It is up to providers to clearly document all the conditions a patient has at the time of visit.
- OIG/HHS/CMS is using ICD coding, a system created to gather statistics for reimbursement. Regardless, in many of these cases, the provider has documented the condition in their assessment and treatment plan using a diagnostic statement and the code was not counted as validated by the OIG.
- There is an inherent danger to using fee for service (FFS) payment criteria to calculate risk adjustment. This exists because FFS requires the condition to be assessed at the time of visit, while risk adjustment ~~also~~ requires inclusion of chronic conditions at the time of the visit per correct coding guidelines. This creates a mismatch where coders may be more apt to validate a code for risk adjustment vs FFS, but the OIG audit uses FFS logic. Risk adjustment, as advised by CMS in Chapter 7 of Medicare Managed Care Manual,[2] only asks for the code to be correctly documented once per year, but the OIG audit only looks at a particular date of service to validate a code as with FFS.
- The OIG is not following CMS' RADV methodology. Coders are not expected to validate all codes from acceptable face to face visits, allowable provider, and ICD Guidelines.
- The OIG penalty calculation methodology does not account for HCCs identified within the charts that are below the targeted HCCs in the hierarchy. It also does not include additive value for new HCCs identified during the audit.
- For the seven samples in the audit that BCBSRI reviewed prior to the OIG audit, OIG and BCBSRI concurred on the validity of these diagnoses, indicating BCBSRI coding guidelines align with the OIG auditors' guidance. BCBSRI had also deleted one of the samples prior to the audit; this sample should be removed from the samples found as invalid.

2. *It is recommended BCBSRI identify 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.*

---

[1] *Pub 100-08 Medicare Program Integrity,* Section 8.4.1.2 - The Purpose of Statistical Sampling

[2] *Pub 100-16 Medicare Managed Care Manual,* Section 130 - Glossary of Terms (Rev. 118; Effective: ICD-10: Upon Implementation of ICD-10, ASC X12: January 1, 2012 (for ASC X12 5010); Implementation: ICD-10: Upon Implementation of ICD-10, ASC X12: January 1, 2012 (for ASC X12 5010))

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BCBSRI concurs with the recommendation to identify high risk diagnoses for noncompliance. In October 2021, BCBSRI communicated procedures have already been established to review these high-risk diagnoses and that the periods after the audited period have been or are in the process of being reviewed.

3. *It is recommended BCBSRI continue its examination of 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.*

BCBSRI concurs with the recommendation to examine existing compliance procedures to identify opportunities to ensure compliance with high-risk diagnosis codes. BCBSRI is committed to continually evaluating its processes for compliance. In addition to implementing the aforementioned procedures to ensure high-risk diagnosis codes comply with Federal requirements, BCBSRI has expanded its coding quality team to enhance compliance with CMS guidelines, provide insights to educate physicians, providers, coders, and billers, and continue to enhance internal audit and compliance activities.

Blue Cross & Blue Shield of Rhode Island is committed to conducting business in accordance with all legal and regulatory requirements and with the highest standards of ethical behavior. We look forward to continuing to improve our compliance and service to our members by addressing the opportunities identified in the report.

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Exhibit A – Justification for Disagreed Codes

Sample Case	HCC	Statement
6	100	This is inpatient admission and codable per inpatient guidelines. The MD assessment on page 2 states: "64 y/o male admitted for CVA and multiple falls now with fall."
10	100	Please add Hierarchal Code Condition (HCC) 107 for I74.9. Per RADV Intake Guide, the MD is a cardiologist, who is an allowable provider for tests, the indication was TIA, stroke and the conclusion was no cardioembolic source of emboli, stroke was not ruled out. Indications are codable per RADV Intake Evaluation Guidance – Version 4.3 February 3, 2015, pages 45-47. Embolism non specified = I749, HCC 107.
21	100	Please add HCC 103. Agree stroke is a Past Medical History, however, there is a description of residuals/sequela on page 2: " had a CVA...bilateral leg weakness...." I69.351, I69.354 per AHA Coding Clinic, 2015, 1Q, page 25.
25	100	Diagnosis of CVA, still has gait instability page 7 and top of page 9: Left-sided paresis. Active problem list: status post CVA. IMP/REC: is undergoing PT. Sequelae I69.354. Submitting 3 more records for wave 3 supporting sequelae post CVA.
62	11	Per MD History of Present Illness "she is positive for cancer cell in stool" on page 3, diagnosis page 5 "malignant neoplasm of colon, unspecified part of colon" and per Plan on page 5 "colo-guard positive for ca colon and she is going for scope next week." Correct coding is based on the MD documentation and diagnostic statement of this individual face-to-face encounter resulting in the correct assignment of HCC 011. I have an example, the same scenario for malignant neoplasm of the kidney, that was validated by CMS CON15 RADV auditors.
63	11	This member continues with bi-yearly monitoring, evaluation, assessment, and testing by his oncologist for stage 3B colon cancer. CMS validated two CON15 RADV medical records with a history of malignancy with continued MD and testing follow-up.
81	11	Please add HCC 08. 01: 11/18/16 DOS: The MD assessment and diagnostic statement is "malignant neoplasm of colon", a new diagnosis of "colon cancer metastasized to bone," it is also documented "pt refused chemotherapy." He is on hydrocodone and a fentanyl patch was added to his treatment
98	108	S/P TKR with a repeat venous doppler + thrombus of left lessor saphenous vein. ICD Index: thrombosis, vein (acute) deep, it leads you to I82.4x-Per ICD official coding conventions, words in paratheses are non-essential modifiers, supplemental words that may be present or absent without affecting code number. Submitted via claims by MD.
100	107	“PE/DVT: 1/2015” is the reason for the visit, in assessment, MD diagnostic statement " other pulmonary embolism without acute cor pulmonale" assessed on physical exam, ASA is utilized as long term anticoagulant. CMS validated two CON15 medical records with history of embolism maintained on anticoagulants.
107	107	MD diagnostic statement is “PE”, is allergic to plavix and aspirin is listed as a current med. CMS validated two CON15 medical records with history of embolism maintained on anticoagulants. Attestation not needed: per CMS, an acceptable Physician signatures in electronic medical records is indicated with notation “Created by." Found at the top of page 2 is this PA progress note on 5/22/2015 at 8:58am along with documentation stating, "created by" Leane M Nadeau PA-C.
109	108	The reason for the visit, assessment and plan all state DVT and he remains on coumadin.

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		There is no documentation of DVT being a past medical history. It does state "DVT since last Oct" however there are no time restrictions/parameters for a diagnosis of DVT. CMS validated two CON15 medical records with history of embolism maintained on anticoagulants. Additionally, when you look up thrombosis, vein (acute) deep, it leads you to I82.4x-Per ICD official coding conventions, words in paratheses are non-essential modifiers, supplemental words that may be present or absent without affecting code number.
134	9	"Suspected" is coded per inpatient coding guidelines. Submitting 134-02-IP.
136	9	The submitted DOS lists among reasons for visits as f/u for lung cancer and has assessment/plans/MD diagnostic statements of primary neoplasm of the lung. The treatment plan is pending. Specialist recommendation post review of CT scan. CMS validated two CON15 medical records with a history of malignancies with continued follow-up.
145	9	Non-small cell lung ca in Subjective, Active Problems/PMH and Assessment. A lung exam is conducted and per CT scan, she continues to have a 4.2mm RUL nodule post sterotactic radioactive therapy. MD diagnostic statement states "non-small cell lung ca". CMS validated two CON15 medical records with a history of malignancy with continued MD and testing follow-up.
149	9	This code was submitted for deletion on 1/31/2017. This sample should be removed from the sample frame.
158	58	"Moderate episode of recurrent major depressive disorder" is one of the diagnoses listed following the reason for visit section. She is on klonopin and per the evidence-based guidelines for depression included with this DOS, physical activity should be recommended, and discussion takes place surrounding "continues to stay active and goes to the gym 3 times/week."
171	58	MD documents depressive disorder, chronic, moderate, exacerbated (assessed), 29632. Index: Chronic: see condition.
206	87	Member was admitted to VA hospital 6/29/15-7/2/15 w/DX NSTEMI. He transferred from the VA hospital to Nursing and Rehab Center "293 Legris Avenue Operations" for continuation of care within 4 weeks of diagnosis. Submitting Inpatient record "206-03-IP" for HCC 86, NSTEMI, initial episode of care.
210	86	Refer to the emergency department Impression and plan with the diagnosis "elevated troponin 0.05, NSTEMI" resulting in an inpatient admission to telemetry.
214	12	Per the 3/31/16 office visit, he was diagnosed with biopsy-proven prostate cancer in 2011, had no surgery, and remains on active surveillance every 6 months, consisting of PSA, DRE, and bladder scans. Most recent PSA of 6.78 3/16.
220	12	MD documented in History of Present Illness, reviewed problems, diagnostic statement/assessment/plan. CMS validated two CON15 RADV medical records with a history of malignancy with continued MD and testing follow-up.
222	12	The MD diagnostic statement is prostate cancer and the chief complaint states: "prostate cancer status-post lap prostatectomy, positive prostate margins." Positive margins are indicative of residual prostate cancer, the decision was made for a conservative approach postponing radiation by watching while waiting. CMS validated two CON15 medical records with a history of malignancy with continued MD and testing follow-up.
228	12	Per the Urologist's note, surgery/procedure radical prostatectomy in 2012 but was (+) prostate cancer 12/19/12, 2013, 11/20/13, 6/4/14, 12/17/14 and again 6/3/15. CMS validated two CON15 medical records with history of malignancy with continued MD and testing follow up.

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241	108	The MD (cardiologist) note documents carotid artery disease, I77.9, HCC108.
248	108	Submitting 248-02-PHY. Per RADV Medical Record review Guidance, diagnostic testing with MD interpretation.
270	108	We are in the process of submitting credentials. The electronic medical record was signed with "[redacted] (Physician)". This MD moved to Ascension Medical Group Hospital in Wichita Kansas and did not return phone calls requesting attestation. Per page 120 of 2021 Benefit Year Protocols ACA HHS Risk Adjustment Data Validation, Version 1.0, May 20, 2022, a source system screenshot containing the provider's name and verified credentials can be used in lieu of attestation. - Home · PI 127576495 · Neurology https://npidb.org/doctors/allopathic_osteopathic_physicians/neurology_2084n0400x/1275764953.aspx?src=1 **NPI Profile & details for [redacted] · (Female)** NPI Number: 1275764953 Status: Active Credentials: MD Entity: Individual Enumeration date: 07/29/2009 Last updated: 10/06/2021 - About 8 months ago Sole proprietor [1]: No Identifiers: • KS License # 04-39528 • RI License # MD14985 • KS Medicaid 201147490A Hospital affiliation(s): • *VIA CHRISTI HOSPITALS WICHITA INC - (Acute Care) 929 NORTH ST FRANCIS STREET WICHITA, KS 67214*

DocuSigned by:

By: Christina Pitney
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Printed Name: Christina Pitney

Title: Sr. Vice President, Government Programs

Date: 7/15/2022