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Medicare Advantage Compliance Audit of Specific Diagnosis Codes Blue Care Network of Michigan (Contract H5883) Submitted to CMS

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Why OIG Did This Audit

- Under the Medicare Advantage (MA) program, CMS makes monthly payments to MA organizations based in part on the health status of the enrollees being covered.

- To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from its providers and submit these codes to CMS. Some diagnoses are at 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 high-risk diagnosis codes that MA organizations submitted to CMS for use in its risk adjustment program.

What OIG Found

Blue Care Network of Michigan (BCN) did not submit most of the selected high-risk diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements.

- For 192 of the 210 sampled enrollee-years, either the medical records that BCN provided did not support the diagnosis codes, or BCN could not locate the medical records to support the diagnosis codes, which resulted in $542,164 in overpayments.
- On the basis of our sample results, we estimated that BCN received at least $6.4 million in overpayments for 2017 and 2018.

As demonstrated by the errors found in our sample, BCN's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. Due to Federal regulations that limit the use of extrapolation for recovery purposes to 2018 and forward, we limited our recommended recovery to $3.4 million.

What OIG Recommends

We recommend that BCN:

1. refund to the Federal Government the $3.4 million of estimated overpayments;
2. identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
3. continue to examine its 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.

BCN did not agree with our findings or with our recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

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

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS.[2] Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 65 breast cancer diagnoses into 1 group.) This audit covered Blue Care Network of Michigan (BCN), for contract number H5883, and focused on seven groups of high-risk diagnosis codes for payment years 2017 and 2018.[3]

OBJECTIVE

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

BACKGROUND

Medicare Advantage Program

The MA program offers people eligible for Medicare managed care options by allowing them to enroll in private health care plans rather than having their care covered through Medicare's

[1] The providers code diagnoses using the International Classification of Diseases (ICD), Clinical Modification (CM), *Official Guidelines for Coding and Reporting* (ICD Coding Guidelines). The ICD is a coding system that is used by physicians and other health care providers to classify and code all diagnoses, symptoms, and procedures.

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

[3] All subsequent references to "BCN" in this report refer solely to contract number H5883.

traditional fee-for-service program.[4] Individuals who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

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

For 2022, CMS paid MA organizations $403.3 billion, which represented 45 percent of all Medicare payments for that year.

Risk Adjustment Program

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

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

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

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

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

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

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

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

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

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

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

CMS multiplies the risk scores by the base rates to calculate the total monthly Medicare payment that an MA organization receives for each enrollee before applying the budget sequestration reduction.[9] Thus, if the factors used to determine an enrollee's risk score are incorrect, CMS will make an improper payment to an MA organization. Specifically, if medical records do not support the diagnosis codes that an MA organization submitted to CMS, the HCCs are not validated, which causes overstated enrollee risk scores and overpayments from

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

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

CMS.[10] Conversely, if medical records support the diagnosis codes that an MA organization did not submit to CMS, validated HCCs may not have been included in enrollees' risk scores, which may cause those risk scores to be understated and may result in underpayments.

High-Risk Groups of Diagnoses

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

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

- *Acute myocardial infarction*: An enrollee received one diagnosis that mapped to the HCC for Acute Myocardial Infarction on only one physician or outpatient claim during the service year but did not have an acute myocardial infarction 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 myocardial infarction (which does not map to an HCC) typically should have been used.

- *Embolism*: An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease With Complications (Embolism HCCs) on only one claim during the service year but did not have an anticoagulant medication dispensed on 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.

- *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.

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

- *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 before or after the diagnosis. In these instances, a diagnosis of history of prostate cancer (which does not map to an HCC) typically should have been used.

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

BLUE CARE NETWORK OF MICHIGAN

BCN is an MA organization based in Detroit, Michigan. As of December 2018, BCN provided coverage under contract number H5883 to 89,889 enrollees. For the 2017 and 2018 payment years (audit period), CMS paid BCN approximately $1.7 billion to provide coverage to its enrollees.[11, 12]

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of the seven high-risk groups during the 2016 and 2017 service years, for which BCN received increased risk-adjusted payments for payment years 2017 and 2018, respectively. Because enrollees could be classified into more than one high-risk group or could have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to their condition and the payment year, which we refer to as "enrollee-years."

[11] The 2017 and 2018 payment year data were the most recent data available at the start of the audit.

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

We identified 3,438 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes ($7,456,645).[13] We selected for audit a stratified random sample of 210 enrollee-years as shown in Table 1.

Table 1: Sampled Enrollee-Years
(Strata for Sample Design Based on High-Risk Groups)

High Risk Group	Number of Sampled Enrollee Years		
	Payment Year 2017	**Payment Year 2018**	**Total**
1. Acute stroke	19	11	30
2. Acute myocardial infarction	17	13	30
3. Embolism	17	13	30
4. Lung cancer	16	14	30
5. Breast cancer	15	15	30
6. Colon cancer	18	12	30
7. Prostate cancer	11	19	30
8. **Total for All High-Risk Groups**	**113**	**97**	**210**

BCN provided medical records as support for the selected diagnosis codes associated with 181 of the 210 sampled enrollee-years.[14] 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 (GAGAS). 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.

[13] The 3,438 unique enrollee-years and associated payments that we reviewed consisted of 1,707 enrollee-years ($3,689,790) for payment year 2017 and 1,731 enrollee-years ($3,766,855) for payment year 2018.

[14] BCN could not locate medical records for the remaining 29 sampled enrollee-years.

FINDINGS

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that BCN submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 18 of the 210 sampled enrollee-years, the medical records validated the reviewed HCCs. For the remaining 192 enrollee-years, however, either the medical records that BCN provided did not support the diagnosis codes or BCN could not locate the medical records to support the diagnosis codes, and the associated HCCs were therefore not validated and resulted in $542,164 in overpayments.

As demonstrated by the errors found in our sample, BCN'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 BCN received at least $6,485,972 in overpayments for 2017 and 2018.[15] Because of Federal regulations that limit the use of extrapolation in Risk Adjustment Data Validation (RADV) audits for recovery purposes to payment year 2018 and forward, we are reporting the overall estimated overpayment amount but are recommending a refund of $3,412,369 in overpayments ($312,286 for the sampled enrollee-years from 2017 and an estimated $3,100,083 for 2018).[16]

FEDERAL REQUIREMENTS

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

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

Federal regulations also state that MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes and that

[15] To be conservative, we estimate overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

[16] CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643 (Feb. 1, 2023)). Therefore, for sampled enrollee-years from payment year 2017, we limited our calculation of overpayments to the financial impact associated with these enrollee-years. For sampled enrollee-years from payment year 2018, we used the financial impact associated with the enrollee-years to estimate the total amount of overpayments for that year. See also footnotes 25 and 38 later in this report.

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). (See 42 CFR § 422.504(a).)

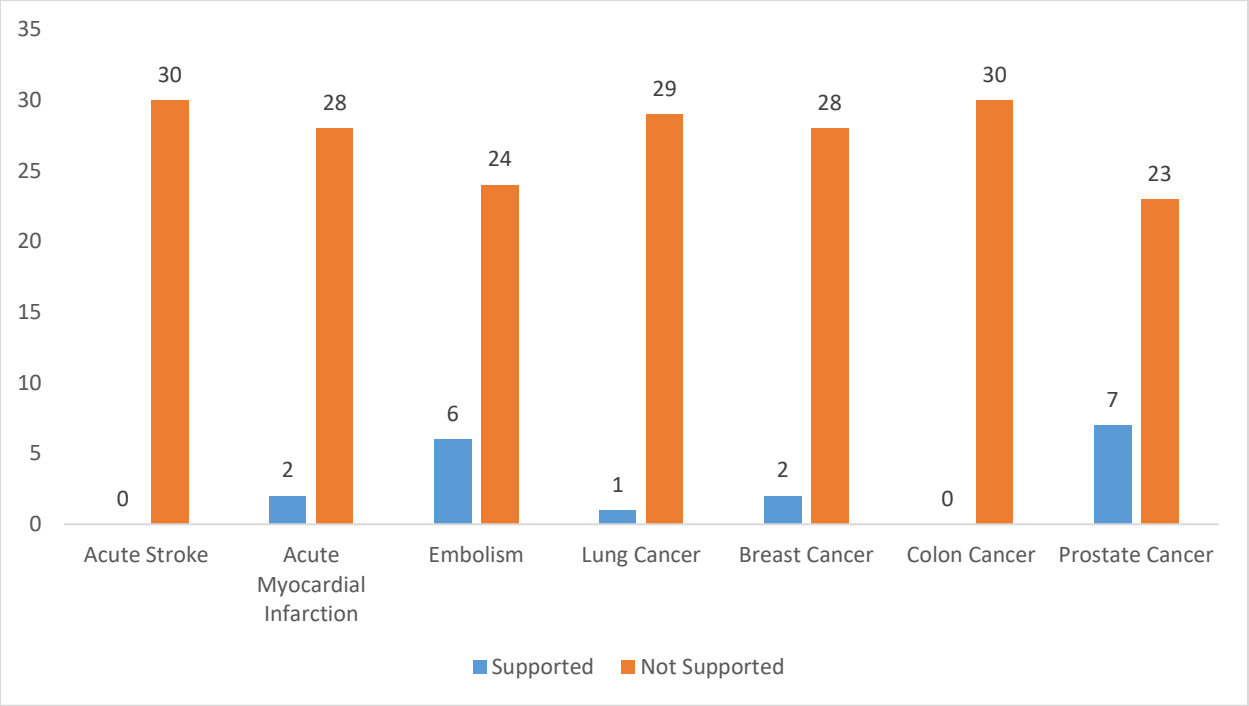
CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chapter 7 (last revised Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face encounter (the Manual, chapter 7, § 40). The diagnosis must be coded according to the International Classification of Diseases (ICD), Clinical Modification (CM), *Official Guidelines for Coding and Reporting* (ICD Coding Guidelines) (42 CFR § 422.310(d)(1) and 45 CFR §§ 162.1002(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, chapter 7, § 40).

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

MOST OF THE SELECTED HIGH-RISK DIAGNOSIS CODES THAT BLUE CARE NETWORK OF MICHIGAN SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Most of the selected high-risk diagnosis codes that BCN submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, as shown in the figure on the following page, the medical records for 192 of the 210 sampled enrollee-years did not support the diagnosis codes or BCN could not locate the medical records to support the diagnosis codes. In these instances, BCN 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

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

- For 19 enrollee-years, the medical records indicated in each case that the individual had previously had a stroke, but the records did not justify an acute stroke diagnosis at the time of the physician's service.

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

- For 6 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.

[17] Residuals, or sequelae, are the late effects of an injury that can occur only after the acute phase of the injury or illness has passed.

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] HCC [for Ischemic or Unspecified Stroke] or a related HCC.

- For 1 enrollee-year, BCN submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiplegia (which was supported in the medical records).[18] For this enrollee-year, the independent medical review contractor stated that "there is no evidence of an acute stroke, however the patient has hemiplegia from an old stroke . . . [which] would result in the assignment of [the] HCC [for Hemiplegia/Hemiparesis] which should have been assigned instead of the submitted HCC." This error caused an overpayment.[19]

- For the remaining 4 enrollee-years, BCN in each case could not locate any medical records to support the acute stroke diagnosis; therefore, the HCC for Ischemic or Unspecified Stroke was not validated.[20]

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and BCN received $64,331 in overpayments ($39,696 for 2017 and $24,635 for 2018) for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Myocardial Infarction

BCN incorrectly submitted diagnosis codes for acute myocardial infarction for 28 of 30 sampled enrollee-years. Specifically:

- For 8 enrollee-years, the medical records in each case did not support an acute myocardial infarction diagnosis.

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

[19] The identification of the hemiplegia diagnosis affected this enrollee-year's risk score in two ways. First, as stated above, the HCC for Hemiplegia/Hemiparesis should have been used instead of the HCC for Ischemic or Unspecified Stroke. Second, the HCC for Hemiplegia/Hemiparesis is a more severe manifestation of another related-disease group. Accordingly, including the Hemiplegia/Hemiparesis HCC results in removing the less severe manifestation HCC (Monoplegia, Other Paralytic Syndromes, which had been included in the risk score). These affects caused an overpayment for this enrollee-year.

[20] 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, chapter 7, §§ 40 and 120.1)). For 1 of these enrollee-years, the documentation that BCN submitted did not reflect a face-to-face visit or any type of encounter. Because this record did not meet CMS's requirements for acceptable data sources, the reviewed HCC was not validated (Footnote 14).

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 HCC [for Acute Myocardial Infarction]."

- For 9 enrollee-years, the medical records indicated in each case that the individual had an old myocardial infarction diagnosis, but the records did not justify an acute myocardial infarction diagnosis at the time of the physician's service.[21]

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

- For 6 enrollee-years, the medical records did not support an acute myocardial infarction diagnosis. 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, BCN should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the other diagnosis identified.

- For the remaining 5 enrollee-years, BCN in each case could not locate any medical records to support the acute myocardial infarction diagnosis; therefore, the HCC for Acute Myocardial Infarction was not validated.[22]

As a result of these errors, the HCC for Acute Myocardial Infarction was not validated, and BCN received $51,343 in overpayments ($31,659 for 2017 and $19,684 for 2018) for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

BCN incorrectly submitted diagnosis codes for embolism for 24 of 30 sampled enrollee-years. Specifically:

- For 9 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Embolism HCC.

[21] 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.

[22] For 1 of the 5 enrollee-years, we identified support for another diagnosis on CMS's systems that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, BCN should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the other diagnosis identified.

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 With Complications]. There is documentation of deep vein thrombosis as a suspected diagnosis that would not be assigned as a confirmed diagnosis."[23]

- For 9 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not justify a diagnosis that mapped to an Embolism HCC at the time of the physician's service.

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

- For 6 enrollee-years, BCN could not in each case locate any medical records to support the embolism diagnosis; therefore, the Embolism HCCs were not validated.

As a result of these errors, the Embolism HCCs were not validated, and BCN received $71,160 ($44,695 for 2017 and $26,465 for 2018) in overpayments for these 24 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

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

- For 15 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 6 enrollee-years, the medical records in each case did not support a lung cancer diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, BCN should not have received an increased payment for the lung cancer diagnosis but should have received a lesser increased payment for the other diagnosis identified.

[23] 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 3 enrollee-years, the medical records in each case did not support a lung cancer diagnosis.

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

- For the remaining 5 enrollee-years, BCN in each case could not locate any medical records to support the lung cancer diagnosis; therefore, the HCC for Lung and Other Severe Cancers was not validated.[24]

As a result of these errors, the HCC for Lung and Other Severe Cancers was not validated, and BCN received $209,565 in overpayments ($114,649 for 2017 and $94,916 for 2018) for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

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

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

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

- For 1 enrollee-year, the medical record did not support a breast cancer diagnosis. For this enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors]."

- For the remaining 2 enrollee-years, BCN could not in each case locate any medical records to support the breast cancer diagnosis; therefore, the Breast Cancer HCC was not validated.

[24] For 1 of the 5 enrollee-years, we identified support for another diagnosis on CMS's systems that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, BCN should not have received an increased payment for the lung cancer diagnosis but should have received a lesser increased payment for the other diagnosis identified.

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and BCN received $45,364 in overpayments ($24,424 for 2017 and $20,940 for 2018) for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

BCN incorrectly submitted diagnosis codes for colon cancer for all 30 sampled enrollee-years. Specifically:

- For 19 enrollee-years, the medical records indicated in each case that the individual had previously had colon cancer, but the records did not justify a colon cancer diagnosis at the time of the physician's service.

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

- For 6 enrollee-years, the medical records in each case did not support a colon cancer diagnosis.

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

- For 3 enrollee-years, the medical records in each case 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, BCN should not have received an increased payment for the submitted colon cancer diagnoses. Rather, it should have received a lesser increased payment for the other diagnosis identified.

- For the remaining 2 enrollee-years, BCN could not in each case locate any medical records to support the colon cancer diagnosis; therefore, the HCC for Colorectal, Bladder, and Other Cancers was not validated.

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and BCN received $71,380 in overpayments ($44,705 for 2017 and $26,675 for 2018) for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

BCN incorrectly submitted diagnosis codes for prostate cancer for 23 of 30 sampled enrollee-years. Specifically:

- For 18 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 the remaining 5 enrollee-years, BCN could not in each case locate any medical records to support the prostate cancer diagnosis; therefore, the Prostate Cancer HCC was not validated.

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and BCN received $29,022 in overpayments ($12,458 for 2017 and $16,564 for 2018) for these 23 sampled enrollee-years.

Summary of Incorrectly Submitted Diagnosis Codes

In summary and with respect to the seven high-risk groups covered by our audit, BCN received $542,164 in overpayments for the 192 sampled enrollee-years ($312,286 for 2017 and $229,878 for 2018).

THE POLICIES AND PROCEDURES BLUE CARE NETWORK OF MICHIGAN 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 BCN had to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations (42 CFR § 422.503(b)(4)(vi)), could be improved.

As part of its preventive measures, BCN had compliance procedures that included provider-specific outreach efforts designed to educate its providers on proper medical record documentation and coding. For example, BCN had a procedure to have its certified professional coders educate its providers by performing medical record reviews together. This educational outreach was designed to help prevent the reoccurrence of inaccurate diagnoses and insufficient medical record documentation.

BCN's compliance procedures also included detection and correction measures designed to determine whether diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. BCN performed, using both internal reviewers and contracted third-party reviewers, various diagnosis coding audits in which it reviewed supporting medical documentation. If diagnoses were not supported, BCN had procedures to report overpayments to CMS. Conversely, if diagnoses not previously included on claims were identified, BCN had procedures to capture the additional associated payments from CMS. BCN also had a procedure to review the medical records of its enrollees who had HCCs for various chronic conditions (including HCCs in six of the seven high-risk groups we reviewed) to determine whether the diagnosis was active during the current year.

Additionally, BCN's compliance procedures had a quality-assurance measure by which it rated how accurately its coders identified diagnosis codes in medical records. For coders who scored less than a 95-percent rate for accuracy and completeness, BCN's procedure called for the individuals to receive remedial training of the coding guidelines and one-on-one shadowing with a quality-assurance reviewer or a senior coder. BCN also required that these coders have all of their coding decisions reviewed until they reached a quality and accuracy rate of 95 percent.

With respect to the 29 enrollee-years for which BCN could not locate medical records to support the diagnosis, BCN cited issues with (1) medical record storage agencies that were short staffed, (2) pandemic slowdowns, and (3) retired or unresponsive providers.

We acknowledge that BCN's compliance procedures had measures designed to prevent, detect, and correct high-risk diagnosis codes that those procedures had identified as incorrect. However, because we found that 192 of the 210 sampled enrollee-years were not supported by medical records, we believe that these procedures could be improved.

BLUE CARE NETWORK OF MICHIGAN 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 BCN received at least $6,485,972 in overpayments for our audit period.

Because of Federal regulations that limit the use of extrapolation in RADV audits for recovery purposes to payment years 2018 and forward,[25] we are reporting the overall estimated overpayment amount, but are recommending a refund of $3,412,369 in overpayments ($312,286 for the sampled enrollee-years from 2017 and an estimated $3,100,083 for 2018). (See footnote 16 and Appendix D for sample results and estimates.)

[25] CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643 (Feb. 1, 2023)). RADV audits are conducted to verify that diagnoses submitted by MA organizations for risk-adjusted payment are supported by medical record documentation.

RECOMMENDATIONS

We recommend that Blue Care Network of Michigan:

- refund to the Federal Government the $3,412,369 of estimated overpayments;[26]

- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and

- continue to examine its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

BLUE CARE NETWORK OF MICHIGAN COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, BCN did not agree with our findings or with our recommendations. Specifically, BCN disagreed with our findings for 13 of the 198 enrollee-years identified as errors in our draft report and provided explanations as to why it believed the reviewed HCCs were validated. BCN did not directly agree or disagree with our findings for the remaining 185 enrollee-years.

BCN stated that we have a sampling bias inherent in this audit and our other audits of MA organizations that has "significantly misrepresented the degree of improper payments" that we identified. BCN also stated that it objected to our conclusions and recommendations and said that we "should reconsider [our] inappropriate and unnecessary auditing of [MA organizations] and engage with CMS on next steps to improve the risk adjustment payment model."

After reviewing BCN's comments and the additional explanations that it provided, we reduced the number of enrollee-years in error from 198 (in our draft report) to 192 and adjusted our calculation of overpayments. Accordingly, we reduced the recommended refund in our first recommendation from $3,518,894 to $3,412,369 for this final report. We maintain that our second and third recommendations remain valid.

A summary of BCN's comments and our responses follow. BCN's comments and additional explanations appear in their entirety as Appendix F.

[26] OIG audit recommendations do not represent final determinations. Action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures. In accordance with 42 CFR § 422.311, which addresses audits conducted by the Secretary (including those conducted by 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.

BLUE CARE NETWORK OF MICHIGAN DID NOT AGREE WITH OIG'S RECOMMENDATION THAT IT REFUND OVERPAYMENTS

Blue Care Network of Michigan Did Not Agree With OIG's Findings for 13 Sampled Enrollee-Years

BCN Comments

BCN did not agree with our findings for 13 of the sampled enrollee-years (as shown in Table 2) and provided explanations on why the medical records it provided to us validated the reviewed HCCs.

Table 2: Summary of Enrollee-Years for Which BCN Disagreed With Our Findings

High Risk Group	Number of Sampled Enrollee Years
Acute Stroke	1
Acute Myocardial Infarction	4
Embolism	1
Lung Cancer	3
Colon Cancer	2
Prostate Cancer	2
Total	**13**

BCN also stated that we "failed to acknowledge relevant documentation and follow correct coding guidelines." In doing so, BCN made these points:

- BCN stated that some of the disputed codes (for acute stroke and acute myocardial infarction) were "emergency department . . . visits followed by an inpatient hospitalization. All diagnoses were documented as actual conditions and not suspect or preliminary, despite OIG's assertion that they were." According to BCN, "the provider documented either the [acute stroke] or [acute myocardial infarction] as the actual diagnosis and reason for admission." BCN also stated that "[t]he provider's statement that the patient has a particular condition is sufficient to capture the code at hand."

- For some of the disputed cancer diagnosis codes, BCN stated that we ignored "industry guidance that a cancer can be coded as current so long as the patient is still receiving treatment, refused treatment, or is in observation status." In this respect, BCN stated that the medical records associated with these disputed codes met one of these "status conditions" to support the cancer diagnosis codes.

BCN requested that we reconsider our determinations for all 13 enrollee-years.

Office of Inspector General Response

For the 13 enrollee-years for which BCN provided additional explanations, our independent medical review contractor reviewed the documentation and reaffirmed that 7 of the 13 HCCs were not validated. For the remaining 6 enrollee-years, our contractor reversed its original decision and stated that the HCCs were validated.[27] Our contractor also completed a quality review of the enrollee-years for which it reversed its original decision based on BCN's explanations of previously submitted medical records and reported that it did not identify any systemic issues. We reduced the number of sampled enrollee-years in error from 198 (in our draft report) to 192 and reduced the associated statistical estimates and monetary recommendation.

With regard to BCN's statements that we failed to acknowledge relevant documentation and follow correct coding guidelines:

- Our independent medical review contractor confirmed that it had reviewed all emergency room and inpatient claims in accordance with the ICD Coding Guidelines. The ICD Coding Guidelines allow for unconfirmed diagnoses to be used on an inpatient claim, but not on a non-inpatient claim (i.e., an emergency department claim). Our contractor followed these requirements to determine if the medical records supported the diagnoses under review.

- Our independent medical review contractor did not ignore industry guidance about coding cancer. Nonetheless, our contractor reviewed the explanations that BCN provided for enrollees with a cancer diagnosis and reversed some of its determinations, which are reflected in our statements just above. However, in some instances, our contractor could not validate that the patients were "still receiving treatment, refused treatment or [were] in observation status." For example, for one enrollee-year, our contractor stated that "[a]lthough lung cancer is listed in the assessment, there is no indication that the patient has an active lung cancer, with no documented evaluation, treatment, or monitoring of lung cancer."

[27] The 6 enrollee-years were in the following high-risk groups: acute myocardial infarction (2), prostate cancer (2), embolism (1), and lung cancer (1).

BLUE CARE NETWORK OF MICHIGAN STATED THAT OIG'S AUDITS HAVE FAILED TO ACHIEVE POLICY CHANGE WITHIN THE AGENCY RESPONSIBLE FOR MEDICARE ADVANTAGE

BCN Comments

BCN stated that "OIG lacks the authority to conduct audits of [MA organizations] under the Inspector General Act (the IG Act) and, for this reason, CMS should disregard OIG's findings and recommendations from this improperly conducted audit." BCN cited provisions from the IG Act and court decisions to support its statement that "[t]he IG Act grants OIG the power to audit federal agencies, such as CMS, not the power to audit [MA organizations] on behalf of CMS as OIG has done here." To this point, BCN also stated that "[i]n conducting these audits, OIG has exceeded its authority with regard to the MA program by assuming program operating responsibility reserved for CMS." In addition, BCN said that we have "impermissibly performed audits" on approximately 30 MA organizations. Specifically, BCN stated that we performed RADV audits for which Federal regulations, according to BCN, "specify that CMS will conduct these audits."

In addition, BCN stated that the IG Act called for us to investigate CMS's administration of the risk adjustment program and not to investigate individual MA organizations. In this respect, BCN said that we could make recommendations to CMS to "fix flaws" in the risk adjustment program.

Office of Inspector General Response

Our audit of BCN and of other MA organizations did not violate statutory or regulatory requirements. The IG Act of 1978, 5 U.S.C. Chapter 4., provides OIG with independent authority to provide oversight of the Department's programs through audits and investigations. As such, we conduct our audits in accordance with generally accepted government auditing standards, which require that audits be planned and performed so as to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions. These audits represent OIG's exercise of its central statutory authorities under the IG Act as an independent oversight entity.

Further, BCN has incorrectly interpreted the Federal regulations governing the RADV audits. These regulations, as BCN points out in its footnote 12, discuss provisions for the Secretary of the Department of Health and Human Services (HHS) to perform RADV audits. The Secretary includes the Office of Inspector General. See 79 Fed. Reg., 29844, 29934 (May 23, 2014). Thus, our audits of MA organizations, including this audit of BCN, are appropriate.

BLUE CROSS NETWORK OF MICHIGAN DISAGREED WITH SEVERAL ASPECTS OF OIG'S AUDIT METHODOLOGY AND OVERPAYMENT CALCULATIONS

Blue Cross Network of Michigan Stated That OIG's Methodology Failed To Comply With the Actuarial Equivalence Requirement

BCN Comments

BCN stated that we violated a statutory requirement known as "actuarial equivalence," which according to BCN means that "CMS's risk adjusted payments to [MA organizations] must be equivalent to what CMS would have paid to cover the same individuals under the traditional FFS [fee-for-service] Medicare program." BCN stated that we violated the requirement because we failed "to include undercoding that might offset any alleged overcoding and by failing to account for inherent errors in the FFS data."

BCN stated that the MA payment system relies on FFS data that is not perfect for various reasons. According to BCN, "a problem arises when payments to the [MA organizations] are based on imperfect FFS data, but audits of [MA organizations] demand 100% accuracy." BCN stated that "CMS has consistently acknowledged the inherent errors in FFS data." BCN also stated that CMS announced in 2008 that it would apply an "FFS Adjuster" to audit results to account for these inherent errors. In addition, BCN noted that in 2023, CMS released its final rule that "provided for extrapolation without a FFS adjuster." BCN explained that it objected to this decision.

Office of Inspector General Response

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

With regard to BCN's comment regarding actuarial equivalence in our overpayment calculations or that our audit fails to account for errors in FFS data, we note that CMS stated that it "will not apply an adjustment factor (known as an FFS Adjuster) in RADV audits."[28] To this point, we recognize that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program.

[28] 88 Fed. Reg. 6643 (Feb. 1, 2023).

Blue Cross Network of Michigan Stated That OIG Failed To Consider Underpayments

BCN Comments

BCN stated that we looked only for overpayments and failed to look for possible underpayments. To this point, BCN stated: "The fact that OIG found errors in its highly biased sample in this audit does not demonstrate that BCN received overpayments in a meaningful sense." BCN pointed out that, under traditional Medicare and MA, providers are generally paid based on the services they provide, rather than based on the diagnoses of their patients, giving providers little incentive to correctly code and document patient diagnoses. BCN stated that while providers "omitting valid diagnosis codes (or failing to accurately code diagnoses that are included) may reduce payments to the [MA organization], it will have no impact on the compensation received by the provider." According to BCN, these inaccuracies lead "to both over and underpayments to the [MA organizations]" for which BCN also stated that we seek only "to recoup very old alleged overpayments."

BCN also stated that we performed "a one-sided review of payment so laden with bias that OIG's repayment recommendations must be disregarded." BCN said that our "approach is oddly inconsistent with the position taken by [the Department Of Justice] in litigation against [MA organizations]" for conducting "one-sided" chart reviews to identify only additional diagnosis codes to submit to CMS instead of unsupported codes that should be deleted.

In addition, BCN stated that, in its RADV audits, CMS considers any incorrectly omitted diagnosis code found during an audit as long as the diagnosis was included in a medical record. BCN stated that we, however, considered underpayments in limited situations and did not consider other supported diagnosis codes not previously submitted that mapped to unrelated HCCs that could have, at a minimum, offset the alleged overpayment.

Office of Inspector General Response

We disagree with BCN's comments that we failed to consider underpayments. Our objective was to determine whether selected high-risk diagnosis codes that BCN submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements. We identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into seven specific high-risk groups. This process involved a carefully designed audit methodology. (See Appendix A.) Our objective did not extend to diagnosis codes not previously submitted by BCN or to HCCs that were beyond the scope of our audit. For the HCCs that were not validated, if the independent medical review 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. A valid estimate of overpayments, given the objective of our audit, does not need to take into consideration all potential HCCs or underpayments within the audit period. We based our estimate of overpayments on the results of the independent medical review contractor's

review; this estimate addressed only the accuracy of the portion of payments related to the reviewed HCCs and did not extend to HCCs that were beyond the scope of this audit.

Blue Cross Network of Michigan Stated That OIG Inappropriately Deemed Diagnosis Codes as Unsupported When Medical Records Could Not Be Located

BCN Comments

BCN stated that we inappropriately deemed diagnosis codes as unsupported when providers' offices could not locate medical records. Specifically, BCN stated that we "assumed" that the diagnosis codes associated with 29 of the 210 sampled enrollee-years were unsupported. BCN stated: "This audit covered payment years 2017 and 2018, which correspond with service years 2016 and 2017, meaning that the records sought were from six or seven years ago." BCN gave several reasons why providers may have been unable to locate the requested medical records (e.g., providers may have misplaced records, moved, retired, or died). BCN also said that providers did not have incentives to cooperate with the request. In this respect, BCN stated that this "should not result in a presumption that the codes were unsupported." BCN stated that counting these codes as unsupported is "magnified greatly when OIG extrapolates from the findings."

Office of Inspector General Response

We do not agree with BCN's comment that we inappropriately deemed codes unsupported when providers' offices were unable to locate medical records. Medicare requirements are clear that in order for a diagnosis code that has been submitted to CMS to be appropriately included in the calculation of the risk score, the diagnosis needs to be documented in, and supported by, an acceptable medical record.

CMS also provides guidance for medical records that are unavailable because of "extraordinary circumstances" (Contract-Level Risk Adjustment Data Validation CMS Submission Instructions). The reasons that BCN stated for not being able to locate medical records do not qualify as extraordinary circumstances. With regard to BCN's comment that "the records sought were from six or seven years ago," we sought records from service years 2016 and 2017, which would have been less than six years old. BCN provided its medical records in 2021 through 2022 and did not request any hardship exceptions for medical records that it could not obtain from providers.

Accordingly, we did not reverse any of our decision for the 29 enrollee-years for which BCN could not provide medical records.

Blue Cross Network of Michigan Stated That OIG's Methodology Is Contrary to Statutory and Regulatory Requirements

BCN Comments

BCN stated that our audit methodology was contrary to statutory and regulatory requirements and made the following points:

- BCN stated that the IG Act does not authorize us to extrapolate in audits of MA organizations. In addition, and according to BCN, the statutory provisions governing Medicare allow extrapolation (1) if performed by Medicare contractors, (2) if there "is a sustained or high level of payment error and documented evidence that educational intervention failed to correct the payment error," or (3) "for audits of providers in Medicare Parts A and B, not of plans in Medicare Part C." BCN also said that CMS's statement (in the 2023 Final rule) that CMS "could also collect extrapolated amounts calculated by OIG in its audits for payment year 2018 and beyond" lacked statutory support.

- BCN also stated that our "audit approach differs fundamentally from the approach that CMS has used for years in its RADV audits." According to BCN, our use of this approach is impermissible because it violates the statutory provisions relating to Medicare because we imposed a substantive change retroactively.

- In addition, BCN stated that our methodology should not have been adopted without going "through the notice and comment rulemaking process." In this regard, BCN stated that, in response to a similar comment in another audit, "OIG has stated that rulemaking was not required because its 'audit does not make major changes to a CMS-administered program. . . .'" BCN stated that, in reality, our methodology does impose new substantive standards because we differ our approach from what CMS does. To support its position, BCN reiterated its comments on how our audit differed from CMS regarding underpayments (discussed above) and stated that we demanded 100-percent accurate data (discussed just below).

- BCN stated that our "audit approach effectively imposes a standard of perfection," which "is inconsistent with previous acknowledgements by both CMS and OIG that complete accuracy in MA data is not possible or required." Specifically, BCN stated that CMS has acknowledged "it is not possible for [MA organizations] to review every claim or to ensure perfect accuracy in what providers submit to CMS." According to BCN, "CMS regulations require only that [MA organizations] take reasonable steps to ensure the 'accuracy, completeness, and truthfulness' of data based on their 'best knowledge, information, and belief.'" BCN also cited previous OIG guidance to MA organizations that stated that an MA organization's certification "does not constitute an absolute guarantee of accuracy."

Office of Inspector General Response

We do not agree with BCN's comments regarding our audit methodology.

- Extrapolation has long been recognized as a permissible method of calculating overpayments in Medicare. BCN relied on 42 U.S.C. § 1395ddd(f)(3) to say that we do not have the authority to extrapolate. However, no statutory or other authority limits our ability to (1) extrapolate in audits of MA organizations and (2) make recommendations that MA organizations refund overpayments based on sampling and extrapolation. Further, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.[29]

- We do not agree with BCN's comment that our audit methodology is impermissible or that we have effectively imposed new substantive standards. Our audit approach was generally consistent with the methodology used by CMS in its RADV audits; however, it did not mirror CMS's approach in all aspects, nor did it have to. Further, the differences between our audit methodology and the approach of that of CMS do not, as BCN contends, represent a substantive change, or retroactive application of rules.

- Further, we do not agree with BCN's comments regarding the need for notice-and-comment rulemaking to establish the methodology we used in this audit. 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. Our audits are intended to provide an independent assessment of HHS programs and operations in accordance with the IG Act of 1978, 5 U.S.C. Ch. 4.

- We do not agree with BCN's interpretation of Federal requirements. As stated earlier, we recognize that MA organizations have the latitude to design their own federally mandated compliance programs. We also recognize that the requirement that MA organizations certify the data they submit to CMS is based on "best knowledge, information, and belief." Further, BCN's comments implied that we opined on its responsibilities to ensure 100-percent accuracy of all the data it submitted to CMS. That was not our intention or our focus for this audit. We limited our audit and recommendations to certain diagnosis codes that we had determined to be at high risk for being miscoded.

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

Blue Cross Network of Michigan Stated That OIG's Audits Raise Significant Public Policy Concerns

BCN Comments

BCN stated that our audits are unpredictable and could harm the MA program. BCN contends that because our audit methodology has changed over time to focus on "high-risk groups," and because it differs from CMS's RADV audit methodology, our "constantly shifting and opaque policies make it difficult for [MA organizations] to know how much money they will ultimately receive and retain and thus will deter [MA organizations] from participating in the MA program. . . ." BCN goes on to say "[t]his may cause premium instability, deter [MA organizations] from participating in the MA program, and lead to reduced benefits for[enrollees]."

BCN also stated that "there is no mechanism available for plans [to correct] data if estimated or extrapolated amounts are repaid." BCN contends that "CMS has not created a way in which [MA organizations] can submit 'deletes' for the associated codes" that OIG found in error. Therefore, "[w]ere a[n] [MA organization] to follow OIG's recommendations and remit the extrapolated amount identified in OIG's audit, this would leave open the possibility that the [MA organization] would end up paying for the same coding errors again in subsequent internal or external audits or other investigation related recoveries, effectively double dipping . . . ."

Office of Inspector General Response

We do not agree that our audit is unpredictable or that it could harm the MA program. Our audit is intended to provide an independent assessment of HHS programs and operations in accordance with the IG Act. Our mission is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve. By identifying errors, we strive to ensure the efficiency and integrity of the MA program and promote the effective delivery of services to BCN enrollees.

With regard to BCN's statement about the correction of data that involve extrapolated amounts, we reiterate that action officials at CMS, after determining whether any overpayments exist, will recoup any overpayments consistent with its policies and procedures. Further, we provided a list of the enrollee-years in our sampling frame to CMS to ensure that the individuals and the associated HCCs identified for this audit would be excluded from future CMS RADV audits. We believe that this audit methodology pre-empts any overlapping or duplicative audit findings.

BLUE CROSS NETWORK OF MICHIGAN DID NOT AGREE WITH OIG'S RECOMMENDATION TO PERFORM ADDITIONAL REVIEWS OF HIGH-RISK DIAGNOSIS CODES FOR THE YEARS BEFORE AND AFTER THE AUDIT PERIOD

BCN Comments

BCN disagreed with our second recommendation—that it perform additional reviews to determine whether similar instances of noncompliance for high-risk diagnoses occurred before or after the audit period. BCN stated that "the errors identified in the audit could be more than offset by errors in undercoding during the same time period. However, CMS does not permit [MA organizations] to submit any new diagnostic data identified beyond the closed period. Therefore, this exercise would only benefit the government, and unfairly and harshly handicap an [MA organization], effectively re-opening a closed year and disregarding the actuarial equivalence standard."

In addition, BCN stated that it "has implemented an effective compliance program and has processes in place to identify noncompliance. It has implemented processes moving forward to reduce recurrence of issues identified through OIG's audit, including providing training, data analytics and focused auditing. However, BCN will wait to engage with CMS on any further actions regarding this recommendation as CMS has never provided similar guidance . . . ."

Office of Inspector General Response

We do not agree with BCN that it should not perform additional reviews because it cannot offset errors for potential undercoding. As we stated earlier, Federal regulations require MA organizations to implement procedures and a system for investigating "potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence" (42 CFR § 422.503(b)(4)(vi)(G)). (See Appendix E.) In this regard, CMS allows MA organizations at least 13 months beyond the end of the service year to detect and submit diagnosis codes that are supported in medical records but were omitted from previous claims.

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

Federal regulations, assigned the responsibility for dealing with potential compliance issues to the MA organizations.

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

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

CMS does not have deadlines for submitting corrections for diagnoses that were not supported by medical records. The errors identified in our audit (192 of 210 sampled enrollee-years) (Appendix D) demonstrates that BCN has compliance issues that need to be addressed, and these issues may extend to periods of time beyond our scope. Accordingly, we maintain the validity of our recommendation that BCN identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government.

BLUE CROSS NETWORK OF MICHIGAN DID NOT AGREE WITH OIG'S RECOMMENDATION TO CONTINUE TO EXAMINE ITS EXISTING COMPLIANCE PROCEDURES

BCN Comments

BCN stated that it "does not believe that the results of the audit indicate that BCN's compliance program is inadequate or needs improvement. In fact, BCN has a robust compliance program in place." BCN added: "However, BCN strives to continue improvement of its compliance function and agrees, in part, to regularly examine its existing risk adjustment specific compliance policies and procedures and take necessary steps to enhance its procedures."

Office of Inspector General Response

We disagree with BCN's assertion that our audit did not demonstrate that its compliance program needs improvement. We limited our audit to selected diagnoses that we determined to be at high risk for being miscoded. Our audit revealed a substantial number of errors for all of these high-risk areas. We acknowledge that BCN had compliance procedures in place to promote the accuracy of diagnosis codes submitted to CMS to calculate risk-adjusted payments, including procedures related to some of the high-risk diagnosis codes that are the subject of this

audit. Continued improvement of BCN's existing compliance program, based on the results of this audit, will assist BCN in attaining better assurance about the "accuracy, completeness and truthfulness" of the risk adjustment data that it submits in the future. Accordingly, we maintain that our third recommendation is valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid BCN $1,678,680,640 to provide coverage to its enrollees for 2017 and 2018. We identified a sampling frame of 3,438 unique enrollee-years (footnote 13) on whose behalf providers documented high-risk diagnosis codes during the 2016 and 2017 service years; BCN received $50,919,013 in payments from CMS for these enrollee-years for 2017 and 2018. We selected for audit 210 enrollee-years with payments totaling $3,460,683.

The 210 enrollee-years included 30 acute stroke diagnoses, 30 acute myocardial infarction diagnoses, 30 embolism diagnoses, 30 lung cancer diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, and 30 prostate cancer diagnoses (Table 1, page 6). We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $626,053 for our sample.

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

We performed audit work from March 2020 through April 2024.

METHODOLOGY

To accomplish our objective, we performed the following steps:

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

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

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

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

    - 74 diagnosis codes for acute stroke,
    - 38 diagnosis codes for acute myocardial infarction,
    - 85 diagnosis codes for embolism,
    - 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)[30] and the Encounter Data System (EDS)[31] to identify enrollees who received high-risk diagnosis codes from a physician during the service years,

  - Risk Adjustment System (RAS)[32] to identify enrollees who received an HCC for the high-risk diagnosis codes,

  - Medicare Advantage Prescription Drug System (MARx)[33] to identify enrollees for whom CMS made monthly Medicare payments to BCN, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C),

  - EDS to identify enrollees who received specific procedures,[34] and

  - Prescription Drug Event (PDE) file[35] to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.

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

- We selected for audit a stratified random sample of 210 enrollee-years (Appendix C).

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

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

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

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

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

[35] 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 181[36] enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.[37]

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

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

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

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

        - If the second senior coder found support, then the coding supervisor reviewed the medical record(s) to make the final determination.

    - If either the first or second senior coder asked the coding supervisor for assistance, then the coding supervisor's decision became the final determination. In addition, at any point in the review process, a senior coder or coding supervisor may have consulted a physician reviewer for additional clarification.

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

    - 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 BCN during the audit period.

[36] BCN could not locate medical records for the remaining 29 sampled enrollee-years.

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

- We calculated the recommended recovery amount in accordance with CMS's regulations that limit the use of extrapolation in RADV audits for recovery purposes.[38] Specifically, we calculated the recommended recovery amount as the sum of the overpayments identified for the sampled enrollee-years from payment year 2017 and the estimate of total overpayments made to BCN for the enrollee-years from payment year 2018.

- We discussed the results of our audit with BCN officials.

We conducted this performance audit in accordance with GAGAS. 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.

[38] Federal regulations at 42 CFR § 422.311(a) state: "[T]he Secretary annually conducts RADV audits to ensure risk-adjusted payment integrity and accuracy." Recovery of improper payments from MA organizations will be conducted in accordance with the Secretary's payment error extrapolation and recovery methodologies. CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years. 88 Fed. Reg. 6643, 6655 (Feb. 1, 2023)."

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HealthAssurance, Pennsylvania, Inc. (Contract H5522) Submitted to CMS	A-05-22-00020	9/23/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Humana Health Plan, Inc. (Contract H2649) Submitted to CMS	A-02-22-01001	9/23/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Independent Health Association, Inc. (Contract H3362) Submitted to CMS	A-07-19-01194	6/26/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MediGold (Contract H3668) Submitted to CMS	A-07-20-01198	2/16/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That SelectCare of Texas, Inc. (Contract H4506), Submitted to CMS	A-06-19-05002	11/27/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Aetna, Inc. (Contract H5521) Submitted to CMS	A-01-18-00504	10/2/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS	A-07-20-01197	8/3/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS	A-07-20-01202	7/10/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. (H3952) Submitted to CMS	A-03-20-00001	5/31/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS	A-05-19-00013	4/4/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring Life & Health Insurance Company, Inc. (Contract H4513) Submitted to CMS	A-07-19-01192	3/28/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS	A-02-20-01008	3/24/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS	A-09-21-03011	3/16/2023

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified BCN enrollees who (1) were continuously enrolled in BCN throughout all of the 2016 or 2017 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 2016 or 2017 or in January of the following year, and (3) received a high-risk diagnosis during 2016 or 2017 that caused an increased payment to BCN for 2017 or 2018, respectively.

We presented the data for these enrollees to BCN 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 BCN. After we performed these steps, our finalized sampling frame consisted of 3,438 enrollee-years.

SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2017 or 2018.

SAMPLE DESIGN AND SAMPLE SIZE

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

- 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 an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim (1,102 enrollee-years);

- an acute myocardial infarction diagnosis (that mapped to the HCC for Acute Myocardial Infarction) on only one physician or outpatient claim during the service year but did not have an acute myocardial infarction diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician or outpatient claim (465 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 (284 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 (133 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 (562 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 (231 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 (661 enrollee-years).

The specific strata are shown in Table 3.

Table 3: Sample Design for Audited High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee-Years	CMS Payment for HCCs in Audited High-Risk Groups	Sample Size
1 – Acute stroke	1,102	$2,323,394	30
2 – Acute myocardial infarction	465	954,542	30
3 – Embolism	284	817,693	30
4 – Lung cancer	133	1,077,740	30
5 – Breast cancer	562	788,753	30
6 – Colon cancer	231	612,394	30
7 – Prostate cancer	661	882,129	30
Total	**3,438**	**$7,456,645**	**210**

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 unique enrollee identifier and payment year and then consecutively numbered the items in each stratum in the stratified sampling frame. After

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

ESTIMATION METHODOLOGY

Estimated Overpayments

We used the OIG, OAS, statistical software to estimate the total overpayments made to BCN for payment years 2017 and 2018 at the lower limit of the two-sided 90-percent confidence interval (Appendix D, Table 7). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

Estimated Overpayments for Recommended Recovery

Because CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward, we calculated the recommended recovery amount in accordance with CMS's regulations (footnote 16). Specifically, we calculated the recommended recovery amount as the sum of the overpayments identified for the sampled enrollee-years from payment year 2017 and the estimate of total overpayments made to BCN for the enrollee-years from payment year 2018 (Appendix D, Table 8).

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Details and Results for Payment Year 2017

Audited High-Risk Groups	Frame Size	CMS Payments for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payments for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With HCCs That Were Not Validated	Overpayments for HCCs That Were Not Validated (for Sampled Enrollee-Years)
1 – Acute stroke	551	$1,160,876	19	$41,019	19	$39,696
2 – Acute myocardial infarction	204	408,449	17	36,023	16	31,659
3 – Embolism	137	386,252	17	52,723	14	44,695
4 – Lung cancer	74	602,728	16	129,895	15	114,649
5 – Breast cancer	281	381,353	15	27,011	13	24,424
6 – Colon cancer	118	306,419	18	47,041	18	44,705
7 – Prostate cancer	342	443,713	11	13,815	10	12,458
Total	**1,707**	**$3,689,790**	**113**	**$347,527**	**105**	**$312,286**

Table 5: Sample Details and Results for Payment Year 2018

Audited High-Risk Groups	Frame Size	CMS Payments for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payments for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With HCCs That Were Not Validated	Overpayments for HCCs That Were Not Validated (for Sampled Enrollee-Years)
1 – Acute stroke	551	$1,162,518	11	$24,635	11	$24,635
2 – Acute myocardial infarction	261	546,093	13	26,460	12	19,683
3 – Embolism	147	431,441	13	35,820	10	26,465
4 – Lung cancer	59	475,012	14	118,569	14	94,916
5 – Breast cancer	281	407,400	15	20,940	15	20,940
6 – Colon cancer	113	305,975	12	27,757	12	26,675
7 – Prostate cancer	319	438,416	19	24,345	13	16,564
Total	**1,731**	**$3,766,855**	**97**	**$278,526**	**87**	**$229,878**

Table 6: Sample Details and Results
(Payment Years 2017 and 2018 Combined)

Audited High-Risk Groups	Frame Size	CMS Payments for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payments for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With HCCs That Were Not Validated	Overpayments for HCCs That Were Not Validated (for Sampled Enrollee-Years)
1 – Acute stroke	1,102	$2,323,394	30	$65,654	30	$64,331
2 – Acute myocardial infarction	465	954,542	30	62,483	28	51,342
3 – Embolism	284	817,693	30	88,543	24	71,160
4 – Lung cancer	133	1,077,740	30	248,464	29	209,565
5 – Breast cancer	562	788,753	30	47,951	28	45,364
6 – Colon cancer	231	612,394	30	74,798	30	71,380
7 – Prostate cancer	661	882,129	30	38,160	23	29,022
Total	**3,438**	**$7,456,645**	**210**	**$626,053**	**192**	**$542,164**

Table 7: Estimated Overpayments in the Sampling Frame
(Payment Years 2017 and 2018 Combined)
(*Limits Calculated for a 90-Percent Confidence Interval)*

Point Estimate	$6,800,502
Lower Limit	6,485,972
Upper Limit	7,115,031

Table 8: Total Estimated Overpayments in the Sampling Frame for Recommended Recovery
(*Limits Calculated for a 90-Percent Confidence Interval)*

	Overpayments for Sampled Enrollee-Years for 2017	Estimated Overpayments for Statistical Sample for 2018	Total Estimated Overpayments
Point Estimate	$312,286	$3,249,982	$3,562,268
Lower Limit	312,286	3,100,083	3,412,369
Upper Limit	312,286	3,399,882	3,712,168

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: BLUE CARE NETWORK OF MICHIGAN COMMENTS

Blue Cross
Blue Shield
Blue Care Network
of Michigan

July 12, 2024

Patricia Wheeler
Regional Inspector General for Audit Services
U.S. Department of Health & Human Services
Office of Inspector General
Office of Audit Services
1100 Commerce Street, Room 632
Dallas, TX 75242

Re: BCN Response to OIG Draft Report for Audit Number A-06-20-02000

Dear Ms. Wheeler,

I am writing on behalf of Blue Care Network (BCN) in response to the draft report *Medicare Advantage Compliance Audit of Selected Diagnosis Codes that Blue Care Network of Michigan (Contract H5833) Submitted to CMS* (the Draft Report) that BCN received from the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) Office of Audit Services (OAS). OIG conducted an audit of targeted diagnosis codes previously submitted to the Center for Medicare and Medicaid Services (CMS) to determine whether BCN received improper payments. BCN disagrees with OIG's findings and believes the sampling bias inherent in OIG's audits has significantly misrepresented the degree of improper payments made to BCN and all other Medicare Advantage organizations (MAOs) similarly audited. BCN believes OIG should reconsider its inappropriate and unnecessary auditing of MAOs and engage with CMS on next steps to improve the risk adjustment payment model. In the meantime, OIG should revise the Draft Report and withdraw its recommendations to BCN for the reasons described below.

I. OIG's Unauthorized and Unnecessary MAO Audits Have Failed to Achieve Policy Change Within the Agency Responsible for Medicare Advantage

A. The Inspector General Act Does Not Give OIG the Authority to Audit MAOs

OIG lacks the authority to conduct audits of MAOs under the Inspector General Act (the IG Act)[1] and, for this reason, CMS should disregard OIG's findings and recommendations from this improperly conducted audit. The IG Act grants OIG the power to audit federal agencies, such as CMS, not the power to audit MAOs on behalf of CMS as OIG has done here. Specifically, the Act

[1] 5a U.S.C. §§ 1-11.

provides that it shall be the duty of each Inspector General "to conduct, supervise, and coordinate audits and investigations relating to the programs and operations of the establishment."[2] The term "establishment" is defined to include HHS,[3] of which CMS is a part.

The IG Act also provides that there shall be transferred "to the Office of the Inspector General, such other offices or agencies, or functions, powers, or duties thereof, as the head of the establishment involved may determine are properly related to the functions of the Office and would, if so transferred, further the purposes of this Act, *except* that there shall not be transferred to an Inspector General under paragraph (2) *program operating responsibilities.*"[4] In *Burlington Northern R. Co. v. Office of Inspector General, R.R. Retirement Bd.*, the Fifth Circuit acknowledged this limitation on the powers of an agency's Inspector General, stating: "If an Inspector General were to assume an agency's regulatory compliance function, his independence and objectiveness … would, in our view, be compromised."[5] Thus, the court concluded:

> In particular, we hold that an Inspector General lacks statutory authority to conduct, as part of a long-term, continuing plan, regulatory compliance investigations or audits. By "regulatory compliance investigations or audits," we mean those investigations or audits which are most appropriately viewed as being within the authority of the agency itself. Thus, as a general rule, when a regulatory statute makes a federal agency responsible for ensuring compliance with its provisions, the Inspector General of that agency will lack the authority to make investigations or conduct audits which are designed to carry out that function directly.[6]

The court noted that this conclusion found support in the legislative history of the Inspector General Act, including a statement by a co-sponsor of the Act that:

> [T]he offices of Inspector General would not be a new "layer of bureaucracy" to plague the public. *They would deal exclusively with the internal operations of the departments and agencies.* Their public contact would only be for the beneficial and needed purpose of receiving complaints about problems with agency administration and

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[2] 5a U.S.C. § 4(a); 5 U.S.C. § 404(a).

[3] 5a U.S.C. § 12(2); 5 U.S.C. § 401(1).

[4] 5a U.S.C. § 9(a)(2), 5 U.S.C § 422(a)(2) (emphasis added).

[5] 983 F.2d 631, 642 (5th Cir. 1993).

[6] *Id.* at 642.

> in the investigation of fraud and abuse by those persons who are misusing or stealing taxpayer dollars.[7]

Further, the court found support for its interpretation in a memorandum prepared by the Department of Justice's (DOJ) Office of Legal Counsel in 1989, which concluded that the Act did not generally vest authority in the Inspector General to conduct investigations that "have as their objective regulatory compliance by private parties." The report stated:

> Thus, the Inspector General has an oversight rather than a direct role in investigations conducted pursuant to regulatory statutes: he may investigate the Department's conduct of regulatory investigations but may not conduct such investigations himself.[8]

Thus, the court held that the Inspector General was "without statutory authority to conduct the proposed tax compliance audit of Burlington Northern."[9] In reaching this conclusion, the court noted that "If the Inspector General were allowed to conduct regularly-scheduled, tax-compliance audits, there would be no one, so to speak, to "watch the watchdog."[10]

The Act does not give OIG the authority to conduct regulatory audits of private entities on behalf of CMS. This is exclusively within CMS's purview. In conducting these audits, OIG has exceeded its authority with regard to the MA program by assuming program operating responsibility reserved for CMS. To date, OIG has impermissibly performed audits on approximately thirty MAOs. CMS already performs this function through its Risk Adjustment Data Validation (RADV) audits. A RADV audit is defined as "a payment audit of an MAO administered by the Secretary that ensures the integrity and accuracy of risk adjustment payment data."[11] Like OIG's audits, CMS's RADV audits review diagnosis codes to determine if they are supported by the enrollees' medical records. The regulations governing RADV audits specify that CMS will conduct these audits.[12] And because these audits are part of CMS's program operating responsibilities, CMS may not, and has not attempted to, delegate its responsibility to audit MAOs to OIG.

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[7] *Id.* (quoting 124 CONG.REC. 10,405 (1978)) (emphasis added). *See also Truckers United for Safety v. Mead*, 251 F.3d 183 (D.D.C. 2001) ("discretionary transfers of authority only can be made if the duties are properly related to the functions of the IG, further the purpose of the Act, and do not constitute program operating responsibilities.").

[8] *Id.* at 643 (quoting March 9, 1989 memorandum prepared by the Department of Justice's Office of Legal Counsel).

[9] *Id.*

[10] *Id.*

[11] 42 C.F.R. 422.2 Definitions.

[12] 42 C.F.R. § 422.311(a) ("In accordance with §§ 422.2 and 422.310(e), *the Secretary annually conducts* RADV audits to ensure risk-adjusted payment integrity and accuracy.") (emphasis added); 42 C.F.R. § 422.308 ("Risk adjustment data validation (RADV) audit means a payment audit of a MA organization *administered by the Secretary* that ensures the integrity and accuracy of risk adjustment payment data.") (emphasis added).

OIG's proper role under the IG Act is to investigate CMS's administration of the risk adjustment program, not to conduct investigations of MAOs itself. Rather than adding a "a new layer of bureaucracy" by targeting individual MAOs and recommending extrapolated recoupment amounts based on inconsistent, unfair, and unauthorized audits, OIG should recommend corrective action that CMS could take to fix flaws in the risk adjustment system. Because OIG is not authorized under the IG Act to conduct audits of individual MAOs, the conclusions and recommendations of this audit should be discarded by both BCN and by CMS, the agency that actually has administrative authority over the MA program.

B. Instead of Seeking Unfair and Unpredictable Recoupments from Individual MAOs, OIG Should Encourage CMS to Make Programmatic Changes

Based on publicly available documents, it appears that OIG has audited over thirty MAOs in the last four years. Most of these audits have used data-mined samples of "high-risk" coding patterns (such as a heart attack without a related hospital admission) and each audit has found that a large percentage of the codes in these categories were submitted by providers in error. OIG has discovered what CMS and the insurance industry have always known – that providers are not, and cannot, code ICDs with 100% accuracy. Moreover, OIG ignores the fact that, given corporate practice of medicine and similar state licensure controls, MAOs have limited ability to influence provider diagnostic behavior. Without providing any real suggestion on how plans can change provider coding pattern, OIG essentially instructs MAOs to "do better."

Little to no new information is gained by OIG's continued audits of MAOs. OIG clearly has identified consistent and programmatic level issues with provider diagnostic coding that also exist in Fee-for-Service (FFS) coding that CMS can, and should, address by model changes (subject, of course to FFS model consideration noted infra) or data integrity improvement. Given that OIG does not have the authority under the IG Act to conduct audits on behalf of CMS, and that the audits are largely doppelgangers of each other, we urge OIG to focus its efforts on working with CMS at a programmatic level to address the source of the errors.

II. OIG's Methodology Does Not Establish That Inappropriate Payments Occurred

A. OIG's Approach Fails to Comply with the Actuarial Equivalence Requirement

The statutes governing Medicare Advantage provide that CMS must compensate MAOs in a way that ensures "actuarial equivalence" with traditional Medicare.[13] Further, the statute states that CMS must compute risk scores for FFS and MA beneficiaries using the "same methodology."[14]

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[13] 42 U.S.C. § 1395w-23(a)(1)(C)(i) ("[T]he 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, including adjustment for health status ... so as to ensure ***actuarial equivalence***.") (emphasis added).

[14] 42 U.S.C. § 1395w-23(b)(4)(C) and (D) ("The Secretary ... shall provide for the computation and publication ... of the following information for the original Medicare fee-for-service program ... (C) The average risk factor for the covered population based on diagnoses reported for Medicare inpatient services, using the ***same methodology*** as is

These provisions essentially mean that CMS's risk adjusted payments to MAOs must be equivalent to what CMS would have paid to cover the same individuals under the traditional FFS Medicare program. As discussed in more detail below, OIG's approach violates the actuarial equivalence and same methodology requirements by failing to include undercoding that might offset any alleged overcoding and by failing to account for inherent errors in the FFS data.

B. OIG's Approach Fails to Consider Underpayments

1. To determine whether an MAO was paid appropriately, it is necessary to consider whether the overall payment, including overpayments and underpayments, was accurate

OIG's audit methodology treats Medicare Advantage like FFS by focusing on a small number of codes pertaining to select groups of patients and providers. It does not take into account that MA involves population-based payments or whether those payments were appropriate overall. In fact, OIG specifically looks only for possible overpayments (which benefited the MAOs) and fails to look for possible underpayments (which harmed the MAOs and which could offset the overpayments). The fact that OIG found errors in its highly biased sample in this audit does not demonstrate that BCN received overpayments in a meaningful sense.

Consideration of underpayments is necessary because, under the MA program, MAOs receive prospective, capitated, risk adjusted payments to manage an entire Medicare eligible population. These payments are based on underlying FFS data that predict the costs associated with a similarly situated population diagnosed with the same conditions. The problem is that this FFS data is highly flawed.[15]

Under both traditional Medicare and MA, providers are generally paid on a FFS basis, meaning that they are paid for each procedure they perform and each service they provide, rather than based on the diagnoses of the patients they see. Thus, providers generally have little incentive to ensure that all diagnoses are correctly coded and documented. In most instances, in order to receive payment, providers need only to include on a claim diagnosis codes sufficient to support the reason for the visit and the level of care provided. Providers are not required, nor asked, to accurately diagnose, or code for, all present conditions of a patient. While omitting valid diagnosis codes (or failing to accurately code diagnoses that are included) may reduce payments to the MAO, it will have no impact on the compensation received by the provider. This discrepancy in incentives,

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expected to be applied in making payments under subsection (a) [regarding monthly payments to MAOs]. (D) Such average risk factor based on diagnoses for inpatient and other sites of service, using the ***same methodology*** as is expected to be applied in making payments under subsection (a) [regarding monthly payments to MAOs].") (emphasis added).

[15] As is discussed in more detail below, after CMS announced that it believed that a FFS Adjuster was unnecessary, a number of industry consultants, including Milliman, Avalere, and Wakely Consulting Group, undertook their own analyses and determined that when errors in CMS's methodology were accounted for, the overall adjuster needed to account for errors in the FFS data was in the range of 8 to 21%.

together with the complexity of the coding system itself,[16] means that there are often inaccuracies in the data, leading to both over and underpayments to MAOs. Unfortunately, the open period for risk adjustment submissions only extends to thirteen months after the year of service ends. Beyond this period, CMS does not allow MAOs to be compensated for underpayments that result from missing diagnosis data. OIG, however, as evidenced by this action, seeks to recoup very old alleged overpayments.

2. Because it is designed to find only overpayments, OIG's methodology does not give a meaningful indication of whether improper payments occurred

What OIG refers to as a "targeted" sample is a one-sided review of payment so laden with bias that OIG's repayment recommendations must be disregarded. Because it uses a biased sample aimed only at finding overpayments rather than underpayments, OIG's audit does not shed light on whether an MAO was truly overpaid.[17] OIG's approach is oddly inconsistent with the position taken by DOJ in litigation against MAOs, in which DOJ has overtly challenged MAOs for conducting "one sided" or "one way" chart reviews designed only to find additional diagnosis codes that could be submitted, rather than unsupported codes that should be deleted. In *United States ex rel. Swoben v. United Healthcare Ins. Co.*, the court stated:

> [W]hen, as alleged here, Medicare Advantage organizations 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.[18]

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[16] For purposes of both FFS Medicare and Medicare Advantage, providers record ICD-10-CM codes (to report diagnoses); ICD-10-PCS codes (to report inpatient services and procedures); CPT (HCPCS Level I) codes (to report outpatient services and procedures); and HCPCS Level II codes (to report equipment, drugs, and supplies). CMS, Medicare Learning Network Fact Sheet, *Health Care Code Sets: ICD-10* (July 2023), *available at* https://www.cms.gov/files/document/mln900943-health-care-code-sets-icd-10.pdf. The number of codes is vast. There are approximately 69,832 ICD-10-CM codes and 71,920 ICD-10-PCS codes. HHS, *ICD-10 Frequently Asked Questions*, available at https://cohhs.ri.gov/sites/g/files/xkgbur226/files/2021-03/ICD10_FAQ.pdf. There are approximately 11,163 CPT codes. JMA, *AMA releases the CPT 2024 code set* (September 8, 2023), *available at* https://www.ama-assn.org/press-center/press-releases/ama-releases-cpt-2024-code-set.

[17] *See generally* Stephen Bittinger et al., The Health Lawyer, *Statistical Sampling and Extrapolation: Due Process Challenges in the False Claims Act Litigation and Medicare Appeals Arenas* at 8 (December 28, 2022), *available at* https://www.americanbar.org/groups/health_law/publications/health_lawyer_home/december-2022/statistical-sampling-and-extrapolation/ (noting, in the context of FFS payments, that "[f]or the statistical sampling and extrapolation process to function properly and not be biased against the provider, underpayments, including unpaid or zero-paid claims, must be present in the universe, sampling frame, and sample to ensure the actual net overpayment is calculated.")

[18] *United States ex rel. Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1175 (9th Cir. 2016). *See also United States ex rel. Ormsby v. Sutter Health*, 444 F. Supp. 3d 1010, 1070 (N.D. Cal. 2020) (alleging that "the MA

By targeting only codes whose discovery will benefit the government, OIG is essentially undertaking the same activity that DOJ has challenged MAOs for doing. In response to criticisms regarding its failure to consider underpayments and errors in the FFS data, OIG has stated that consideration of diagnosis codes that could have been submitted, but were not, was "beyond the scope" of the audit.[19] But this is exactly the problem. OIG is measuring an "improper" payment improperly. Because the audits are not designed to take underpayments or errors in the FFS data into account, the audit design is fundamentally flawed and sheds no light on whether the MAOs in question have actually been overpaid. Therefore, the audit results should not serve as the basis for any recommendation to recoup payments from an MAO, much less as the basis to demand repayment of *extrapolated* amounts.

3. OIG takes underpayments into account only in extremely limited circumstances

CMS has consistently taken underpayments into consideration in its RADV audits to some extent. Specifically, CMS takes into account *any* incorrectly omitted diagnosis code that would have resulted in increased compensation to the MAO if it had been submitted so long as it was included in a medical record that validated a Hierarchical Condition Category (HCC) in its audit. The value associated with the newly found diagnosis codes (underpayments) is applied against the identified overpayment amount. OIG failed to follow this same methodology, considering underpayments only in very limited situations in which a diagnosis code mapped to the same HCC or an HCC within the same HCC category as the audited HCC. It did not consider other supported diagnosis codes not previously submitted that mapped to unrelated HCCs that could have, at a minimum, offset the alleged overpayment.

4. An analysis suggests that underpayments exist in the audited years of service that could offset the extrapolated overpayments alleged by OIG for 2017 dates of service

CMS requires MAOs to re-submit diagnostic data on its members on an annual basis, even for those chronic conditions that do not resolve. There are multiple reasons why these chronic conditions do not get resubmitted to CMS each year, including incomplete claims data, non-comprehensive diagnosis capture by providers and / or poor documentation in the medical record. However, a MAO continues to incur costs related to these conditions for its members. To show that OIG's overpayment analysis is incomplete and allegations inaccurate, BCN conducted an

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Organizations conducted *one-sided reviews* to capture under-reporting errors but not over-reporting errors.") (emphasis added); *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, No. CV 16-8697 MWF (SSX), 2018 WL 11350603, at *2 (C.D. Cal. Oct. 23, 2018) ("The Government alleges that United's MA plans engaged in so-called *'one-way' chart reviews.*") (emphasis added).

[19] *See, e.g., HumanaChoice Audit Report* at 19; SCAN Health Audit Report at 15; *Cigna HealthSpring Audit Report* at 18; *Cariten Audit Report* at 19; *BCBS of Tennessee Audit Report* at 21; *Inter Valley Audit Report* at 17; *Regence BCBS of Oregon Audit Report* at 22; *MediGold Audit Report* at 21. Note that a list of OIG audit reports with full report names and links is attached as Exhibit A.

underpayment analysis for 2017 DOS. Using data mining techniques similar to those used by OIG, BCN identified instances where a code was submitted and accepted for a chronic condition in DOS years 2016 and 2018 but not for 2017. Intuitively, chronic conditions generally do not spontaneously resolve for one year only to reappear the next. Instead, logically, a coding error dropped the code and this led to an underpayment to BCN for that year. BCN focused on HCCs related to seven chronic conditions and estimated the associated financial impact of non-capture of seven chronic conditions to be an estimated $10.6 million. This underpayment amount far exceeds the extrapolated approximate "overpayment" of $3.2 million identified by OIG for 2017 DOS. Recognizing that the conditions would still need to be supported by documentation in the medical record, BCN would only need to show a validation rate of 33% to off-set the extrapolated "overpayment". Again, this shows that OIG targeted focus on conditions often overcoded fails to provide the complete picture on payments made to MAOs.

C. OIG Fails to Account for Errors in FFS Data

As previously noted, the MA payment system relies on FFS data. FFS data is not perfect for various reasons, as noted above. However, CMS chose to use this data as the basis for the coefficient values assigned to HCCs, which contribute to the risk scores that drive payment under MA. The error rate in the FFS data is not necessarily problematic if MA data has approximately the same error rate. However, a problem arises when the payments to the MAOs are based on imperfect FFS data, but audits of the MAOs demand 100% accuracy.

This issue has been recognized by the Actuarial Standards Board of the American Academy of Actuaries, which sets standards used in the MA bidding process. When submitting bids, MAOs are required to have an actuary certify that the bids "were prepared in compliance with the current standards of practice, as promulgated by the Actuarial Standards Board of the American Academy of Actuaries."[20] For purposes of this certification, "[e]mphasis is placed on … Actuarial Standards of Practice … No. 45, which states that "[t]he type of input data that is used in the application of risk adjustment should be reasonably consistent with the type of data used to develop the model."[21]

CMS has consistently acknowledged the inherent errors in FFS data. In 2008, CMS announced that it would apply a FFS Adjuster to audit results to account for errors in the FFS data.[22]

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[20] CMS, *Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contract Year 2023* (April 8, 2022), *available at* https://www.cms.gov/files/document/cy2023-ma-bpt-instructions20220408pdf.pdf.

[21] Actuarial Standards Board, *Actuarial Standard of Practice No.* 45 ("ASOP 45") (January 2012) at 3.2 and 3.2.3, *available at* http://www.actuarialstandardsboard.org/wp-content/uploads/2014/02/asop045_164.pdf.

[22] *See Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* at 4-5 (Feb. 24, 2012), *available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2012294414-tc-noticeoffinalpaymenterrorcalculationmethodologyradvdatavalidationcontractlevelaudits.pdf.

More recently, in October of 2018, CMS released a study evaluating whether the FFS Adjuster was necessary.[23] Despite the study's conclusion that there was a claim-level error rate for each HCC between 21 to 46%,[24] CMS ultimately concluded that the errors offset one another, leading to appropriate reimbursement to MAOs.[25] Thus, CMS concluded that no FFS Adjuster was needed after all.[26]

Industry consultants found otherwise, conducting separate analyses and concluding that the methodology that CMS used in its study was highly flawed. For example, Milliman concluded that a FFS Adjuster in the range of 8% to 21% was required.[27] Similarly, Avalere concluded that "the audit miscalibration bias yields underpayments of nearly 8%."[28] A follow up study by Avalere indicated that, for MAOs with significant beneficiaries who are dually eligible for Medicare and Medicaid, the

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("[T]o determine the final payment recovery amount, *CMS will apply a Fee-for-Service Adjuster* (FFS Adjuster) amount as an offset to the preliminary recovery amount. If the FFS Adjuster amount is greater than the preliminary recovery amount, the final recovery amount is equal to zero. The FFS adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims). The actual amount of the adjuster will be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data.") (emphasis added).

[23] CMS, *Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits* (Oct. 26, 2018) (available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/FFS-Adjuster-Executive-Summary.pdf).

[24] *Id.* at 2-3 ("[T]he first step in evaluating the impact of the audit miscalibration is to do a RADV-like audit on a sample of FFS claims to estimate the prevalence of diagnoses unsupported by medical record documentation. This was done by first mapping every diagnosis on a claim to an HCC. The medical record documentation for each claim was [then] reviewed to confirm there was support for every HCC on the claim. *A claim level discrepancy rate was derived for each HCC. The discrepancy rates ranged from 21 to 46 percent.*") (emphasis added).

[25] *Id.* at 5 ("while a particular HCC's relative factor may have inaccuracy attached to it, the fact that the relative factors are summed across each enrollee's HCCs and then across a plan's enrollment, *leads the inaccuracies to mitigate each other due to offsetting effects*") (emphasis added); *id.* at n.9 ("As a statistical phenomenon, certain individual HCCs with measurement error may be subject to downward biases. However, this will result in upward biases to other HCCs and demographic factors. *Across HCCs, these biases are likely to offset.*") (emphasis added).

[26] *Id.* at 6 ("[W]e *no longer believe it is appropriate to include a FFS Adjuster* in any RADV extrapolated audit methodology.") (emphasis added).

[27] Rob Pipich, Milliman, *Medicare Advantage RADV FFS adjuster: White paper* at 4 (Aug. 23, 2019), *available at* https://www.milliman.com/-/media/milliman/importedfiles/ektron/medicare_advantage_radv_ffs_adjuster_8-23-2019.ashx. Milliman concluded that CMS underestimated the level of diagnosis coding errors in the FFS data by: (1) incorrectly assuming that diagnosis coding errors are independent from each other; (2) using an average number of claims per HCC rather than a distribution of the number of claims; and (3) excluding claims that do not have medical records or necessary documentation available.

[28] Avalere, *Eliminating the FFS Adjuster from the RADV Methodology May Affect Plan Payment* (March 2019), *available at* https://avalere.com/wp-content/uploads/2019/03/20190318-FFS-Adjuster-Analysis-Final-.pdf. Avalere noted a number of potential issues with CMS's methodology, including that CMS assumed that "every beneficiary with a particular HCC has the average number of claims supporting that HCC" and that "each claim supporting an HCC has a probability of error equal to the average probability of error for that HCC overall."

underpayment would be even higher, at approximately 9.1%.[29] Another study conducted by Wakely Consulting Group, LLC identified numerous flaws in CMS's analysis and concluded that accounting for just two of these flaws indicated that there is a "downward MA risk score bias of approximately 9.93%."[30]

The CMS analysis calling for a FFS Adjuster states that, "[w]hile a particular HCC's relative factor may have inaccuracy attached to it, the fact that the relative factors are summed across each enrollee's HCCs and then across a plan's enrollment, leads the inaccuracies to mitigate each other due to offsetting effects."[31] Even if this were true in the case of a CMS RADV audit, it would not be the case when, as here, an audit targets only a handful of coding patterns (which OIG refers to as "high-risk groups").

Significantly, the size of the FFS Adjuster in the OIG audits that target "high-risk groups" would have to be much higher than in a CMS RADV audit, as the relevant measure here is not the overall error rate in the FFS data, but, rather, the error rate in the FFS data for the same situations targeted in OIG's audit. In the context of these audits, the FFS Adjuster for each high-risk group would need to take into account both the rate at which the HCCs for the high-risk group are unsupported and the frequency with which each high-risk group occurs in the data. Given that the providers submitting FFS codes are generally the same providers who submit MA codes, logically the same error rates would appear in both FFS and MA.

Notably, CMS itself calculates an "improper payment rate" for Medicare FFS claims for each year through its Comprehensive Error Rate Testing (CERT) program. CMS has explained that the CERT dataset provides information on a random sample of FFS claims to determine whether providers were paid properly under Medicare coverage, coding, and payment rules. The 2023 report

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[29] Avalere, *Impact of Eliminating the FFS Adjuster May Vary Based on Plan Enrollee Characteristics, available at* https://avalere.com/wp-content/uploads/2019/08/20190821_FFS-Adjuster-Subgroup-Analysis-Final.pdf; *see also* Sean Creighton, Avalere, *The FFS Adjuster matters for accurate Medicare Advantage payment: An examination of the methodology and evidence behind a regulatory proposal to eliminate the adjuster*, RISE (December 11, 2019), *available at* https://www.risehealth.org/insights-articles/the-ffs-adjuster-matters-for-accurate-medicare-advantage-payment-an-examination-of-the-methodology-and-evidence-behind-a-regulatory-proposal-to-eliminate-the-adjuster/.

[30] Ross Winkelman, Wakely Consulting Group, *Actuarial Report on CMS' November 1, 2018 Proposed Rule* (Aug. 27, 2019), *available at* https://downloads.regulations.gov/CMS-2018-0133-0267/attachment_4.pdf). This study concluded that the CMS study contained many flaws, including the following: the study did not follow CMS's RADV audit methodology and did not use a representative sample set to conduct the analysis; CMS excluded claims for which no medical record was available, which is not what CMS does in a RADV audit; CMS incorrectly assumed that the probability that a HCC on a given claim will be substantiated is independent of the probability of substantiation for the same HCC on other claims submitted for the same beneficiary or by the same healthcare provider; CMS used average, rather than actual beneficiary claim counts; CMS improperly attempted to recalibrate the HCC model by deleting HCCs at random; and CMS used an improper deflationary adjustment in its normalization process.

[31] CMS, *Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits* at 5 (Oct. 26, 2018), *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/FFS-Adjuster-Excecutive-Summary.pdf.

shows an overall improper payment rate of 7.4%.[32] While this figure relates to the rate of errors in payments, rather than to the rate of unsupported diagnosis codes, it does provide further evidence that the FFS data submitted by providers is not 100% accurate.

In short, CMS's study and its conclusion that no FFS Adjuster was necessary were highly flawed. Despite this, in November of 2023, CMS released its final rule, which, like the proposed rule, provided for extrapolation without a FFS Adjuster. However, in contrast to the proposed rule, the final rule did not rely on the CMS study regarding the need for a FFS Adjuster. Instead, CMS asserted that, under the D.C. Circuit Court's ruling in *UnitedHealthcare Ins. Co. v. Becerra*,[33] the actuarial equivalence requirement "applies only to how CMS risk adjusts the payments it makes to MAOs, and not to the obligation to return improper payments ..."[34] Under this reasoning, although CMS is required to comply with the actuarial equivalence requirement in setting rates, it could effectively undermine this compliance by ignoring actuarial equivalence in the context of its audit system. This is not a logical reading of the Congressionally imposed actuarial equivalence requirement.

CMS also asserted in the final rule that the requirement that it apply a coding intensity adjustment factor in the Medicare Advantage context showed that it was not required to apply a FFS Adjuster in the audit context. CMS stated that, "it would be unreasonable to interpret the [Social Security] Act as requiring a minimum reduction in payments in one provision (the coding pattern provision), while at the same time prohibiting CMS in an adjacent provision (the actuarial equivalence provision) from enforcing those longstanding requirements (by requiring an offset to the recovery amount calculated for CMS audits)."[35] This is not a reasonable conclusion. As CMS itself has noted, the coding adjustment factor and the FFS Adjuster account for two separate issues – increased coding intensity on the one hand and errors in the FFS data on the other.[36] The fact that Congress has imposed an adjustment factor to take into account coding intensity does not mean that errors in the FFS data, and the requirement that CMS ensure actuarial equivalence, can be ignored.

D. OIG Inappropriately Deemed Codes Unsupported When Providers' Offices Were Unable to Locate Medical Records

Another problem with OIG's approach is that when a medical record was unavailable, OIG assumed the code was unsupported. For 29 of the 210 enrollee years sampled in OIG's audit of

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[32] HHS, *2023 Medicare Fee-for-Service Supplemental Improper Payment Data*, *available at* https://www.cms.gov/files/document/2023medicarefee-servicesupplementalimproperpaymentdatapdf.pdf.
[33] 16 F.4th 867 (D.C. Cir. 2021).

[34] CMS, Final Rule, 88 Fed. Reg. 6643, 6656 (Feb. 1, 2023).

[35] *Id.*

[36] CMS, *Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* at 18-19 (Apr. 5, 2010) , *available at* https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2011.pdf ("the MA coding adjustment factor is not intended to adjust for inaccurate coding, but for the impact on risk scores of coding patterns that differ from FFS coding.").

BCN, over 13% of the audited sample, BCN was unable to obtain medical records from providers and OIG, therefore, deemed the HCC not validated.[37]

This audit covered payment years 2017 and 2018, which correspond with service years 2016 and 2017, meaning that the records sought were from six or seven years ago. CMS does not require MAOs to collect medical records for all encounter data submitted. Rather, MAOs must attempt to obtain these records from providers when an audit is conducted. During the last seven years, providers may have moved, retired, or died. Providers may have misplaced paper records as the use of electronic medical record (EMR) systems became more prevalent. EMRs have evolved significantly and with each upgrade older records are typically more difficult, if not impossible, to access. Additionally, providers have little incentive to cooperate with requests for such old records given that there are few, if any, repercussions if they are unable to fulfill the request.

The failure of providers to produce medical records should not result in a presumption that the codes were unsupported. The problem created by counting these instances as unsupported codes is, of course, magnified greatly when OIG extrapolates from the findings. A more fair and accurate method would be to simply disregard those instances or provide alternative charts to ensure that a fair and representative sample of enrollees is achieved.

E. OIG Applied Incorrect Coding Standards

BCN disputes thirteen OIG determinations in its initial coding audit review. OIG failed to acknowledge relevant documentation and follow correct coding guidelines. Five of the thirteen codes were related to acute myocardial infarction (MI) and cerebrovascular accident (CVA). None of the disputed codes originated from a regular provider visit or annual wellness exam. Instead, these were all emergency department (ED) visits followed by an inpatient hospitalization. All diagnoses were documented as actual conditions and not suspect or preliminary, despite OIG's assertion that they were. BCN understands that OIG used a physician in its coding determinations when there was a coding dispute. However, MAOs are not required to review the encounters from a clinical perspective and second guess the ED physician's determination. For each of these instances, the provider documented either the CVA or MI as the actual diagnosis and reason for admission. The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient to capture the code at hand. [38]

Six of the challenges to OIG determinations are cancer codes. Again, OIG ignores industry guidance that a cancer can be coded as current so long as the patient is still receiving treatment, refused treatment, or is in observation status. There is evidence to meet one of these status

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[37] OIG's Draft Report notes that "with respect to the 29 enrollee-years for which BCN could not locate medical records to support the diagnosis, BCN cited issues with (1) medical record storage agencies that were short staffed, (2) pandemic slowdowns, and (3) retired or unresponsive providers." Draft Report at 16.

[38] CMS, ICD-10-CM Official Guidelines for Coding and Reporting FY 2024 -- UPDATED October 1, 2023 (October 1, 2023 - September 30, 2024).

conditions in the medical record to support the cancer code chosen. See Exhibit B for more detail on BCN's coding disputes of OIG's initial determinations.

III. OIG's Methodology Is Contrary to Statutory and Regulatory Requirements

A. OIG Does Not Have Authority to Extrapolate in Audits Conducted Under the Inspector General Act

Even if the OIG had the authority to conduct such audits and the calculation of the error rate was appropriate, OIG does not have the authority to extrapolate in audits of MAOs. OIG has stated that it is conducting these audits pursuant to the IG Act.[39] But that statute does not authorize extrapolation. Furthermore, the statutory provisions governing Medicare allow extrapolation only in very limited contexts. First, extrapolation is permitted only by Medicare contractors, not by OIG.[40] Second, extrapolation is permitted only where there is a sustained or high level of payment error and documented evidence that educational intervention failed to correct the payment error, none of which are present here.[41] Third, extrapolation is permitted only for audits of providers in Medicare Parts A and B, not of plans in Medicare Part C.

Specifically, 42 U.S.C. § 1395ff relates to determinations regarding benefits under Parts A and B and the rights of individuals and providers to appeal. Similarly, 42 U.S.C. § 1395oo relates to appeals by providers to a Provider Reimbursement Review Board. Given the context, it is clear that extrapolation is authorized only in the context of Parts A and B and only against providers and suppliers. It does not apply to efforts to recoup payments from plans under Medicare Part C.[42]

OIG has argued that "Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid."[43] But the cases cited by OIG are incomparable to the present one. the cases all involve providers that

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[39] *See, e.g., HumanaChoice Audit Report* at 19 ("In accordance with the Inspector General Act of 1978, 5 U.S.C. App., our audits are intended to provide an independent assessment of Department of Health and Human Services (HHS) programs and operations.").

[40] *See* 42 U.S.C. § 1395ddd(f)(3). *See also* HHS, CMS, *Medicare Program: Changes to the Medicare Claims Appeal Procedures, Final Rule*, 74 Fed. Reg. 65296, 65303 ("In section 1893(f)(3) of the [Social Security] Act [42 U.S.C. § 1395ddd(f)(3)] ... Congress placed restrictions on the use of extrapolation to determine overpayment amounts to be recovered from Medicare providers, suppliers or beneficiaries. In order to calculate an overpayment by extrapolation, there must be a determination of either: (1) A sustained or high level of payment error, or (2) a documented educational intervention that has failed to correct the payment error. In addition, ... *Congress required contractors to identify a likelihood of sustained or high level of payment error...*") (emphasis added).

[41] *Id.*

[42] *See* AHIP, *Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 ("Proposed Rule")* at 25 (August 27, 2019), *available at* https://ahiporg-production.s3.amazonaws.com/documents/AHIP_RADV_comments_FINAL_8_27.pdf).

[43] *See, e.g., HumanaChoice Audit Report* at 23; *BCBS of Tennessee Audit Report at 23*; *Highmark Audit Report* at 22.

were reimbursed on a FFS basis, either in the context of state Medicaid programs[44] or the traditional FFS Medicare program.[45] These are not cases that address population-based or global payments with an expected level of data inaccuracy such as in MA. If extrapolation was a way in which to determine overpayments in MA, then why would CMS, after noting extrapolation in the preamble to the final rule in 2012, provide notice and comment to codify the possibility of extrapolation in MA? "[T]o enhance transparency and provide ample notice to MAOs, we proposed to codify in regulation our methodological approach to RADV audits and would apply to all of the payment year audits that have not yet been finalized. These methodologies would apply to PY 2011 and subsequent year and include our proposals to use extrapolation and not apply an FFS Adjuster to our RADV audit findings."[46]

While CMS asserted in the preamble to its recent final rule that it could also collect extrapolated amounts calculated by OIG in its audits for payment year 2018 and beyond, this proposition lacks statutory support.[47] There was no intent to codify CMS's or OIG's authority to calculate extrapolated amounts based on OIG's audit findings. OIG is attempting to create a statutory standard just as CMS previously did with CMS RADV extrapolation. Extrapolation is not appropriate to use in MA.

B. The Retroactive Application of OIG's Methodology Is Impermissible

OIG's audit approach differs fundamentally from the approach that CMS has used for years in its RADV audits. OIG's use of this approach to review years old data violates the statutory provisions relating to Medicare because it imposes a substantive change retroactively. Under the statute, this is allowed only where it is necessary to comply with statutory requirements or where failure to apply the change retroactively would be contrary to the public interest.[48] Neither of these conditions applies here.

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[44] *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991) (provider challenged use of extrapolation to recover FFS payments made under state Medicaid program); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982) (provider challenged constitutionality of state rule that allowed extrapolation to recover FFS payments in state Medical Assistance Program).

[45] *Momentum EMS, Inc. v. Sebelius*, No. 4:11-CV-298, 2014 WL 199061, at 1 (S.D. Tex. Jan. 13, 2014) (provider challenged use of extrapolation by Medicare contractor in case relating to FFS payments); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012) (same); *Miniet v. Sebelius*, No. 10-24127-CIV, 2012 WL 2930746, at *1 (S.D. Fla. July 18, 2012) (same); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010) (same).

[46] 88 Fed. Reg. 6643, 6648 (February 1, 2023).

[47] CMS, Final Rule, 88 Fed. Reg. 6643, 6645, n.6 (Feb. 1, 2023) ("CMS contract-level RADV audits focus on specific MAO contracts to determine and recoup improper payments. The HHS–OIG also undertakes audits of MAOs, similar to RADV audits, as part of its oversight functions. CMS can collect the improper payments identified during those HHS– OIG audits, including the extrapolated amounts calculated by the OIG.").

[48] 42 U.S.C. §1395hh(e)(1)(A) ("*A substantive change* in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this subchapter *shall not be applied* (by extrapolation or otherwise) *retroactively* to items and services furnished before the effective date of the change, *unless* the Secretary determines that—(i) such retroactive application is *necessary to comply with statutory requirements*, or (ii) failure to apply the change retroactively *would be contrary to the public interest*.") (emphasis added). *See also Lifestar*

C. OIG's Methodology Should Not Have Been Adopted Without Rulemaking

Before adopting any "rule, requirement, or other statement of policy" that "establishes or changes a substantive legal standard governing ... the payment for services" the government must go through the notice and comment rulemaking process.[49] The Supreme Court has stated that "[n]otice and comment gives affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes—and it affords the agency a chance to avoid errors and make a more informed decision."[50]

In response to criticism that OIG failed to engage in notice and comment rulemaking prior to adopting its audit methodology, OIG has stated that rulemaking was not required because its "audit does not make major changes to a CMS-administered program" and that OIG's audits "are intended to provide an independent assessment of [HHS] programs and operations in accordance with the Inspector General Act of 1978, 5 U.S.C. Ch. 4."[51]

In reality, however, OIG's audit methodology imposes new substantive standards completely different from those used by CMS in the RADV audit process. In CMS's RADV audits, a sample is chosen and underpayments found within that sample are used to offset overpayments within the sample. While the RADV approach still fails to take into account patients for whom no diagnosis codes mapping onto an HCC were submitted (and so does not consider all undercoding), it gives a far more representative look at an MAO's overall payment than does OIG's approach, which targets only likely overpayments. Further, OIG's approach is contrary to the previous statements from CMS that 100% accuracy is not required. Because OIG's approach amounts to a change in a substantive legal standard, it should not have been adopted without notice and comment rulemaking from CMS, the agency with regulatory authority concerning Medicare.

D. OIG Inappropriately Attempts to Impose a Requirement of 100% Accuracy

OIG's audit approach effectively imposes a standard of perfection. This is inconsistent with previous acknowledgements by both CMS and OIG that complete accuracy in MA data is not possible or required.

Most risk adjustment data is submitted not by MAOs but by independent providers. As CMS has acknowledged, it is not possible for MAOs to review every claim or to ensure perfect accuracy in what providers submit to CMS. For this reason, CMS regulations require only that MAOs take reasonable steps to ensure the "accuracy, completeness, and truthfulness" of data based on their

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Ambulance Serv., Inc. v. U.S., Dep't of Health & Hum. Servs., 604 F. Supp. 2d 1372, 1379 (M.D. Ga. 2009) ("The Medicare statute itself also establishes a *general presumption against the retroactive application* of its regulations.") (emphasis added).

[49] 42 U.S.C. § 1395hh(a)(2).

[50] *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1816 (2019).

[51] *MediGold Audit Report* at 22.

"best knowledge, information, and belief."[52] Further, MAOs are given broad discretion to design their own compliance plans.[53]

At the time it implemented the current regulatory scheme, CMS's predecessor, the Health Care Financing Administration (HCFA) acknowledged that "M+C organizations" (the prior term for MAOs) "cannot reasonably be expected to know that every piece of data is correct"[54] and that "attestation of 100 percent accuracy"[55] was not required.

Similarly, in *UnitedHealthcare Ins. Co. v. Becerra*, the D.C. Circuit Court of Appeals held that CMS's Overpayment Rule would not require insurers to audit their data:

> Nothing in ***the Overpayment Rule*** obligates insurers to audit their reported data. As the district court held, and CMS does not here dispute, the 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. That limited scope ***does not impose a self-auditing mandate***.[56]

Notably, in explaining the use of a coding intensity adjustment, CMS has stated that an MAO codes "accurately" when it codes in a manner similar to FFS coding:

> Given the fact that the MA payment methodology is based on fee-for-service payments, and that the risk adjustment methodology is designed to compare the risk scores of MA plan enrollees to other

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[52] 42 C.F.R. § 422.504(l) ("As a condition for receiving a monthly payment under subpart G of this part, the MA organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on *best knowledge, information, and belief*) the accuracy, completeness, and truthfulness of relevant data that CMS requests.") (emphasis added).

[53] HCFA, HHS, *Medicare Program; Medicare + Choice Program, Final rule with comment period*, 65 Fed. Reg. 40,169, 40,265 ("M+C organizations and contract applicants have *broad discretion ... to design their compliance plan* structure to meet the unique aspects of each organization. We recognize that there is no one best way for an organization to take steps to ensure that it is operating in compliance with all applicable regulations and requirements. Thus, we intend to work with M+C organizations and contract applicants to apply a flexible standard in reviewing M+C compliance plans, while still ensuring that these compliance plans serve their intended purpose: to detect and prevent compliance problems, in addition to identifying aspects of the organization that may be vulnerable to such problems.") (emphasis added).

[54] *Id.* at 40,268 ("M+C organizations *cannot reasonably be expected to know that every piece of data is correct*, nor is that the standard that HCFA, the OIG, and DoJ believe is reasonable to enforce") (emphasis added).

[55] *Id.* at 40,312 ("As suggested by many commenters, we have revised the requirements to establish *a 'good faith' compliance standard as opposed to requiring an attestation of 100 percent accuracy* for encounters and enrollment (payment related) data. We believe this change should alleviate commenters concerns over the undue financial burdens associated with attestation requirements.") (emphasis added).

[56] *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 884 (D.C. Cir. 2021), *cert. denied*, 142 S. Ct. 2851 (2022) (citations omitted and emphasis added).

> plan enrollees and beneficiaries not enrolled in MA plans, ***for this comparison to be valid, MA plans must code the way Medicare Part A and B providers do*** in order for risk adjustments to be valid. This means that ***MA organizations are coding "accurately" when they are coding in a manner similar to fee-for-service coding*** used on the beneficiaries to whom MA plan enrollees are being compared.[57]

Like CMS, OIG has acknowledged that MAOs are not expected to ensure perfect accuracy of data, stating that an MAO's certification "does not constitute an absolute guarantee of accuracy."[58] OIG's approach in its audits of MAOs is inconsistent with these previous statements by both OIG and CMS.

IV. OIG's Audits Raise Significant Public Policy Concerns

A. OIG's Unpredictable Audits Could Harm the MA Program

Another problem is that OIG's approach differs from CMS's RADV audit methodology and even changes from one OIG audit to the next. Some of OIG's audits did not target particular coding patterns (or "high-risk groups") but instead involved the review of a sample of enrollees. In the audits that did target particular "high-risk groups," the HCCs targeted and the total number of "high-risk groups" evaluated changed from audit to audit. Additionally, in some audits OIG recommended extrapolation and in others it did not.

OIG has acknowledged that its approaches "have evolved over time" and that, as a result, the methodology used in recent audits is not the same as that used in earlier audits.[59] It has also acknowledged that its methodology differs from the methodology used by CMS in its RADV audits.[60] OIG contends that its audit approach does not have to be consistent from one audit to the next and does not have to be consistent with CMS's approach.[61]

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[57] CMS, *Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies* at 20 (April 6, 2009) , *available at:* https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/announcement2010.pdf (emphasis added).

[58] OIG, HHS, *Publication of the OIG's Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans*, Notice, 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999) ("The requirement that the CEO or CFO certify as to the accuracy, completeness and truthfulness of data, based on best knowledge, information and belief, *does not constitute an absolute guarantee of accuracy*. Rather, it creates a duty on the Medicare+Choice organization to put in place an information collection and reporting system reasonably designed to yield accurate information.... The exact methods used by the Medicare+Choice organization to accomplish this can be determined by the organization, however, it should ordinarily conduct sample audits and spot checks of this system to verify whether it is yielding accurate information.") (emphasis added).

[59] *See MediGold Audit Report* at 21.

[60] *Id.*

[61] *Id.*

However, OIG's constantly shifting and opaque policies make it difficult for MAOs to know how much money they will ultimately receive and retain and thus will deter MAOs from participating in the MA program going forward. Moreover, even for MAOs that remain in the MA program, "unpredictability impacts efforts to make investments in innovation and care delivery programs that better meet the needs of Medicare Advantage enrollees and may negatively impact beneficiary cost sharing reductions or enhanced benefits."[62]

Further, in setting the bid prices and creating benefit packages, MAOs must make assumptions regarding the amount of money they will receive and retain from CMS. Under the Affordable Care Act (ACA), MAOs are required to submit data on the proportion of premium revenues spent on clinical services and quality improvement, known as the Medical Loss Ratio (MLR). MAOs must spend at least 85% of premium dollars on MLR expenses. MAOs that do not meet this MLR standard must return the difference between 85% and their MLR to the government.[63] This makes it very important for MAOs to be able to predict how much they will be paid when they are planning their bids and benefits packages. The randomness and unpredictability of OIG's audits make it impossible for MAOs to know how much of the payments they receive they will ultimately retain. This may cause premium instability, deter MAOs from participating in the MA program, and lead to reduced benefits for beneficiaries.

B. There Is No Mechanism Available for Plans Presently for Correcting Data if Estimated or Extrapolated Amounts are Repaid

Significantly, even if a MAO were to reconcile extrapolated overpayment amounts against current monthly payments from CMS, CMS has not created a way in which MAOs can submit "deletes" for the associated codes. Were a MAO to follow OIG's recommendations and remit the extrapolated amount identified in OIG's audit, this would leave open the possibility that the MAO would end up paying for the same coding errors again in subsequent internal or external audits or other investigation related recoveries, effectively double dipping and further financially handicapping the MAO.

The vast majority of diagnosis codes for any MAO are submitted by providers rather than by the MAO. In the past, MAOs filtered the data and submitted it to CMS through the Risk Adjustment Processing System (RAPS). Over the past few years, CMS has been transitioning to the Encounter Data Processing System (EDPS) and now all data is submitted through EDPS. Under EDPS, MAOs no longer filter diagnosis codes. Instead, all diagnoses codes are submitted to CMS and CMS applies its own filtering process. Given this, the sensible solution is for OIG to work with

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[62] Better Medicare Alliance, *Understanding Medicare Advantage Payment & Policy Recommendations*, at 13 (September 2018), *available at* https://bettermedicarealliance.org/wp-content/uploads/2020/03/BMA_WhitePaper_MA_Bidding_and_Payment_2018_09_19-1.pdf.

[63] 42 C.F.R. § 422.2410(b) provides: "MLR requirement. If CMS determines for a contract year that an MA organization has an MLR for a contract that is less than 0.85, the MA organization has not met the MLR requirement and must remit to CMS an amount equal to the product of the following: (1) The total revenue of the MA contract for the contract year. (2) The difference between 0.85 and the MLR for the contract year."

CMS to determine whether any of these so-called high-risk groups should be filtered out of both the MA data and the FFS data.

V. BCN Disagrees with OIG's Suggestion That BCN Replicate OIG's Audit for Other Payment Years

The Draft Report states that OIG recommends BCN "identify, for the high-risk diagnoses, included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government." BCN disagrees with this recommendation.

As described above, the errors identified in the audit could be more than offset by errors in undercoding during the same time period. However, CMS does not permit MAOs to submit any new diagnostic data identified beyond the closed period. Therefore, this exercise would only benefit the government, and unfairly and harshly handicap an MAO, effectively re-opening a closed year and disregarding the actuarial equivalence standard.

BCN acknowledges CMS's requirement for MAOs to "implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS program requirements"[64] and to implement procedures to investigate "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."[65] BCN has implemented an effective compliance program and has processes in place to identify noncompliance. It has implemented processes moving forward to reduce recurrence of issues identified through OIG's audit, including provider training, data analytics and focused auditing. However, BCN will wait to engage with CMS on any further actions regarding this recommendation as CMS has never provided similar guidance, which essentially holds MAOs to a 100% accuracy standard of FFS diagnostic data.

VI. BCN Has an Effective Compliance Program in Place

The Draft Report states that the "policies and procedures [BCN] had to prevent, detect and correct noncompliance with federal requirements could be improved" and recommends that BCN "continue to examine its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are high-risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take necessary steps to enhance those procedures."

For the reasons discussed above, BCN does not believe that the results of the audit indicate that BCN's compliance program is inadequate or needs improvement. In fact, BCN has a robust compliance program in place. OIG acknowledged BCN's efforts through the years regarding appropriate auditing and monitoring efforts, provider and coder training and quality assurance

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[64] 42 C.F.R. §422.503(b)(vi).
[65] *Id.*

reviews, and appropriate follow through when errors were identified. BCN has continued to implement these and other processes to reduce the occurrence of unsupported diagnosis codes.

However, BCN strives to continue improvement of its compliance function and agrees, in part, to regularly examine its existing risk adjustment specific compliance policies and procedures and take necessary steps to enhance its procedures.

VII. Conclusion

For the reasons stated above, BCN objects to OIG's conclusions and recommendations in the Draft Report. More specifically, BCN disagrees with OIG's recommendations that BCN refund the $3,518,894 extrapolated amount calculated by OIG, identify similar issues of high-risk diagnosis codes in other time periods and refund overpayment amounts accordingly, and modify its compliance program. BCN will wait on a final agency action from CMS to better understand CMS's position on OIG's audit and recommendations.

Sincerely,

Kelly Lange
Vice President, Medicare Compliance

Exhibit A
To BCN Response to OIG Draft Report
List of OIG Audit Reports Relating to Medicare Advantage Organizations

Short Name	Report Date	Sample Type	Full Name and Link
PacifiCare of Texas	5/30/2012	100 beneficiaries	*Risk Adjustment Data Validation of Payments Made to PacifiCare of Texas for Calendar Year 2007 (Contract Number H4590)* https://oig.hhs.gov/oas/reports/region6/60900012.pdf
Paramount	9/25/2012	100 beneficiaries	*Risk Adjustment Data Validation of Payments Made to Paramount Care, Inc., for Calendar Year 2007 (Contract Number H3653)* https://oig.hhs.gov/oas/reports/region5/50900044.asp
Excellus Health	10/5/2012	98 beneficiaries	*Risk Adjustment Data Validation of Payments Made to Excellus Health Plan, Inc., for Calendar Year 2007 (Contract Number H3351)* https://oig.hhs.gov/oas/reports/region2/20901014.asp
PacifiCare of California	11/30/2012	100 beneficiaries	*Risk Adjustment Data Validation of Payments Made to PacifiCare of California for Calendar Year 2007 (Contract Number H0543)* https://oig.hhs.gov/oas/reports/region9/90900045.asp
Essence	4/30/2019	2 categories	*Some Diagnosis Codes That Essence Healthcare, Inc. Submitted to CMS Did Not Comply With Federal Requirements* https://oig.hhs.gov/oas/reports/region7/71701170.asp
BCBSM	2/24/2021	7 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS* https://oig.hhs.gov/oas/reports/region2/21801028.asp
Humana	4/19/2021	200 enrollees	*Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc. (Contract H1036) Submitted to CMS* https://oig.hhs.gov/oas/reports/region7/71601165.asp
Anthem	5/21/2021	7 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS* https://oig.hhs.gov/oas/reports/region7/71901187.asp
Coventry	10/28/2021	6 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS* https://oig.hhs.gov/oas/reports/region7/71701173.asp
UPMC	11/5/2021	10 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS* https://oig.hhs.gov/oas/reports/region7/71901188.asp

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Short Name	**Report Date**	**Sample Type**	**Full Name and Link**
Healthfirst	1/5/2022	7 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc. (Contract H3359) Submitted to CMS* https://oig.hhs.gov/oas/reports/region2/21801029.asp
SCAN Health	2/3/2022	200 enrollees	*Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS* https://oig.hhs.gov/oas/reports/region7/71701169.asp
Tufts	2/14/2022	7 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS* https://oig.hhs.gov/oas/reports/region1/11900500.asp
Peoples Health	5/25/2022	7 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health Network (Contract H1961) Submitted to CMS* https://oig.hhs.gov/oas/reports/region6/61805002.asp
Cariten	7/18/2022	9 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc. (Contract H4461) Submitted to CMS* https://oig.hhs.gov/oas/reports/region2/22001009.asp
Cigna HealthSpring of Florida	8/19/2022	200 enrollees	*Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS* (August 2022) https://oig.hhs.gov/oas/reports/region3/31800002.asp
Wellcare of Florida	8/29/2022	7 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc. (Contract H1032) Submitted to CMS* https://oig.hhs.gov/oas/reports/region4/41907084.asp
Regence BCBS of Oregon	9/13/2022	7 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS* https://oig.hhs.gov/oas/reports/region9/92003009.asp
Inter Valley	9/26/2022	200 enrollees	*Medicare Advantage Compliance Audit of Diagnosis Codes That Inter Valley Health Plan, Inc. (Contract H0545) Submitted to CMS* https://oig.hhs.gov/oas/reports/region5/51800020.asp
Highmark	9/29/2022	6 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (H3916) Submitted to CMS*

Exhibit A To BCN Response to OIG Draft Report List of OIG Audit Reports Relating to Medicare Advantage Organizations			
Short Name	**Report Date**	**Sample Type**	**Full Name and Link**
			https://oig.hhs.gov/oas/reports/region3/31900001.asp
BCBS of Tennessee	9/29/2022	9 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS* https://oig.hhs.gov/oas/reports/region7/71901195.asp
HumanaChoice	9/30/2022	9 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract R5826) Submitted to CMS* https://oig.hhs.gov/oas/reports/region5/51900039.asp
California Physicians' Service	11/10/2022	7 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That California Physicians' Service, Inc. (Contract H0504) Submitted to CMS* https://oig.hhs.gov/oas/reports/region9/91903001.asp
BCBS of Rhode Island	11/16/2022	9 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BCBS of Rhode Island (Contract H4152) Submitted to CMS* https://oig.hhs.gov/oas/reports/region1/12000500.asp
Cigna HealthSpring of Tennessee	12/22/2022	10 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring of Tennessee, Inc. (Contract H4454) Submitted to CMS* https://oig.hhs.gov/oas/reports/region7/71901193.asp
Geisinger	3/16/2023	9 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS* https://oig.hhs.gov/oas/reports/region9/92103011.asp
MCS Advantage	3/24/2023	9 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS* https://oig.hhs.gov/oas/reports/region2/22001008.asp
Cigna HealthSpring Life & Health Insurance	3/28/2023	9 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring Life & Health Insurance Company, Inc. (Contract H4513) Submitted to CMS* https://oig.hhs.gov/oas/reports/region7/71901192.asp
HumanaChoice	4/4/2023	7 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS* https://oig.hhs.gov/oas/reports/region5/51900013.asp

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List of OIG Audit Reports Relating to Medicare Advantage Organizations

Short Name	Report Date	Sample Type	Full Name and Link
Keystone Health	5/31/2023	9 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. (Contract H3952) Submitted to CMS* https://oig.hhs.gov/oas/reports/region3/32000001.asp
Excellus Health	7/10/2023	7 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS* https://oig.hhs.gov/oas/reports/region7/72001202.asp
Presbyterian	8/3/2023	7 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS* https://oig.hhs.gov/oas/reports/region7/72001197.asp
Health Net of California	9/22/2023	200 enrollees	*Medicare Advantage Compliance Audit of Diagnosis Codes That Health Net of California, Inc. (Contract H0562) Submitted to CMS* https://oig.hhs.gov/oas/reports/region9/91803007.asp
Aetna	10/2/2023	7 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Aetna, Inc. (Contract H5521) Submitted to CMS* https://oig.hhs.gov/oas/reports/region1/11800504.asp
CarePlus Health Plans	10/26/2023	200 enrollees	*Medicare Advantage Compliance Audit of Diagnosis Codes That CarePlus Health Plans, Inc. (Contract H1019) Submitted to CMS* https://oig.hhs.gov/oas/reports/region4/41907082.asp
SelectCare of Texas	11/27/2023	10 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That SelectCare of Texas, Inc. (Contract H4506), Submitted to CMS* https://oig.hhs.gov/oas/reports/region6/61905002.asp
MediGold	2/16/2024	7 categories	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MediGold (Contract H3668) Submitted to CMS* https://oig.hhs.gov/oas/reports/region7/72001198.asp

Exhibit B
BCN 2016/2017 H5883
Responses to OIG Determinations

Blue Cross Network (BCN) reviewed the Office of Inspector General's (OIG) coding determinations in its audit of contract H5883 for certain diagnosis codes submitted for 2016/2017 dates of service (DOS). BCN believes OIG should reconsider its determinations in the following samples based on the relevant medical records and guidance provided by CMS and ICD-10-CM Official Guidelines for Coding and Reporting, as described below.

HCC 100 – Cerebrovascular Accident (CVA)

OIG Sample #28 (HCC 100)

- OIG noted in its decision, "[b]ased on review of the medical record/s submitted for this HCC, there is no documentation of any condition that will result in the assignment of HCC 100. There is documentation of cerebrovascular accident (I63.9) in the assessment and plan. As per outpatient coding guidelines a preliminary diagnosis is a working diagnosis which should not be assigned as an established diagnosis." The OIG cited this as "past medical history."
- BCN provided an emergency department (ED) encounter record (28-01-PHY) from 06/17/2016 to support the diagnosis code:
  - ***The patient's medical history.*** The patient was a 72-year-old female who presented to the ED after having a syncopal episode on the day before. In the ED, the patient had right-sided facial droop, slurred speech, right foot drag, and was unsteady and confused. The husband reported that the patient had a history of a stroke "that presented similarly." The patient's pertinent history included CVA, diabetes, hypertension, and hyperlipidemia.
  - ***The patient's encounter.*** The provider examined the patient and ordered various diagnostic tests.
  - ***The patient's disposition.*** The provider diagnosed the patient with a "Cerebrovascular Accident (CVA) (ICD-10 I63.9)," which was noted under the Impression and Plan section, as well as an order to admit the patient.
- Relevant Coding Guidelines:
  - "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2017; Section A, Section I.A. Conventions for the ICD-10-CM 19. Code assignment and Clinical Criteria).
  - "Codes from category I69 may be assigned on a health care record with codes from I60-I67, if the patient has a current cerebrovascular disease and deficits from an old cerebrovascular disease." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2017; Section C. Chapter-Specific Coding Guidelines 9. Chapter 9: Diseases of the Circulatory System d.2. Codes from category I69 with codes from I60-I67).

- "MA Organizations should report only conditions either documented by or clearly reviewed and signed off by an acceptable RA physician / practitioner specialty. Conditions ruled out during the ED testing or conflicting with Emergency Room (ER) physician /practitioner's (i.e., MD, Physician Assistant (PA), Nurse Practitioner (NP) final note should not be submitted." (CMS's Contract-Level Risk Adjustment Data Validation (RADV), Medical Record Review Guidance, 2020).

- BCN believes that the diagnosis of a CVA (I63.9) is validated by the medical record submitted to OIG. BCN does not agree with OIG's determination that CVA was a preliminary diagnosis. OIG fails to show that this is the case. Although the patient had a history of a CVA, the patient was admitted for a separate CVA. The provider documented CVA as a current diagnosis and the reason for the required admission. If the provider believed that CVA was a preliminary diagnosis, the provider would have preceded CVA with a qualifier such as "rule out," "suspect," or "probable." In that case, per guidance in outpatient settings, CVA would not have been coded. However, the provider diagnosed this patient with a CVA, and as noted, a provider's diagnostic statement is sufficient to support the assignment of a diagnosis code.

HCC 86 – Myocardial Infarction (MI)

OIG Sample #31 (HCC 86)

- OIG noted in its decision, "[b]ased on review of the medical record/s submitted for this HCC, there is no documentation of any condition that will result in the assignment of HCC 86. There is documentation of a non-ST elevation MI (I21.4) as a working diagnosis, that would not be coded based on coding guidelines for preliminary diagnosis."
- BCN provided an admission record (31-01-PHY) documented by the admitting physician after evaluating the patient in the ED on 11/06/2017 to support the diagnosis code:
  - ***The patient's medical history.*** The patient was a 69-year-old female who presented to the ED for chest pain with associated shortness of breath. The patient was under the care of a cardiologist for a history of atrial fibrillation, cardiac pacemaker, hypertension, CVA, and peripheral vascular disease (PVD).
  - ***The patient's encounter.*** The patient's laboratory results revealed an elevated troponin level (a cardiac marker that indicates damage to the heart muscle from a myocardial infarction).
  - ***The patient's disposition.*** The admitting physician captured in the "Diagnoses" section that the patient had a "[n]on-ST elevation myocardial infarction."
- Relevant Coding Guidelines:
  - "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2017; Section A, Section I.A. Conventions for the ICD-10-CM 19. Code assignment and Clinical Criteria).
  - "The ICD-10 CM codes for acute myocardial infarction (AMI) identify the site, such as anterolateral wall or true posterior wall. Code I21.4, non-ST elevation (NSTEMI) myocardial infarction, is used for type 1 non-ST elevation myocardial infarction (NSTEMI) and non-transmural MIs." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2018; Section I.C. Chapter-Specific Coding Guidelines 9.

Chapter 9: Diseases of the Circulatory System (100-199) e. Acute Myocardial Infarction (AMI) 1) Type 1 ST elevation myocardial infarction (STEMI) and non-ST elevation myocardial infarction (NSTEMI)).

- "MA Organizations should report only conditions either documented by or clearly reviewed and signed off by an acceptable RA physician / practitioner specialty. Conditions ruled out during the ED testing or conflicting with Emergency Room (ER) physician /practitioner's (i.e., MD, Physician Assistant (PA), Nurse Practitioner (NP) final note should not be submitted." (Contract-Level RADV Medical Record Review Guidance).

- BCN believes that the diagnosis of a NSTEMI (I21.4) is validated by the medical record submitted to OIG. BCN does not agree with OIG's determination that the NSTEMI was a preliminary diagnosis. OIG fails to show that this is the case. The patient had signs and symptoms, as well as elevated cardiac markers, that were consistent with having an NSTEMI. The provider documented NSTEMI as a current condition and the reason for the required admission. If the provider opined that the NSTEMI was a preliminary diagnosis, the provider would have preceded the diagnosis with a qualifier such as "rule out," "suspect," or "probable." If that were the case, per guidance in outpatient settings, NSTEMI would not have been coded. However, the provider documented the patient's diagnosis of a NSTEMI, and as noted, a provider's diagnostic statement is sufficient to support the assignment of a diagnosis code.

OIG Sample #39 (HCC 86)

- OIG noted in its decision, "[b]ased on review of the medical record/s submitted for this HCC, there is no documentation of any condition that will result in the assignment of HCC 86. There is documentation of a NSTEMI as a working diagnosis that would not be assigned based on outpatient coding guidelines on unconfirmed diagnoses."
- BCN provided an ED encounter note (39-01-PHY) from 04/26/2016 to support the diagnosis code:
  - ***The patient's medical history.*** The patient was a 78-year-old male who presented to the ED with shortness of breath, left lower extremity edema, and worsening dyspnea on exertion. The patient's pertinent history included COPD, MI, diabetes, hyperlipidemia, and hypertension.
  - ***The patient's encounter.*** The patient's laboratory results revealed an elevated troponin level (a cardiac marker that indicates damage to the heart muscle from a myocardial infarction). The patient's electrocardiogram (EKG) showed a right bundle branch block (RBBB) pattern with acute changes compared to the previous EKG. RBBB can happen as a result of an MI and indicate significant heart muscle damage.
  - ***The patient's disposition.*** The provider documented "non-ST elevation (NSTEMI) myocardial infarction" under Clinical Impression, which prompted an inpatient admission for this patient.
- Relevant Coding Guidelines:
  - "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2017; Section A, Section I.A. Conventions for the ICD-10-CM 19. Code assignment and Clinical Criteria).

- "The ICD-10 CM codes for acute myocardial infarction (AMI) identify the site, such as anterolateral wall or true posterior wall. Code I21.4, non-ST elevation (NSTEMI) myocardial infarction, is used for type 1 non-ST elevation myocardial infarction (NSTEMI) and non-transmural MIs." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2018; Section I.C. Chapter-Specific Coding Guidelines 9. Chapter 9: Diseases of the Circulatory System (100-199) e. Acute Myocardial Infarction (AMI) 1) Type 1 ST elevation myocardial infarction (STEMI) and non-ST elevation myocardial infarction (NSTEMI)).
- "MA Organizations should report only conditions either documented by or clearly reviewed and signed off by an acceptable RA physician / practitioner specialty. Conditions ruled out during the ED testing or conflicting with Emergency Room (ER) physician /practitioner's (i.e., MD, Physician Assistant (PA), Nurse Practitioner (NP) final note should not be submitted." (Contract-Level RADV Medical Record Review Guidance).

- BCN believes that the diagnosis of a NSTEMI (I21.4) is validated by the medical record submitted to OIG. BCN does not agree with OIG's determination that the NSTEMI was a "working" diagnosis. OIG fails to show that this is the case. The patient had signs and symptoms, as well as elevated cardiac markers, that were consistent with having a NSTEMI. The provider documented NSTEMI as a current diagnosis, and this prompted an inpatient admission. If the provider opined that the NSTEMI was a preliminary diagnosis, the provider would have preceded the diagnosis with a qualifier such as "rule out," "suspect," or "probable." If that were the case, per guidance in outpatient settings, NSTEMI would not have been coded. However, the provider documented the patient's diagnosis of a NSTEMI, and as noted, a provider's diagnostic statement is sufficient to support the assignment of a diagnosis code.

OIG Sample #55 (HCC 86)

- OIG noted in its decision, "[b]ased on review of the medical record/s submitted for this HCC, there is no documentation of any condition that will result in the assignment of HCC 86. There is documentation of non-ST elevation myocardial infarction as a differential diagnosis that would not be assigned based on outpatient guidelines on uncertain diagnoses."
- BCN provided an ED encounter note (55-01-PHY) from 01/13/2016 to support the diagnosis code:
  - ***The patient's medical history.*** The patient was a 93-year-old female who presented to the ED with shortness of breath, hypoxia (oxygen level was in the 50s), and dyspnea on exertion. The patient's pertinent history included hypertension and a transient ischemic attack (TIA).
  - ***The patient's encounter.*** Patient was examined and placed on a non-rebreather. The patient was only saturating in the low 90s on the non-rebreather mask. The patient's laboratory results revealed an elevated troponin level (a cardiac marker that indicates damage to the heart muscle from a myocardial infarction) and an increased B-type natriuretic peptide (BNP) level (a value that is indicative of congestive heart failure (CHF) exacerbation).
  - ***The patient's disposition.*** The provider noted the following: "Creatinine above baseline, likely due to CHF; NSTEMI likely due to CHF." The provider further noted under Clinical Impression: (1) SOB (shortness of breath); (2) CAP (community

acquired pneumonia); (3) AKI (acute kidney injury); (4) NSTEMI (non-ST elevated myocardial infarction); (5) Acute CHF. As such, the patient was admitted to the intermediate critical care area with a cardiology consult.

- Relevant Coding Guidelines:
  - "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2017; Section A, Section I.A. Conventions for the ICD-10-CM 19. Code assignment and Clinical Criteria).
  - "The ICD-10 CM codes for acute myocardial infarction (AMI) identify the site, such as anterolateral wall or true posterior wall. Code I21.4, non-ST elevation (NSTEMI) myocardial infarction, is used for type 1 non-ST elevation myocardial infarction (NSTEMI) and non-transmural MIs." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2018; Section I.C. Chapter-Specific Coding Guidelines 9. Chapter 9: Diseases of the Circulatory System (100-199) e. Acute Myocardial Infarction (AMI) 1) Type 1 ST elevation myocardial infarction (STEMI) and non-ST elevation myocardial infarction (NSTEMI)).
  - "MA Organizations should report only conditions either documented by or clearly reviewed and signed off by an acceptable RA physician / practitioner specialty. Conditions ruled out during the ED testing or conflicting with Emergency Room (ER) physician /practitioner's (i.e., MD, Physician Assistant (PA), Nurse Practitioner (NP) final note should not be submitted." (Contract-Level RADV Medical Record Review Guidance).

- BCN believes that the diagnosis of a NSTEMI (I21.4) is validated by the medical record submitted to OIG. BCN does not agree with OIG's determination that the STEMI was a "differential" diagnosis. OIG fails to show that this is the case. Differential diagnoses are diagnoses that are considered but are not necessarily confirmed. All diagnoses listed under Clinical Impression are not differential diagnoses but current diagnoses that were confirmed by the provider based on the patient's examination and/or diagnostic results. The patient had signs and symptoms, as well as elevated cardiac markers, that were consistent with having a NSTEMI. The provider documented NSTEMI as a current diagnosis, which prompted an inpatient admission. If the provider opined that the NSTEMI was a preliminary diagnosis, the provider would have preceded the diagnosis with a qualifier such as "rule out," "suspect," or "probable." If that were the case, per guidance in outpatient settings, NSTEMI would not have been coded. However, the provider documented the patient's diagnosis of a NSTEMI, and as noted, a provider's diagnostic statement is sufficient to support the assignment of a diagnosis code.

OIG Sample #59 (HCC 86)

- OIG noted in its decision, "[b]ased on review of the medical record/s submitted for this HCC, there is no documentation of any condition that will result in the assignment of HCC 86. There is documentation of an old myocardial infarction (I25.2) that does not result in an HCC."
- BCN provided an ED encounter note (59-01-PHY) from 06/27/2016 to support the diagnosis code:

- ***The patient's medical history.*** The patient was a 74-year-old female who presented to the ED with respiratory distress. The patient's pertinent history included COPD, coronary artery disease (CAD), previous cardiac bypass, hyperlipidemia, and hypertension.
- ***The patient's encounter.*** The patient was examined and underwent diagnostic tests. Her laboratory results revealed an elevated troponin level (a cardiac marker that indicates damage to the heart muscle from a myocardial infarction).
- ***The patient's disposition.*** The provider documented under current diagnosis (DX): 1. Right lower lobe pneumonia by history; 2. Chronic obstructive pulmonary disease with exacerbation; 3. Hypoxia; 4. Type 2 myocardial infarction with known coronary artery disease, previous bypass grafting, and unremarkable EKG at this time. As such, the patient was admitted.

- Relevant Coding Guidelines:
  - "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2017; Section A, Section I.A. Conventions for the ICD-10-CM 19. Code assignment and Clinical Criteria).
  - "The ICD-10 CM codes for acute myocardial infarction (AMI) identify the site, such as anterolateral wall or true posterior wall. Code I21.4, non-ST elevation (NSTEMI) myocardial infarction, is used for type 1 non-ST elevation myocardial infarction (NSTEMI) and non-transmural MIs." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2018; Section I.C. Chapter-Specific Coding Guidelines 9. Chapter 9: Diseases of the Circulatory System (100-199) e. Acute Myocardial Infarction (AMI) 1) Type 1 ST elevation myocardial infarction (STEMI) and non-ST elevation myocardial infarction (NSTEMI)).
  - "MA Organizations should report only conditions either documented by or clearly reviewed and signed off by an acceptable RA physician / practitioner specialty. Conditions ruled out during the ED testing or conflicting with Emergency Room (ER) physician /practitioner's (i.e., MD, Physician Assistant (PA), Nurse Practitioner (NP) final note should not be submitted." (Contract-Level RADV Medical Record Review Guidance).

- BCN believes that the diagnosis of a NSTEMI (I21.4) is validated by the medical record submitted to OIG. BCN does not agree with OIG's determination that the NSTEMI was documented as being in the past medical history, or that there was "documentation of an old myocardial infarction" in the medical record. OIG fails to show that this is the case. There is no mention of an old myocardial infarction in the patient's medical history. Presumably, this assumption is based on the fact that the patient had a previous bypass. However, myocardial infarction is listed under the "DX" section, which includes all active diagnoses that were confirmed during this encounter based on evaluation and diagnostic results. The patient had signs and symptoms, as well as elevated cardiac markers, that were consistent with having a NSTEMI. The provider documented "Type 2 myocardial infarction" as a current diagnosis, which prompted an inpatient admission. Type 2 myocardial infarction is a defined as a myocardial infarction secondary to ischemia due to either increased oxygen demand or decreased supply. The provider documented this as a current diagnosis relating to the patient's

decreased oxygen supply due to COPD exacerbation, and as noted, a provider's diagnostic statement is sufficient to support the assignment of a diagnosis code.

HCC 107 - Pulmonary Embolism

OIG Sample #88 (HCC 107)

- OIG noted in its decision, "[b]ased on review of the medical record/s submitted for this HCC, there is no documentation of any condition that will result in the assignment of HCC 107. There is documentation of prophylactic measures being taken for pulmonary embolism (I26.99) that would not be assigned as a confirmed diagnosis."
- BCN provided a primary care visit record (88-01-PHY) from 12/04/2017 to support the diagnosis code:
  - ***The patient's medical history.*** The patient was a 73-year-old female who presented for an annual wellness visit. She had a history of deep vein thrombosis in the left leg and bilateral pulmonary embolism.
  - ***The patient's encounter.*** The provider included "recurrent pulmonary embolism" on the Problem List. Under Assessment and Plan, the provider noted the following: "Recurrent pulmonary embolism – est – stable, 126.99: other pulmonary embolism without acute cor pulmonale." The provider also included a laboratory order (i.e., INR) that was performed monthly, which was related to the diagnosis of recurrent pulmonary embolism. Lastly, the patient was on Warfarin for the recurrent pulmonary embolism.
- Relevant Coding Guidelines:
  - "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2018; Section A, Section I.A. Conventions for the ICD-10-CM 19. Code assignment and Clinical Criteria).

- BCN believes that the diagnosis of pulmonary embolism (I26.99) is validated by the medical record submitted to OIG. BCN does not agree with OIG's determination that "there is no documentation of any condition that will result in the assignment of HCC 107." In fact, pulmonary embolism is a current diagnosis that is listed under the Problem List, Past Medical History, and the Assessment and Plan sections. OIG claims that the patient was being treated prophylactically to prevent further embolisms. However, nowhere in the record does the provider note that the treatment is prophylactic. Instead, the treatment is clearly indicated to treat the "recurrent" pulmonary embolism. As previously noted, a provider's diagnostic statement is sufficient to support the assignment of a diagnosis code.

HCC 9 - Lung Cancer

OIG Sample #93 (HCC 9)

- OIG noted in its decision, "[b]ased on review of the medical record/s submitted for this HCC, there is no documentation of any condition that will result in the assignment of HCC 9. There is documentation of a past medical history of lung cancer (Z85.118) that does not result in an HCC."

- BCN provided an office visit encounter note (93-01-PHY) from 08/29/2017 to support the diagnosis code:
  - ***The patient's medical history.*** The patient was a 74-year-old female who presented for an annual wellness visit.
  - ***The patient's encounter.*** The provider listed several diagnoses under Assessment, including "primary malignant neoplasm of lung [ICD 10: C34.90]."
- Relevant Coding Guidelines:
  - "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2018; Section A, Section I.A. Conventions for the ICD-10-CM 19. Code assignment and Clinical Criteria).

- BCN believes that the diagnosis of lung cancer (C34.30) is validated by the medical record submitted to OIG. BCN does not agree with OIG's determination that lung cancer is a historical condition. This condition is not documented in the patient's past medical history. Instead, it is captured in the Assessment section by the provider as one of the active diagnoses. As noted, the assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists.

OIG Sample #95 (HCC 9)

- OIG noted in its decision, "[b]ased on review of the medical records submitted for this HCC, there is no documentation of any condition that will result in the assignment of HCC 9. There is documentation of a lung mass (R91.8) that does not result in an HCC."
- BCN provided an office visit encounter note (95-01-PHY) from 04/28/2016 to support the diagnosis code:
  - ***The patient's medical history.*** The patient was a 90-year-old male who presented for low back pain. The provider noted several diagnoses in the patient's past medical history. Notably, the provider did not include lung cancer as one of the past medical history diagnoses.
  - ***The patient's encounter.*** While assessing the patient's low back pain, the provider documented that the patient had certain "[r]isk factors," including a "history of cancer (patient has active lung cancer and a history of prostate cancer)." Under the Back Exam section, the provider noted that the patient was experiencing tenderness in the thoracic region. The provider wrote the following: "He also has lung cancer. Possible met[astasized] to spine. He does not desire treatment for the cancer."
- Relevant Coding Guidelines:
  - "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2018; Section A, Section I.A. Conventions for the ICD-10-CM 19. Code assignment and Clinical Criteria).
  - Per AAPC guidelines, in defining terms of care in cancer, "**Current:** Cancer is coded as current if the record clearly states active treatment is for the purpose of curing or palliating

cancer, or states cancer is present but unresponsive to treatment; the current treatment plan is observation or watchful waiting; or the patient refused treatment." AAPC, Clear Up Confusion as to When Cancer Becomes "History Of", available at https://www.aapc.com/blog/40016-clear-up-confusion-as-to-when-cancer-becomes-history-of/.

- BCN believes that the diagnosis of lung cancer (C3430) is validated by the medical record submitted to OIG. OIG ignored numerous pieces of documentation by the provider that the patient has active lung cancer, for which the patient refuses treatment. The refusal of treatment does not mean that the cancer is no longer current. OIG referenced a lung mass documented in the problem list. This only further substantiates the diagnosis of the lung cancer. BCN does not agree with OIG's determination that there is no documentation of any condition that would trigger the lung cancer HCC. As noted, cancer can continue to be coded as current even if the patient refused treatment, and the provider's diagnostic statement that the condition exists is enough to support the assignment of a diagnosis code.

OIG Sample #116 (HCC 9)

- OIG noted in its decision, "[b]ased on review of the medical record/s submitted for this HCC, there is no documentation of any condition that will result in the assignment of HCC 9. There is documentation of a past medical history of lung cancer (Z85.118) that does not result in an HCC."
- BCN provided an office visit encounter note (116-02-PHY) from 04/17/2016 to support the diagnosis code:
  - ***The patient's medical history.*** The patient was a 65-year-old female who presented for a recheck of lung cancer, COPD, and occasional cough.
  - ***The patient's encounter.*** The patient underwent an examination and certain diagnostic tests. A CT scan of chest revealed that the patient's right lung lesion appeared to be unchanged. The tiny left lung nodule was unchanged. There was no new pulmonary parenchymal abnormality. As such, the provider documented under the Assessment and Plan: "Current Plans: Lung Cancer, lower lobe; Today's Impression: T3B (T3N3M0) undergoes chemo+XRT [radiation therapy]. Lung Mass; Today's Impression: NSCL [non-small cell lung] cancer, status post chemoradiation."
- Relevant Coding Guidelines:
  - "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2018; Section A, Section I.A. Conventions for the ICD-10-CM 19. Code assignment and Clinical Criteria).
  - Also, according to the ICD-10-CM guidelines, patients receiving active treatment for cancer should be coded using the malignant neoplasm code for the affected site. This code should be used even if the patient has had surgery but is still receiving treatment.

- BCN believes that the diagnosis of lung cancer (C3430) is validated by the medical record submitted to OIG. OIG ignored documentation by the provider at least two times that the patient has active cancer and "undergoes chemo + XRT [radiation therapy]". The CT scan revealed a current lesion, which further substantiates the diagnosis of the lung cancer. BCN does not agree

with OIG's determination that there is no documentation of any condition that would trigger the lung cancer HCC. As noted, cancer should be treated as current when the patient is on current treatment, and the provider's diagnostic statement that the condition exists is enough to support the assignment of a diagnosis code. The code for lung cancer is supported by the medical record provided.

HCC 11 - Colon Cancer

OIG Sample #166 (HCC 11)

- OIG noted in its decision, "[b]ased on review of the medical record/s submitted for this HCC, there is no documentation of any condition that will result in the assignment of HCC 11. There is documentation of a past medical history of colon cancer (Z85.038) that does not result in an HCC."
- BCN provided a consultation note (166-02-PHY) from 03/23/2017 to support the diagnosis code:
  - ***The patient's medical history.*** The patient was a 68-year-old male who presented with foot pain. The provider documented that the patient had a medical history of colon cancer and a surgical history of bowel surgery.
  - ***The patient's encounter.*** The provider documented "colon cancer" under the Impression section for this visit.
- Relevant Coding Guidelines:
  - "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2018; Section A, Section I.A. Conventions for the ICD-10-CM 19. Code assignment and Clinical Criteria).

- BCN believes the diagnosis of colon cancer (C189) is validated by the medical record submitted to OIG. OIG ignored documentation under the Impression section and only focused on the notation made in the past medical history. If the diagnosis is documented as a current impression, then it is a current condition. A provider's diagnostic statement that the condition exists is enough to support the assignment of a diagnosis code. The code for colon cancer is supported by the medical record provided.

OIG Sample #173 (HCC 11)

- OIG noted in its decision, "[b]ased on review of the medical records submitted for this HCC, there is no documentation of any condition that would result in the assignment of the submitted HCC. Although the diagnosis of colon cancer (C18.9) was listed, the medical record does not include additional support that the condition still exists."
- BCN provided an office visit encounter note (173-01-PHY) from 11/14/2017 to support the diagnosis code:
  - ***The patient's medical history.*** The patient was a 77-year-old male who presented with moderate persistent asthma with exacerbation.
  - ***The patient's encounter.*** The provider documented under the Assessment section the following: "Diagnoses and all orders for this visit: Primary colon cancer – patient just had colonoscopy a U of M recently".

- Relevant Coding Guidelines:
  - "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2018; Section A, Section I.A. Conventions for the ICD-10-CM 19. Code assignment and Clinical Criteria).

- BCN believes that the diagnosis of colon cancer (C18.9) is validated by the medical record submitted to OIG. OIG ignored documentation regarding a recent colonoscopy to assess status of the patient's colon cancer. The provider clearly indicated that this was a current condition, and it was coded accordingly. A provider's diagnostic statement that the condition exists is enough to support the assignment of a diagnosis code. The code for colon cancer is supported in the medical record provided.

HCC 12 - Prostate Cancer

OIG Sample #195 (HCC 12)

- OIG noted in its review, "[b]ased on review of the medical record/s submitted for this HCC, there is no documentation of any condition that will result in the assignment of HCC 12. There is documentation of a past medical history of prostate cancer (Z85.46) that does not result in an HCC."
- BCN provided an office visit encounter record (195-01-PHY) from 10/10/2017 to support the diagnosis code:
  - ***The patient's medical history.*** The patient was a 68-year-old male who was evaluated by the urologist to follow up on his diagnosis of prostate cancer.
  - ***The patient's encounter.*** Provider documented the following: "Back in 2009, he had an aborted prostatectomy. We could not feel his prostate. It was too far under the pubic bone to do anything. He had radiation and has done extremely well." Additionally, the provider noted the following impression: "Impression and Plan: Prostate cancer. We will do nothing other than observe. We will see him back in a year."
- Relevant Coding Guidelines:
  - "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2018; Section A, Section I.A. Conventions for the ICD-10-CM 19. Code assignment and Clinical Criteria).
  - "When a primary malignancy has been previously excised or eradicated from its site and there is no further treatment directed to that site and there is no evidence of any existing primary malignancy, a code from category Z85, Personal history of malignant neoplasm, should be used to indicate the former site of the malignancy." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2018; Section I. C. Chapter-Specific Coding Guidelines 2. Chapter 2: Neoplasms (C00-D49) d. Primary malignancy previous excised).

- Per AAPC guidelines, in defining terms of care in cancer, "**Current:** Cancer is coded as current if the record clearly states active treatment is for the purpose of curing or palliating cancer, or states cancer is present but unresponsive to treatment; the current treatment plan is observation or watchful waiting; or the patient refused treatment." AAPC, Clear Up Confusion as to When Cancer Becomes "History Of", available at https://www.aapc.com/blog/40016-clear-up-confusion-as-to-when-cancer-becomes-history-of/.

- BCN believes that the diagnosis of prostate cancer (C61) is validated by the medical record submitted to OIG. OIG ignored documentation that the patient has prostate cancer with a failed excision. Although the patient underwent radiation, the prostate cancer did not resolve and is currently under "observation status." As noted, when the current treatment plan of the cancer is watchful waiting, it can be diagnosed as current. In order for the diagnosis to be coded as personal history of malignant neoplasm, the neoplasm would have had to be excised. A failed prostatectomy indicates that the patient did not have a successful excision. Additionally, the provider's diagnostic statement that the condition exists is enough to support the assignment of a diagnosis code. The code for prostate cancer is supported in the medical record provided.

OIG Sample #203 (HCC 12)

- OIG noted in its decision, "[b]ased on review of the medical record/s submitted for this HCC, there is no documentation of any condition that will result in the assignment of HCC 12. There is documentation of a past medical history of prostate cancer (Z85.46) that does not result in an HCC."
- BCN provided an office visit record (203-01-PHY) from 06/06/2017 to support the diagnosis code:
  - ***The patient's medical history.*** The patient was a 70-year-old male who presented to this office visit for management of prostate cancer.
  - ***The patient's encounter.*** The provider noted the following: the patient "presents to clinic today for a follow up of his prostate cancer s/p XRT. Patient was seen by Dr. Soloman in March 2015. In September 2012, he was diagnosed with Gleason 3+4=7 adenocarcinoma involving 5% of biopsied tissue. This was located in the left base, mid and apex. He presented with a PSA of 5.69 ng/ml and a gland volume of 79 cc. In February 2023, a da Vinci prostatectomy was attempted, but due to his size, procedure was canceled. He had a course of external beam radiation therapy given to him by Dr. Forman at 21st Century Oncology. He completed radiation therapy in June 2013." Under the Problem List, primary malignant neoplasm of prostate is listed as a current diagnosis for which the patient was being seen by oncology. The provider's impression included the following: Problem #1, Prostate Cancer s/p XRT. Under Assessment / Plan, the following was included: "PSA Diagnostics to be performed in 1 year on 06/06/2018; Today's Plan: follow up in 12 months for PSA."
- Relevant Coding Guidelines:
  - "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2018; Section A, Section I.A. Conventions for the ICD-10-CM 19. Code assignment and Clinical Criteria).

- "When a primary malignancy has been previously excised or eradicated from its site and there is no further treatment directed to that site and there is no evidence of any existing primary malignancy, a code from category Z85, Personal history of malignant neoplasm, should be used to indicate the former site of the malignancy." (Respective ICD-10-CM Official Guidelines for Coding and Reporting FY 2018; Section I. C. Chapter-Specific Coding Guidelines 2. Chapter 2: Neoplasms (C00-D49) d. Primary malignancy previous excised).
- Per AAPC guidelines, in defining terms of care in cancer, "**Current:** Cancer is coded as current if the record clearly states active treatment is for the purpose of curing or palliating cancer, or states cancer is present but unresponsive to treatment; the current treatment plan is observation or watchful waiting; or the patient refused treatment." AAPC, Clear Up Confusion as to When Cancer Becomes "History Of", available at https://www.aapc.com/blog/40016-clear-up-confusion-as-to-when-cancer-becomes-history-of/.

- BCN believes that the diagnosis of prostate cancer (C61) is validated by the medical record submitted to OIG. OIG ignored documentation that the patient has prostate cancer with a failed excision. Although the patient underwent radiation, the prostate cancer did not resolve and is currently being watched with follow ups with oncologists and annual labs. As noted, when the current treatment plan of the cancer is watchful waiting, it can be diagnosed as current. In order for the diagnosis to be coded as personal history of malignant neoplasm, the neoplasm would have had to be excised. A failed prostatectomy indicates that the patient did not have a successful excision. Additionally, the provider's diagnostic statement that the condition exists is enough to support the assignment of a diagnosis code. The code for prostate cancer is supported in the medical record provided.

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