

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE COMPLIANCE  
AUDIT OF SPECIFIC DIAGNOSIS CODES  
THAT BLUECROSS BLUESHIELD OF  
TENNESSEE, INC. (CONTRACT H7917)  
SUBMITTED TO CMS**

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## Report in Brief

Date: September 2022  
Report No. A-07-19-01195

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



### Why OIG Did This Audit

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

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

For this audit, we reviewed one MA organization, BlueCross BlueShield of Tennessee, Inc. (BCBST), and focused on nine groups of high-risk diagnosis codes. Our objective was to determine whether selected diagnosis codes that BCBST 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 BCBST 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 \$683,651.

## Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS

### What OIG Found

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that BCBST submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 210 of the 270 sampled enrollee-years, the medical records that BCBST provided did not support the diagnosis codes and resulted in \$491,269 in overpayments.

As demonstrated by the errors found in our sample, BCBST's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that BCBST received approximately \$7.8 million in overpayments for 2016 and 2017.

### What OIG Recommends and BCBST Comments

We recommend that BCBST: (1) refund to the Federal Government the \$7.8 million of estimated overpayments; (2) identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before and after our audit period and refund any resulting overpayments to the Federal Government; and (3) continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

BCBST concurred that most of the reviewed diagnosis codes were not supported by medical records and agreed to refund the Federal Government the associated payments. However, BCBST did not concur with the other findings associated with our first recommendation and provided additional documentation. BCBST did not agree with our audit methodology, use of extrapolation, and application of CMS requirements to calculate overpayments. Additionally, BCBST did not concur with our second and third recommendations.

After reviewing BCBST's comments and the additional documentation that it provided, we revised the number of enrollee-years in error and adjusted our calculation of overpayments. We followed a reasonable audit methodology and correctly applied applicable Federal requirements underlying the MA program. We reduced the amount in our first recommendation and made no changes to our second and third recommendations.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations based in part on the characteristics of the enrollees being covered. Using a system of risk adjustment, CMS pays MA organizations the anticipated cost of providing Medicare benefits to a given enrollee, depending on such risk factors as the age, gender, and health status of that individual. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources relative to healthier enrollees, who would be expected to require fewer health care resources. To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS.<sup>1</sup> 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.<sup>2</sup> 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 BlueCross BlueShield of Tennessee, Inc. (BCBST), for contract number H7917 and focused on nine groups of high-risk diagnosis codes for payment years 2016 and 2017.<sup>3, 4</sup>

### OBJECTIVE

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

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<sup>1</sup> 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.

<sup>2</sup> See Appendix B for a list of related Office of Inspector General (OIG) reports.

<sup>3</sup> BCBST is an independent licensee of the BlueCross BlueShield Association.

<sup>4</sup> All subsequent references to "BCBST" in this report refer solely to contract number H7917.



## BACKGROUND

### Medicare Advantage Program

The MA program offers beneficiaries managed care options by allowing them to enroll in private health care plans rather than having their care covered through Medicare's traditional fee-for-service (FFS) program.<sup>5</sup> Beneficiaries who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

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

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

### Risk Adjustment Program

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

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

- *Base rate*: Before the start of each year, each MA organization submits bids to CMS that reflect the MA organization's estimate of the monthly revenue required to cover an enrollee with an average risk profile.<sup>7</sup> CMS compares each bid to a specific benchmark amount for each geographic area to determine the base rate that an MA organization is paid for each of its enrollees.<sup>8</sup>

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<sup>5</sup> 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.

<sup>6</sup> The Social Security Act (the Act) §§ 1853(a)(1)(C) and (a)(3); 42 CFR § 422.308(c).

<sup>7</sup> The Act § 1854(a)(6); 42 CFR § 422.254 *et seq.*

<sup>8</sup> CMS's bid-benchmark comparison also determines whether the MA organization must offer supplemental benefits or must charge a basic beneficiary premium for the benefits.

- *Risk score:* A risk score is a relative measure that reflects the additional or reduced costs that each enrollee is expected to incur compared with the costs incurred by enrollees on average. CMS calculates risk scores based on an enrollee's health status (discussed below) and demographic characteristics (such as the enrollee's age and 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).<sup>9</sup> 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 one year (known as the service year) to determine HCCs and calculate risk scores for the following calendar year (known as the payment year). Thus, an enrollee's risk score does not change for the year in which a diagnosis is made. Instead, the risk score changes for the entirety of the year after the diagnosis has been made. Further, the risk score calculation is an additive process: As HCC factors (and, when applicable, disease interaction factors) accumulate, an enrollee's risk score increases, and the monthly risk-adjusted payment to the MA organization also increases. In this way, the risk adjustment program compensates MA organizations for the additional risk of providing coverage to enrollees expected to require more health care resources.

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

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<sup>9</sup> During our audit period CMS calculated risk scores based on the Version 22 CMS-HCC model.

sequestration reduction.<sup>10</sup> 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.<sup>11</sup> 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 indicating a history of a myocardial infarction (which does not map to an HCC) typically should have been used.
- *Embolism*: An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease With Complications (Embolism HCCs) 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.

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

<sup>11</sup> 42 CFR § 422.310(e) requires MA organizations (when undergoing an audit conducted by the Secretary) to submit “medical records for the validation of risk adjustment data.” For purposes of this report, we use the terms “supported” or “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.

- *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.<sup>12</sup> In these instances, the diagnosis related to vascular claudication may not be supported in the medical records.
- *Major depressive disorder*: An enrollee received one major depressive disorder diagnosis (that mapped to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) during the service year but did not have an antidepressant medication dispensed on his or her behalf. In these instances, a major depressive disorder diagnosis 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) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period either before or after the diagnosis. In these instances, a diagnosis of history of lung cancer (which does not map to an HCC) typically should have been used.
- *Breast cancer*: An enrollee received one breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of breast cancer (which does not map to an HCC) typically should have been used.
- *Colon cancer*: An enrollee received one colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of colon cancer (which does not map to an HCC) typically should have been used.
- *Prostate cancer*: An enrollee 74 years old or younger received one prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period

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

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.”

### **BlueCross BlueShield of Tennessee, Inc.**

BCBST is an MA organization based in Chattanooga, Tennessee. As of December 2017, BCBST provided coverage under contract number H7917 to 111,204 enrollees. For the 2016 and 2017 payment years (audit period), CMS paid BCBST approximately \$1.8 billion to provide coverage to its enrollees.<sup>13, 14</sup>

### **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 BCBST 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 5,663 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$12,011,395). We selected for audit a stratified random sample of 270 enrollee-years as shown in Table 1 on the following page.

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<sup>13</sup> The 2016 and 2017 payment year data were the most recent data available at the start of the audit.

<sup>14</sup> All of the payment amounts that CMS made to BCBST and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

**Table 1: Sampled Enrollee-Years**

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

BCBST provided medical records as support for the selected diagnosis codes associated with 264 of the 270 sampled enrollee-years.<sup>15</sup> We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. For the HCCs that were not validated, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or if we identified another diagnosis code (on CMS’s systems) that mapped to an HCC in the related-disease group, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

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

## **FINDINGS**

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that BCBST submitted to CMS for use in CMS’s risk adjustment program did not comply with Federal requirements. For 60 of the 270 sampled enrollee-years, the medical records validated the reviewed HCCs. For the remaining 210 enrollee-years, however, either the medical records that BCBST provided did not support the diagnosis codes or BCBST could not

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<sup>15</sup> BCBST could not locate medical records for the remaining 6 sampled enrollee-years.

locate 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, BCBST'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 BCBST received approximately \$7.8 million in overpayments for 2016 and 2017.<sup>16</sup>

## 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. Sep. 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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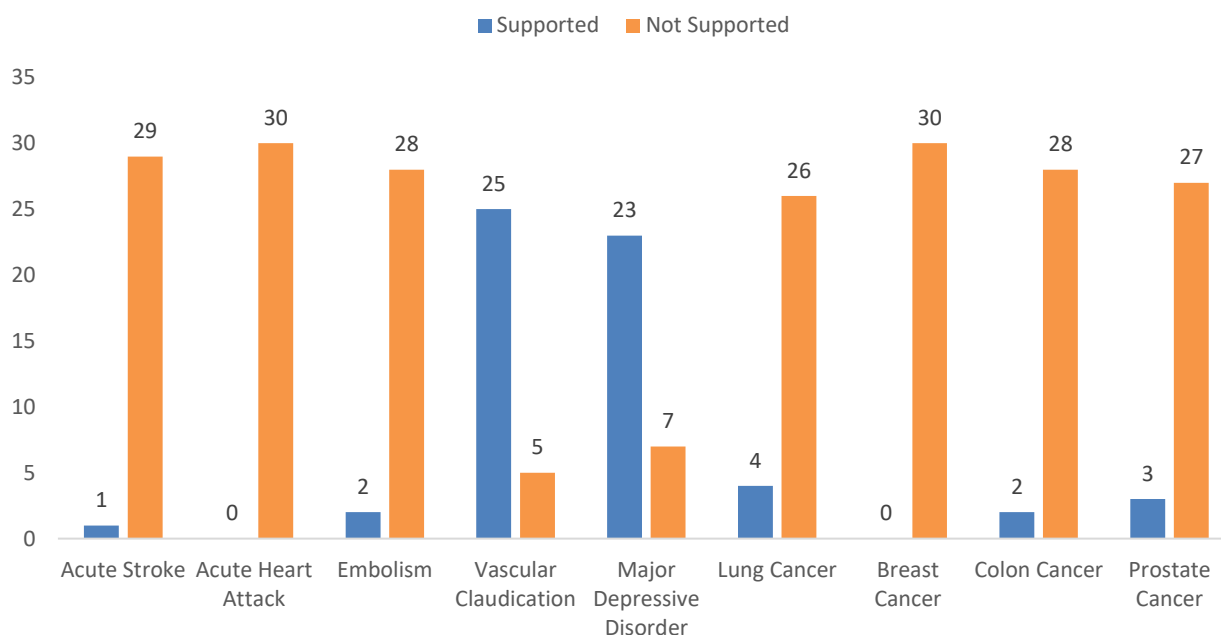
<sup>16</sup> Specifically, we estimated that BCBST received at least \$7,784,540 in overpayments. To be conservative, we recommend recovery at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 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’ 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 BLUECROSS BLUESHIELD OF TENNESSEE SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS**

Most of the selected high-risk diagnosis codes that BCBST 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 210 of the 270 sampled enrollee-years did not support the diagnosis codes. In these instances, BCBST should not have submitted the diagnosis codes to CMS and received the resulting overpayments.

**Figure: Analysis of High-Risk Groups**



**Incorrectly Submitted Diagnosis Codes for Acute Stroke**

BCBST incorrectly submitted diagnosis codes for acute stroke for 29 of 30 sampled enrollee-years. Specifically:

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



For example, for 1 enrollee-year, the medical record (for a service that occurred in 2015) indicated that the individual had a stroke in 2012. The independent medical review contractor stated that “there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC [for Ischemic or Unspecified Stroke] or a related HCC. There is mention of a history of a stroke [diagnosis] . . .” The history of stroke diagnosis code does not map to an HCC.

- For each of the remaining 8 enrollee-years, the medical records did not support an acute stroke diagnosis.

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

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and BCBST received \$57,485 in overpayments for these 29 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Acute Heart Attack**

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

- For 17 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.<sup>17</sup>

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

- For 7 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.<sup>18</sup> Accordingly, BCBST should not have received an increased payment for the submitted

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

<sup>18</sup> Angina pectoris is defined as 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.

diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

- For each of the remaining 6 enrollee-years, the medical records did not support either a diagnosis that mapped to an Acute Heart Attack HCC or a diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Acute Myocardial Infarction]. The echocardiogram interpretation summary does not mention any diagnosis that would result in an HCC.”<sup>19</sup>

As a result of these errors, the Acute Heart Attack HCCs were not validated, and BCBST received \$48,573 in overpayments for these 30 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Embolism**

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

- For 14 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 assignment of [an Embolism] HCC. There is documentation of a past medical history of a deep vein thrombosis [diagnosis] which does not result in an HCC.”<sup>20</sup>

- For 12 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.”

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<sup>19</sup> An echocardiogram (ECG) uses sound waves to produce images of the heart, which allow a physician to see the heart beating and pumping blood. An ECG can also be used to identify heart disease.

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

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

As a result of these errors, the Embolism HCCs were not validated, and BCBST received \$79,908 in overpayments for these 28 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Vascular Claudication**

BCBST incorrectly submitted diagnosis codes for vascular claudication for 5 of 30 sampled enrollee-years. Specifically:

- For 4 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].”

- For the remaining 1 enrollee-year, the medical record that BCBST gave us had not been signed by the provider in accordance with Medicare requirements. BCBST informed us that in spite of multiple attempts, it could not obtain an attestation from the provider to authenticate a diagnosis that was related to vascular claudication.<sup>21</sup> Therefore, we could not validate the HCC for Vascular Disease.

As a result of these errors, the HCC for Vascular Disease was not validated, and BCBST received \$11,943 in overpayments for these 5 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder**

BCBST incorrectly submitted diagnosis codes for major depressive disorder for 7 of 30 sampled enrollee-years. Specifically:

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<sup>21</sup> For purposes of medical review, services provided or ordered must be authenticated by a signature in accordance with CMS policies (*Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance*). MA organizations may submit attestations for eligible medical records that have missing or illegible signatures or credentials (42 CFR § 422.2).

- For 6 enrollee-years, the medical records in each case did not support a major depressive disorder diagnosis.<sup>22</sup>

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

- For the remaining 1 enrollee-year, BCBST could not locate any medical records to support the major depressive disorder diagnosis; therefore, the HCC for Major Depressive, Bipolar, and Paranoid Disorders was not validated.

As a result of these errors, the HCC for Major Depressive, Bipolar, and Paranoid Disorders was not validated, and BCBST received \$17,094 in overpayments for these 7 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Lung Cancer**

BCBST incorrectly submitted diagnosis codes for lung cancer for 26 of 30 sampled enrollee-years. Specifically:

- For 14 enrollee-years, the medical records indicated in each case 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 [diagnosis] that does not result in an HCC.”

- For 8 enrollee-years, the medical records 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, BCBST should not have received an increased payment for the submitted lung cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

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<sup>22</sup> For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources (a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3); the Manual, chap. 7, §§ 40 and 120.1). For 1 of these enrollee-years, the medical record that BCBST provided to support the reviewed HCC was a care area assessment summary that was not signed and not credentialed by an acceptable provider. Because this record did not meet CMS’s requirements for acceptable data sources, we could not validate the reviewed HCC.

Table 2 identifies the HCCs for the less severe manifestations of the related-disease groups that were supported for the 8 enrollee-years.

**Table 2: Hierarchical Condition Categories (HCCs) for a Less Severe Manifestation of the Related-Disease Group That Were Supported (Instead of the HCC for Lung and Other Severe Cancers)**

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

- For 3 enrollee-years, the medical records in each case did not support either a lung cancer diagnosis or a diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group.<sup>23</sup>

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].”

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

As a result of these errors, the HCC for Lung and Other Severe Cancers was not validated, and BCBST received \$149,289 in overpayments for these 26 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Breast Cancer**

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

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<sup>23</sup> For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources (a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3); the Manual, chap. 7, §§ 40 and 120.1). For 1 of these enrollee-years, the medical record that BCBST provided to support the reviewed HCC was a radiology report. Because this record did not meet CMS’s requirements for acceptable data sources, we could not validate the reviewed HCC.

- For 28 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 each of the remaining 2 enrollee-years, BCBST could not locate any medical records to support the breast cancer diagnosis; therefore, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated.

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and BCBST received \$33,905 in overpayments for these 30 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Colon Cancer**

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

- For 18 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 a diagnosis that results in [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 6 enrollee-years, the medical records in each case did not support either a colon cancer diagnosis or a diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group.<sup>24</sup>

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].”

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<sup>24</sup> For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources (a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3); the Manual, chap. 7, §§ 40 and 120.1). For 1 of these enrollee-years, the medical record that BCBST provided to support the reviewed HCC was a radiology report. Because this record did not meet CMS’s requirements for acceptable data sources, we could not validate the reviewed HCC.

- For each of the remaining 4 enrollee-years, the medical records did not support the submitted colon cancer diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors, which is a less severe manifestation of the related-disease group. Accordingly, in each case BCBST should not have received an increased payment for the submitted colon cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and BCBST received \$57,906 in overpayments for these 28 sampled enrollee-years.

### **Incorrectly Submitted Diagnosis Codes for Prostate Cancer**

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

- For 19 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 each of the remaining 8 enrollee-years, the medical records did not support a prostate cancer diagnosis.<sup>25</sup>

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 BCBST received \$35,166 in overpayments for these 27 sampled enrollee-years.

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<sup>25</sup> For risk adjustment purposes, CMS uses only diagnoses that enrollees receive from acceptable data sources (a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3); the Manual, chap. 7, §§ 40 and 120.1). For 1 of these enrollee-years, the medical record that BCBST provided to support the reviewed HCC was a continuity of care document. Because this record did not meet CMS’s requirements for acceptable data sources, we could not validate the reviewed HCC.

## **THE POLICIES AND PROCEDURES THAT BLUECROSS BLUESHIELD OF TENNESSEE 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 BCBST 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.

BCBST had compliance procedures in place to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. These procedures included a provider education program that was designed to promote the use of appropriate diagnosis codes. BCBST also provided education on the risk adjustment program to some of its larger providers. An aspect of BCBST's MA-specific education program focused on accurate coding for high-risk diagnosis codes, including diagnoses reviewed in the Acute Stroke and Cancer high-risk groups.

Additionally, BCBST's compliance procedures included routine internal medical reviews to compare diagnosis codes from a random sample of claims to the diagnoses that were documented on the associated medical records. Because these internal medical reviews involved random sampling, they did not necessarily focus on specific high-risk diagnosis codes, including those we identified as being at a higher risk for being miscoded.

We therefore concluded that BCBST's compliance procedures to prevent, detect, and correct miscoded high-risk diagnoses during our audit period could be improved.

## **BLUECROSS BLUESHIELD OF TENNESSEE RECEIVED 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 BCBST received at least \$7,784,540 in overpayments for 2016 and 2017. (See Appendix D for sample results and estimates).

## **RECOMMENDATIONS**

We recommend that BlueCross BlueShield of Tennessee, Inc.:

- refund to the Federal Government the \$7,784,540 of estimated overpayments;
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before and after our audit period and refund any resulting overpayments to the Federal Government; and
- continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being



miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

## **BLUECROSS BLUESHIELD OF TENNESSEE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, BCBST did not concur with some of our findings and recommendations. BCBST concurred that the reviewed diagnosis codes were not supported by medical records for 198 of the 212 enrollee-years in error and agreed to refund the Federal Government the payments associated with those sample items. However, BCBST did not concur with findings associated with our first recommendation for the remaining 14 enrollee-years and provided additional documentation for our consideration. BCBST also stated that our audit and extrapolation methodologies presented "major methodological problems" and did not agree with our application of CMS requirements to calculate overpayments. Additionally, BCBST did not concur with our second recommendation to perform additional reviews before and after our audit period. With respect to our third recommendation, BCBST did not concur with our assessment of its compliance program.

We reviewed the entirety of BCBST's comments and the additional information that it provided and, accordingly, reduced the number of enrollee-years in error from 212 to 210 and adjusted our calculation of overpayments for this final report. After consideration of BCBST's comments and adjusting our findings, we reduced the first recommendation from \$7,826,292 to \$7,784,540. We maintain that our second and third recommendations remain valid.

A summary of BCBST's comments and our responses follows. BCBST's comments appear as Appendix F. We excluded an attachment (which BCBST identified as a "table" in its comments) that contained additional information for our independent medical review contractor to consider as a part of its coding review. We are separately providing BCBST's comments and the additional information that it provided in their entirety to CMS.

### **BLUECROSS BLUESHIELD OF TENNESSEE DID NOT CONCUR WITH THE OFFICE OF INSPECTOR GENERAL'S FINDINGS FOR 14 SAMPLED ENROLLEE-YEARS**

#### **BlueCross BlueShield of Tennessee Comments**

BCBST did not concur with our findings for 14 of the sampled enrollee-years (as shown in Table 3 on the following page) and provided additional information supporting its belief that the HCCs in question were validated.

**Table 3: Summary of Specific Enrollee-Years for Which BCBST Disagreed With Our Findings**

<b>High-risk group</b>	<b>Number of Enrollee-Years</b>
Acute stroke	3
Acute heart attack	1
Embolism	2
Vascular claudication	1
Lung cancer	3
Colon cancer	1
Prostate cancer	3
<b>Total</b>	<b>14</b>

For these 14 sampled enrollee-years, BCBST either disagreed with our independent medical review contractor’s coding review of the reviewed HCC or stated that the HCC was not validated on “technical grounds” because it could not obtain requested medical record documentation. For the latter category, BCBST stated that it had contractual provisions requiring its providers to maintain medical records—provisions that “fully satisfied” CMS requirements. Additionally, BCBST stated it was “due to unfortunate circumstances outside of BCBST’s control” and a “multi-year lag between the medical records’ creation and the audit” that it was unable to locate the requested medical record documentation. In this regard, BCBST cited as an example a sampled medical record that lacked the provider’s signature and explained that BCBST could not obtain a signature because the provider’s office had closed.

### **Office of Inspector General Response**

For 2 of the 14 enrollee-years (both in the prostate cancer high-risk group), our independent medical review contractor reversed its original decision after reviewing the additional information that BCBST submitted, and determined that the HCCs were validated.

For example, for 1 enrollee-year from the prostate cancer high-risk group, BCBST submitted additional information that the medical record documentation noted that prostate cancer was “framed throughout the [physician’s] note as current with plans to ‘continue active surveillance’.” Our independent medical review contractor reversed its original decision after reviewing this additional information. In so doing, the contractor stated: “There is documentation of [prostate cancer] with the patient on watchful waiting. [The] HCC [for Breast, Prostate, and Other Cancers and Tumors] is validated.”

Accordingly, we reduced the number of enrollee-years in error from 212 (in our draft report) to 210 for this final report. We also revised our findings and reduced the associated monetary recommendation. Our independent medical review contractor confirmed that BCBST’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 quality issues” in its reviews.

For the remaining 12 enrollee-years for which BCBST disagreed with the results of the independent medical contractor’s coding review, our contractor reaffirmed that the HCCs were not validated and thus upheld its original decision. For example, for 1 enrollee-year from the lung cancer high-risk group, the contractor stated that the medical record documentation noted that “a past medical history of lung cancer is documented . . . which does not result in an HCC.” Further, the contractor stated that “there is no documentation of a recurrence [of lung cancer] nor does the physical exam show any evidence of an active lung cancer. The patient was seen and treated for influenza and bronchitis that do not result in the assignment of an HCC.”

Further, for the enrollee-years for which BCBST argued that the HCCs were not validated on “technical grounds,” our independent medical review contractor confirmed that the documentation provided was incomplete and, therefore, upheld its original decision. We understand that it may not always be possible to obtain records, addenda, and transcriptions for reasons that are outside of an auditee’s control. We followed CMS’s Risk Adjustment Data Validation (RADV) methodology when determining whether BCBST was unable to obtain a record, addenda, or transcription due to either “extraordinary circumstances,” which would be granted a hardship waiver, or “ordinary circumstances,” which would not be granted a hardship waiver. According to CMS, “ordinary circumstances” include “[d]elay caused by difficulty in communicating with the provider” or “difficulty in locating the record” or a “[d]elay caused by health information management system issues.”<sup>26</sup> Accordingly, CMS regards an “[i]nability to obtain a medical record or attestation because the provider has relocated, retired or died” as an “ordinary circumstance.” Based on the information that BCBST gave us, we determined that all of the records, addenda, and transcriptions that BCBST was unable to obtain were for reasons that CMS would classify as “ordinary circumstances.”

## **BLUECROSS BLUESHIELD OF TENNESSEE DID NOT AGREE WITH THE AUDIT METHODOLOGY THAT THE OFFICE OF INSPECTOR GENERAL USED TO CONDUCT THE AUDIT**

### **BlueCross BlueShield of Tennessee Comments**

BCBST stated that our audit had “major methodological problems,” which resulted in recommendations that were “inconsistent” with principles set forth by both CMS, in its performance of RADV audits, and the Department of Justice (DOJ), in its litigation with MA organizations under the False Claims Act.<sup>27</sup> According to BCBST’s comments, CMS, while conducting RADV audits, performs “a two-way record review” that “looks at all the diagnosis codes [for an enrollee-year] to determine which were correct, and which were not.” BCBST cited a Federal district court decision to support its view that a “sound review is one that looks

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<sup>26</sup> *Calendar Year 2013 Contract-Level Risk Adjustment Data Validation CMS Submission Instructions* (Sep. 7, 2016).

<sup>27</sup> The False Claims Act, 31 U.S.C. §§ 3729-3733. The False Claims Act protects the Government from being overcharged or sold shoddy goods or services. It is illegal to knowingly submit false claims for Medicare or Medicaid.

for both missing [diagnosis codes] to be submitted as well as incorrectly submitted [diagnosis] codes that should be removed.”<sup>28</sup>

BCBST stated that our audit started with “a preordained conclusion about selected diagnosis codes and then applie[d] criteria designed to validate that conclusion.” Further, BCBST said we used “one-way reviews” because we did not “look at all diagnosis codes” for each enrollee-year in a randomly selected audit sample. Thus, BCBST stated, our use of “one-way reviews” instead of “two-way reviews” resulted in an “unsound” methodology that contradicted CMS and DOJ principles. Further, BCBST stated that because our methodology differed from that of the CMS RADV program, our audit recommendations have “the unintended consequence of increasing the regulatory uncertainty for BCBST.”

BCBST also questioned our use of a physician as a “tiebreaker” (as described in Appendix A) in instances when two coding reviewers disagree. Specifically, BCBST stated that “CMS takes the exact opposite approach” in that if two coding reviewers in a RADV audit disagree, the second coder’s decision stands and the HCC is substantiated.

### **Office of Inspector General Response**

We agree with BCBST that our review methodology is different from that of the CMS RADV audit methodology. Although our approach for reviewing the medical records was generally consistent with the methodology used by CMS in its RADV audits, it did not mirror CMS’s approach in all aspects, nor did it have to.

Additionally, we disagree with BCBST’s characterization of our audit methodology as “one-sided”—that is, we disagree that our audit methodology contradicted the United States’ position in False Claims Act litigation with MA organizations. It was beyond the scope of our audit to identify: (1) all possible diagnosis codes that BCBST could have submitted on behalf of the sampled enrollee-years and (2) enrollees for whom BCBST did not submit any risk-adjusted diagnosis codes.

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

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<sup>28</sup> *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161 (9th Cir. 2016).

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

We therefore disagree with BCBST's statement that our audits will result in increased regulatory uncertainty. We believe that our audit was planned and performed so as to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions. Action officials at CMS will review our audit methodology, findings, and recommendations and determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures.

With respect to BCBST's comments about our use of a physician as a tiebreaker, we believe that the independent medical review contractor's use of senior coders to perform a coding review, as well as its use of a physician—who was board-certified and who did not apply clinical judgment when serving as the final decision maker—was a reasonable method for determining whether the medical records adequately supported the reported diagnosis codes.

## **BLUECROSS BLUESHIELD OF TENNESSEE DID NOT AGREE WITH THE EXTRAPOLATION METHODOLOGY THAT THE OFFICE OF INSPECTOR GENERAL USED TO CALCULATE THE RECOMMENDED OVERPAYMENT AMOUNT**

### **BlueCross BlueShield of Tennessee Comments**

BCBST stated that our use of extrapolation strayed from the spirit of the law in some ways and contravened the law in others. Specifically, BCBST stated that the Inspector General Act of 1978, 5 U.S.C. App., does not authorize the Office of Inspector General (OIG) "to extrapolate and recover overpayments through audits" and that therefore we do not have "the statutory authority to extrapolate." Further, BCBST stated that the use of extrapolation in the MA program should be set forth by CMS under notice-and-comment rulemaking, not by an OIG audit. In this regard, BCBST said that our audit methodology "would use the audit process as a tool for making major changes to a CMS-administered program."

Additionally, BCBST disagreed with how we calculated the overpayment amount that we recommended for BCBST to refund to the Federal Government. Specifically, BCBST did not agree with our use of a 90-percent confidence interval. BCBST noted that CMS uses the "statistically valid and more common" lower bound of a 95-percent or 99-percent confidence interval level for its RADV audits.

BCBST contrasted these "methodological problems" with "the strong CMS measures of BCBST's diagnosis coding in recent years" and cited coding accuracy rates from certain CMS audits for a

recent 5-year period.<sup>29</sup> These rates ranged from 96 to 100 percent. BCBST stated that the “stark contrast” between these rates and our findings “is a sure sign that any extrapolation would be unreliable.”

### Office of Inspector General Response

With respect to BCBST’s comments that the Inspector General Act of 1978, 5 U.S.C. App does not authorize us to extrapolate, we note that neither that statute nor any other authority limits our ability to recommend a recovery to CMS based on extrapolation. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.<sup>30</sup> The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.<sup>31</sup> 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. Additionally, we did not apply any new regulatory requirements that would be subject to notice-and-comment rulemaking, and in that sense our audit does not make major changes to a CMS-administered program.

Moreover, our estimation methodology does not need to mirror CMS’s estimation methodology. Our policy recommends recovery at the lower limit of a two-sided 90 percent confidence interval. We believe that the lower limit of a two-sided 90 percent confidence interval provides a reasonably conservative estimate of the total amount overpaid to BCBST for the enrollee-years and time period covered in our sampling frame. This approach, which is

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<sup>29</sup> CMS conducts an annual Part C Improper Payment Measure (IPM) activity, formerly known as National RADV, to estimate the national MA improper payment rate. Each year, CMS selects a random sample of MA enrollees from all eligible MA organizations’ contracts and reviews all HCCs assigned to the selected enrollees for accuracy. CMS determines the accuracy rates for the selected enrollees and gives that information (by contract) to the appropriate MA organizations.

<sup>30</sup> 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).

<sup>31</sup> 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).

routinely used by HHS for recovery calculations,<sup>32</sup> results in a lower limit (the estimated overpayment amount to refund) that is designed to be less than the actual overpayment total 95 percent of the time.

Lastly, the coding accuracy rates that BCBST cited are not relevant to our decision to extrapolate. We made that decision based on the number of errors that we identified for sampled enrollee-years; this decision is in accordance with long-established OIG statistical sampling methodology.

## **BLUECROSS BLUESHIELD OF TENNESSEE DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S APPLICATION OF CMS REQUIREMENTS FOR CALCULATIONS OF OVERPAYMENTS**

### **BlueCross BlueShield of Tennessee Comments**

BCBST stated that our audit did not apply an adjustment called a Fee-for-Service Adjuster (FFSA) to ensure a payment principle known as “actuarial equivalence” between the MA and FFS programs. BCBST cited the provision of the Act that mandates that risk-adjusted payments be made in a manner that ensures actuarial equivalence between CMS payments for health care coverage under MA and CMS payments under Medicare’s traditional FFS program. BCBST stated that actuarial equivalence is a “core structural feature of the MA program” and that by not applying an FFSA, our audit would “hold the MA program to a different standard of coding accuracy” than does Medicare’s traditional FFS program.

### **Office of Inspector General Response**

We recognize that CMS is responsible for making operational and program payment determinations for the MA program, including the application of any FFSA requirements. Moreover, CMS has not issued any requirements that compel us to reduce our net overpayment calculations.<sup>33</sup> If CMS deems it appropriate to apply an FFSA when evaluating our recommendations, it will adjust our overpayment finding by whatever amount it determines

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<sup>32</sup> For example, HHS has used the two-sided 90-percent confidence interval when calculating recoveries in both the Administration for Child and Families and Medicaid programs. See e.g., *New York State Department of Social Services*, HHS Departmental Appeals Board (DAB) No. 1358, 13 (1992); *Arizona Health Care Cost Containment System*, DAB No. 2981, 4-5 (2019). In addition, HHS contractors rely on the one-sided 90-percent confidence interval, which is less conservative than the two-sided interval, for recoveries arising from Medicare FFS overpayments. See e.g., *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 17-18 (E.D.N.Y. 2012).

<sup>33</sup> In 2018, CMS proposed “not to include an FFS adjuster in any final RADV payment error methodology” (Proposed Rule at 83 Fed. Reg. 54982, 55041 (Nov. 1, 2018)). To BCBST’s point about actuarial equivalence, we reiterate that CMS has not issued any guidance that compels us to reduce our overpayment calculations.

necessary. Thus, we believe that the steps we followed in this audit provide a reasonable basis for our findings and conclusions, including our calculation of overpayments.<sup>34</sup>

## **BLUECROSS BLUESHIELD OF TENNESSEE DID NOT CONCUR WITH THE OFFICE OF INSPECTOR GENERAL'S RECOMMENDATION TO PERFORM ADDITIONAL REVIEWS BEFORE AND AFTER THE AUDIT PERIOD**

### **BlueCross BlueShield of Tennessee Comments**

BCBST did not concur with our second recommendation—that it perform additional reviews to determine whether similar instances of high-risk diagnoses occurred before or after the audit period—because that recommendation “goes beyond what the law requires and what OIG and CMS have recommended in the past.” Specifically, BCBST cited another Federal district court decision that “the Overpayment Rule” requires MA organizations like BCBST to return only “identified” overpayments (i.e., payments made as a result of diagnoses that the MA organization is aware are not supported in medical records).<sup>35, 36</sup> BCBST stated that our second recommendation constituted “constructive notice of an overpayment” and added that our audit would result in a “self-auditing mandate,” which “contravene[d] the holding” under the *UnitedHealthcare* ruling (footnote 28).

Additionally, BCBST stated that “neither CMS nor OIG” has recommended or required BCBST to review “100% of any specified diagnosis codes or achieve 100% accuracy in coding.” BCBST cited 42 CFR § 422.504, which requires MA organizations to certify the “accuracy, completeness and truthfulness” of risk-adjusted data based on “best knowledge, information, and belief.” To that end, BCBST cited subregulatory guidance from CMS that MA organizations cannot “reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the OIG, and DOJ believe is reasonable to enforce.”<sup>37</sup> BCBST also cited related

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<sup>34</sup> OIG audit findings and recommendations do not represent final determinations by CMS. Action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures. In accordance with 42 CFR § 422.311, which addresses audits conducted by the Secretary (including those conducted by the OIG), if a disallowance is taken, MA organizations have the right to appeal the determination that an overpayment occurred through the Secretary’s RADV appeals process.

<sup>35</sup> *UnitedHealthcare Ins. Co. v. Becerra*, No. 18-5326, 2021 WL 3573766 (D.C. Cir. Aug. 13, 2021). BCBST’s initial citation to this case (conveyed in footnote 2 of BCBST’s written comments at Appendix F of this report) alludes to the fact that UnitedHealthcare Ins. Co. was appealing the decision by the D.C. Circuit Court upholding CMS’s Overpayment Rule as well as holding that actuarial equivalence does not apply to this rule. BCBST posited in its written comments that the U.S. Supreme Court could reverse this D.C. Circuit Court ruling. The U.S. Supreme Court recently declined to hear UnitedHealthcare’s appeal of the August 2021 ruling upholding CMS’s Overpayment Rule.

<sup>36</sup> BCBST’s comments cited to 42 U.S.C §§ 1301-1320a-7. When an MA organization identifies overpayments, the Overpayment Rule requires that the MA organization must refund that payment within 60 days.

<sup>37</sup> 65 Fed. Reg. 40,170, 40,268 (Jun. 29, 2000).



subregulatory guidance that stated that MA organizations are encouraged to conduct only “sample audits and spot checks.”<sup>38</sup>

### **Office of Inspector General Response**

We do not agree with BCBST’s interpretation of the Federal requirements. Contrary to BCBST’s assertions, we maintain that our recommendation that BCBST review whether similar instances of high-risk diagnoses occurred before or after our audit period remains valid and conforms to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (Appendix D)).

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

Lastly, BCBST’s comments implied that we opined on its responsibilities to ensure 100-percent accuracy on 100 percent of the data submitted to CMS. That was not our intention or our focus for this audit. In this respect, we also disagree with BCBST that our recommendation contravened the Overpayment Rule. To accomplish our objective, we limited our review to selected diagnoses that we had (through data mining techniques and discussions with medical professionals) determined to be at higher risk of being miscoded. Our findings revealed a significant number of errors in most of these high-risk groups and as such, demonstrate that although BCBST has compliance procedures in place, we believe the types of errors we identified may extend to periods of time beyond our scope. Thus, our recommendation that BCBST identify any similar instances of noncompliance before or after our audit period is not, as BCBST suggested, a “constructive notice of overpayment.” Rather, we are recommending that BCBST identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred outside of our audit period and take corrective action.

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<sup>38</sup> 64 Fed. Reg. 61,893, 61,900 (Nov 15, 1999).

## **BLUECROSS BLUESHIELD OF TENNESSEE DID NOT CONCUR WITH THE OFFICE OF INSPECTOR GENERAL'S RECOMMENDATION TO ENHANCE ITS EXISTING COMPLIANCE PROGRAM**

### **BlueCross BlueShield of Tennessee Comments**

BCBST did not concur with our recommendation that it continue to examine its existing compliance procedures for diagnoses that are at high risk for being miscoded and enhance those procedures as necessary. Specifically, BCBST stated that it had “a robust compliance program” and that our recommendation implied that it should improve its compliance procedures by “undertaking one-way, 100% audits of diagnosis codes.” Additionally, BCBST stated that it “works continuously to improve its compliance program and will do so going forward. BCBST, however, does not believe that the approach recommended . . . would yield a methodological improvement.” Therefore, BCBST requested that we reconsider our third recommendation.

### **Office of Inspector General Response**

As stated earlier in this report, we acknowledge that BCBST performed routine internal medical reviews to compare diagnosis codes from a random sample of claims to the diagnoses that were documented on the associated medical records. However, we concluded that these internal medical reviews did not always focus on specific high-risk diagnosis codes and therefore could be improved. We reiterate, too, that at no point in this report do we specifically recommend that BCBST perform “one-way, 100% audits” of high-risk diagnosis codes.

The continued improvement of BCBST's policies and procedures, based on the results of this audit as well as the results of BCBST's internal medical reviews, will assist BCBST in attaining better assurance with regard to the “accuracy, completeness, and truthfulness” of the high-risk diagnosis codes that it submits in the future. Accordingly, we maintain that our third recommendation is valid.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

CMS paid BCBST \$1,841,305,786 to provide coverage to its enrollees for 2016 and 2017. We identified a sampling frame of 5,663 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2015 and 2016 service years. BCBST received \$78,718,093 in payments from CMS for these enrollee-years for 2016 and 2017. We selected for audit 270 enrollee-years with payments totaling \$4,134,994.

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 \$683,651 for our sample.

Our audit objective did not require an understanding or assessment of BCBST'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 September 2019 through September 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,
  - 36 diagnosis codes for acute heart attack,
  - 85 diagnosis codes for embolism,
  - 4 diagnosis codes for vascular claudication,
  - 29 diagnosis codes for major depressive disorder,
  - 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)<sup>39</sup> to identify enrollees who received high-risk diagnosis codes from a physician during the service years,
    - Risk Adjustment System (RAS)<sup>40</sup> to identify enrollees who received an HCC for the high-risk diagnosis codes,
    - Medicare Advantage Prescription Drug System (MARx)<sup>41</sup> to identify enrollees for whom CMS made monthly Medicare payments to BCBST, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C),
    - Encounter Data System (EDS)<sup>42</sup> to identify enrollees who received specific procedures, and
    - Prescription Drug Event (PDE) file<sup>43</sup> to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.
  - We interviewed BCBST officials to gain an understanding of: (1) the policies and procedures that BCBST followed to submit diagnosis codes to CMS for use in the risk-adjustment program and (2) BCBST’s monitoring of those diagnosis codes to identify and detect noncompliance with Federal requirements.
  - We selected for audit a stratified random sample of 270 enrollee-years (Appendix C).

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<sup>39</sup> MA organizations use the RAPS to submit diagnosis codes to CMS.

<sup>40</sup> The RAS identifies the HCCs that CMS factors into each enrollee’s risk score calculation.

<sup>41</sup> The MARx identifies the payments made to MA organizations.

<sup>42</sup> The EDS contains information on each item (including procedures) and service provided to enrollees.

<sup>43</sup> 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.<sup>44</sup>
- 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 BCBST during the audit period.
- We discussed the results of our audit with BCBST officials.

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

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<sup>44</sup> 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.

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**

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS</i>	<a href="#"><u>A-09-20-03009</u></a>	9/13/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc., (Contract H1032) Submitted to CMS</i>	<a href="#"><u>A-04-19-07084</u></a>	8/29/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS</i>	<a href="#"><u>A-03-18-00002</u></a>	8/19/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS</i>	<a href="#"><u>A-02-20-01009</u></a>	7/18/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health Network (Contract H1961) Submitted to CMS</i>	<a href="#"><u>A-06-18-05002</u></a>	5/25/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS</i>	<a href="#"><u>A-01-19-00500</u></a>	2/14/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS</i>	<a href="#"><u>A-07-17-01169</u></a>	2/3/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS</i>	<a href="#"><u>A-02-18-01029</u></a>	1/5/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS</i>	<a href="#"><u>A-07-19-01188</u></a>	11/5/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS</i>	<a href="#"><u>A-07-17-01173</u></a>	10/28/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS</i>	<a href="#"><u>A-07-19-01187</u></a>	5/21/2021
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS</i>	<a href="#"><u>A-07-16-01165</u></a>	4/19/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS</i>	<a href="#"><u>A-02-18-01028</u></a>	2/24/2021

Report Title	Report Number	Date Issued
<i>Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements</i>	<a href="#">A-07-17-01170</a>	4/30/2019



## APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

### SAMPLING FRAME

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

We presented the data for these enrollees to BCBST for verification and performed an analysis of the data included on CMS's systems to ensure that the high-risk diagnosis codes increased CMS's payments to BCBST. After we performed these steps, our finalized sampling frame consisted of 5,663 enrollee-years.

### SAMPLE UNIT

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

### SAMPLE DESIGN AND SAMPLE SIZE

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

- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on only one physician claim during the service year but did not have that diagnosis on a corresponding inpatient or outpatient hospital claim (1,453 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 (577 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 (350 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 (582 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 (947 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 (171 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 (747 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 (284 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 (552 enrollee-years).

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

**Table 4: Sample Design for Audited High-Risk Groups**

<b>Stratum (High-Risk Groups)</b>	<b>Frame Count of Enrollee- Years</b>	<b>CMS Payment for HCCs in Audited High-Risk Groups</b>	<b>Sample Size</b>
1 – Acute stroke	1,453	\$2,986,294	30
2 – Acute heart attack	577	1,032,945	30
3 – Embolism	350	899,983	30
4 – Vascular claudication	582	1,257,285	30
5 – Major depressive disorder	947	2,373,347	30
6 – Lung cancer	171	1,229,632	30
7 – Breast cancer	747	891,504	30
8 – Colon cancer	284	673,981	30
9 – Prostate cancer	552	666,424	30
<b>Total</b>	<b>5,663</b>	<b>\$12,011,395</b>	<b>270</b>

**SOURCE OF RANDOM NUMBERS**

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

**METHOD FOR SELECTING SAMPLE ITEMS**

We sorted the items in each stratum by beneficiary identification number, 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 BCBST 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**

<b>Audited High-Risk Groups</b>	<b>Frame Size</b>	<b>CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)</b>	<b>Sample Size</b>	<b>CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)</b>	<b>Number of Sampled Enrollee-Years With Unvalidated HCCs</b>	<b>Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)</b>
1 – Acute stroke	1,453	\$2,986,294	30	\$59,904	29	\$57,485
2 – Acute heart attack	577	1,032,945	30	55,410	30	48,573
3 – Embolism	350	899,983	30	84,292	28	79,908
4 – Vascular claudication	582	1,257,285	30	64,635	5	11,943
5 – Major depressive disorder	947	2,373,347	30	76,786	7	17,094
6 – Lung cancer	171	1,229,632	30	203,625	26	149,289
7 – Breast cancer	747	891,504	30	33,840	30	33,905
8 – Colon cancer	284	673,981	30	66,097	28	57,906
9 – Prostate cancer	552	666,424	30	39,062	27	35,166
<b>Totals</b>	<b>5,663</b>	<b>\$12,011,395</b>	<b>270</b>	<b>\$683,651</b>	<b>210</b>	<b>\$491,269</b>

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

Point Estimate	\$8,312,368
Lower Limit	\$7,784,540
Upper Limit	\$8,840,196

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

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

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

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

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

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

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

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

(3) Implement the operation of the compliance program;

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

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

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

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

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

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

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

## APPENDIX F: BLUECROSS BLUESHIELD OF TENNESSEE COMMENTS

May 6, 2022

James Korn  
Regional Inspector General  
for Audit Services  
601 East 12th Street, Room 0429  
Kansas City, MO 64106

Re: *Comments on U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), draft Report Number A-07-19-01195, entitled “Medicare Advantage Compliance Audit of Specific Diagnosis Codes that BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS”*

Dear Mr. Korn,

BlueCross BlueShield of Tennessee, Inc. (BCBST or We) appreciates the opportunity to comment on OIG’s draft audit report about diagnosis codes that BCBST submitted to the Centers for Medicare & Medicaid Services (CMS) in BCBST’s capacity as a Medicare Advantage Organization (MAO) participating in the Medicare Advantage (MA) program.

BCBST is a taxpaying not-for-profit organization that is dedicated to partnering with the best health care providers to give Medicare beneficiaries access to quality, affordable care. CMS recognized the quality of our MA products by awarding us a rating of 4.5 stars in 2021. We remain fully committed to serving Medicare beneficiaries and support OIG’s mission of promoting the economy, efficiency, effectiveness, and integrity of HHS programs, including MA. Our approach with HHS and its divisions has always been collaborative, and we strive to maintain that collaboration in all our interactions.

To that end, although we support OIG’s mission, we have significant concerns about OIG’s draft report. We want to be transparent about those concerns so that OIG may give them due consideration prior to finalizing the report. We believe that transparency will further our mission of providing access to quality, affordable care and also assist OIG and other federal agencies in making better-informed decisions about the MA program.

OIG’s stated objective for the audit “was to determine whether *selected* diagnosis codes that BCBST submitted to CMS for use in CMS’s risk adjustment program complied with Federal requirements.” Draft Report at p.1 (emphasis added). OIG used data mining to select diagnosis codes that OIG deems high risk, identified BCBST enrollees with those diagnosis codes in their records, took a random sample of those enrollees’ records, and looked at the portions of the payments BCBST associated with the codes. Based on its review of the targeted diagnosis codes, OIG extrapolated and recommended that BCBST return an alleged overpayment of \$7.8 million. In addition, OIG recommended that BCBST apply the same methodology on a larger scale to identify and return more alleged overpayments, and that BCBST make changes to its compliance program to address OIG’s concerns about the diagnosis codes.

BCBST concurs in part, and non-concurs in part, with OIG’s draft recommendation that BCBST return payments associated with the selected diagnosis codes in the audit sample. BCBST



agrees that some of the selected diagnosis codes in the audit sample are unsupported and will return the payments associated with those unsupported codes in the audit sample. BCBST respectfully non-concurs and requests that OIG reconsider the remainder of its draft recommendations for the reasons stated below.

We begin our comments by outlining the methodological problems that we see in the draft report, and the unintended consequences that we fear will result from finalizing the draft report as written. Then we address each of OIG's draft recommendations to BCBST.

*1. The draft report has major methodological problems and the finalization of the report as drafted may have unintended consequences for the MA program*

The finalization of the draft report as written would present three major methodological problems. *First*, it would stray from the spirit of the law in some ways, while contravening the law in others.

OIG conducted the audit under the Inspector General Act of 1978 (IGA). The IGA does not authorize OIG to extrapolate and recover overpayments through audits. OIG would nonetheless exercise its audit authority by applying a risk adjustment audit methodology that differs from that used by CMS in its administration of the MA program, and making recommendations to BCBST about the identification and return of alleged overpayments thereunder. Any adoption of the OIG's separate methodology not only would require substantial time and resources to implement on the scale envisioned by OIG but would also require the concurrent application of two distinct and arguably conflicting risk adjustment-related methodologies. BCBST respectfully submits that the finalization of the draft report as written would stray from the spirit of the IGA because it would use the audit process as a tool for making major changes to a CMS-administered program.<sup>1</sup>

The OIG's proposed audit methodology would also contravene the holding by the U.S. Court of Appeals for the District of Columbia Circuit in *UnitedHealthcare Insurance Company v. Becerra*, 16 F.4th 867, 884 (D.C. Cir. 2021), that the "the Overpayment Rule only requires insurers to refund amounts they know were overpayments, i.e., payments they are aware lack support in a beneficiary's medical records." The D.C. Circuit expressly held that such "limited scope does not impose a self-auditing mandate." *Id.* But the OIG's finalization of its draft audit methodology and recommendations would set up a "self-auditing mandate" for the codes selected by OIG, which is not required under *UnitedHealthcare*.

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<sup>1</sup> OIG has noted in other reports that the IGA permits OIG to make recommendations. But that misses the larger point, which is that Congress did not contemplate the use of the audit authority in the IGA as an indirect mechanism for making major changes to CMS programs outside of ongoing notice-and-comment rulemaking. Congress "does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Associations, Inc.*, 121 S.Ct. 903, 910 (2001). If Congress had wanted OIG to have the independent authority to make major changes to CMS programs, then Congress would have said so expressly in the IGA. Congress did not.

Second, the draft audit methodology and recommendations are one-sided and inconsistent with the principles applied by CMS in its administration of the Risk Adjustment Data Validation (RADV) Program for MA as well as the U.S. Department of Justice (DOJ) in litigation against MAOs under the federal False Claims Act (FCA).

CMS, under a RADV Program audit, takes a random sample of enrollee records and does a two-way record review. That is, CMS looks at all the diagnosis codes in each record to determine which were correct, and which were not. The incorrect codes translate into an error rate.

Similarly, DOJ has successfully argued in court that retrospective record reviews that are one-sided because they look only for supported yet missed diagnosis codes (to be added to an enrollee's risk profile) are a basis for FCA liability because such reviews deliberately avoid looking for incorrect diagnosis codes (that should be removed from the enrollee's risk profile). See *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161 (9th Cir. 2016) (“[W]e hold that when, as alleged here, [MAOs] design retrospective reviews of enrollees' medical records deliberately to avoid identifying erroneously submitted diagnosis codes that might otherwise have been identified with reasonable diligence, they can no longer certify, based on best knowledge, information and belief, the accuracy, completeness and truthfulness of the data submitted to CMS.”) DOJ's basic critique has been that a sound review is one that looks for both missing claims to be submitted as well as incorrectly submitted codes that should be removed.

The OIG's draft audit methodology is a form of one-way review that DOJ and CMS have not embraced in court or the RADV Program, respectively. The OIG begins with a preordained conclusion about selected diagnosis codes and then applies criteria designed to validate that conclusion. It does not look at all diagnosis codes for each record in an audit sample that has been selected completely at random. The critiques of one-way reviews and the use of two-way reviews by DOJ and CMS, respectively, demonstrate that the OIG's draft audit methodology and parallel recommendations to BCBST are methodologically unsound.

Third, the draft audit methodology and recommendations do not apply a fee-for-service adjuster to ensure actuarial equivalency between the MA and Medicare fee-for-service programs, which is a core structural feature of the MA program. See 42 U.S.C. § 1395w-23(a)(1)(C)(i) (“... the Secretary shall adjust the payment amount ... for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate ... so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.”)<sup>2</sup> In other words, the OIG compounds the bias inherent in its one-way review by then failing to adjust the error rate in relation to the coding that occurs in the Medicare fee-for-service program,

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<sup>2</sup> BCBST agrees with the view of the appellants in *UnitedHealthcare Ins. Co. v. Becerra*, S. Ct. No. 21-1140, that the holding by the D.C. Circuit that the actuarial equivalency mandate is inapplicable to the statute's overpayment provision rests on a misreading of the statute and should be reversed. The funds to which an MAO is entitled can only be determined by applying the statutory requirement of actuarial equivalence. If the Supreme Court grants the appellants' petition for a writ of certiorari and reverses the D.C. Circuit, then OIG's draft audit methodology and recommendations will be not only methodologically unsound but also contrary to case law.

Mr. Korn  
Regional Inspector General for Audit Services  
May 6, 2022

consistent with how Congress designed the program. The finalization of the OIG’s draft methodology and recommendations would hold the MA program to a different standard of coding accuracy than the Medicare fee-for-service program against which the MA program is judged.

These and other methodological problems discussed below present serious concerns for BCBST given the strong CMS measures of BCBST’s diagnosis coding in recent years:

<u>Assessment</u>	<u>Audit Confirmation Rate</u>
2015 National Risk Adjustment Data Validation Audit	96%
2016 National Risk Adjustment Data Validation Audit	100%
2017 National Risk Adjustment Data Validation Audit	100%
Part C Improper Payment Measure (IPM) – Calendar Year 2018	100%
Part C Improper Payment Measure – Calendar Year 2019	97%

BCBST attributes these high marks partly to its good-faith efforts for accurate and complete coding and substantial investments of resources over many years in a compliance program that aligns with the CMS methodology for the RADV Program. As the OIG recognized in its draft report, the BCBST compliance program includes robust provider education on appropriate coding practices as well as retrospective, two-way record reviews for all diagnosis codes. BCBST does not limit its review to supported but missed diagnosis codes, or diagnosis codes that the OIG deems high-risk. BCBST (like CMS) looks both ways at all diagnosis codes. *See Draft Report at p. 17.*

OIG would nevertheless recommend that BCBST refund \$7.8 million and begin conducting one-way, 100% reviews of selected codes, based on findings of inaccuracies that OIG made through its own one-way review of the codes. Such an approach would turn sharply and abruptly away from CMS’s operation of the MA program that has guided the good-faith efforts and substantial investments by BCBST over many years. BCBST believes that OIG’s finalization of the draft report as written would have the unintended consequence of increasing the regulatory uncertainty for BCBST as a result of different agencies applying two arguably inconsistent methodologies. Any adoption of multiple methodologies would divert resources away from core functions (including existing, demonstrably effective compliance work). BCBST urges OIG to weigh such risks for the MA program as a whole before OIG finalizes its report.

2. *BCBST concurs that certain diagnosis codes in the audit sample were unsupported and agrees to refund the associated payments*

OIG asserts that “for 212 of the 270 sampled enrollee-years, the medical records that BCBST provided did not support the diagnosis codes and resulted in \$493,405 in overpayments.” Draft Report in Brief – Draft. BCBST concurs that the diagnosis codes from most of the 212 sampled enrollee-years were unsupported, but requests that OIG reconsider its findings regarding the medical record support for diagnosis codes in 14 of the sampled enrollee-years. We have attached a table that identifies the 14 samples, OIG’s findings, and our responses.

BCBST respectfully submits that OIG read some medical records incorrectly, while rejecting other medical records on technical grounds. We believe that OIG's rejections of medical records on technical grounds were contrary to CMS regulations and guidance for the MA Program, and unduly harsh given that BCBST exhausted all reasonable efforts to satisfy OIG.

CMS requires MAOs to ensure that their contracts with providers contain "accountability provisions." 42 C.F.R. § 422.504(d)(2). The accountability provisions include a requirement that the provider will maintain "records" for a minimum timeframe of 10 years. Additionally, MAOs and their providers are required to submit a sample of medical records for use in validating risk adjustment data. 42 C.F.R. § 422.310(e). When there is an audit, "the *MAO must request* medical records from hospitals (for Hospital Inpatient and Hospital Outpatient records) and physicians/practitioners (for Physician records) that provided services to the selected enrollees." CMS, Contract-Level Risk Adjustment Data Validation, Medical Record Reviewer Guidance, at 6 (emphasis added). BCBST fully satisfied these obligations: BCBST ensured that its provider contracts included accountability provisions and requested medical records from all providers. Its only due to unfortunate circumstances outside of BCBST's control and due to the multi-year lag between the medical records' creation and the audit that made BCBST unable to obtain addenda to or transcriptions of the records for OIG.

Sample #139 / Chart Submission 139-01-PHY is one example. OIG noted that "HCC 108 was documented in the medical record but could not be substantiated due to a lack of provider signature." BCBST contacted the provider to obtain a signature. Unfortunately, in the five years since the date of service, the provider's office closed. BCBST cannot control when or whether a provider closes their office. Yet that is the standard the OIG would enforce here.

In another example, OIG found that "diagnosis code (C61) [was] listed in the assessment without a diagnosis narrative." Sample #250 / Chart Submission 250-01-PHY. OIG requested an attestation for the signature because the note was handwritten. BCBST asked the provider for an attestation and got one. OIG then asked for a full transcription. Unfortunately, the office was unable to provide a transcription because the date of service occurred before the office employed an electronic medical record system. OIG would treat the coding as unsupported notwithstanding BCBST's reasonable efforts in furtherance of the OIG's request and the technological limitations of the provider.

As stated above, BCBST concurs with the balance of OIG's recommendation related to the specific unsupported diagnosis codes in the audit sample and agrees to return the payments associated with those particular codes in the audit sample.

3. *BCBST requests that OIG reconsider its draft recommendation that BCBST return an extrapolated overpayment of \$7.8 million based on the audit sample*

BCBST, building on the broad methodological critiques made above in Section 1, requests that OIG reconsider its draft recommendation that BCBST return an extrapolated overpayment of \$7.8 million because that recommendation departs from the spirit of the IGA and is rooted in an unsound audit methodology.

As BCBST explained in Section 1, OIG lacks the statutory authority to extrapolate and recover the alleged overpayment of \$7.8 million from BCBST. BCBST respectfully submits that use of the IGA audit authority to back into an outcome that Congress never contemplated would depart from the spirit of the IGA. This is especially true when the proper use of extrapolation in the MA program is a core issue in the pending CMS rulemaking on RADV audits. The better mechanism for setting HHS policy on the use of extrapolation in the MA program is notice-and-comment rulemaking by CMS, not an audit under the IGA.

Regardless, OIG's draft recommendation still turns on a retrospective, one-way review of selected diagnosis codes that lacks a fee-for-service adjuster (and therefore departs from how Congress designed and CMS operates the MA program). These methodological problems are glaring when the OIG's draft findings are compared against BCBST's accuracy rates under CMS measures, which have ranged from 96% to 100% since 2015. The stark contrast between the CMS measures and OIG's draft findings is a sure sign that any extrapolation would be unreliable and reflect only the structural bias in the draft audit methodology.

The draft audit methodology also has more particularized features that amplify the broad structural bias against MAOs and likewise cut against extrapolation. OIG, for example, uses the lower bound of a 90% confidence interval to calculate its extrapolated overpayment amount, rather than the statistically valid and more common lower bound of a 95% or 99% confidence interval (which CMS uses in RADV audits). In addition, OIG relies on a physician "tiebreaker" in the event two coders disagree whether a diagnosis code on the medical record supports the hierarchical condition category (HCC). Draft Report at p. 20. That is, if OIG's first coder does not find support on a particular medical record, but the second coder does, "then a physician independently review[s] the medical record to make the final determination." *Id.* CMS takes the exact opposite approach; if two coders disagree in a RADV audit, and the second coder finds that the medical record substantiates a diagnosis code that maps to the HCC, then CMS treats the HCC as substantiated. *See* CMS, Risk Adjustment Data Validation (RADV) Medical Record Intake Process and Guidance To Coders CY2011 ver. 4.0, at 18-19 (May 8, 2014). If OIG applied the same rules as CMS, then the extrapolated overpayment would probably be lower (setting aside the broader structural flaws of one-way review and lack of a fee-for-service adjuster). The MAO should receive the benefit of the doubt in any extrapolation, not vice-versa; this seems particularly appropriate given the OIG's recognition that BCBST maintains policies and procedures intended to prevent, detect and correct noncompliance with CMS's program requirements.

OIG should reconsider its draft methodology and recommend the return of an extrapolated overpayment only if a new and reliable methodology supports the recommendation.

4. *BCBST requests that OIG reconsider its draft recommendation that BCBST audit the selected diagnosis codes for the time before and after OIG's audit period*

BCBST requests that OIG reconsider its draft recommendation on auditing because it goes beyond what the law requires and what OIG and CMS have recommended in the past.

As discussed above, the finalization of the draft recommendation would contravene the holding in *UnitedHealthcare* that the “the Overpayment Rule only requires [MAOs] to refund amounts they know were overpayments, *i.e.*, payments [the MAOs] are aware lack support in a beneficiary’s medical records,” and that such “limited scope does not impose a self-auditing mandate.” 16 F.4th at 884. The finalization of the draft audit methodology and recommendations would set up a “self-auditing mandate” for the codes selected by OIG, which is not required under *UnitedHealthcare*.

The finalization of OIG’s draft recommendation would also be inconsistent with the vacatur in *UnitedHealthcare* of the section of the Overpayment Rule that defined the term “identified” in the overpayment statute at 42 U.S.C. § 1320a-7k(d)(2)(A). The regulatory definition stated that a “MAO has identified an overpayment when the [MAO] has determined *or should have determined through the exercise of reasonable diligence*, that the [MAO] has received an overpayment.” 42 C.F.R. § 422.326(c) (emphasis added). The district court vacated that definition because it exposed MAOs to FCA liability under a negligence standard where the FCA requires a higher level of intent. *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 190 (D.D.C. 2018). DOJ, for the United States, did not contest the vacatur on appeal, and the district court recently entered final judgment against the United States on the issue.

OIG’s treatment of its recommendation as constructive notice of an overpayment for all claims outside the audit sample would be contrary to the acceptance of the vacatur of the reasonable diligence standard in *UnitedHealthcare*. Plus, the recommendation would be unreasonable to implement. The underlying methodology has major problems, as described herein, and OIG has not provided information about a single overpayment outside its own audit sample. The implementation would also require an overpayment review process that departs materially from how CMS administers the MA program and CMS’s expectations for MAOs.

Indeed, neither CMS nor OIG has previously recommended, much less required, that BCBST review 100% of any specified diagnosis codes or achieve 100% accuracy in coding. In fact, CMS requires that the CEO or CFO of BCBST or their delegate certify the “accuracy, completeness, and truthfulness” of BCBST’s risk adjustment data based on “best knowledge, information, and belief.” 42 C.F.R. § 422.504(l). CMS has explained that BCBST cannot “reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the OIG, and DOJ believe is reasonable to enforce.” Medicare Program: Medicare+Choice Program, 65. Fed. Reg. 40,268 (June 29, 2000).

OIG has similarly stated that “[t]he requirement that the CEO or CFO certify as to the accuracy, completeness and truthfulness of [risk adjustment] data, based on best knowledge, information and belief, does not constitute an absolute guarantee of accuracy.” Publication of the OIG’s Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans, 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999). Consistent with that statement, OIG has encouraged MAOs conduct “sample audits and spot checks.” *Id.* Now OIG is proposing to change course and recommend that BCBST conduct a one-way review of 100% of all enrollee years for OIG-selected diagnosis codes.

Data perfection has never been the standard in the MA program, and it is not the standard today, even for selected diagnosis codes. OIG should reconsider its draft audit methodology and recommendations, as they would depart from the law and historical program operations.

5. *BCBST requests that OIG reconsider its draft recommendation that BCBST improve its compliance program by conducting one-way reviews*

As discussed above, OIG found in its draft report that BCBST has a robust compliance program, yet nevertheless asserts that BCBST should improve the program by undertaking one-way, 100% audits of diagnosis codes selected by OIG:

Additionally, BCBST's compliance procedures included routine internal medical reviews to compare diagnosis codes from a random sample of claims to the diagnoses that were documented on the associated medical records. Because these internal medical reviews involved random sampling, they did not necessarily focus on specific high-risk diagnosis codes, including those we identified as being at a higher risk for being miscoded.

We therefore concluded that BCBST's compliance procedures to prevent, detect, and correct miscoded high-risk diagnoses during our audit period could be improved.

Draft Report at p. 17.

BCBST works continuously to improve its compliance program and will do so going forward. BCBST, however, does not believe that the approach recommended by OIG would yield a methodological improvement for all of the reasons explained above. BCBST respectfully requests that OIG reconsider its draft recommendation for the same reasons that BCBST has asked OIG to reconsider its other draft recommendations.

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BCBST is fully committed to serving Medicare beneficiaries in a compliant matter and maintaining a collaborative relationship with HHS and its divisions. We present our views on OIG's draft report with the intent of helping OIG and other stakeholders make better-informed decisions about the MA program. The finalization of the draft report as written may have unintended consequences. We urge OIG to weigh those consequences and reconsider its draft report.

Mr. Korn  
Regional Inspector General for Audit Services  
May 6, 2022

Sincerely,

/ J o s e p h T o d d R a y /

Todd Ray, Senior Vice President, BCBST

cc: Anne W. Hance, Senior Vice President and General Counsel, BCBST