Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE ADVANTAGE COMPLIANCE AUDIT OF SPECIFIC DIAGNOSIS CODES THAT EXCELLUS HEALTH PLAN, INC. (CONTRACT H3351) SUBMITTED TO CMS

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> July 2023 A-07-20-01202

Office of Inspector General

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Report in Brief

Date: July 2023

Report No. A-07-20-01202

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

Why OIG Did This Audit

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

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

For this audit, we reviewed one MA organization, Excellus Health Plan, Inc. (Excellus), and focused on seven groups of high-risk diagnosis codes. Our objective was to determine whether selected diagnosis codes that Excellus submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

How OIG Did This Audit

We sampled 210 unique enrollee-years with the high-risk diagnosis codes for which Excellus received higher payments for 2017 through 2018. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$515,090.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS

What OIG Found

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that Excellus submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, for 202 of the 210 sampled enrollee-years, the medical records that Excellus provided did not support the diagnosis codes and resulted in \$479,487 in overpayments. As demonstrated by the errors found in our sample, Excellus's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements could be improved. On the basis of our sample results, we estimated that Excellus received approximately \$5.4 million in overpayments for 2017 and 2018. Because of Federal regulations (updated after we issued our draft report) that limit the use of extrapolation in Risk Adjustment Data Validation audits for recovery purposes to payment years 2018 and forward, we are reporting the overall estimated overpayment amount but are recommending a refund of \$3.1 million (\$235,453 for the sampled enrollee-years from 2017 and an estimated \$2.9 million for 2018).

What OIG Recommends and Excellus Comments

We recommend that Excellus: (1) refund to the Federal Government the \$3.1 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 its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements and take the necessary steps to enhance those procedures.

Excellus disagreed with our recommendations and disagreed with our findings for 2 sampled enrollee-years which, according to Excellus, were supported by the medical records. Excellus did not directly agree or disagree with our findings for the remaining 200 enrollee-years. Excellus did not agree with our audit methodology, use of extrapolation, standards for data accuracy, and medical record review process. After reviewing Excellus's comments, we maintain that our findings and recommendations are valid. We revised the amount in our first recommendation in accordance with CMS's updated regulations. We made no changes to our second and third recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

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

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS.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 Excellus Health Plan, Inc. (Excellus), for contract number H3351 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 Excellus submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

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

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

³ All subsequent references to "Excellus" in this report refer solely to contract number H3351.

BACKGROUND

Medicare Advantage Program

The MA program offers beneficiaries managed care options by allowing them to enroll in private health care plans rather than having their care covered through Medicare's traditional fee-for-service program.⁴ Beneficiaries who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

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

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

Risk Adjustment Program

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

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

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

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

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

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

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

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

To determine an enrollee's health status for purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from acceptable data sources, including certain physicians and hospitals. MA organizations collect the diagnosis codes from providers based on information documented in the medical records and submit these codes to CMS. CMS then maps certain diagnosis codes, on the basis of similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs).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 one year (known as the service year) to determine HCCs and calculate risk scores for the following calendar year (known as the payment year). Thus, an enrollee's risk score does not change for the year in which a diagnosis is made. Instead, the risk score changes for the entirety of the year after the diagnosis has been made. Further, the risk score calculation is an additive process: As HCC factors (and, when applicable, disease interaction factors) accumulate, an enrollee's risk score increases, and the monthly risk-adjusted payment to the MA organization also increases. In this way, the risk adjustment program compensates MA organizations for the additional risk of providing coverage to enrollees expected to require more health care resources.

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

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (H3351) Submitted to CMS (A-07-20-01202)

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

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

High-Risk Groups of Diagnoses

Using data mining techniques and discussions with medical professionals, we identified diagnoses that were at higher risk 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 that diagnosis on a corresponding inpatient or outpatient hospital claim. In these instances, a diagnosis of history of stroke (which does not map to an HCC) typically should have been used.
- Acute 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 that diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician or outpatient claim). In these instances, a diagnosis indicating a history of 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.

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.

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 "unsupported" to denote whether or not the reviewed diagnoses were evidenced in the medical records. If our audit determines that the diagnoses are supported or unsupported, we accordingly use the terms "validated" or "unvalidated" with respect to the associated HCC.

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

EXCELLUS HEALTH PLAN, INC.

Excellus is an MA organization based in Rochester, New York. As of December 2018, Excellus provided coverage under contract number H3351 to 96,254 enrollees. For the 2017 and 2018 payment years (audit period), CMS paid Excellus approximately \$1.5 billion to provide coverage to its enrollees. 11, 12

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 Excellus and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

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

We identified 3,217 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$5,824,956).¹³ We selected for audit a stratified 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	12	18	30
2. Acute myocardial infarction	12	18	30
3. Embolism	13	17	30
4. Lung cancer	18	12	30
5. Breast cancer	15	15	30
6. Colon cancer	10	20	30
7. Prostate cancer	18	12	30
8. Total for All High-Risk Groups	98	112	210

Excellus provided medical records as support for the selected diagnosis codes associated with 201 of the 210 enrollee-years. We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. For the HCCs that were not validated, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or if we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group, we included the financial 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

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¹³ The 3,217 unique enrollee-years and associated payments that we reviewed consisted of 1,464 enrollee-years (\$2,671,441) for payment year 2017 and 1,753 enrollee-years (\$3,153,515) for payment year 2018.

¹⁴ Excellus could not locate medical records for the remaining 9 sampled enrollee-years.

obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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

FINDINGS

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that Excellus submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 8 of the 210 sampled enrollee-years, the medical records validated the reviewed HCCs. For the remaining 202 enrollee-years, however, either the medical records that Excellus provided did not support the diagnosis codes or Excellus could not locate the medical records to support the diagnosis codes and the associated HCCs were therefore not validated and resulted in \$479,487 in overpayments.

As demonstrated by the errors found in our sample, Excellus'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 Excellus received at least \$5,373,270 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 \$3,103,290 in overpayments (\$235,453 for the sampled enrollee-years from 2017 and an estimated \$2,867,837 for 2018). ¹⁶

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 After we had issued our draft report, CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643 (Feb. 1, 2023)). 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 44 later in this report.

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 such data must conform to all relevant national standards (42 CFR §§ 422.504(I) 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, chap. 7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7, § 40). The diagnosis must be coded according to the International Classification of Diseases (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, chap. 7, § 40).

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

MOST OF THE SELECTED HIGH-RISK DIAGNOSIS CODES THAT EXCELLUS HEALTH PLAN, INC., SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Most of the selected high-risk diagnosis codes that Excellus 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 202 of the 210 sampled enrollee-years

did not support the diagnosis codes. In these instances, Excellus should not have submitted the diagnosis codes to CMS and received the resulting overpayments.

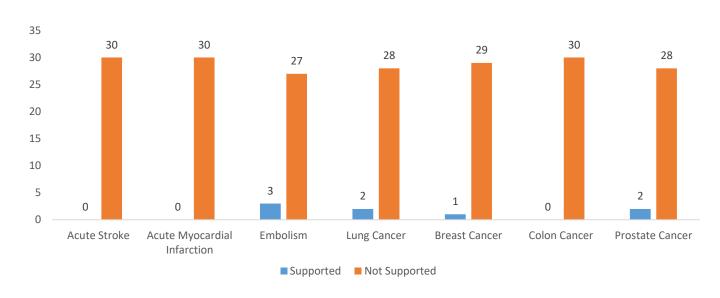


Figure: Analysis of High-Risk Groups

Incorrectly Submitted Diagnosis Codes for Acute Stroke

Excellus incorrectly submitted diagnosis codes for acute stroke for all 30 sampled enrolleeyears. Specifically:

 For 22 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 7 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no evidence of an acute stroke or any related condition that would result in an

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.

assignment of [the] HCC [for Ischemic or Unspecified Stroke] or a related HCC. There is documentation of cerebral arteriosclerosis [diagnosis] that does not result in an HCC."18

 For the remaining 1 enrollee-year, Excellus could not locate any medical records to support the acute stroke diagnosis; therefore, the HCC for Ischemic or Unspecified Stroke was not validated.

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and Excellus received \$62,486 in overpayments (\$25,225 for 2017 and \$37,261 for 2018) for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Myocardial Infarction

Excellus incorrectly submitted diagnosis codes for acute myocardial infarction for all 30 sampled enrollee-years. Specifically:

 For 16 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.¹⁹

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in 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 in each case did not support an acute myocardial infarction 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 HCC [for Acute Myocardial Infarction]."

• For 6 enrollee-years, the medical records did not support an acute myocardial infarction diagnosis.²⁰ 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-

¹⁸ Cerebral arteriosclerosis is the result of thickening and hardening of the walls of the arteries in the brain.

¹⁹ 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.

²⁰ For 1 of the 6 enrollee-years, Excellus could not locate any medical records to support the myocardial infarction diagnosis. However, for this enrollee-year we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group.

disease group. Accordingly, Excellus 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 Acute Myocardial Infarction]. There is documentation of acute coronary syndrome that results in [the] HCC [for Unstable Angina and Other Acute Ischemic Heart Disease] which should have been assigned instead of the submitted HCC."²¹

 For the remaining 2 enrollee-years, Excellus could not locate any medical records to support the acute myocardial infarction diagnosis; therefore, the HCC for Acute Myocardial Infarction was not validated.

As a result of these errors, the HCC for Acute Myocardial Infarction was not validated, and Excellus received \$44,997 in overpayments (\$19,806 for 2017 and \$25,191 for 2018) for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

Excellus incorrectly submitted diagnosis codes for embolism for 27 of 30 sampled enrolleeyears. Specifically:

 For 18 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Embolism HCC.²²

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 patient testing negative for pulmonary embolism."²³

 For 6 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.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (H3351) Submitted to CMS (A-07-20-01202)

²¹ Acute coronary syndrome refers to a group of diseases in which blood flow to the heart is decreased.

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

²³ A pulmonary embolism is a blood clot that develops in a blood vessel in the body. It then travels to a lung artery where it blocks blood flow.

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."²⁴

• For 3 enrollee-years, Excellus could not 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 Excellus received \$59,711 (\$22,332 for 2017 and \$37,379 for 2018) overpayments for these 27 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

Excellus incorrectly submitted diagnosis codes for lung cancer for 28 of 30 sampled enrolleeyears. Specifically:

 For 18 enrollee-years, the medical records indicated in each case that the individual had previously had lung cancer, but the records did not justify a lung cancer diagnosis at the time of the physician's service.

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

- For 8 enrollee-years, the medical records 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, Excellus 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.
- For 1 enrollee-year, the medical records did not support a lung cancer diagnosis.
 Specifically, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Lung and Other Severe Cancers]."
- For the remaining 1 enrollee-year, Excellus could not locate any medical records to support the lung cancer diagnosis; therefore, the HCC for Lung and Other Severe Cancers was not validated.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (H3351) Submitted to CMS (A-07-20-01202)

²⁴ Deep vein thrombosis occurs when a blood clot forms in one or more of the deep veins in the body, usually in the legs.

As a result of these errors, the HCC for Lung and Other Severe Cancers was not validated, and Excellus received \$184,220 in overpayments (\$110,902 for 2017 and \$73,318 for 2018) for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

Excellus incorrectly submitted diagnosis codes for breast cancer for 29 of 30 sampled enrolleeyears. Specifically:

- For 27 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, 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 the remaining 2 enrollee years, the medical records in each case did not support a breast cancer diagnosis.

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

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Excellus received \$33,341 in overpayments (\$17,074 for 2017 and \$16,267 for 2018) for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

Excellus incorrectly submitted diagnosis codes for colon cancer for all 30 sampled enrolleeyears. Specifically:

- For 22 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 5 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 2 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, Excellus 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 1 enrollee-year, Excellus could not 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 Excellus received \$62,783 in overpayments (\$21,750 for 2017 and \$41,033 for 2018) for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

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

- For 27 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 1 enrollee-year, the medical records did not support a prostate cancer diagnosis. Specifically, 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 prostate cancer that can't be ruled out, which means prostate cancer is not confirmed."

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Excellus received \$31,949 in overpayments (\$18,364 for 2017 and \$13,585 for 2018) for these 28 sampled enrollee-years.

Summary of Incorrectly Submitted Diagnosis Codes

In summary and with respect to the seven high-risk groups covered by our audit, Excellus received \$479,487 in overpayments for the 202 sampled enrollee-years (\$235,453 for 2017 and \$244,034 for 2018).

THE POLICIES AND PROCEDURES THAT EXCELLUS HEALTH PLAN, INC., 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 Excellus 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 preventative measures, Excellus had compliance procedures that included a variety of provider-specific outreach efforts designed to educate its providers on medical record documentation and coding. These outreach efforts included monthly newsletters that provided information on coding accuracy, including how to: (1) accurately document on the medical record several of the high-risk groups identified in this audit (myocardial infarction, cancers), and (2) distinguish between active and historical medical conditions. The outreach efforts also provided information regarding changes to the ICD Coding Guidelines.

Excellus's compliance procedures also included detection and correction measures designed to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. Excellus performed various diagnosis coding audits for which it selected previously submitted claims, through either a random sample or a focused selection, to determine the accuracy of the diagnosis codes. If the coding audits identified any coding errors, Excellus's policies and procedures provided guidance on how to submit the corrections to CMS.

In addition, Excellus routinely educated its coders on best coding practices and acceptable medical documentation guidelines. This coder education emphasized how to accurately code several of the high-risk groups identified in this audit (acute stroke, myocardial infarction, embolism, and cancers), and how to differentiate between current conditions and historical conditions.

We acknowledge that Excellus'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 202 of the 210 sampled enrollee-years were not supported by medical records, we believe that these procedures could be improved.

EXCELLUS HEALTH PLAN, INC., 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 Excellus received at least \$5,373,270 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 estimated overpayment amount, but are recommending \$3,103,290 in overpayments (\$235,453 for the sampled enrollee-years from 2017 and an estimated \$2,867,837 for 2018). (See footnote 16 and Appendix D for sample results and estimates.)

RECOMMENDATIONS

We recommend that Excellus Health Plan, Inc.:

- refund to the Federal Government the \$3,103,290 of estimated overpayments;
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
- continue its examination of 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.

EXCELLUS HEALTH PLAN, INC., COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Excellus disagreed with some of our findings and requested that we withdraw all of our recommendations. More specifically, Excellus did not agree with our findings for 2 of the 202 enrollee-years in error identified in our draft report. For these 2 enrollee-years, Excellus provided explanations as to why it believed that the medical records that it previously gave us validated the reviewed HCCs. Excellus did not directly agree or disagree with our findings for the remaining 200 enrollee-years. With respect to the estimated overpayments, Excellus stated that we "applied inconsistent audit methodologies" that departed from Federal and CMS requirements and practices and that we "fail[ed]to account for potentially unreported diagnosis codes."

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

We reviewed the entirety of Excellus's comments and for the reasons detailed below, we maintain that our findings are valid. After we issued our draft report, CMS updated its regulations for RADV audits to specify that extrapolated overpayments could only be recouped beginning with payment year 2018 (footnote 16). Because our audit period covered payment years 2017 and 2018, we revised the amount in our first recommendation for this final report. 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. We made no changes to our second and third recommendations.

A summary of Excellus's comments and our responses follows. Excellus's comments appear in their entirety as Appendix F.

EXCELLUS HEALTH PLAN, INC., DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S RECOMMENDATION THAT IT REFUND OVERPAYMENTS

Excellus Health Plan, Inc., Did Not Agree With the Office of Inspector General's Findings for 2 Sampled Enrollee-Years

Excellus Health Plan, Inc., Comments

Excellus did not agree with our findings for 2 of the sampled enrollee-years in the breast cancer high-risk group and provided explanations as to why it believed that the medical records that it previously gave us validated the reviewed HCCs.

For both of these sampled enrollee-years, Excellus stated that "the medical records indicate[d] that the patients were prescribed medications that indicate[d] active treatment for breast cancer." The prescribed medications in each case "appeared on the patient's problem list."

Office of Inspector General Response

Our independent medical review contractor reviewed the additional explanations for the 2 sampled enrollee-years and reaffirmed that the HCCs for both of the enrollee-years were not validated, thus upholding its original decision. For example, for 1 of the enrollee-years in question, the contractor reviewed Excellus's additional explanations and stated that "[t]he submitted record is an ophthalmology report. There is mention of bilateral mastectomy that the patient underwent almost a decade ago. Personal history . . . should be assigned." 26

The independent medical review contractor confirmed that Excellus's additional explanations had no impact on the decisions that the contractor made for other sampled enrollee-years.

²⁶ Ophthalmology is the study of medical conditions relating to the eye. A bilateral mastectomy is the surgical removal of both breasts to treat or prevent breast cancer.

Excellus Health Plan, Inc., Did Not Agree With How the Office of Inspector General Characterized Its Audit Results

Excellus Health Plan, Inc., Comments

Excellus stated that we "unfairly and inaccurately" characterized our audit results, specifically, our statement (at the beginning of our "Findings" section above) that "most of the selected diagnosis codes that Excellus submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements." This statement could, according to Excellus, inaccurately suggest that we made this conclusion about all diagnosis codes that Excellus has submitted to CMS. Excellus requested that we revise the statement to clarify that our conclusions refer only to the selected diagnosis codes sampled in Excellus's contract H3351 for 2016 and 2017 dates of service.

Office of Inspector General Response

We disagree with Excellus's assertion. Our objective and our explanation of the scope of our audit (Appendix A) make it clear that our audit considered only *selected* diagnoses that Excellus, under contract number H3351, submitted to CMS. We conveyed our findings and recommendations (i.e., our audit results) within the framework of these limitations.

Excellus Health Plan, Inc., Stated That the Office of Inspector General's Use of Different Audit Methodologies Between Audits of Medicare Advantage Organizations Was Arbitrary and Capricious

Excellus Health Plan, Inc., Comments

Excellus stated that we "appl[ied] materially different methodologies from one audit to another." Excellus commented that we "selected a shifting set of 'high risk' diagnosis codes" in our audits and added that we "used inconsistent methodologies across this 'series of audits' to calculate [our] recommended repayment amounts."

To this point, Excellus stated that this audit reviewed four cancer-related groups of high-risk diagnosis codes, whereas other reports we have issued did not review any cancer-related groups. Excellus also noted that "[n]either OIG [Office of Inspector General] nor CMS has ever defined what it means for a diagnosis code to be 'high risk.' [MA organizations] therefore have no notice of the [diagnosis] codes OIG might consider 'high risk' and no way to glean what standard OIG is utilizing to determine the universe of supposedly 'high risk' diagnosis codes."

Furthermore, Excellus stated that our audit applied "inconsistent methodologies" (i.e., judgmental samples without extrapolation for some audits and statistical sampling with extrapolation for other audits) when calculating overpayments. According to Excellus, "[s]uch variations [in audit methodologies] introduce unfairness and inconsistency into the Medicare Advantage model."

Office of Inspector General Response

Both our selection of high-risk diagnosis codes across our series of audits and our calculation of recommended overpayment amounts were planned and performed in accordance with GAGAS. We designed this audit to determine whether the diagnosis codes that Excellus submitted to CMS for use in the risk adjustment program were adequately supported in the medical records, and thus complied with Federal requirements.

As explained in Appendix C, our sampling methodology identified specific diagnoses as high risk if they met certain parameters. The parameters helped us determine whether the identified diagnoses were at high risk for being miscoded. We therefore disagree with Excellus's comment that we did not define how we identified a diagnosis code as high risk. We provided this information in detail to Excellus at the beginning of the audit.

We note as well that Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.²⁷ Moreover, the methodology and approaches that we have used to identify highrisk diagnosis codes and calculate overpayments for our series of audits of MA organizations have evolved over time. Although our early audits of high-risk diagnosis codes (Appendix B) included only non-statistical sampling, we subsequently determined that the best and most appropriate use of our resources was to transition to statistical sampling and estimation for subsequent audits. As a result, the methodology used in this audit did not mirror the methodology used in those early audits—nor did it have to.

Excellus Health Plan, Inc., Stated That the Office of Inspector General's Audit and Repayment Calculation Methodologies Were Not Issued Via Proper Rulemaking Procedures and Arbitrarily and Capriciously Departed From Established CMS Practices

Excellus Health Plan, Inc., Comments

Excellus stated that we did not use notice-and-comment rulemaking to establish the methodology used in our audits. According to Excellus, notice-and-comment rulemaking is required for RADV audits. Excellus also stated that our audit "departs significantly from CMS's established risk adjustment audit standards and methodologies." Furthermore, Excellus stated that without "advance notice and without publishing [our] methodologies in a formal manner," our audit was "procedurally defective, arbitrary and capricious."

²⁷ See Yorktown Med. Lab., Inc. v. Perales, 948 F.2d 84 (2d Cir. 1991); Illinois Physicians Union v. Miller, 675 F.2d 151 (7th Cir. 1982); Momentum EMS, Inc. v. Sebelius, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); Anghel v. Sebelius, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); Miniet v. Sebelius, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012); Bend v. Sebelius, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

Excellus elaborated on its concerns that we did not use notice-and-comment rulemaking with two related points:

- Excellus stated that our use of the lower limit of a two-sided 90-percent confidence interval to calculate the extrapolated repayment amount "departs with CMS methodology and is statistically flawed." Excellus stated that "CMS uses the lower bound of a 99% confidence interval to calculate RADV repayment amounts" and that we "must recalculate the extrapolated 'overpayment' amount using the lower bound of the more statistically robust 99% confidence interval consistent with CMS practice for RADV audits as OIG has not explained its reasoning for its departure from this approach and has not issued another approach via notice and comment rulemaking."
- Excellus also questioned our use of a physician as a "tie-breaker" in instances when two coding reviewers disagree, stating that this practice "arbitrarily and capriciously departed from CMS and industry best practices." Excellus said that under CMS RADV procedures, our coding reviews should only have reviewed medical records to determine whether the records "included documentation supporting the assigned diagnosis code." According to Excellus, our use of a physician as a "tie-breaker" sought to apply a "clinical accuracy analysis for underlying diagnoses," which would require "an entirely different process and methodology" than the ones we describe in our report. Excellus stated that we did not follow "proper notice and comment rulemaking procedures for establishing a process that handles coding disagreements in a manner inconsistent with CMS practice."

Furthermore, Excellus elaborated on its position that we departed from CMS RADV standards and methodologies with the following two additional points related to our independent medical record coding review process:

- Excellus stated that the coding reviewers employed by our independent medical review contractor did "not appear to have the requisite backgrounds and certifications that CMS guidance indicates is necessary for conducting risk adjustment [coding] reviews." Excellus specifically mentioned that the information about these reviewers that we gave to Excellus did not directly state that these coding reviewers were experienced in CMS's risk adjustment methodology. Excellus said that the coding reviewers should have had, at a minimum, the following qualifications: a credential with either the American Health Information Management Association (AHIMA) or the American Academy of Professional Coders (AAPC), along with the Certified Risk Adjustment Coder (CRC) certification.
- Excellus also stated that we did not provide it "with the specific coding guidance that
 [our] coders relied upon in doing their work. OIG has only provided Excellus a list of
 references that OIG coders used as guidance in the materials provided after the exit
 conference." Excellus expressed its concern that we did not conform to CMS's coding

guidance and added that the coding guidance we provided to our independent medical review contractors "undoubtedly had a substantial impact on the results of the audit."

Office of Inspector General Response

We do not agree with Excellus'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 Department of Health and Human Services (HHS) programs and operations in accordance with the Inspector General Act of 1978, 5 U.S.C. Ch. 4. Therefore, we do not agree with Excellus's assertion that our audit was "defective, arbitrary and capricious." We make the following additional points in response to Excellus's related points regarding notice-and-comment rulemaking:

- OIG is an independent oversight agency; therefore, our estimation methodology does
 not need to mirror CMS's estimation methodology. Our policy recommends recovery at
 the lower limit of a two-sided 90-percent confidence interval. We believe that the lower
 limit of a two-sided 90-percent confidence interval provides a reasonably conservative
 estimate of the total amount overpaid to Excellus for the enrollee-years and time period
 covered in our sampling frame. This approach, which is routinely used by HHS for
 recovery calculations,²⁸ results in a lower limit (the estimated overpayment amount)
 that is designed to be less than the actual overpayment total 95 percent of the time.
- To Excellus's point questioning our use of a physician as a "tie-breaker" in instances when two coding reviewers disagree, the independent medical review contractor used both skilled coders and physicians (when necessary) to review medical record documentation. This approach was in accordance with the relevant CMS guidance, which states that "reviewers should evaluate all listed conditions for consistency . . . within the full provider documentation" (emphasis added). The coders and physicians did not make clinical judgments, but rather applied coding rules to accurately assign applicable ICD codes that translated to HCCs. Physician input was not an assessment of clinical support; rather, it constituted an assessment of documented evidence in support

²⁸ For example, HHS has used the two-sided 90-percent confidence interval when calculating recoveries in both the Administration for Child and Families and Medicaid programs. See e.g., *New York State Department of Social Services*, HHS Departmental Appeals Board (DAB) No. 1358, 13 (1992); *Arizona Health Care Cost Containment System*, DAB No. 2981, 4-5 (2019). In addition, HHS contractors rely on the one-sided 90-percent confidence interval, which is less conservative than the two-sided interval, for recoveries arising from Medicare fee-for-service (FFS) overpayments. See e.g., *Maxmed Healthcare*, *Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 17-18 (E.D.N.Y. 2012).

²⁹ CMS, Contract-Level Risk Adjustment Data Validation, Medical Record Reviewer Guidance, in effect as of 3/20/2019. Available online at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/Medical-Record-Reviewer-Guidance.pdf. Accessed on Oct. 26, 2022.

of the assignment of diagnosis codes. We believe that the use of a physician to serve as the final decision maker (i.e., tie-breaker), was a reasonable method for determining whether the medical records adequately supported the reported diagnosis codes.

We also do not agree with Excellus's comments regarding the qualifications and certifications of the senior coders used by our independent medical review contractor. Nor do we agree with Excellus's characterization of our independent medical record coding review process. Specifically:

- Our independent medical review contractor used the following coding and documentation standards: (1) the CMS-published Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance,³⁰ (2) the 2015 ICD-10-CM Official Guidelines for Coding and Reporting,³¹ (3) the American Hospital Association (AHA) Coding Clinic for ICD-9-CM, and (4) the AHA Coding Clinic for ICD-10-CM and ICD-10-PCS.³² We gave Excellus information on coding guidelines and our independent medical record coding review process shortly after the exit conference. We also discussed at a meeting prior to the entrance conference that our audit shared similarities with CMS's RADV audits. Excellus officials expressed to us at that time that Excellus was familiar with the CMS RADV audits.
- During the course of our audit and again in our draft report, we informed Excellus that our medical reviews were performed by professional coders credentialed by the AHIMA and the AAPC.³³ These coders are experienced in coding ICD-9-CM and ICD-10-CM diagnosis codes for hospital inpatient, outpatient, and physician medical records. Diagnoses documented on the medical records submitted to CMS for risk adjustment purposes must be coded in accordance with the ICD Coding Guidelines. Thus, the senior coders that our independent medical review contractor used do in fact have the requisite backgrounds and certifications called for by CMS guidance.

³⁰ CMS, Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance As of 9/27/2017. Available online at https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-risk-adjustment-data-validation-program/other-content-types/radv-docs/coders-guidance.pdf. Accessed on Oct. 26, 2022.

³¹ ICD-10-CM Official Guidelines for Coding and Reporting FY 2015. Available online at https://www.cdc.gov/nchs/data/icd/10cmguidelines-2015-updated-9-26-14.pdf. Accessed on May 15, 2023.

³² The "PCS" acronym in the ICD-10-PCS refers to the Procedure Coding System, which is a medical classification coding system that tracks various health inventions taken by medical professionals. See also footnote 1.

³³ 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 CRC. RHITs have completed a 2-year degree program and have passed an AHIMA certification exam. AHIMA also credentials individuals with CCS and CCS-P certifications and the AAPC credentials both CPCs and CRCs. This information also appears in a footnote in Appendix A of both our draft and final reports.

Excellus Health Plan, Inc., Stated That the Office of Inspector General's Audits Improperly Ignored Potential Underpayments

Excellus Health Plan, Inc., Comments

Excellus stated that we "failed to account for unreported diagnosis codes . . . and ignored potential underpayments." Specifically, according to Excellus, we "targeted encounters with certain purported 'high risk' diagnosis codes for the purpose of confirming whether those codes could be substantiated by underlying medical records," and that we "ignored additional medical records for enrollees in the audit sample, which could have contained support for additional diagnosis codes not submitted to CMS." Excellus also stated that our failure to account for underpayments not only departed from CMS practices, but also rendered our estimated repayment amount "overstated and erroneous." Excellus requested that we "withdraw and revise [our] repayment calculations to address these biases."

Office of Inspector General Response

Our objective was to determine whether selected high-risk diagnosis codes that Excellus 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 Excellus 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.

Excellus Health Plan, Inc., Stated That the Office of Inspector General's Recommended Repayment Amount Is Incorrect Because It Was Not Adjusted To Ensure Actuarial Equivalence

Excellus Health Plan, Inc., Comments

Excellus stated that our audit methodology did not account for a payment principle known as "actuarial equivalence," because we did not apply an adjustment called a Fee-for-Service (FFS) Adjuster. Excellus noted that CMS published a notice in 2012 that notified MA organizations that it was (in Excellus's words) "incorporating a method to ensure actuarial equivalence into its calculations of recovery amounts for unsubstantiated HCCs identified during its RADV audits."

Excellus added that in 2018, CMS "backed away from the position that an FFS Adjuster is necessary in the RADV context, but a final rule is still pending." Accordingly, Excellus stated that "[a]ny calculation of an overpayment . . . must be calculated to ensure actuarial equivalence," and that our audit was therefore "violating [the Act's] mandate of actuarial equivalence." Excellus also stated that it raised this same point in response to an earlier OIG audit, and that "CMS never sought to pursue the supposed 'overpayments' identified in [the earlier OIG] audit, as requiring those repayments would have disrupted actuarial equivalence."

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 Excellus's comment regarding actuarial equivalence in our overpayment calculations, we note that after we issued our draft report, CMS stated that it "will not apply an adjustment factor (known as an FFS Adjuster) in RADV audits." To this point, we recognize that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program.

EXCELLUS HEALTH PLAN, INC., DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S RECOMMENDATION TO PERFORM ADDITIONAL REVIEWS BEFORE OR AFTER THE AUDIT PERIOD

Excellus Health Plan, Inc., Comments

Excellus disagreed with our second recommendation—that it perform additional reviews to determine whether similar instances of high-risk diagnoses occurred before or after the audit period. According to Excellus, "Medicare Advantage regulations do not require [MA organizations] to audit to the standard that OIG suggests," and our draft report "include[d] misleading statements regarding the nature of [MA organizations'] obligations to ensure data accuracy." Specifically, Excellus stated that "there is an inherent imprecision in risk adjustment data" and that CMS has acknowledged that MA organizations "cannot reasonably be expected to know that every piece of data is correct."

³⁴ The previous report to which Excellus referred was *Risk Adjustment Data Validation of Payments Made to Excellus Health Plan, Inc., for Calendar Year 2007 (Contract Number H3351)* (A-02-09-01014; Oct. 2012).

³⁵ 88 Fed. Reg. 6643 (Feb. 1, 2023).

³⁶ For this statement, Excellus cited to 65 Fed. Reg. 40,169, 40,268 (Jun. 29, 2000).

In addition, Excellus stated that "neither CMS nor OIG nor any other government agency has provided guidance about what specific steps MA plans must take in order to attest to the accuracy, completeness, and truthfulness of risk adjustment data." Moreover, Excellus said that under the annual data accuracy attestation requirements, MA organizations are required only to certify that the risk adjustment data are accurate based on "best knowledge, information, and belief" (42 CFR § 422.504(I)(2). Excellus added that both CMS and OIG have "acknowledged that the attestation requirement 'does not constitute an absolute guarantee of accuracy."³⁷

Excellus also stated that we mischaracterized MA organizations' obligations to ensure data accuracy and added that it "disagrees that HCCs associated with a 'missing' record should be counted as an error." Excellus said that "[t]he provider's submission of a diagnosis code to Excellus is evidence that the condition exists, and the mere fact that Excellus cannot obtain the underlying record many years after the fact for reasons Excellus cannot control should not be sufficient to invalidate the HCC."

Office of Inspector General Response

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

These Federal regulations state that MA organizations must "implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS' program requirements." Furthermore, these regulations specify that Excellus'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.

Furthermore, Excellus's comments implied that we opined on its responsibilities to ensure 100-percent accuracy on 100 percent of 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. We believe that

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (H3351) Submitted to CMS (A-07-20-01202)

³⁷ For this statement, Excellus cited to 64 Fed. Reg. at 61,900 (Nov. 15, 1999).

the error rate identified in our audit (202 of 210 enrollee-years (see Appendix D)) demonstrates that Excellus has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope.

With respect to Excellus's assertions regarding missing 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). Based on our assessment of the information provided by Excellus, we determined that no extraordinary circumstances prevented Excellus from locating the medical records for the enrollee-years in question.

Accordingly, we maintain the validity of our recommendation that Excellus identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period.

EXCELLUS HEALTH PLAN, INC., DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S RECOMMENDATION THAT IT CONTINUE TO EXAMINE ITS EXISTING COMPLIANCE PROCEDURES

Excellus Health Plan, Inc., Comments

Excellus disagreed with our third recommendation—that it continue to examine its existing compliance procedures for diagnoses that are at high risk for being miscoded and enhance those procedures as necessary. Specifically, Excellus stated that it had "a robust and effective compliance program" that "meets applicable legal and regulatory requirements." Excellus also stated that MA organizations "have been given broad discretion to implement compliance programs and are not required to implement the specific types of compliance measures recommended by OIG."

Excellus also said that the results of our audit do not support our conclusion that "Excellus's compliance and education programs could be improved." Excellus stated that our audit "was limited to 2016 and 2017 dates of service and the compliance functions in place to monitor claims data for those years. It is beyond the scope of the audit to arrive at a recommendation for current practices, which were not subject to OIG's audit."

Office of Inspector General Response

Excellus's response implied that we opined on the effectiveness of its entire compliance program. That was not our intention or our focus for this audit. Rather, we limited our audit to selected diagnoses that we determined to be at high risk for being miscoded. Our audit revealed a significant error rate for all of these high-risk groups. Thus, we continue to believe

that Excellus should continue to examine its compliance procedures with respect to these highrisk groups of diagnoses.

Moreover, although we acknowledge that CMS gives discretion to MA organizations when designing a compliance plan, Federal regulations also require MA organizations to implement procedures for "promptly responding to compliance issues as they are raised" and "[correct] such problems promptly and thoroughly to reduce the potential for recurrence" (42 CFR § 422.503(b)(4)(vi)(G). The continued improvement of Excellus's existing procedures and internal data quality reviews (based on the results of this audit) will assist Excellus in attaining better assurance with regard to the "accuracy, completeness and truthfulness" of the risk adjustment data that it submits in the future. Accordingly, we maintain that our third recommendation remains valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid Excellus \$1,466,973,189 to provide coverage to its enrollees for 2017 and 2018. We identified a sampling frame of 3,217 unique enrollee-years (footnote 13) on whose behalf providers documented high-risk diagnosis codes during the 2016 and 2017 service years; Excellus received \$36,099,885 in payments from CMS for these enrollee-years for 2017 and 2018. We selected for audit 210 enrollee-years with payments totaling \$2,530,327.

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). We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$515,090 for our sample.

Our audit objective did not require an understanding or assessment of Excellus'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 July 2022.

METHODOLOGY

To accomplish our objective, we performed the following steps:

- We reviewed applicable Federal laws, regulations, and guidance.
- We discussed with CMS program officials the Federal requirements that MA organizations should follow when submitting diagnosis codes to CMS.
- We identified, through data mining and discussions with medical professionals at a
 Medicare administrative contractor, diagnosis codes and HCCs that were at high risk for
 noncompliance. We also identified the diagnosis codes that potentially should have
 been used for cases in which the high-risk diagnoses were miscoded.
- We consolidated the high-risk diagnosis codes into specific groups, which 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

- o 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)³⁸ to identify enrollees who received high-risk diagnosis codes from a physician during the service years,
 - Risk Adjustment System (RAS)³⁹ to identify enrollees who received an HCC for the high-risk diagnosis codes,
 - Medicare Advantage Prescription Drug System (MARx)⁴⁰ to identify enrollees for whom CMS made monthly Medicare payments to Excellus, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C),
 - Encounter Data System (EDS)⁴¹ to identify enrollees who received specific procedures, and
 - Prescription Drug Event (PDE) file⁴² to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.
- We interviewed Excellus officials to gain an understanding of: (1) the policies and procedures that Excellus followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Excellus'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).

³⁸ MA organizations use the RAPS to submit diagnosis codes to CMS.

³⁹ The RAS identifies the HCCs that CMS factors into each enrollee's risk score calculation.

⁴⁰ The MARx identifies the payments made to MA organizations.

⁴¹ The EDS contains information on each item (including procedures) and service provided to enrollees.

⁴² 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 210 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.⁴³
- The independent medical review contractor's coding review followed a specific process to determine whether there was support for a diagnosis code and the associated HCC:
 - If the first senior coder found support for the diagnosis code on the medical record, the HCC was considered validated.
 - If the first senior coder did not find support on the medical record, a second senior coder performed a separate review of the same medical record:
 - If the second senior coder also did not find support, the HCC was considered to be not validated.
 - If the second senior coder found support, then a physician independently reviewed the medical record to make the final determination.
 - If either the first or second senior coder asked a physician for assistance, the physician's decision became the final determination.
- We used the results of the independent medical review contractor, and CMS's systems, to calculate overpayments or underpayments (if any) for each enrollee-year.
 Specifically, we calculated:
 - o a revised risk score in accordance with CMS's risk adjustment program and
 - o the payment that CMS should have made for each enrollee-year.
- We estimated the total overpayment made to Excellus during the audit period.

⁴³ 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 is RADV audits for recovery purposes.⁴⁴ 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 Excellus for the enrollee-years from payment year 2018.
- We discussed the results of our audit with Excellus 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.

⁴⁴ 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 Keystone Health Plan East, Inc.	A-03-20-00001	5/31/2023
(H3952) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That HumanaChoice (Contract H6609)	A-05-19-00013	4/4/2023
Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Cigna-HealthSpring Life & Health	A-07-19-01192	3/28/2023
Insurance Company, Inc. (Contract H4513) Submitted to	A-07-19-01192	3/20/2023
CMS		
Medicare Advantage Compliance Audit of Specific		ļ
Diagnosis Codes That MCS Advantage, Inc. (Contract	A-02-20-01008	3/24/2023
H5577) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Geisinger Health Plan (Contract	A-09-21-03011	3/16/2023
H3954) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes that Cigna-HealthSpring of Tennessee,	A-07-19-01193	12/22/2022
Inc. (Contract H4454) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That BCBS of Rhode Island (Contract	A-01-20-00500	11/16/2022
H4152) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That California Physician's Service, Inc.	A-09-19-03001	11/10/2022
(Contract H0504) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That HumanaChoice (Contract R5826)	A-05-19-00039	9/30/2022
Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Highmark Senior Health Company	<u>A-03-19-00001</u>	9/29/2022
(H3916) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That BlueCross BlueShield of Tennessee,	<u>A-07-19-01195</u>	9/29/2022
Inc. (Contract H7917) Submitted to CMS		
Medicare Advantage Compliance Audit of Diagnosis		
Codes that Inter Valley Health Plan, Inc. (Contract H0545),	<u>A-05-18-00020</u>	9/26/2022
Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Regence BlueCross BlueShield of	A-09-20-03009	9/13/2022
Oregon (Contract H3817) Submitted to CMS		

Report Title	Report Number	Date Issued
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That WellCare of Florida, Inc., (Contract	A-04-19-07084	8/29/2022
H1032) Submitted to CMS		
Medicare Advantage Compliance Audit of Diagnosis		
Codes That Cigna HealthSpring of Florida, Inc. (Contract	A-03-18-00002	8/19/2022
H5410) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Cariten Health Plan, Inc., (Contract	A-02-20-01009	7/18/2022
H4461) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Peoples Health Network (Contract	A-06-18-05002	5/25/2022
H1961) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Tufts Health Plan (Contract H2256)	A-01-19-00500	2/14/2022
Submitted to CMS		
Medicare Advantage Compliance Audit of Diagnosis		
Codes That SCAN Health Plan (Contract H5425) Submitted	<u>A-07-17-01169</u>	2/3/2022
to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Healthfirst Health Plan, Inc.,	<u>A-02-18-01029</u>	1/5/2022
(Contract H3359) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That UPMC Health Plan, Inc. (Contract	<u>A-07-19-01188</u>	11/5/2021
H3907) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Coventry Health Care of Missouri,	<u>A-07-17-01173</u>	10/28/2021
Inc. (Contract H2663) Submitted to CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Anthem Community Insurance	<u>A-07-19-01187</u>	5/21/2021
Company, Inc. (Contract H3655) Submitted to CMS		
Medicare Advantage Compliance Audit of Diagnosis		
Codes That Humana, Inc., (Contract H1036) Submitted to	<u>A-07-16-01165</u>	4/19/2021
CMS		
Medicare Advantage Compliance Audit of Specific		
Diagnosis Codes That Blue Cross Blue Shield of Michigan	A-02-18-01028	2/24/2021
(Contract H9572) Submitted to CMS		
Some Diagnosis Codes That Essence Healthcare, Inc.,		
Submitted to CMS Did Not Comply With Federal	<u>A-07-17-01170</u>	4/30/2019
Requirements		

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified Excellus enrollees who: (1) were continuously enrolled in Excellus 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 Excellus for 2017 or 2018, respectively.

We presented the data for these enrollees to Excellus 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 Excellus. After we performed these steps, our finalized sampling frame consisted of 3,217 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:

- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on only one physician claim during the service year but did not have that diagnosis on a corresponding inpatient or outpatient hospital claim (967 enrollee-years);
- a 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 that diagnosis on
 a corresponding inpatient hospital claim either 60 days before or 60 days after the
 physician or outpatient claim (345 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 (201 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 (134 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 (752 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 (196 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 (622 enrollee-years).

The specific strata are shown in Table 2.

Table 2: Sample Design for Audited High-Risk Groups

Stratum (High-Risk	Frame Count of	CMS Payment for HCCs in Audited	
Groups)	Enrollee-Years	High-Risk Groups	Sample Size
1 – Acute stroke	967	\$1,785,264	30
2 – Acute myocardial			
infarction	345	621,226	30
3 – Embolism	201	450,404	30
4 – Lung cancer	134	925,062	30
5 – Breast cancer	752	895,800	30
6 – Colon cancer	196	446,692	30
7 – Prostate cancer	622	700,508	30
Total	3,217	\$5,824,956	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 a beneficiary identification number and payment year and then consecutively numbered the items in each stratum in the stratified sampling frame. After generating 210 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 Excellus for payment years 2017 and 2018 at the lower limit of the two-sided 90-percent confidence interval (Appendix D, Table 6). 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

After we had issued our draft report, CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (footnote 44). Therefore, we calculated the recommended recovery amount in accordance with CMS's regulations. 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 Excellus for the enrollee-years from payment year 2018.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 3: Sample Details and Results for Payment Year 2017

		CMS		CMS		
		Payments for		Payments		
		HCCs in		for HCCs in		
		Audited		Audited	Number of	
		High-Risk		High-Risk	Sampled	Overpayments
		Groups (for		Groups (for	Enrollee-	for Unvalidated
		Enrollee-		Sampled	Years With	HCCs (for
Audited High-Risk	Frame	Years in	Sample	Enrollee-	Unvalidated	Sampled
Groups	Size	Frame)	Size	Years)	HCCs	Enrollee-Years)
1 – Acute stroke	454	\$836,274	12	\$25,225	12	\$25,225
2 – Acute myocardial						
infarction	146	263,762	12	20,940	12	19,806
3 – Embolism	91	208,358	13	27,751	10	22,332
4 – Lung cancer	62	444,249	18	123,116	17	110,902
5 – Breast cancer	341	410,858	15	17,074	15	17,074
6 – Colon cancer	83	192,142	10	22,969	10	21,750
7 – Prostate cancer	287	315,798	18	20,864	16	18,364
Total	1,464	\$2,671,441	98	\$257,939	92	\$235,453

Table 4: 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 Unvalidated HCCs	Overpayments for Unvalidated HCCs (for Sampled Enrollee-Years)
1 – Acute stroke	513	\$948,990	18	\$37,261	18	\$37,261
2 – Acute myocardial	313	7540,550	10	737,201	10	737,201
infarction	199	357,464	18	31,530	18	25,191
3 – Embolism	110	242,046	17	37,379	17	37,379
4 – Lung cancer	72	480,813	12	77,825	11	73,318
5 – Breast cancer	411	484,942	15	17,347	14	16,267
6 – Colon cancer	113	254,550	20	42,224	20	41,033
7 – Prostate cancer	335	384,710	12	13,585	12	13,585
Total	1,753	\$3,153,515	112	\$257,151	110	\$244,034

Table 5: 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 Unvalidated HCCs	Overpayments for Unvalidated HCCs (for Sampled Enrollee-Years)
1 – Acute						
stroke	967	\$1,785,264	30	\$62,486	30	\$62,486
2 – Acute myocardial						
infarction	345	621,226	30	52,470	30	44,997
3 – Embolism	201	450,404	30	65,130	27	59,711
4 – Lung cancer	134	925,062	30	200,941	28	184,220
5 – Breast cancer	752	895,800	30	34,421	29	33,341
6 – Colon cancer	196	446,692	30	65,193	30	62,783
7 – Prostate cancer	622	700,508	30	34,449	28	31,949
Total	3,217	\$5,824,956	210	\$515,090	202	\$479,487

Table 6: Estimated Overpayments in the Sampling Frame (Payment Years 2017 and 2018 Combined)
(Limits Calculated for a 90-Percent Confidence Interval)

Point Estimate	\$5,662,854
Lower Limit	5,373,270
Upper Limit	5,952,438

Table 7: 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	\$235,453	\$3,078,999	\$3,314,452
Lower Limit	235,453	2,867,837	3,103,290
Upper Limit	235,453	3,290,161	3,525,614

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.



October 24, 2022

BY EMAIL AND FEDEX

James Korn Regional Inspector General for Audit Services Health and Human Services Office of Inspector General 601 East 12th Street Kansas City, MO 64106

RE: Excellus's Response to OIG's Draft Report for Audit No. A-07-20-01202

Dear Mr. Korn:

Excellus Health Plan, Inc. ("Excellus") writes in response to the United States Department of Health and Human Services ("HHS") Office of Inspector General's ("OIG's") Draft Report for Audit No. A-07-20-01202 of Contract H3351 ("Draft Report"). For the reasons discussed below, Excellus respectfully asks that OIG withdraw its recommendations that Excellus repay an extrapolated amount of \$5,373,270, conduct additional audits beyond OIG's sample and make repayments based on those audits. Excellus welcomes a further discussion with OIG regarding the comments contained in this letter and OIG's Draft Report.

I. EXCELLUS REQUESTS THAT OIG MODIFY THE DRAFT REPORT BECAUSE IT MISCHARACTERIZES ITS AUDIT RESULTS

Excellus requests that OIG clarify its statements in the Draft Report that unfairly characterize its audit results. As described in the Draft Report, OIG limited its audit of Excellus to select diagnosis codes and dates of service. Thus, OIG's characterization of its audit results, namely that "most of the selected diagnosis codes that Excellus submitted to CMS for use in CMS's risk adjustment program did not comply with federal requirements" unfairly and inaccurately suggests that OIG has made a conclusion about *all* diagnosis codes Excellus has submitted to the Centers for Medicare and Medicaid Services ("CMS"). Excellus therefore requests that OIG revise its statement that "[m]ost of the selected diagnosis codes that Excellus submitted to CMS for use in CMS's risk adjustment program did not comply" to clarify that OIG's conclusions apply only to select diagnosis codes that OIG sampled in its audit of Contract H3351 for 2016 and 2017 dates of service.

II. EXCELLUS REQUESTS THAT OIG WITHDRAW ITS RECOMMENDED REPAYMENT AMOUNT BECAUSE OIG CALCULATED THAT AMOUNT USING FLAWED AUDIT METHODOLOGIES THAT FAILS TO "ENSURE ACTUARIAL EQUIVALENCE" AS REQUIRED BY STATUTE

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¹ Draft Report at 7.

Excellus disagrees with OIG's recommendation that Excellus repay \$5,373,270 and respectfully requests that OIG recalculate its estimated and extrapolated repayment amounts. Excellus disagrees with the repayment amounts described in the Draft Report for several reasons. First, OIG has applied inconsistent audit methodologies across audits of various Medicare Advantage Organizations ("MAOs"), rendering its audits arbitrary and capricious. Second, OIG's repayment amount is based on audit methodologies that depart from established agency practices. Third, OIG's audit methodologies fail to account for potentially unreported diagnosis codes. Finally, OIG's estimated repayment amount is not adjusted to ensure the statutorily-required actuarial equivalence between expected costs in Medicare Advantage and Fee-For-Service Medicare.

A. OIG's Use of Different Audit Methodologies Between MAOs is Arbitrary and Capricious

Recently, OIG has released reports on a "series of audits" of MAOs' risk adjustment data submissions. These reports that indicate OIG is applying materially different methodologies from one audit to another.

For example, OIG has selected a shifting set of "high risk" diagnosis codes across its audits. Neither OIG nor CMS have ever defined what it means for a diagnosis code to be "high risk." MAOs therefore have had no notice of the codes OIG might consider "high risk" and no way to glean what standard OIG is utilizing to determine the universe of supposedly "high risk" diagnosis codes. This is exacerbated by OIG's selection of significantly different sets of purported "high risk" codes in various audits. For example, in one audit, OIG reviewed two groups of "high risk diagnosis codes." Yet, in two later audits, OIG reviewed nine or ten groups of "high risk diagnosis codes." In other audits, OIG reviewed six or seven groups of "high risk diagnosis codes."

In this audit of Excellus, OIG reviewed seven groups of "high risk diagnosis codes" which included acute stroke, acute myocardial infarction, embolism, breast cancer, prostate cancer, lung cancer, and colon cancer. Only two other audits aside from the one of Excellus has

² Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements, OIG Report No. A-07-17-01170 (April 2019) ("Essence Audit").

³ Medicare Advantage Compliance Audit of Specific Diagnosis Codes that UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS, OIG Report No. A-07-19-01188 (November 2021) ("UPMC Audit"); Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS, OIG Report No. A-02-20-01009 (July 2022) ("Cariten Audit").

⁴ Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS, OIG Report No. A-02-18-01028 (February 2021) ("BC Michigan Audit"); Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS, OIG Report No. A-07-19-01187 (May 2021) ("Anthem Audit"); Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS, OIG Report No. A-07-17-01173 (October 2021) ("Coventry Audit"); Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS, OIG Report No. A-02-18-01029 (January 2022) ("Healthfirst Audit"); Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Tufts Health Plan (Contract H2256) Submitted to CMS, OIG Report No. A-01-19-00500 (February 2022) ("Tufts Audit"); Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Peoples Health Network (Contract H1961) Submitted to CMS, OIG Report No. A-06-18-05002 (May 2022) ("Peoples Health Audit").

deemed any cancer codes to be "high risk" and OIG did not explain in either case why these cancer codes were "high risk," what made them "high risk," and why they were not considered part of the "high risk" universe of codes for audits of other MAOs. The absence of official CMS and OIG guidance defining "high risk" diagnosis codes paired with OIG's unexplained, inconsistent use of the term across this "series of audits" renders OIG's audit of Excellus arbitrary and capricious.

OIG has also used inconsistent methodologies across this "series of audits" to calculate its recommended repayment amounts. For some MAOs, OIG has recommended that the audited MAOs repay "net overpayments" based on OIG's "judgmentally selected" subset of "unique enrollee-years." For others, OIG calculated "net overpayments" based on its audit sample and then estimated a total net overpayment amount using extrapolation. In these cases, OIG recommended audited MAOs repay the total extrapolated amount. OIG has elected to use the second described methodology for its audit of Excellus.

It is arbitrary and capricious for OIG to conduct auditing in a manner that is varied in scope and methodologies across MAOs. Such variations introduce unfairness and inconsistency into the Medicare Advantage model. To ensure fairness not only between audited and unaudited MAOs, but also between MAOs that OIG has audited using different methodologies, OIG should implement a consistent methodology that has been adopted under notice and comment rulemaking, as discussed infra.

В. OIG's Audit and Repayment Calculation Methodologies Were Not Issued Via Proper Rulemaking Procedures and Arbitrarily and Capriciously Depart from Established Agency Practices in Several Respects

CMS has promulgated its methodology for conducting Risk Adjustment Data Validation ("RADV") audits via notice and comment rulemaking, as is required. OIG's audit of Excellus, however, departs significantly from CMS's established risk adjustment audit standards and methodologies. And OIG has so departed without advance notice and without publishing its methodologies in a formal manner pursuant to notice and comment rulemaking. OIG's audit of Excellus is therefore procedurally defective, arbitrary, and capricious.

OIG's Extrapolated Repayment Amount Relies on a Confidence Interval 1. that is Too Low

OIG recommends that Excellus refund estimated overpayments at the lower limit of a two-sided 90% confidence interval. OIG's use of a 90% confidence interval departs with CMS methodology and is statistically flawed. CMS uses the lower bound of a 99% confidence interval to calculate RADV repayment amounts. 6 OIG must recalculate the extrapolated "overpayment" amount using the lower bound of the more statistically robust 99% confidence interval consistent with CMS practice for RADV audits as OIG has not explained its reasoning

⁵ See UPMC Audit and Cariten Audit.

⁶ CMS, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits (Feb. 24, 2012) at 4.

for its departure from this approach and has not issued another approach via notice and comment rulemaking.

2. <u>OIG's Use of a Physician Tie-Breaker is Against CMS Coding Guidance</u> and Procedures

OIG has again arbitrarily and capriciously departed from CMS and industry best practices by resolving disagreements between coders with an independent clinical review of the medical record by a physician.

The use of a clinical "tie breaker" in a diagnosis coding review is inconsistent with CMS RADV procedures and available coding guidance. A clinical review does not address whether a particular code was correctly assigned based on existing provider documentation, which is the relevant question for purposes of a coding audit. OIG should have only reviewed records to determine whether the record included documentation supporting the assigned diagnosis code. To the extent OIG seeks to apply a clinical accuracy analysis for underlying diagnoses, this would require an entirely different process and methodology than the one OIG describes in its report.

Furthermore, OIG has not followed proper notice and comment rulemaking procedures for establishing a process that handles coding disagreements in a manner inconsistent with CMS practice. In a RADV audit by CMS, if a coder views a Hierarchical Condition Category ("HCC") code as unsubstantiated, the HCC is escalated to a second coder for "Discrepant Confirmation." If the second coder determines that the medical record in question substantiates a diagnosis code that maps to the HCC, then CMS treats the HCC as substantiated without further review. Departure from this methodology without any pre-audit explanation or notice and comment process is arbitrary and capricious.

3. Not All of the OIG Contract Coders Appear to Have the Requisite

Backgrounds and Certifications that CMS Requires for Performing Risk
Adjustment Coding Reviews

The contract coders utilized by OIG do not appear to have the requisite backgrounds and certifications that CMS guidance indicates is necessary for conducting risk adjustment reviews. According to CMS guidance, "CMS RADV reviewers are certified coders, experienced in risk adjustment data validation that are familiar with a variety of medical record layouts, electronic medical record entries, and handwritten medical record documentation." ¹⁰

⁷ See CMS, ICD-10-CM Official Guidelines for Coding and Reporting FY 2019, at 13 (effective October 1, 2018) ("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.").

⁸ *Id*.

⁹ See CMS, Risk Adjustment Data Validation (RADV) Medical Record Intake Process and Guidance to Coders CY2011 version 4.0 at 18-19 (May 8, 2014) ("RADV Guidance.").

¹⁰ CMS, Contract-Level 15 Risk Adjustment Data Validation, Medical Record Reviewer Guidance In effect as of 01/10/2020* Version 2.0, p. 14 (emphasis added).

Excellus respectfully submits that all of the OIG contract coders should have had, at a minimum the following qualifications: a credential with either the ("AHIMA") (e.g., CCS) or the AAPC¹¹ (such as a CPC) along with the Certified Risk Adjustment Coder (CRC) certification. These qualifications would align with CMS guidance that reviewers be "certified [coders], experienced in risk adjustment data validation."¹²

While materials provided to Excellus noted that the coders were overseen by a Medical Director with experience in risk adjustment, the materials do not note that the coders themselves are experienced in risk adjustment. Experience in risk adjustment coding is critical for reviewers assessing medical records to substantiate diagnosis codes. Experience in coding for different settings or circumstances, such as hospital or service-based coding, would not provide sufficient coding experience to perform a diagnosis code-focused coding review of this nature.

4. <u>It is Unclear Whether OIG Coders Relied on Appropriate CMS Coding</u> Guidance

Excellus was not provided with the specific coding guidance that OIG coders relied upon in doing their work. OIG has only provided Excellus a list of references that the OIG coders used as guidance in the materials provided after the exit conference. The coding guidance, including any interpretations of the guidance, OIG provided its coders undoubtedly had a substantial impact on the results of the audit. Given the other inconsistencies with OIG's audit methodologies, Excellus is concerned that OIG did not conform to CMS coding guidance. Excellus reiterates its prior request for information regarding the written guidance and instructions relied upon by OIG's coders in conducting this audit.

C. OIG's Sampling and Review Methodologies Improperly Ignored Potential Underpayment

Excellus also contests OIG's recommended repayment amount because OIG did not conduct a comprehensive medical record review and therefore failed to account for unreported diagnosis codes. OIG designed its audit in a manner that biased the results towards identifying "overpayments" and ignored potential underpayments resulting from diagnosis codes supported by the medical records that were not previously submitted to CMS. In particular, OIG targeted encounters with certain purported "high risk" diagnosis codes for the purpose of confirming

¹¹ AAPC was previously known as the American Academy of Professional Coders.

¹² CMS, Contract-Level 15 Risk Adjustment Data Validation, Medical Record Reviewer Guidance In effect as of 01/10/2020* Version 2.0, p. 14.

¹³ For example, Excellus disagrees with two of OIG's determinations that HCCs for sampled enrollee years are not substantiated by documentation in the relevant medical records. Specifically, OIG highlighted in its draft report that for certain 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." Draft Report at 13. However, for two of these records (Sample 133 and Sample 139), the medical records indicate that the patients were prescribed medications that indicate active treatment for breast cancer. For Sample 133, the medical record notes the patient was being treated with Anastrozole and the diagnosis of breast cancer appeared on the patient's problem list. For Sample 139, the medical record indicates the patient was being treated with Arimidex and the diagnosis of breast cancer appeared on the patient's problem list. Therefore, in both cases, these records contain evidence of active treatment of breast cancer and support the diagnoses recorded rather than a diagnosis of history of cancer, as indicated by OIG's findings. *See*, *e.g.*, ICD-9-CM Coding Clinic, Third Quarter 2009, at 3-4.

whether those codes could be substantiated by underlying medical records. In doing so, OIG ignored additional medical records for enrollees in the audit sample, which could have contained support for additional diagnosis codes not submitted to CMS. Furthermore, even within the medical records that Excellus submitted, OIG did not review for diagnosis codes not submitted to CMS that were un-related to the "high risk" codes at issue. ¹⁴

Not only does OIG's failure to account for underpayments depart from CMS practices, it renders OIG's estimated repayment amount overstated and erroneous. And, in turn, extrapolation of OIG's audit results is statistically unsupported given the biases in the repayment calculation. Therefore, OIG must withdraw and revise its repayment calculations to address these biases.

D. The Recommended Repayment Amount Also is Incorrect Because it is Not Adjusted to Ensure Actuarial Equivalence

Excellus respectfully disagrees with OIG's conclusion that Excellus was overpaid by \$479,486 stemming from the diagnosis codes subject to OIG's audit. In addition to the reasons described above, this figure overstates any overpayment because it has not been adjusted to ensure actuarial equivalence. The Social Security Act ("SSA") and the design of the risk adjustment payment model require CMS to make payments to MAOs in a manner that ensures actuarial equivalence between the MA program and the Medicare Fee-For-Service ("FFS") program. Therefore, payments under risk adjustment should be based on actuarially sound calculations of the cost of providing FFS Medicare benefits to a similar beneficiary. Under the model, these payments are adjusted based on the demographics and health status of the beneficiary. However, the model used to adjust these payments is based on unaudited FFS claims data from the FFS Medicare program—which CMS has acknowledged contain high levels of erroneous diagnoses. To comply with the SSA's mandate of actuarial equivalence, CMS must account for those FFS Medicare data errors when measuring whether similar erroneous diagnoses for Medicare Advantage enrollees result in an overpayment.

In the past, CMS has acknowledged the need to adjust for the errors in Medicare FFS when conducting its own RADV audits. In 2012, CMS published a notice stating that it was incorporating a method to ensure actuarial equivalence into its calculations of recovery amounts for unsubstantiated HCCs identified during its RADV audits. Specifically, CMS said it "[would] apply a Fee-for-Service Adjuster ('FFS Adjuster') amount as an offset to the preliminary recovery amount. CMS explained the FFS Adjuster would be calculated based "on a RADV-like review of records submitted to support [traditional Medicare] claims data." 16

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¹⁴ As described in Draft Report at 6, OIG coders only reviewed for the targeted HCC under review. Diagnoses that resulted in other HCCs were not reviewed or validated.

¹⁵ CMS, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation for Contract-Level Audits, at 4–5 (Feb. 24, 2012).

¹⁶ *Id.* In 2018, CMS backed away from the position that an FFS Adjuster is necessary in the RADV context, but a final rule is still pending. Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program for All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54982 (proposed Nov. 1, 2018) (to be codified at 42 C.F.R. §§ 422, 423, 438, 498).

OIG must also comply with the Medicare Advantage program requirements that govern CMS's RADV audits and overpayment calculations. Any calculation of an overpayment on a contract-wide level must be calculated to ensure actuarial equivalence. This is even more critical in this instance where OIG's audit, as discussed above, was designed to target encounters likely to contain supposed "high risk" diagnosis codes. While OIG's methodology for selecting such "high risk" diagnosis codes remains unclear, it is highly likely that the unaudited FFS Medicare data underlying the risk adjustment model contains similar levels of unsubstantiated codes. By treating these diagnosis codes as "overpayments" in the audit context without adjusting for the underlying unsubstantiated codes in the FFS Medicare data, OIG is violating the SSA's mandate of actuarial equivalence.

Excellus firmly believes that OIG is unable to determine whether Excellus has been overpaid without first establishing an actuarially sound overpayment methodology that takes into account the levels of diagnosis code substantiation in the FFS Medicare program. This is the same point Excellus raised years ago in response to an earlier OIG audit. ¹⁹ It is telling that CMS never sought to pursue the supposed "overpayments" identified in that audit, as requiring those repayments would have disrupted actuarial equivalence. Excellus accordingly again requests that OIG withdraw its recommendation that Excellus repay the amounts identified in the Draft Report.

III. EXCELLUS REQUESTS THAT OIG WITHDRAW ITS RECOMMENDATION THAT EXCELLUS UNDERTAKE ADDITIONAL AUDITING FOR THE CONDITION CATEGORIES SUBJECT TO OIG'S AUDIT BECAUSE MAOS ARE NOT REQUIRED TO ACHIEVE DATA PERFECTION

OIG recommends that Excellus "identify, for the high-risk diagnoses included in [the Draft Report], similar instances of noncompliance that occurred before or after [the] audit period and refund any resulting overpayments to the Federal Government[.]"²⁰ Excellus disagrees with

¹⁷ *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 886 (D.C. Cir. 2021) (holding actuarial equivalence requirement inapplicable to individual diagnosis coding errors, emphasizing it is "[s]ignificant[]" that the term "actuarial" in the SSA "necessarily implies an assessment made at the group or population level, not the individual level").

¹⁸ A court has held that the actuarial equivalence requirement, does not apply to CMS's 2014 "Overpayment Rule." *Id.* But a court has yet to adjudicate whether an FFS Adjuster is required in the RADV audit context. *See id.* at 871, 893 n.1 (rejecting assertion that the Overpayment Rule was inconsistent with CMS's 2012 proposal to include an FFS Adjuster in calculating RADV audit recoveries—a proposal CMS made "in direct response to concerns about actuarial equivalence," and "express[ing] no opinion on whether the [SSA's] actuarial-equivalence requirement . . . requires" an FFS Adjuster in the RADV audit context).

¹⁹ Excellus previously argued in its response to Risk Adjustment Data Validation of Payments Made to Excellus Health Plan, Inc., for Calendar Year 2007 (Contract Number H3351), OIG Report No. A-02-09-01014 (October 2012) that an adjustment should be made OIG's overpayment calculation to account for the FFS error rate underlying the MA model. In response, OIG agreed to only recommend repayment for the particular "overpayments" identified during its audits because of "the potential impact of [the FFS] error rate on the CMS model that we used to recalculate MA payments." OIG instead recommended Excellus work with CMS to calculate the "the correct contract-level adjustments for the projected overpayments."

²⁰ Draft Report at 16.

this recommendation because Medicare Advantage regulations do not require MAOs to audit to the standard that OIG suggests.

Due to the nature of the Medicare risk adjustment payment model—which depends heavily on large quantities of data generated by numerous healthcare providers (and typically not Excellus) applying a complex diagnosis coding system—there is an inherent imprecision in risk adjustment data. As CMS itself has stated, MAOs "cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the [OIG], and [the Department of Justice] believe is reasonable to enforce."

This understanding is reflected in MAOs' annual data accuracy attestation requirements. MAOs are only required to certify that their risk adjustment data is accurate based on "best knowledge, information, and belief." CMS and OIG have both acknowledged that the attestation requirement "does not constitute an absolute guarantee of accuracy." Furthermore, neither CMS nor OIG nor any other government agency has provided guidance about what specific steps MA plans must take in order to attest to the accuracy, completeness, and truthfulness of risk adjustment data, beyond OIG generally suggesting in non-binding guidance that MA plans implement an "information collection and reporting system reasonably designed to yield accurate information" and "exercise due diligence to ensure that these systems are working properly." ²⁴

OIG's Draft Report includes misleading statements regarding the nature of MAOs' obligations to ensure data accuracy. For example, the Draft Report concludes "[f]ederal regulations state that [MAOs] must monitor the data that they receive from providers and submit to CMS."²⁵ As described above, neither OIG nor CMS has prescribed specific monitoring that must occur, nor have MAOs ever been required to monitor every piece of data received from providers.

OIG extends its mischaracterization of MAOs' obligations through its recommendation that Excellus undertake additional auditing for the conditions subject to OIG's audit.²⁶ This

²¹ Medicare Program: Medicare+Choice Program, 65 Fed. Reg. 40,169, 40,268 (June 29, 2000).

²² 42 C.F.R. § 422.504(1)(2).

²³ 64 Fed. Reg. at 61,900.

²⁴ HHS-OIG's Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans, 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999).

²⁵ Draft Report at 7.

²⁶ OIG also overstates MAO's obligations to ensure data accuracy through its treatment of "missing" records. OIG's current audit covers 2016 and 2017 dates of service, which occurred in some cases more than five years before the timing of OIG's Draft Report. The gap between OIG's audits and the service years at issue generates significant practical difficulties for MAOs when collecting records associated with the enrollee years selected for this audit. MAOs face many factors outside of their control, such providers moving away, retiring, or even passing away. In response to this audit, Excellus diligently worked to collect all records requested by OIG, however, Excellus was not able to locate the records for nine sampled enrollee years. Excellus disagrees that HCCs associated with a "missing" record should be counted as an error, particularly since Excellus has diligently attempted to collect those records. The provider's submission of a diagnosis code to Excellus is evidence that the condition exists, and the mere fact that Excellus cannot obtain the underlying record many years after the fact for reasons Excellus cannot control should not be sufficient to invalidate the HCC. Furthermore, Excellus disagrees that an error associated with a missing record should be combined with OIG's other findings when OIG calculates an estimated and extrapolated

directive impermissibly expands Medicare Advantage compliance program requirements as there is no requirement that MAOs audit "high risk" codes. As noted above, the concept of a "high risk" code is not defined anywhere, and OIG cannot identify any statutory or regulatory authority that would allow it to unilaterally impose new substantive requirements on Excellus or other MAOs included in this series of audits. Doing so would subject the industry to unfairness between audited and unaudited MAOs. To the extent HHS intends to impose new regulatory requirements on Excellus, it must do so through notice and comment, under both the Administrative Procedure Act and the SSA.

IV. EXCELLUS REQUESTS THAT OIG WITHDRAW ITS RECOMMENDATION THAT EXCELLUS IMPROVE ITS COMPLIANCE PROGRAM

Excellus requests that OIG withdraw this recommendation because Excellus's compliance and education programs comply with all legal and Medicare Advantage regulatory requirements. Furthermore, there is no basis for OIG's apparent conclusion that Excellus's current compliance programs could be improved. OIG's audit was limited to 2016 and 2017 dates of service and the compliance functions in place to monitor claims data for those years. It is beyond the scope of the audit to arrive at a recommendation for current practices, which were not subject to OIG's audit.

A. Excellus's Compliance Program is Robust, Effective, and Compliant with Applicable Legal and Regulatory Requirements

OIG acknowledges that Excellus has a robust and effective compliance program. The Draft Report recognizes that Excellus has a compliance program that "included detection and correction measures designed to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct" and that Excellus has "compliance procedures that included a variety of provider-specific outreach efforts designed to educate its providers on medical record documentation and coding," as well as "coder education [that] emphasized how to accurately code several of the high-risk areas identified in this audit." Additionally, OIG acknowledges that Excellus's detection procedures are "designed to prevent, detect, and correct high-risk diagnosis codes that those procedures had identified as incorrect." Additionally of the high-risk diagnosis codes that those procedures had identified as incorrect.

Excellus's compliance program meets applicable legal and regulatory requirements. As discussed above, MAOs have been given broad discretion to implement compliance programs and are not required to implement the specific types of compliance measures recommended by OIG. Instead, CMS regulations require MAOs to "[a]dopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS's program requirements as well as measures that prevent, detect, and

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overpayment amount. MAOs cannot reasonably be expected to achieve perfection in record retrieval, and failure to obtain a record does not in and of itself have any bearing on the overall accuracy of an MAO's risk adjustment data. Extrapolating the findings for missing records in combination with other errors only exacerbates this unfairness and is arbitrary and capricious.

²⁷ Draft Report at 15.

²⁸ *Id*.

correct fraud, waste, and abuse."²⁹ CMS has not prescribed any specific compliance measures and instead has stated that it expects MAOs to use their "discretion . . . to design their compliance plan structure to meet the unique aspects of each organization."³⁰ In accordance with these requirements, Excellus has developed programs and processes to evaluate, monitor, and improve risk adjustment data accuracy and completeness, a fact which OIG acknowledges in its report.

B. OIG Has Failed to Identify Any Material Flaws in Excellus's Compliance Program

The results of OIG's audit do not support its conclusion that Excellus's compliance and education programs could be improved. As discussed above, OIG's audit methodology was skewed to identify unsubstantiated diagnosis codes. Therefore, the results of this audit are not indicative of the overall quality of Excellus's data or compliance programs.

Furthermore, even after a thorough review of Excellus's current compliance programs, OIG did not identify any specific aspects of Excellus's compliance programs that are deficient. It is improper, therefore, for OIG to suggest such Excellus's compliance programs need improvement.

V. CONCLUSION

Excellus respectfully disagrees with OIG's proposed recommendations for the reasons explained above and requests that OIG withdraw each one. Excellus welcomes the opportunity to further discuss OIG's methodology, findings, and recommendations. Excellus reserves all rights to challenge any current or revised recommendations.

Sincerely,

DocuSigned by:

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James R. Reed President & CEO

Excellus Health Plan, Inc.

²⁹ 42 C.F.R. § 422.503(b)(4)(vi). This requirement is not specific to the collection or submission of risk adjustment data.

³⁰ 65 Fed. Reg. at 40,265.