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Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Gateway Health Plan, Inc., (Contract H5932) Submitted to CMS

REPORT HIGHLIGHTS

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Why OIG Did This Audit

- Under the Medicare Advantage (MA) program, CMS makes monthly payments to MA organizations based in part on the health status of the enrollees being covered.
- To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from its providers and submit these codes to CMS. Some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.
- This audit of Gateway Health Plan, Inc., is part of a series of audits in which we are reviewing high-risk diagnosis codes that MA organizations submitted to CMS for use in its risk adjustment program.

What OIG Found

Most of the selected diagnosis codes that Gateway submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements.

- For 232 of the 286 sampled enrollee-years, medical records did not support the diagnosis codes and resulted in $830,334 in net overpayments.
- On the basis of our sample results, we estimated that Gateway received at least $4.3 million in net overpayments for 2018 and 2019.

As demonstrated by the errors found in our sample, Gateway's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved.

What OIG Recommends

We recommend that Gateway:

1. refund to the Federal Government the $4.3 million of estimated net overpayments;
2. identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred after our audit period and refund any resulting overpayments to the Federal Government; and
3. continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

Gateway disagreed with some of our findings and all of our recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

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

This audit is part of a series of Office of Inspector General (OIG) 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 54 breast cancer diagnoses into 1 group.) This audit covered Gateway Health Plan, Inc. (Gateway), for contract number H5932, and focused on 10 groups of high-risk diagnosis codes for payment years 2018 and 2019 (audit period).[3, 4]

OBJECTIVE

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

BACKGROUND

Medicare Advantage Program

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

[1] The providers code diagnoses using the International Classification of Diseases (ICD), Clinical Modification, *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 OIG reports.

[3] All subsequent references to "Gateway" in this report refer solely to contract number H5932.

[4] The 2018 and 2019 payment year data were the most recent data available at the start of the audit.

traditional fee-for-service program.[5] Individuals who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers, including hospitals and physicians.

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

For 2024, CMS paid MA organizations $494 billion, which represented 44 percent of all Medicare payments for that year.

Risk Adjustment Program

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

CMS uses two principal components to calculate the risk-adjusted payment that it will make to an MA organization for an enrollee: 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.[7] 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.[8]

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

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

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

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

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

process results in an individualized risk score for each enrollee, which CMS calculates annually.

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

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

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

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

CMS multiplies the risk scores by the base rates to calculate the total monthly Medicare payment that an MA organization receives for each enrollee before applying the budget sequestration reduction.[10] Thus, if the factors used to determine an enrollee's risk score are

[9] During our audit period, CMS calculated risk scores based on the Version 22 CMS-HCC model for payment year 2018 and the Version 23 CMS-HCC model for payment year 2019.

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

incorrect, CMS will make an improper payment to an MA organization. Specifically, if medical records do not support the diagnosis codes that an MA organization submitted to CMS, the HCCs are not validated, which causes overstated enrollee risk scores and overpayments from CMS.[11] Conversely, if medical records support the diagnosis codes that an MA organization did not submit to CMS, validated HCCs may not have been included in enrollees' risk scores, which may cause those risk scores to be understated and may result in underpayments.

High-Risk Groups of Diagnoses

Using data mining techniques and discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. For this audit, we focused on 10 high-risk groups:

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

- *Acute myocardial infarction*: An enrollee received one diagnosis (that mapped to the HCC for Acute Myocardial Infarction) on only one physician or outpatient claim during the service year but did not have an acute myocardial infarction diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician or outpatient claim). In these instances, a diagnosis indicating a history of a myocardial infarction (which does not map to an HCC) typically should have been used.

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

- *Sepsis:* An enrollee received one sepsis diagnosis (that mapped to the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock) on only one physician or outpatient claim during the service year but did not have a sepsis diagnosis

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

on a corresponding inpatient hospital claim. A sepsis diagnosis generally results in an inpatient hospital admission.

- *Pressure Ulcer:* An enrollee received one pressure ulcer diagnosis[12] that mapped to either the HCC for Pressure Ulcer of Skin with Full Thickness Skin Loss or the HCC for Pressure Ulcer of Skin With Necrosis Through to Muscle, Tendon, or Bone (Pressure Ulcer HCCs) on only one claim during the service year but did not have a pressure ulcer diagnosis on another inpatient, outpatient, or physician claim for either the calendar year before or the calendar year after the service year. Individuals diagnosed with the most severe types of pressure ulcers generally receive treatment on multiple occasions.

- *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.

[12] Pressure ulcer diagnoses are categorized into five groups according to severity: stages 1, 2, 3, 4, and unstageable. For this audit, we audited only the most severe types of pressure ulcers: stages 3, 4, and unstageable.

- *Ovarian cancer*: An enrollee received one ovarian cancer diagnosis that mapped to either the HCC for Lymphoma and Other Cancers or to the HCC for Metastatic Cancer and Acute Leukemia (Ovarian Cancer HCCs) on only one claim during the service year but did not have surgical therapy or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of ovarian 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."

Gateway Health Plan, Inc.

Gateway is an MA organization based in Pittsburgh, Pennsylvania. As of December 2019, Gateway provided coverage under contract number H5932 to 46,550 enrollees. For our audit period, CMS paid Gateway approximately $1.5 billion to provide coverage to its enrollees.[13]

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to 1 of the 10 high-risk groups during the 2017 and 2018 service years, for which Gateway received increased risk-adjusted payments for the audit period. Because enrollees could be classified into more than one high-risk group or could have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to their condition and the payment year, which we refer to as "enrollee-years."

We identified 1,823 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes ($6,508,311). We selected for audit a stratified sample of 286 enrollee-years as shown in Table 1 on the following page.

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

Table 1: Sampled Enrollee-Years

High Risk Group	Number of Sampled Enrollee Years
(1) Acute stroke	30
(2) Acute myocardial infarction	30
(3) Embolism	30
(4) Sepsis	30
(5) Pressure ulcer	30
(6) Lung cancer	30
(7) Breast cancer	30
(8) Colon cancer	30
(9) Prostate cancer	30
(10) Ovarian cancer	16*
Total for All High-Risk Groups	**286**

***** For our audit period, we identified 16 enrollee-years for which enrollees received a diagnosis of ovarian cancer. We included all 16 in our review.

Gateway provided medical records as support for the selected diagnosis codes associated with 265 of the 286 sampled enrollee-years.[14] We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. For the HCCs that were not validated, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or if we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

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

FINDINGS

With respect to the 10 high-risk groups covered by our audit, most of the selected diagnosis codes that Gateway submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 54 of the 286 sampled enrollee-years, the medical records

[14] Gateway could not locate medical records for the remaining 21 sampled enrollee-years.

validated the reviewed HCCs.[15] For the remaining 232 enrollee-years, however, either the medical records that Gateway provided did not support the diagnosis codes or Gateway could not locate the medical records to support the diagnosis codes; therefore, the associated HCCs were not validated and resulted in $830,334 in net overpayments.

As demonstrated by the errors found in our sample, Gateway'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 Gateway received at least $4,314,513 in net overpayments for 2018 and 2019.[16]

FEDERAL REQUIREMENTS

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

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

Federal regulations also state that MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes and that such data must conform to all relevant national standards (42 CFR §§ 422.504(l) and 422.310(d)(1)). In addition, MA organizations must contract with CMS and agree to follow CMS's instructions, including the *Medicare Managed Care Manual* (the Manual) (see 42 CFR § 422.504(a)).

CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap. 7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7, § 40). The diagnosis must be coded according to the International Classification of Diseases, Clinical Modification, *Official*

[15] For 2 of the 54 enrollee-years, Gateway informed us that it could not locate the associated medical records because the records had been potentially seized by law enforcement. CMS 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 Gateway, we determined that an extraordinary circumstance prevented Gateway from locating the medical records for these enrollee-years, and we treated the sample items as non-errors.

[16] To be conservative, we estimate net 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.

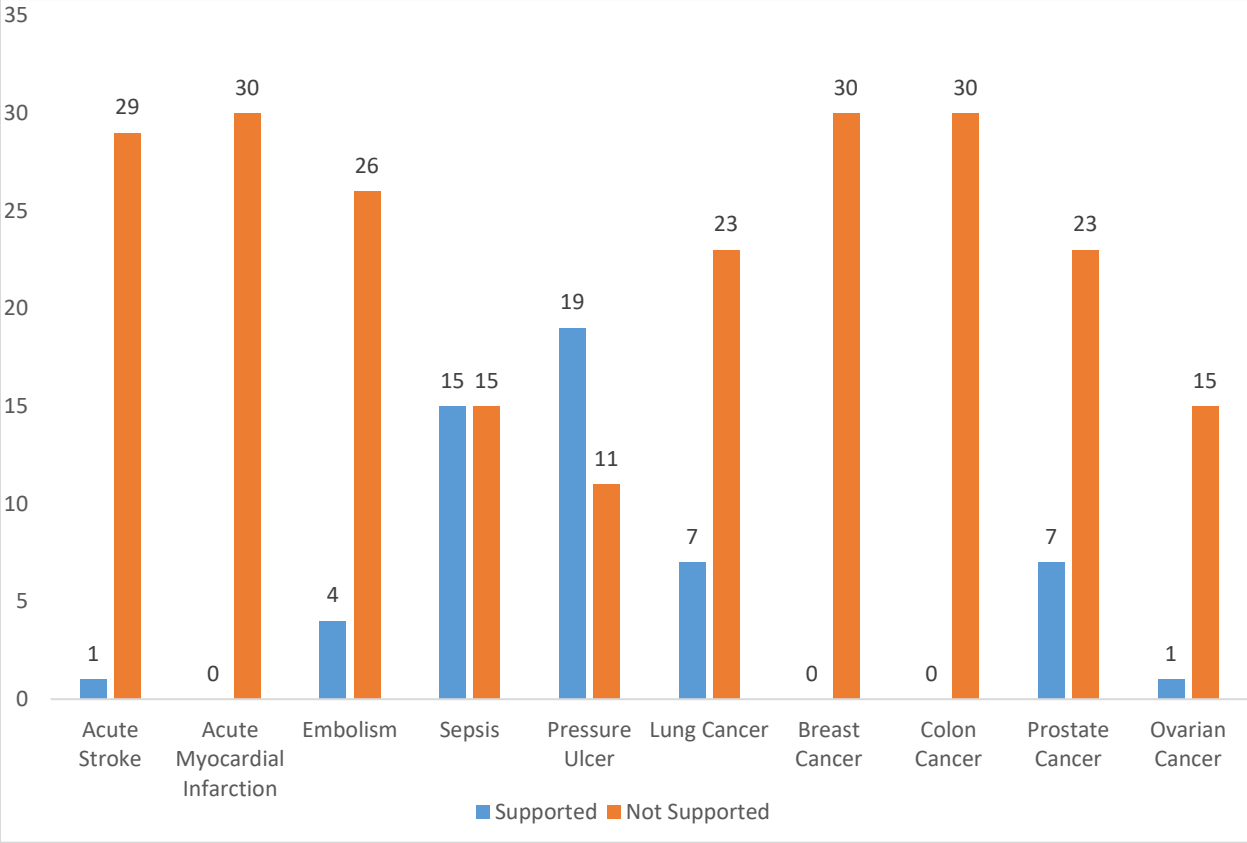
Guidelines for Coding and Reporting (42 CFR § 422.310(d)(1) and 45 CFR §§ 162.1002(c)(2)-(3)). Further, MA organizations must implement procedures to ensure that diagnoses come only from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities, and physicians (the Manual, chap. 7, §§ 40 and 120.1.1).

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 GATEWAY HEALTH PLAN, INC., SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Most of the selected high-risk diagnosis codes that Gateway 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, for 232 of the 286 sampled enrollee-years, either the medical record that Gateway provided did not support the diagnosis codes or Gateway could not locate the medical records to support the diagnosis codes. In these instances, Gateway should not have submitted the diagnosis codes to CMS and received the resulting net overpayments.

Figure: Analysis of High-Risk Groups



Incorrectly Submitted Diagnosis Codes for Acute Stroke

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

- For 21 enrollee-years, the medical records indicated in each case that the individual had previously had a stroke, but the records did not support 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 documentation of an acute cerebrovascular accident (CVA) that results in the assignment of the HCC under review. There is documentation of a past medical history of . . . [a] CVA [diagnosis] which does not result in an HCC."[17]

- For 5 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.

[17] CVA is the medical term for a stroke. A stroke occurs when blood flow to a part of the brain is stopped by either a blockage or the rupture of a blood vessel.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of an acute cerebrovascular accident (CVA) that results in the assignment of the HCC under review. The medical documentation states an ischemic stroke with no indication of active treatment plan to code as a current or historical condition."

- For 2 enrollee-years, Gateway could not locate any medical records to support the acute stroke diagnosis; therefore, the HCCs for Ischemic or Unspecified Stroke were not validated.

- For the remaining 1 enrollee-year, Gateway submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiparesis (which was supported by the medical records).[18] The independent medical review contractor stated that "there is no documentation of an acute cerebrovascular accident (CVA), however, the patient has hemiplegia affecting right dominant side from a past medical history of CVA which should have been assigned instead of the submitted HCC." Accordingly, Gateway should not have received a payment for the acute stroke diagnosis but instead should have received a payment for the hemiplegia diagnosis. This error caused an underpayment.

As a result of these errors, the HCCs for Ischemic or Unspecified Stroke were not validated, and Gateway received $68,236 in net overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Myocardial Infarction

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

- For 13 enrollee-years, the medical records indicated in each case that the individual had an old myocardial infarction diagnosis, but the records did not support 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 under review. There is documentation of [a] past medical history of myocardial infarction diagnosis which does not result in an HCC."

[18] Hemiparesis is the loss of strength in one half of the body. Hemiplegia is the complete paralysis or loss of function of one-half of the body, including one leg and arm. Both hemiparesis and hemiplegia occur because of injury or disease in the motor centers of 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.

- For 8 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 the HCC under review."

- For 7 enrollee-years, the medical records in each case did not support an acute myocardial infarction diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis on CMS's systems that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Gateway should not have received an increased payment for the acute myocardial infarction diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

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

As a result of these errors, the HCCs for Acute Myocardial Infarction were not validated, and Gateway received $105,017 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

Gateway incorrectly submitted diagnosis codes for embolism for 26 of 30 sampled enrollee-years. Specifically:

- For 15 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not support a diagnosis that mapped to an Embolism HCC at the time of the physician's service.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of the HCC under review. There is documentation of a past medical history of pulmonary embolism [diagnosis] which does not result in an HCC."[20]

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

[20] A pulmonary embolism is a blood clot that blocks and stops blood flow to an artery in the lung. In most cases, the blood clot starts in a deep vein in the leg and travels to the lung.

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 under review."

- For 1 enrollee-year, the medical record did not support an embolism diagnosis. However, for this enrollee-year, we identified support for another diagnosis on CMS's systems that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Gateway should not have received an increased payment for the embolism diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

- For the remaining 1 enrollee-year, Gateway could not locate any medical records to support the embolism diagnosis; therefore, the Embolism HCC was not validated.

As a result of these errors, the Embolism HCCs were not validated, and Gateway received $97,602 in overpayments for these 26 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Sepsis

Gateway incorrectly submitted diagnosis codes for sepsis for 15 of 30 sampled enrollee-years. Specifically:

- For 9 enrollee-years, the medical records in each case did not support a sepsis diagnosis.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC under review. There is documentation of the patient having a diagnosis of bacteremia without mention of sepsis which does not result in an HCC."[21]

- For 4 enrollee-years, Gateway could not locate any medical records to support the sepsis diagnosis; therefore, HCCs for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock were not validated.

- For the remaining 2 enrollee-years, the medical records indicated in each case that the individual had previously had sepsis, but the records did not support a sepsis 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 results in the assignment of the HCC under review. There is documentation of a past medical history of sepsis [diagnosis] which does not result in an HCC."

[21] Bacteremia is a bacterial infection of the bloodstream.

As a result of these errors, the HCCs for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock were not validated, and Gateway received $74,319 in overpayments for these 15 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Pressure Ulcer

Gateway incorrectly submitted diagnosis codes for pressure ulcer for 11 of 30 sampled enrollee-years. Specifically:

- For 5 enrollee-years, the medical records in each case did not support a pressure ulcer diagnosis.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC under review. There is documentation of [a] pressure ulcer of other site, Stage II [diagnosis] which does not result in an HCC."[22]

- For 3 enrollee-years, Gateway could not locate any medical records to support the pressure ulcer diagnosis; therefore, the Pressure Ulcer HCCs were not validated.

- For 2 enrollee-years, the medical records in each case did not support a pressure ulcer diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis on CMS's systems that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Gateway should not have received an increased payment for the pressure ulcer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

- For the remaining enrollee-year, Gateway submitted a diagnosis code for pressure ulcer of sacral region, stage 3 (which was not supported in the medical records) instead of a diagnosis code for venous statis ulcers of the bilateral lower extremities (which was supported by the medical records).[23] The independent medical review contractor stated that there "is no documentation of any condition that results in the HCC under review. There is documentation of bilateral venous stasis ulcers which is categorized as varicose veins of unspecified lower extremity with both ulcer of unspecified site and inflammation." As a result, the HCC for Vascular Disease with Complications "should have been assigned instead of the submitted HCC." Accordingly, Gateway should not have received a payment for the HCC for Pressure Ulcer of Skin with Full Thickness Skin

[22] Pressure ulcers are wounds that result from low blood flow. Stage II pressure ulcers are usually open wounds, like an ulcer, with swelling, discoloration, and pain.

[23] Pressure ulcers of the sacral region, stage III, are a full-thickness loss of skin that extends to the subcutaneous tissue but does not cross the facia beneath it. Venous statis ulcers of the bilateral lower extremities are non-healing sores on both lower legs, resulting from chronic poor blood flow (venous insufficiency).

Loss but instead should have received a payment for HCC for Vascular Disease with Complications. This error caused an overpayment.

As a result of these errors, the Pressure Ulcer HCCs were not validated, and Gateway received $110,836 in overpayments for these 11 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

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

- For 13 enrollee-years, the medical records indicated in each case that the individual had previously had lung cancer, but the records did not support 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 under review. There is documentation of a past medical history of lung cancer [diagnosis] which does not result in an HCC."

- For 4 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 on CMS's systems that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Gateway should not have received an increased payment for the lung cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

- For 4 enrollee-years, the medical records in each case did not support a lung cancer diagnosis.

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in an HCC. The medical documentation states there was a lung mass identified in 2015 and removed. The lung mass was negative for malignancy. There is no documentation of a history or current lung cancer documented on this date of service."

- For the remaining 2 enrollee-years, Gateway could not locate any medical records to support the lung cancer diagnosis; therefore, the HCCs for Lung and Other Severe Cancers were not validated.

As a result of these errors, the HCCs for Lung and Other Severe Cancers were not validated, and Gateway received $163,271 in overpayments for these 23 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

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

- For 28 enrollee-years, the medical records indicated in each case that the individual had previously had breast cancer, but the records did not support a breast cancer diagnosis at the time of the physician's service.

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

- For 1 enrollee-year, the medical records did not support a breast cancer diagnosis. The independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of the HCC under review. There is documentation stating that the patient has no past medical history of cancer."

- For the remaining 1 enrollee-year, Gateway could not locate any medical records to support the breast cancer diagnosis; therefore, the HCC for Breast, Prostate, and Other Cancers and Tumors were not validated.

As a result of these errors, the HCCs for Breast, Prostate, and Other Cancers and Tumors were not validated, and Gateway received $39,897 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

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

- For 14 enrollee-years, the medical records indicated in each case that the individual had previously had colon cancer, but the records did not support 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 under review. There is documentation of a past medical history of colon cancer [diagnosis] which does not result in an HCC."

- For 9 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 results in the assignment of the HCC under review."

- For 5 enrollee-years, the medical records in each case did not support a colon cancer diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis on CMS's systems that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Gateway should not have received an increased payment for the colon cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

- For the remaining 2 enrollee-years, Gateway could not locate any medical records to support the colon cancer diagnosis; therefore, the HCCs for Colorectal, Bladder, and Other Cancers were not validated.

As a result of these errors, the HCCs for Colorectal, Bladder, and Other Cancers were not validated, and Gateway received $78,793 in overpayments for these 30 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

Gateway incorrectly submitted diagnosis codes for prostate cancer for 23 of 30 sampled enrollee-years.[24] Specifically:

- For 15 enrollee-years, the medical records indicated in each case that the individual had previously had prostate cancer, but the records did not support 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 result in the assignment of the HCC under review. There is documentation of a past medical history of prostate cancer [diagnosis] which does not result in an HCC."

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

  For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that results in [the] HCC [under review]. The condition of prostate cancer is noted on the active list of conditions with no active plan of treatment. Therefore, the documentation does not support an active prostate

[24] For 1 of the 7 enrollee-years for which we found support for prostate cancer, the independent medical review contractor also found support for a diagnosis of unspecified malignant neoplasm of intrapelvic lymph nodes, a condition in which cancer has spread to the lymph nodes within the pelvic region, that should have been submitted in addition to the reviewed diagnosis code. This diagnosis maps to the HCC for Metastatic Cancer and Acute Leukemia. Accordingly, this caused an underpayment for this enrollee-year, and we account for the difference in our net overpayment calculations.

cancer diagnosis. It is unclear whether the patient has a past medical history of prostate cancer."

- For the remaining 1 enrollee-year, Gateway could not locate any medical records to support the prostate cancer diagnosis; therefore, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated.

As a result of these errors, the HCCs for Breast, Prostate, and Other Cancers and Tumors were not validated, and Gateway received $14,696 in overpayments for these 23 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Ovarian Cancer

Gateway incorrectly submitted diagnosis codes for ovarian cancer for 15 of 16 sampled enrollee-years. Specifically:

- For 9 enrollee-years, the medical records indicated in each case that the individual previously had ovarian cancer, but the records did not support an ovarian 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 results in the assignment of the HCC under review. There is documentation of a past medical history of ovarian cancer [diagnosis] which does not result in an HCC."

- For 4 enrollee-years, the medical records did not support the submitted ovarian cancer diagnosis. However, for these enrollee-years, we identified support for another diagnosis on CMS's systems that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Gateway should not have received an increased payment for the submitted ovarian cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

- For 1 enrollee-year, the medical record did not support an ovarian cancer diagnosis. Specifically, the independent medical review contractor stated that "there is no documentation of any condition that results in the assignment of the HCC under review. There is documentation of a past medical history of uterine cancer [diagnosis] which does not result in an HCC."

- For the remaining 1 enrollee-year, Gateway could not locate any medical records to support the ovarian cancer diagnosis; therefore, the Ovarian Cancer HCC was not validated.

As a result of these errors, the Ovarian Cancer HCCs were not validated, and Gateway received $77,667 in overpayments for these 15 sampled enrollee-years.

Summary of Incorrectly Submitted Diagnosis Codes

In summary and with respect to the 10 high-risk groups covered by our audit, Gateway received $830,334 in net overpayments for 232 of the 286 sampled enrollee-years.

THE POLICIES AND PROCEDURES THAT GATEWAY 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 Gateway 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, Gateway had compliance procedures designed to educate its providers on proper medical record documentation and reporting accurate diagnosis codes on claims. These outreach efforts included annual targeted provider webinars and a web-based provider portal in which Gateway leveraged data analytics to identify providers with coding accuracy gaps and provided targeted educational intervention to address those gaps. Gateway also provided guidance to specific providers on how to improve medical record documentation for key conditions such as embolism, cancer, stroke, and ulcers (including pressure ulcers).

As part of its compliance policies and procedures, Gateway also had measures that it took to detect and correct incorrect diagnosis codes that its providers included on claims. Specifically, Gateway had internal coders, and it hired coding vendors to select and determine whether diagnosis codes on certain claims were supported in medical records. For example, Gateway instructed coders to review 100 percent of claims that included a diagnosis that mapped to an HCC that had not been previously included in the enrollee's risk score. Gateway had other detection and correction measures; however, these measures generally targeted providers and not specific diagnosis codes. For each of these measures, Gateway also had a policy to submit corrections to CMS if the coder detected an unsupported diagnosis code. Gateway also had a quality assurance process by which it reviewed the results of each coder's reviews each month to ensure that the coders attained 95-percent accuracy.

With respect to the 19 enrollee-years for which Gateway could not locate medical records to support the diagnosis, Gateway officials told us that providers were unresponsive or provided incomplete information.[25]

We acknowledge that Gateway had compliance procedures in place that included measures designed to ensure that diagnosis codes complied with Federal requirements. However, because we found that 232 of the 286 sampled enrollee-years were not supported by medical

[25] Gateway could not locate medical records for 21 enrollee-years; however, Gateway provided us with documentation demonstrating that 2 enrollee-years qualified for an extraordinary circumstance exception.

records, we believe that these procedures, as they relate to diagnoses that are at high risk for being miscoded, could be improved.

GATEWAY HEALTH PLAN, INC., RECEIVED NET OVERPAYMENTS

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Gateway received at least $4,314,513 in net overpayments for our audit period.

RECOMMENDATIONS

We recommend that Gateway Health Plan, Inc.:

- refund to the Federal Government the $4,314,513 of estimated net overpayments; [26]
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred 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.

GATEWAY COMMENTS AND OIG RESPONSE

In written comments on our draft report, Gateway disagreed with some of our findings and all of our recommendations. Specifically, Gateway disagreed with our findings for 38 of the 249 enrollee-years identified as errors in our draft report and provided explanations as to why it disagreed for our consideration.[27] Gateway did not agree or disagree with our findings for the remaining 211 enrollee-years.

In addition, Gateway disagreed with the methodology used throughout the audit. Specifically, Gateway stated that we focused only on alleged overpayments and ignored underpayments and that our methodology did not comply with regulatory requirements. Gateway did not agree with our overpayment calculations and stated that we did not have the statutory

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

[27] Gateway indicated that it did not agree with the findings in our draft report for 36 sampled enrollee-years (on page 19 of its response) and 40 sampled enrollee-years (on page 10 of its response). After further analysis, and as explained in the following section, we confirmed that Gateway did not agree with our findings for 38 sampled enrollee-years.

authority to extrapolate overpayments. Gateway also disagreed with our second and third recommendations and stated that it has a robust compliance program, which it continually refines. For these reasons, Gateway requested that we withdraw our recommendations.

After reviewing Gateway's comments and the additional information it provided, we reduced the number of enrollee-years in error from 249 to 232 and adjusted our calculation of net overpayments. Accordingly, we reduced the recommended overpayment in our first recommendation from $4,640,771 to $4,314,513 for this final report. We maintain that our second and third recommendations remain valid.

A summary of Gateway's comments and our responses follows. Gateway's comments appear as Appendix F. We excluded attachments (which Gateway identified as Exhibits A through F in its comments) because they contained personally identifiable information. We are separately providing Gateway's comments and the attachments in their entirety to CMS.

GATEWAY DID NOT AGREE WITH OIG'S FINDINGS FOR 38 SAMPLED ENROLLEE-YEARS

Gateway Comments

Gateway did not agree with our draft report findings for 38 sampled enrollee-years (as shown in Table 2) and requested that we reconsider our findings and modify our estimate of overpayments.

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

High Risk Group	Number of Sampled Enrollee Years
Acute myocardial infarction	4
Embolism	3
Sepsis	8
Pressure ulcer	7
Lung cancer	6
Breast cancer	2
Prostate cancer	6
Ovarian cancer	2
Total	**38**

- For 34 of the 38 enrollee-years, Gateway provided explanations (including attestations for missing physicians' signatures) supporting its position that previously submitted medical records validated the audited HCCs.[28]

- For 2 of the enrollee-years, Gateway did not dispute that the audited HCC was in error, but provided explanations supporting its position that "alternative" diagnosis codes "mapped to an HCC for a less severe manifestation of the related-disease group that should have been submitted to CMS instead of the selected codes."

    - For 1 enrollee-year in the ovarian cancer high-risk group, Gateway stated that a medical record supported the diagnosis code for malignant neoplasm of endometrium (which maps to the HCC for Breast, Prostate, and Other Cancers and Tumors) for which OIG did not validate the audited HCC (Lymphoma and Other Cancers).[29]

    - For 1 enrollee-year in the pressure ulcer high-risk group, Gateway stated that a medical record supported the diagnosis code for non-pressure chronic ulcer of unspecified part of unspecified lower leg (which maps to the HCC for Chronic Ulcer of Skin, Except Pressure) for which OIG did not validate the audited HCC (Pressure Ulcer of Skin with Full Thickness Skin Loss).

- For the remaining 2 enrollee-years, Gateway stated that the medical records were not available because the provider was incarcerated. Gateway stated that these sample items should be excluded because the availability of the medical records was beyond Gateway's control.

Gateway stated that it "will work with CMS to delete individual codes that it determines were unsupported in the audit after OIG reconsiders the . . . HCCs that Gateway found to be supported . . ."

OIG Response

Our independent medical review contractor reviewed all of the explanations that Gateway provided to support its position that HCCs should be validated.

For the 34 sampled enrollee-years in which Gateway stated that the reviewed HCC should be validated:

[28] On page 19 of its response, Gateway referred to 36 errors. These 36 errors included the 34 enrollee-years for which Gateway provided explanations to support its position as well as the 2 enrollee-years for which Gateway validated an alternative HCC.

[29] Malignant neoplasm of the endometrium (endometrial cancer) is a common gynecological cancer that occurs in the uterus lining and primarily affects postmenopausal women.

- For 19 of the enrollee-years, our contractor reaffirmed that the HCCs were not validated. For example, for 1 enrollee-year from the sepsis high-risk group, our contractor upheld its original decision upon reconsideration and stated:

  > "Even though sepsis was documented as present on admission, the medical record documentation does not support active sepsis. The patient was described as stable with no evidence of ongoing infection, organ dysfunction, or treatment directed toward sepsis. The medical record included limited information to clarify the chief complaint, current symptoms, or the site of service, therefore it is not possible to confirm the diagnosis of active sepsis."

- For the remaining 15 enrollee-years, our contractor reversed its original decision and stated that the HCCs were validated. The 15 enrollee-years were in the following high-risk groups: sepsis (5), pressure ulcer (4), lung cancer (3), and prostate cancer (3).

For the 2 sampled enrollee-years for which Gateway stated alternative diagnosis codes validated other HCCs:

- For the enrollee-year for which Gateway stated that a medical record supported the HCC for Breast, Prostate, and Other Cancers and Tumors, our contractor also found support for a diagnosis that mapped to this HCC. However, we had already included the impact of this diagnosis in the results presented in our draft report. Thus, we made no changes for this final report.

- For the enrollee-year for which Gateway stated that a medical record supported the HCC for Chronic Ulcer of Skin, Except Pressure, our contractor did not find support for that HCC. However, our contractor found support for a diagnosis of venous statis ulcers of the bilateral lower extremities, which maps to the HCC for Vascular Disease with Complications. Our contractor stated that this diagnosis "should have been assigned instead" of the audited HCC (Chronic Ulcer of Skin, Except Pressure). Accordingly, Gateway should not have received payment for the audited HCC but instead should have received payment for the Vascular Disease with Complications HCC. This error caused an overpayment that was not accurately calculated for the draft report; however, we made updates for this final report.[30]

For the remaining 2 enrollee-years (lung cancer high-risk group) for which Gateway stated that the medical records were not available because the provider was incarcerated, we worked with Gateway after it commented on our draft report to obtain additional information. We then determined that an extraordinary circumstance (medical records likely seized by law

[30] For our draft report, we calculated the overpayment for the audited HCC (Chronic Ulcer of Skin, Except Pressure) instead of calculating the difference between this HCC and the HCC that should have been used (Vascular Disease with Complications).

enforcement) prevented Gateway from locating the medical records for these enrollee-years. Accordingly, we treated the 2 sample items as non-errors.

As a result of these reevaluations, we reduced the number of enrollee-years in error from 249 (as reported in our draft report) to 232. We also reduced our findings and reduced the associated monetary recommendation. Further, the independent medical review contractor confirmed that its review of the explanations that Gateway gave to us did not have an impact on the decisions that the contractor had made for the sampled enrollee-years that Gateway neither agreed nor disagreed.

GATEWAY STATED THAT OIG DID NOT CONSIDER ALL ELEMENTS OF AN IMPROPER PAYMENT OR THE CONGRESSIONAL DESIGN OF THE MEDICARE ADVANTAGE PROGRAM

Gateway Comments

Gateway stated that we "did not take into consideration all elements of an 'improper payment' or the Congressional design of the MA program" and focused "only on alleged overpayments to Gateway and [ignored] underpayments to Gateway." In this regard, Gateway made several related points:

- Gateway stated that because CMS's payment model for MA organizations "is population-based, any inquiry in MA designed to determine whether an improper payment has occurred must take into account all potential errors that affect payment for the MA organization's population, including undercoding and overcoding." Gateway stated that our findings did not consider "potential undercoding, or underpayments, to the [MA organization] based on all of its data."

  Gateway also stated that an audit seeking to determine whether an MA organization was improperly paid must determine whether, on average, across all codes for all members, the plan received a larger or smaller payment than it should have. To this point, Gateway further stated that, we "[did] not establish that there were actual overall improper payments because OIG chose, and audited, codes for which there was a likely error in the government's favor while ignoring the inverse (i.e., those codes for which there is a likely error in the [MA organization's] favor)."

- Gateway also stated that we "disregarded most instances of undercoding shown in the medical records reviewed." Moreover, Gateway pointed out that our recent audits of MA organizations that did not focus on "high-risk" codes accounted for both overpayments and underpayments and that "these audits are more aligned with maintaining the integrity of the program."

- Gateway also presented the results of two separate, internal reviews that it performed to "demonstrate the potential error in OIG's approach." The first review was a limited analysis of certain chronic conditions that were likely to have existed but were not submitted to CMS. The second review was performed on the medical records that

Gateway provided for this audit and identified support for "new, unique codes for risk adjusting diagnoses." Both reviews, according to Gateway, identified underpayments from CMS to Gateway.

Gateway also stated that OIG's audit methodology and results are inaccurate because we ignored errors in the fee-for-service (FFS) data for which the MA payment rates were based. According to Gateway, "underpayments and overpayments cancel one another *overall*." (Emphasis in original.) Gateway stated that the Act "provides that CMS must compensate [MA organizations] in a way that ensures actuarial equivalence with what CMS would have paid to provide care for the same [individuals] under traditional Medicare." According to Gateway, "overcoding errors in the FFS data artificially inflates the number of HCCs reported in the FFS data, which, in turn, lowers the values of coefficients used in [CMS's payment] model." Gateway stated that "providers make the same coding errors when treating traditional Medicare patients" and, in that respect, our audit approach, which did not consider errors in the FFS data, would result in an MA organization being paid less than it would have cost traditional Medicare to care for the same individuals.

OIG Response

We maintain that our audit methodology was appropriate for the audit objective, and our audit objective and methodology correctly addressed certain aspects unique to the MA program. For reasons listed below, we believe that a recommended refund of estimated net overpayments based on our findings is appropriate.

Our audit methodology correctly applied CMS requirements to properly identify the net overpayment amount associated with HCCs that were not validated for each sampled enrollee-year. We followed CMS's risk adjustment program requirements to determine the payment that CMS should have made for each enrollee and to estimate overpayments.

We identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into 10 specific high-risk groups. This process involved a carefully designed audit methodology (Appendix A). Our objective did not extend to all diagnosis codes for all of Gateway's enrollees; thus, diagnosis codes not previously submitted by Gateway to CMS were beyond the scope of our audit. However, if we identified another diagnosis code (on CMS's systems) that mapped to an HCC in the related-disease group or if we identified a diagnosis code that should have been submitted to CMS instead of the reviewed diagnosis code, we included the financial impact of the resulting HCC (if any) in our calculation of net overpayments.

With regard to the results of the reviews that Gateway provided, we encourage Gateway – in keeping with our third recommendation – to 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.

Further, CMS's requirements do not compel us to consider potential errors in the FFS data for which CMS based its MA payment rates. We continue to recognize that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program. (See footnote 26.)

GATEWAY STATED THAT OIG IS EFFECTIVELY REQUIRING 100-PERCENT CODING ACCURACY

Gateway Comments

Gateway stated that our "audit approach effectively requires [MA organizations] to have a [zero-percent] coding error rate for all of its encounter data." Gateway stated that holding MA organizations to this standard "is inconsistent with previous acknowledgements by both CMS and the OIG that [100-percent] accuracy in the data [MA organizations] submit to CMS is not possible or required." Gateway further stated that diagnostic coding is an inherently subjective process and noted its disagreement with coding error determinations that we made for HCCs identified in the report. In this respect, Gateway stated, "OIG's inability to conduct this audit with [100-percent] accuracy demonstrates that it is unreasonable to hold [MA organizations] to such a standard."

OIG Response

We do not agree that our audit approach effectively requires MA organizations to have a zero-percent coding error rate for all of their encounter data. Gateway's statements implied that we opined on its responsibilities to ensure 100-percent accuracy for all the data it submitted to CMS. That was not our intention nor 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.

GATEWAY STATED THAT OIG DOES NOT HAVE THE AUTHORITY TO EXTRAPOLATE

Gateway Comments

Gateway stated that we did not have the authority to extrapolate and made three related comments to support its position:

- Gateway stated that we conducted this audit under the Inspector General Act, which does not provide us authorization to extrapolate overpayments from MA organizations through audit. Gateway further explained that CMS created a "New RADV Audit Rule" that allows OIG to undertake audits of MA organizations, similar to RADV audits; however, Gateway also stated that this rule does not apply to audits under the Inspector General Act.[31]

[31] New RADV Audit Rule, 88 Fed. Reg. 6643, 6645 (Feb. 1, 2023).

- Gateway stated that it "does not believe that OIG has the authority to extrapolate under the Federal regulations listed at 42 C.F.R. part 422, subpart G."

- Finally, Gateway stated that "no statutory authority exists for OIG or CMS to calculate or extrapolate overpayments."

To these points, Gateway stated that "an agency 'may only take action that Congress has authorized' and lack of Congressional action does not translate to a delegation of authority to an agency."

OIG Response

We do not agree with Gateway's comments regarding extrapolation. Extrapolation has long been recognized as a permissible method of calculating overpayments in Medicare. Gateway relied, in part, on 42 CFR part 422, subpart G, to say that we do not have the authority to extrapolate. However, no statute or other authority limits our ability to recommend a recovery to CMS based on sampling and extrapolation. Further, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.[32] The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.[33] We properly executed our statistical sampling methodology in that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used our statistical sampling software to apply the correct formulas for the extrapolation.

Further, the final rule that Gateway referenced did not give us the authorization to extrapolate; it only instructed CMS on the years for which it could collect extrapolated amounts from OIG audits. We note that after Gateway commented on our draft report, a U.S. District Court vacated and remanded the final rule.[34] Nonetheless, Gateway's comments did not cause us to change our final report regarding extrapolation.

[32] 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 c. Sebelius,* 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

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

[34] U.S. District Court for the Northern District of Texas ruling can be found at: gov.uscourts.txnd.380836.76.0_2.pdf (accessed on Oct. 1, 2025)

GATEWAY STATED THAT OIG'S USE OF EXTRAPOLATION ALONG WITH NOT APPLYING A FEE-FOR-SERVICE ADJUSTER IS ARBITRARY AND CAPRICIOUS

Gateway Comments

Gateway stated that the use of extrapolation in the audit, along with the refusal to apply an FFS Adjuster[35] is arbitrary and capricious for the following reasons:

- According to Gateway, we applied a "new" methodology retroactively, which is prohibited by the Act. Gateway stated that our methodology for conducting MA audits is materially different from the CMS methodology that was in place when Gateway submitted its bids for the years in question (our audit period).

- Gateway stated, "CMS recently promulgated a final rule that does not require RADV audits and purportedly OIG audits to apply an FFS adjuster." To this point, Gateway stated that both CMS and OIG have failed to provide proper justification for this decision outside of a CMS proposal to eliminate the FFS adjuster, which Gateway referred to as a "flawed study criticized by many [MA organizations] and other industry constituents."

- Gateway also stated that the "New RADV Audit Rule eliminating the FFS Adjuster failed to comply with notice and comment requirements," which denied MA organizations "the right to comment on [CMS's] reasoning." Gateway further stated, "In turn, OIG's refusal to apply an FFS adjuster to this audit, based on CMS's reasoning, is arbitrary and capricious."

Gateway also stated that there is "no settlement process, of which Gateway is aware, for which an [MA organization] that refunded an extrapolated amount would obtain a release from liability for errors relating to the same codes in subsequent audits [including CMS RADV audits], investigations, or other disputes."

OIG Response

We do not agree with Gateway's comment that our use of extrapolation, along with our "refusal" to apply an FFS Adjuster, is arbitrary and capricious.

We do not agree with Gateway that we retroactively applied a "new" methodology. Calculating an estimated net overpayment amount according to CMS's risk adjustment program without applying an FFS adjuster does not constitute a new methodology. We used the results of the independent medical review to determine which HCCs were not substantiated and, in some

[35] As discussed earlier, Gateway stated that CMS must pay MA organizations in a way that ensures actuarial equivalence with what CMS would have paid to provide care for the same individuals under traditional Medicare. To achieve actuarial equivalence in the context of a RADV audit, Gateway references the use of an FFS Adjuster, which is a mechanism to offset extrapolated overpayments to account for the coding differences between MA and traditional Medicare.

instances, to identify HCCs that should have been used but were not used in the sampled enrollee-years' risk score calculations. We followed the requirements of CMS's risk adjustment program to determine the payment that CMS should have made for each enrollee-year. We used the overpayments and underpayments identified for each enrollee-year to estimate (extrapolate) net overpayments.

With regard to Gateway's statement that CMS's final rule does not require an FFS adjuster to be used in RADV audits, we note (and as stated above), a U.S. District Court vacated and remanded the final rule. However, this ruling does not impact our findings or cause us to change our recommendations. Notwithstanding this ruling, CMS has not issued any requirements that compel us to reduce our overpayment calculations. If CMS deems it appropriate to apply an FFS adjuster, it will, during the audit resolution process, adjust our overpayment finding by whatever amount it determines necessary. We continue to recognize that CMS, not OIG, is responsible for making operational and program payment determinations for the MA program.

Further, we provided a list of the enrollee-years in our sampling frame to CMS to ensure that the individuals and the associated HCCs identified for this audit would be excluded from future CMS RADV audits. We believe that this audit methodology pre-empts any overlapping or duplicative audit findings.

GATEWAY STATED THAT OIG'S FOCUS ON "HIGH-RISK" CODES, ALONG WITH OIG'S OTHER AUDIT METHODOLOGIES, IS ARBITRARY AND CAPRICIOUS

Gateway Comments

Gateway made related points in stating that our focus on "high-risk" diagnosis codes along with our other audit methodologies is arbitrary and capricious:

- Gateway stated that we adopted "a new audit approach by focusing on 'high-risk' codes that change from audit to audit" and that we "did not engage the requisite notice and comment process." Gateway cited a Federal court ruling that stated the "law requires the government to provide the public with advance notice and a chance to comment on any 'rule, requirement, or other statement of policy' that 'establishes or changes a substantive legal standard governing … the payment for services.'"[36] According to Gateway, "OIG has adopted new substantive legal standards by performing audits that impose different standards from one audit to the next" and "these new standards did not go through the notice and comment process."

[36] *Azar v. Allina Health Servs.*, 587 U.S. 566, 572 (2019) (quoting 42 U.S.C. § 1395hh(a)(2)).

- Gateway stated that our refusal to answer the following questions about our audit methodology "is another example of how OIG's approach to conducting this audit is arbitrary and capricious:"[37]

    - What is OIG's process to determine whether a condition is active or historical?

    - Does OIG acknowledge that the gap between the audit period and the initiation of the audit creates significant validation issues?

    - Has OIG performed similar targeted audits on FFS data?

- Gateway further stated that, while we provided information that outlined the independent medical review contractor's credentials and the review process, medical reviewers' identities "should be disclosed so that the [MA organization] can assess any conflicts of interest and evaluate the contractor's credentials, policies, procedures, and experience."

OIG Response

Our audits are intended to provide an independent assessment of HHS programs and operations in accordance with the Inspector General Act of 1978, 5 U.S.C. chapter 4. No new requirements were imposed, and thus there was no need for notice-and-comment rulemaking.

Gateway is correct in that our audits of specific diagnosis codes are not always the same. For each of these audits, we identify and explain why certain diagnoses are at high risk for being miscoded. However, the review of different high-risk diagnoses does not impose different standards from one audit to the next. The standard that we consistently apply is to determine whether the selected diagnosis codes are supported in medical records. Ensuring that MA organizations comply with Federal requirements does not in itself create a new substantive legal standard that necessitates notice-and-comment rulemaking.

With regard to the three questions posed by Gateway:

- Our independent medical review contractor adheres to ICD coding guidelines to determine whether a condition is active or historical. In general, a condition that is active means there is care to treat or monitor the present condition. A historical condition means the condition is resolved and there is no further treatment or evidence of the condition currently existing.

- We do not believe that the difference in time between our audit period and the initiation of our audit caused validation issues. We initiated our audit in June 2022 and shortly thereafter requested medical records for services that occurred in either 2017 or

[37] Gateway included six questions in its comments; however, we believe that we have addressed three of them in other responses to Gateway's comments.

2018. According to 42 CFR § 422.504(d)(1)(i), MA organizations agree "to maintain for 10 years books, records, documents, and other evidence of accounting procedures and practice that . . . [a]ccommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computations of the bid) of MA organizations." In this respect, we believe that the timing of our requests for medical records was reasonable.

- We performed one audit of high-risk acute stroke diagnoses that were made for individuals who were in traditional Medicare. For this audit, our objective was to determine whether these diagnosis codes, which physicians submitted under traditional Medicare and CMS later used to make payments to MA organizations on behalf of transferred enrollees, complied with Federal requirements.[38]

It is not our practice to name our independent medical review contractor. However, our audit process includes measures to ensure that there are no conflicts of interest among the parties involved in the audit. We contend that providing the contractor's name would not provide information about the contractor's qualifications beyond what we state in this audit report.

Therefore, we disagree with Gateway that our audit methodologies were arbitrary and capricious.

GATEWAY STATED THAT OIG'S APPROACH TO RISK ADJUSTMENT AUDITS COULD NEGATIVELY IMPACT THE MEDICARE ADVANTAGE PROGRAM

Gateway Comments

Gateway stated that our "unpredictable approach and resulting contract offsets may complicate the MA bidding process and negatively impact benefit packages and premiums." For 2018 and 2019, Gateway stated that it considered financial risk associated with repayment obligations in its bidding process that might result from CMS's standard RADV audit process. Gateway stated that it could not have predicted our "completely new approach to audits" when it submitted bids and determined what benefits it could offer to its members. Gateway further stated, "[u]npredictable contract adjustments caused by these audits, especially if OIG uses extrapolation as it intends to do in the future, are likely to, over time, increase premiums, decrease benefits, and harm the breadth and scope of the MA program and the [enrollees] that it serves."

Gateway also stated that it believes that our methodology could destabilize value-based contracting with downstream physician practices. Gateway stated that MA organizations increasingly contract with physicians and other clinicians through value- and risk-based contracts. In many of these arrangements, risk-adjusted revenue is paid directly to providers,

[38] OIG, *Incorrect Acute Stroke Diagnosis Codes Submitted by Traditional Medicare Providers Resulted in Millions of Dollars in Increased Payments to Medicare Advantage Organizations* (A-07-17-01176), Sept. 16, 2020.

and, if we retroactively recoup large sums from MA organizations, it may impact the providers by presenting a significant financial challenge to provider practices.

OIG Response

We do not believe that our audit approach complicates the MA bidding process and negatively impacts benefit packages and premiums. Our audits are intended to provide an independent assessment of HHS programs and operations in accordance with the Inspector General Act. Our mission is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve. By identifying errors, we strive to ensure the efficiency and integrity of the MA program and promote the effective delivery of services to Gateway's enrollees.

With regard to Gateway's comment that our methodology may harm risk-bearing entities, including physicians and other clinicians, the interaction that Gateway has with downstream entities is beyond the scope of our audit.

GATEWAY DID NOT AGREE WITH OIG'S SECOND AND THIRD RECOMMENDATIONS

Gateway Comments

Gateway stated that it did not agree with our second and third recommendations.

With regard to our second recommendation, Gateway also did not agree that it should perform "additional auditing of 'high-risk' codes for payment years beyond the years subject to this audit." According to Gateway, its "current compliance program and auditing and monitoring activities are robust, and such additional auditing is not required under CMS regulations."

With regard to our third recommendation, Gateway did not agree that it should continue its examination of its existing compliance procedures and enhance these procedures because, according to Gateway, it has a robust compliance program and we "did not offer specific improvement recommendations." Gateway stated that it believes that we "cannot reasonably expect [MA organizations] to achieve perfection, especially when measured by an audit specifically designed to identify one-sided errors."

OIG Response

With regard to Gateway's comments on our second recommendation, we do not agree with Gateway's interpretation of CMS's regulations. We recognize that MA organizations have the latitude to design their own federally mandated compliance programs. However, contrary to Gateway's assertions, we believe that our second recommendation 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." 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.

We believe that the error rate identified in our audit (Appendix D) demonstrates that Gateway has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope.

With regard to Gateway's comments on our third recommendation, while we acknowledge that Gateway had compliance procedures in place during our audit period to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct, the diagnosis codes for 232 of the 286 sampled enrollee-years were not supported by the medical records. Continuing to improve compliance program procedures to monitor provider record submissions, with a focus on diagnosis codes at risk for being miscoded, may have prevented these errors.

Accordingly, we maintain that our second and third recommendations are valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid Gateway $1,453,457,020 to provide coverage to its enrollees for 2018 and 2019. We identified a sampling frame of 1,823 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2017 and 2018 service years; Gateway received $45,553,801 in payments from CMS for these enrollee-years for the audit period. We selected for audit 286 enrollee-years with payments totaling $7,386,270.

The 286 enrollee-years included 30 acute stroke diagnoses, 30 acute myocardial infarction diagnoses, 30 embolism diagnoses, 30 sepsis diagnoses, 30 pressure ulcer diagnoses, 30 lung cancer diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, 30 prostate cancer diagnoses, and 16 ovarian cancer diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled $1,291,355 for our sample.

Our audit objective did not require an understanding or assessment of Gateway'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 June 2022 through July 2025.

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:
    - 94 diagnosis codes for acute stroke,
    - 17 diagnosis codes for acute myocardial infarction,
    - 63 diagnosis codes for embolism,
    - 30 diagnosis codes for sepsis,
    - 50 diagnosis codes for pressure ulcers,
    - 17 diagnosis codes for lung cancer,
    - 54 diagnosis codes for breast cancer,

- 10 diagnosis codes for colon cancer,
- 1 diagnosis codes for prostate cancer, and
- 9 diagnosis codes for ovarian 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)[39] and Encounter Data System (EDS) [40] to identify enrollees who received high-risk diagnosis codes from a physician during the service years,

  - Risk Adjustment System (RAS)[41] to identify enrollees who received an HCC for the high-risk diagnosis codes,

  - Medicare Advantage Prescription Drug System (MARx)[42] to identify enrollees for whom CMS made monthly Medicare payments to Gateway, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C),

  - EDS to identify enrollees who received specific procedures, and

  - Prescription Drug Event (PDE) file[43] to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.

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

- We identified a sampling frame of 1,823 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes for the 2017 and 2018 service years.

- We selected for audit a stratified random sample of 286 enrollee-years (Appendix C).

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

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

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

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

[43] 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 265 enrollee-years (footnote 14) to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.[44]

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

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

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

        - 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 the coding supervisor independently reviewed the medical record to make the final determination.

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

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

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

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

- We estimated the total net overpayment made to Gateway for the high-risk groups included in the sampling frame for the audit period in accordance with CMS's regulations for the use of extrapolation in Risk Adjustment Data Validation audits for recovery purposes.

[44] 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 discussed the results of our audit with Gateway officials.

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

APPENDIX B: RELATED OIG REPORTS

Report Title	Report Number	Date Issued
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health and Life Insurance Company (Contract H1608) Submitted to CMS	A-02-22-01020	6/23/2025
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UCare Minnesota (Contract H2459) Submitted to CMS	A-07-22-01209	12/23/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes Blue Care Network of Michigan (Contract H5883) Submitted to CMS	A-06-20-02000	12/20/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Triple-S Advantage, Inc., (Contract H5774) Submitted to CMS	A-04-21-07095	12/19/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Humana Health Plan, Inc. (Contract H2649) Submitted to CMS	A-02-22-01001	9/23/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HealthAssurance, Pennsylvania, Inc. (Contract H5522) Submitted to CMS	A-05-22-00020	9/23/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Independent Health Association, Inc. (Contract H3362) Submitted to CMS	A-07-19-01194	6/26/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MediGold (Contract H3668) Submitted to CMS	A-07-20-01198	02/16/2024
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That SelectCare of Texas, Inc. (Contract H4506) Submitted to CMS	A-06-19-05002	11/27/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Aetna, Inc. (Contract H5521) Submitted to CMS	A-01-18-00504	10/02/2023
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS	A-07-20-01197	8/03/2023

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified Gateway enrollees who: (1) were continuously enrolled in Gateway throughout all of the 2017 or 2018 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 2017 or 2018 or in January of the following year, and (3) received a high-risk diagnosis during 2017 or 2018 that caused an increased payment to Gateway for 2018 or 2019, respectively.

We presented the data for these enrollees to Gateway 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 Gateway. After we performed these steps, our finalized sampling frame consisted of 1,823 enrollee-years.

SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2018 or 2019.

SAMPLE DESIGN AND SAMPLE SIZE

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

- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on only one physician claim during the service year but did not have an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim (869 enrollee-years);

- an acute myocardial infarction diagnosis (that mapped to the HCC for Acute Myocardial Infarction) on only one physician or outpatient claim during the service year but did not have an acute myocardial infarction diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician or outpatient claim (265 enrollee-years);

- an embolism 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 (135 enrollee-years);

- a sepsis diagnosis (that mapped to the HCC for Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock) on only one physician or outpatient claim during the service year but did not have a sepsis diagnosis on a corresponding inpatient hospital claim (182 enrollee-years);

- a pressure ulcer diagnosis (that mapped to a Pressure Ulcer HCC) on only one claim during the service year but did not have a pressure ulcer diagnosis on another inpatient,

outpatient, or physician claim for either the calendar year before or the calendar year after the service year (42 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 (61 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 (124 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 (58 enrollee-years);

- a prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors), for an individual 74 years old or younger, on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (71 enrollee-years); or

- an ovarian cancer diagnosis (that mapped to an Ovarian Cancer HCC) on only one claim during the service year but did not have surgical therapy or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (16 enrollee-years).

The specific strata are shown in Table 3 on the following page.

Table 3: Sample Design for Audited High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee-Years	CMS Payment for HCCs in Audited High-Risk Groups	Sample Size
1 – Acute stroke	869	$2,582,563	30
2 – Acute myocardial infarction	265	1,008,460	30
3 – Embolism	135	522,326	30
4 – Sepsis	182	945,293	30
5 – Pressure ulcer	42	500,168	30
6 – Lung cancer	61	423,572	30
7 – Breast cancer	124	177,467	30
8 – Colon cancer	58	158,755	30
9 – Prostate cancer	71	98,772	30
10 – Ovarian cancer	16	90,935	16
Total	**1,823**	**$6,508,311**	**286**

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We sorted the items in each stratum by the enrollee-year (a combination of the enrollee identifier and the payment year being reviewed), then consecutively numbered the items in each stratum in the stratified sampling frame. After generating random numbers according to our sample design, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to estimate the total amount of net overpayments in the sampling frame made to Gateway at the lower limit of the two-sided 90-percent confidence interval (Appendix D). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Details and Results

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	Net Overpayments for Unvalidated HCCs (for Sampled Enrollee-Years)
1 – Acute stroke	869	$2,582,563	30	$75,648	29	$68,236
2 – Acute myocardial infarction	265	1,008,460	30	112,971	30	105,017
3 – Embolism	135	522,326	30	106,985	26	97,602
4 – Sepsis	182	945,293	30	143,405	15	74,319
5 – Pressure ulcer	42	500,168	30	369,212	11	110,836
6 – Lung cancer	61	423,572	30	222,212	23	163,271
7 – Breast cancer	124	177,467	30	39,897	30	39,897
8 – Colon cancer	58	158,755	30	85,261	30	78,793
9 – Prostate cancer	71	98,772	30	44,829	23	14,696
10 – Ovarian cancer	16	90,935	16	90,935	15	77,667
Total	**1,823**	**$6,508,311**	**286**	**$1,291,355**	**232**	**$830,334**

Table 5: Estimated Net Overpayments in the Sampling Frame
(Limits Calculated at the 90-Percent Confidence Level)

Point Estimate	$4,711,125
Lower Limit	$4,314,513
Upper Limit	$5,107,738

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

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

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

including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

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

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

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

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

APPENDIX F: GATEWAY HEALTH PLAN COMMENTS

August 22, 2025

Nicole Freda, Regional Inspector General for Audit Services
Craig Cohen, Assistant Regional Inspector General for Audit Services
Office of Audit Services, Region III
801 Market Street, Suite 8500
Philadelphia, PA 19107

Re: Response to OIG Draft Audit Report Number: A-03-22-00004 of Gateway Health Plan, Inc. (H5932)

Dear Ms. Freda and Mr. Cohen,

Gateway Health Plan Inc. (**"Gateway"**) writes this letter in response to the draft report issued by the United States Department of Health and Human Services, Office of Inspector General (**"OIG"**) in July of 2025 entitled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Gateway Health Plan, Inc. (Contract H5932) Submitted to CMS* (the **"Draft Report"**). Gateway is a wholly-owned subsidiary of Highmark Inc. (**"Highmark"**) that offers Medicaid plans and Medicare D-SNP plans in Pennsylvania. In the most recent Medicare Star Ratings, this contract scored a 4.5 out of a possible 5 stars for the overall, summary ranking.

Gateway respectfully disagrees with OIG's findings as set forth in its Draft Report and requests that OIG withdraw its recommendations that Gateway (1) refund the government $4.6 million in extrapolated "overpayments" for the years covered by the audit; (2) identify similar instances of noncompliance that occurred after the audit period and refund any resulting overpayments to the government; and (3) continue examining its existing compliance procedures to identify where improvements can be made and take the necessary steps to enhance procedures.

As discussed in more detail below, Gateway requests that OIG withdraw its recommendations for several reasons. ***First,*** OIG did not take into consideration all elements of an "improper payment" or the Congressional design of the Medicare Advantage (**"MA"**) program, focusing only on alleged overpayments to Gateway and ignoring underpayments to Gateway and errors in the fee-for-service (**"FFS"**) data on which MA payment rates are based. ***Second***, OIG does not have the statutory authority to extrapolate under the Inspector General Act. ***Third,*** OIG's use of extrapolation along with the refusal to apply an FFS Adjuster is arbitrary and capricious. ***Fourth***, OIG's focus on "high-risk" codes along with other audit methodologies does not comply with regulatory requirements. ***Fifth***, these unpredictable and inconsistent audits have potential devastating effects to the MA program ranging from plan participation to, most importantly, beneficiary harm. ***Sixth***, Gateway also disagrees that certain codes found by OIG to be invalid were, in fact, unvalidated. ***Seventh and lastly***, Gateway has a robust compliance program, which it continually refines. Gateway disagrees with OIG's suggestion that the

findings of this audit demonstrate that Gateway's compliance program is inadequate.

I. OIG's Audit Does not Comport with the Congressional Design of the MA Program.

A. In a Capitated System, an Audit Should Be Designed to Determine Not Only Whether Individual Coding Errors Occurred, But Also Whether the Overall Payment to the Plan Was Too High.

The MA program, which applies to the contract at issue in the Draft Report, uses a global capitated payment model developed by the Centers for Medicare & Medicaid Services ("**CMS**") (the CMS-HCC model) that relies on data from the traditional Medicare program to determine the value of coefficients used for payment. The traditional Medicare program generally pays providers on a FFS basis, which differs from the capitated payments derived from the CMS-HCC model. Because the model is population-based, any inquiry in MA designed to determine whether an improper payment has occurred must take into account all potential errors that affect payment for the MA Organization's ("**MAO**") population, including undercoding and overcoding, as well as errors in the underlying FFS data on which the capitated payments are based, and the resultant effect on CMS's total *overall* payment to the MAO. OIG's findings, upon which it bases the extrapolated demand, do not take into account: (i) instances of potential undercoding, or underpayments, to the MAO based on all of its data; and (ii) the impact of errors in FFS data on payment. If OIG had taken these into consideration in defining the purported improper payment amount, the overpayment estimate originally reported by OIG would likely be significantly reduced, if not eliminated.

Further, the Social Security Act ("SSA") provides that CMS must compensate MAOs in a way that ensures "actuarial equivalence" with what CMS would have paid to provide care for the same beneficiaries under traditional Medicare.[1] This means, that CMS's overall payment to MAOs must be equivalent to what CMS would have paid to cover the same individuals under traditional Medicare. Application of OIG's audit approach, which does not consider errors in the FFS data, would result in an MAO being paid less than it would have cost traditional Medicare to care for the same beneficiaries. Overcoding errors in the FFS data artificially inflate the number of HCCs reported in the FFS data, which

[1] 42 U.S.C. § 1395w-23(a)(1)(C)(i) ("[T]he Secretary shall adjust the payment amount [of fixed monthly payments to Medicare Advantage insurers] for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status . . . , so as ***to ensure actuarial equivalence***.") (emphasis added); Actuarial Standards Board, Actuarial Standard of Practice No. 45 § 3.2 (Jan. 2012) ("The type of input data . . . used in the application of risk adjustment should be reasonably consistent with the type of data used to develop the model.").

has the effect of lowering the values of coefficients used in the CMS-HCC model to determine MA members' risk scores and the related payments made to MAOs. Despite CMS's contention that *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021) supports its assertion that actuarial equivalence does not apply to RADV audits and, by implication OIG audits,[2] this position is inconsistent with the design of the MA program.

B. OIG Did Not Meaningfully Account for Underpayments.

An audit seeking to determine whether an MAO was improperly paid must determine whether, on average, across all codes for all members, the plan received a larger (or smaller) payment than it should have. OIG acknowledges this itself, stating in the Draft Report: "[I]f medical records do not support the diagnosis codes that an MA organization submitted to CMS, the HCCs are not validated, which causes overstated enrollee risk scores and overpayments from CMS. Conversely, if medical records support diagnoses codes that an MA organization did not submit to CMS, validated HCCs may not have been included in the enrollees' risk scores, which may cause those risk scores to be understated and may result in underpayments."[3] While OIG acknowledges that underpayments also constitute an improper payment,[4] the Draft Report does not account for them in any meaningful way in its methodology.[5] OIG's current audit approach does not establish that there were actual overall *improper payments* because OIG chose, and audited, codes for which there was a likely error in the government's favor while ignoring the inverse (i.e., those codes for which there is a likely error in the MAO's favor).

To demonstrate the potential error in OIG's approach, Gateway performed a limited analysis of certain chronic conditions that were likely to have existed for

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[2] *See* Department of Health and Human Services ("**HHS**"), CMS, *Medicare and Medicaid Programs; policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021*, 88 Fed. Reg. 6643, 6656 (Feb. 1, 2023) (codified at 42 C.F.R. §§ 422.300, 422.310(e), 422.311(a)) (**"New RADV Audit Rule"**).

[3] Draft Report at 4 (footnote omitted).

[4] *See id.* at 3-4.

[5] Where OIG found that the HCC in question was not supported but that a different HCC within the disease hierarchy should have been assigned, that change was incorporated into the calculation. *See, e.g., id.* at 10-11. Further, where one enrollee year was validated for prostate cancer, the OIG also took into account an underpayment that occurred for this same enrollee-year due to the fact that the medical review contractor found support for a separate HCC within the Cancer disease hierarchy that was not under review for this audit. *See id.* at 16 n.22. These few and relatively minor instances were the only ways in which OIG accounted for codes that should have been submitted but were not.

its population during 2018 and 2019 but were not submitted to CMS. Gateway used a targeted approach, similar to OIG's, selecting 10 HCCs that, in its experience, are often undercoded by providers, such as diabetes mellitus with chronic complications (**"DM"**), chronic kidney disease, Stage 5 (**"CKD"**), and chronic obstructive pulmonary disease (**"COPD"**), among others. Gateway focused on members who had one of these diagnoses submitted in a prior and/or subsequent year but not in either 2018 or 2019. Gateway selected a random sample from the universe identified for which medical records were readily available. Experienced, certified coders reviewed the associated medical records.[6]

This analysis revealed 28 conditions documented in medical records but not submitted for payment, representing an underpayment of $64,500 in the sample reviewed. To replicate OIG's approach, Gateway then extrapolated from this amount. Gateway calculated $5 million in underpayments from this limited exercise.[7] This amount more than offsets the $4.6 million in alleged overpayments identified by OIG. Further, Gateway reviewed only ten conditions. If Gateway had evaluated the undercoding associated with additional conditions, the underpayments found would, presumably, have been even more significant.

To be clear, Gateway is not suggesting that CMS now pay Gateway for these missed codes. However, if OIG elects to effectively re-open a long since closed contract period, it should allow MAOs to offset any alleged overpayments with evidence of underpayments during that same period.[8]

C. OIG Did Not Fully Account for Undercoding Evident in the Medical Records Provided to OIG.

As noted above, the appropriate approach to this type of audit would be to consider all potential offsetting underpayments. This is especially important where, here, OIG audited data from a limited universe where a record showed no evidence of direct or follow-up care in conjunction with a diagnosis, thus leading to skewed results since there is a greater likelihood that these codes would not be validated. This type of audit should include consideration of underpayments related to all patients and all medical records and not be limited to those patients and records that

[6] The Gateway coders who conducted this review all had American Academy of Professional Coders ("**AAPC**") Certified Professional Coder ("CPC") and/or AAPC Certified Risk Adjustment Coder ("CRC") certifications. All had at least five years (and most had at least ten years) of risk adjustment coding experience.

[7] A summary of this analysis is attached as **Exhibit A**.

[8] CMS allows correction of underpayments only during a specified period (typically until January 31 of the year following the payment year), although it allows correction of overpayments during a much longer period. Although CMS does not allow MAOs to "add" missing codes after the deadline, there does not appear to be anything that would prevent OIG from allowing an MAO to submit evidence of underpayments to offset the alleged overpayments in the context of this audit.

are the subject of the audit. OIG did not do this and, in fact, disregarded most instances of undercoding shown in the medical records reviewed.

Gateway certified coders reviewed the medical records submitted to OIG and identified support for a total of 40 new, unique codes for risk adjusting diagnoses for the same patient in the same year, with a value of approximately $130,000.[9] Of these 40 new codes, two were within medical records in which OIG found a validated, targeted condition.[10] The diagnosis codes for the two diagnoses that OIG did not find have a value of approximately $9,000, which CMS would offset in a typical contract-level CMS Risk Adjustment Data Validation ("**RADV**") audit. As noted above, the appropriate approach would be to fully credit *any* offsetting underpayments and would reduce the extrapolated estimated amount.

Moreover, OIG has recently performed limited two-way contract-level audits in which it does not focus on specific "high-risk" codes, accounting for both overpayments and underpayments.[11] While there are flaws with these broader two-way audits that do not focus on high-risk codes, such as only including members with at least one HCC in the year, these audits are more aligned with maintaining the integrity of the program. In fact, the MAOs that have gone through these two-way audits that do not focus on high-risk codes have performed significantly better than the MAOs that have gone through audits of specific "high-risk" codes.[12]

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[9] Gateway has attached as **Exhibit B** clinical justifications for 10 of these 40 new, unique codes.

[10] OIG found support for one new diagnosis code, separate from the two codes discussed above, that caused an underpayment for which OIG accounted in its overpayment calculations. This new diagnosis code was supported by the medical records of a patient with a validated HCC for prostate cancer. *See* Draft Report at 16 n.22. This new code OIG found also was found by the Gateway coders and is included in the 40 new, unique codes discussed in this paragraph.

[11] The chart in **Exhibit C**, attached, represents just a few recent examples of limited two-way audits that OIG has performed.

[12] *Compare* Medicare Advantage Compliance Audit of Diagnosis Codes that SCAN Health Plan (Contract H5425) Submitted to CMS at 5 (finding that 1,413 of the 1,577 sampled enrollees' HCCs were validated), Medicare Advantage Compliance Audit of Diagnosis Codes that Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS at 5 (finding that 1,401 of the 1,470 sampled enrolles' HCCs were validated), Medicare Advantage Compliance Audit of Diagnosis Codes that Humana, Inc., (Contract H1036) Submitted to CMS at 5 (finding that 1,322 of the 1,525 sampled enrollees' HCCs were validated) *with* Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Aetna, Inc. (Contract H5521) Submitted to CMS at 7 (finding that only 55 of the 210 sampled enrollee-years' HCCs were validated), Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS at 7 (finding that only 8 of the 210 sampled enrollee-years' HCCs were

D. OIG Made Errors in Applying its Own Methodology for Accounting for Codes That Could Have Been Submitted.

In its audit, OIG stated that it accounted for undercoding only to a very limited extent: "[I]f 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."[13] For instance, OIG noted, "Gateway submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiparesis (which was supported by the medical records). . . . Accordingly, Gateway should not have received a payment for the acute stroke diagnosis but instead should have received a payment for the hemiplegia diagnosis. This error caused an underpayment."[14] Further, OIG also noted instances where an HCC was unvalidated but the medical review contractor found "support for another diagnosis on CMS's systems that mapped to an HCC for a less severe manifestation of the related-disease group."[15]

However, there were two instances in which OIG failed to recognize alternative codes identified in the medical record that mapped to an HCC for a less severe manifestation of the related-disease group and should have been submitted to CMS instead of the selected codes. Specifically, **Exhibit D** shows that a medical record supported an HCC of malignant neoplasm of endometrium (ICD Code C54.1) where the targeted HCC of ovarian cancer (ICD Code C56.9) was found to not be validated. Further, a second medical record supported an HCC of non-pressure chronic ulcer of unspecified part of unspecified lower leg (ICD Code L97.909) where the targeted HCC of pressure ulcer (ICD Code L89.153) was found to not be validated.

E. OIG Did Not Account for the Fact That the Same Errors Are Present in the FFS Data Upon Which MA Reimbursement Rates Are Based.

It is widely recognized that individual providers often submit inaccurate and noncomprehensive diagnosis data. Although coding continues to improve, providers for traditional Medicare beneficiaries often do not code comprehensively and may include only diagnosis codes necessary to support a service. Given the substantial number of ICD codes, providers may also select the wrong diagnosis code or not include documentation in the medical record that is sufficient to support

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validated), Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS at 7 (finding that only 13 of the 211 sampled enrollee-years' HCCs were validated).

[13] Draft Report at 7.

[14] *Id.* at 10.

[15] *See, e.g., id.* at 11.

the code they select. In fact, a CMS analysis of Medicare FFS data showed that the claim-level error rate in diagnoses supporting each HCC ranged from 21 to 46%.[16]

CMS has stated that the traditional Medicare data still leads to appropriate *overall* reimbursement for MAOs because, when the data is considered as a whole, errors tend to "offset" one another.[17] Thus, CMS has argued that there is no need for an "FFS Adjuster" in the context of RADV audits.[18] Notably, others have criticized this conclusion. For instance, a Milliman white paper concluded that CMS's analysis was faulty and that, in fact, an FFS Adjuster is necessary.[19] Even if CMS was correct, however, and underpayments and overpayments cancel one another *overall*, this does not negate the need for OIG to take the error rate in the FFS data into account in the present audit given OIG's more narrow, cherry-picked claims sample. Here, OIG selected coding patterns most likely to have high rates of overcoding and ignored the other side of the equation (underpayments), which, CMS acknowledges, cancels out overpayments. Individual providers submitted the vast majority of codes in the OIG sample. These providers make the same coding errors when treating traditional Medicare patients. CMS then uses the same FFS data to set the coefficient values for specific HCCs, which factor into MAO payments. As stated above, overcoding errors in the FFS data artificially inflate the number of HCCs reported in the FFS data, which, in turn, lowers the values of coefficients used in the CMS-HCC model. Thus, the payments to MAOs already take into account the fact that a large number of the codes submitted in these

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[16] CMS, *Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits* (Oct. 26, 2018) at 3 ("A claim level discrepancy rate was derived for each HCC. The discrepancy rates ranged from 21 to 46 percent.").

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

[18] *See* New RADV Audit Rule, 88 Fed. Reg. at 6644 (codified at 42 C.F.R. §§ 422.300, 422.310(e), 422.311(a)).

[19] Pipich, R., *Medicare Advantage RADV FFS Adjuster: White paper*, Milliman, 24 (Aug. 23, 2019), https://us.milliman.com/en/insight/2019/Medicare-Advantage-RADV-FFS-adjuster; *see also* Avalere, *Eliminating the FFS Adjuster from the RADV Methodology May Affect Plan Payment* (Mar. 2019), https://avalere.com/wp-content/uploads/2019/03/20190318-FFS-Adjuster-Analysis-Final-.pdf (finding that the "audit miscalibration bias yields underpayments of nearly 8%").

situations are likely to be unsupported.[20] Further, the amount of an FFS Adjuster in this type of audit would have to be much higher than in a RADV audit, as the relevant measure here is not the overall error rate in the FFS data, but, rather, the error rate in the FFS data for the same situations targeted in OIG's audit.[21] In this audit, OIG searched for specific coding patterns in which the diagnosis was unlikely to be supported. Notwithstanding CMS's decision to not apply an FFS Adjuster to RADV audits,[22] if OIG is going to use this approach, the results must, at a minimum, be compared to the same coding patterns in the FFS data. Because OIG did not consider the errors in the FFS data, its audit methodology and results are inaccurate.[23]

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[20] For instance, as OIG has discovered, when the code for an acute myocardial infarction ("**MI**") is submitted from a physician's office with no accompanying hospital admission, that code is often an error (and the physician typically meant to capture a history of an acute MI). But this same coding error likely occurs just as frequently in the FFS data. Thus, the value of the coefficient for the related HCC, which is based on what Medicare FFS pays to care for patients with particular conditions, already takes this rate of error into account in the payment. Removing those codes from the MA data without also removing them from the FFS data on which the HCC values are based is likely to result in underpayment to the MAOs.

[21] For example, OIG identified members diagnosed with Pressure Ulcers. OIG found that in these instances, the diagnosis was not supported by the medical record in 15 of 30 instances (or 50% of the time). However, to determine whether this actually represents an improper payment, FFS data for the same set of conditions should be reviewed to determine whether it differs from Gateway's data. If the errors occur with the same frequency in both the FFS and the MA data, then Gateway would be underpaid if it were required to remit these amounts back to CMS.

[22] Below Gateway discusses why not using an FFS Adjuster is arbitrary and capricious.

[23] The failure to account for the error rate in the FFS data is also inconsistent with OIG's previous acknowledgment of the need to take this into account. During its 2012 OIG audit, PacifiCare argued that OIG's results did not account for error rates in Medicare FFS data. OIG withdrew its recommendation that PacifiCare repay an extrapolated amount and recommended instead that PacifiCare "work with CMS to determine the correct contract-level adjustments for the estimated overpayments." HHS OIG, *Risk Adjustment Data Validation of Payments Made to PacifiCare of California for Calendar Year 2007* (Contract Number H0543), A-09-09-00045, 8 (Nov. 2012).

F. OIG Is Effectively Requiring that Providers Performing Services under Medicare Advantage Code 100% Accurately, Which Both OIG and CMS Have Acknowledged Is Not Required Under Medicare Advantage.

OIG's audit approach effectively requires MAOs to have a 0% coding error rate for all of its encounter data. Yet, holding MAOs to a standard of perfection is inconsistent with previous acknowledgements by both CMS and OIG that 100% accuracy in the data MAOs submit to CMS is not possible or required.[24] CMS regulations require that an MAO take reasonable steps to ensure the "accuracy, completeness, and truthfulness" of the data it submits to CMS based on its "best knowledge, information, and belief."[25] At the time it implemented the current regulatory scheme, CMS acknowledged that 100% accuracy could not be expected and was not required, stating, "M+C organizations cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that HCFA, the ***OIG***, and DOJ believe is reasonable to enforce."[26] Similarly, OIG has stated that the requirement that an MAO certify the accuracy of data "does not constitute an absolute guarantee of accuracy."[27]

It is unreasonable for OIG to effectively hold MAOs to a standard of 100% accuracy by constructing an audit consisting solely of a heavily data-mined sample designed to highlight only overpayments and not underpayments. This is particularly true given that both CMS and OIG have previously stated that 100% accuracy is not expected.

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[24] Similarly, in *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), the D.C. Circuit recently held that: "Nothing in the Overpayment Rule obligates insurers to audit their reported data. . . . [T]he Rule only requires insurers to refund amounts they *know* were overpayments, *i.e.*, payments they *are aware* lack support in a beneficiary's medical records. That limited scope does not impose a self-auditing mandate." *Id.* at 884 (emphasis in original).

[25] 42 C.F.R. § 422.504(l) ("As a condition for receiving a monthly payment under subpart G of this part, the MA organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that CMS requests.").

[26] Health Care Financing Administration (**"HCFA"**), HHS *Medicare Program, Medicare+Choice Program*, 65 Fed. Reg. 40170, 40268 (June 29, 2000) (emphasis added).

[27] HHS, OIG *Publication of the OIG's Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans*, 64 Fed. Reg. 61893, 61900 (Nov. 15, 1999).

Further, diagnostic coding is an inherently subjective process and, as noted above, can also result in unintended errors. MAOs cannot be responsible for and control all providers who submit unsubstantiated codes. Gateway is not aware of any specific guidance from OIG or CMS regarding the type of monitoring MAOs are required to undertake with respect to providers and their submission of codes.

Moreover, after review of OIG's audit findings, Gateway disagrees with OIG's determination of a coding error for 40 HCCs identified in OIG's report, as further discussed below, which results in an error rate of 14% within OIG's own determinations. OIG's inability to conduct this audit with 100% accuracy demonstrates that it is unreasonable to hold MAOs to such a standard.

II. OIG Does Not Have the Authority to Extrapolate

OIG conducted this audit under the Inspector General Act ("IGA"), which does not provide OIG with authorization to extrapolate overpayments from MAOs through audits.

Although the CMS Administrator and the HHS Secretary have asserted that OIG has the authority to conduct audits under IGA and 42 C.F.R. part 422, subpart G,[28] the New RADV Audit Rule, promulgated by CMS and the Secretary, does not confirm this assertion. Rather, the rule only states that OIG "undertakes audits of MAOs, similar to RADV audits, as part of its oversight functions[,]" and "CMS can collect the improper payments identified during those HHS-OIG audits, including the extrapolated amounts calculated by the OIG."[29]

Gateway does not believe that OIG has the authority to extrapolate under 42 C.F.R. Part 422, subpart G through the IGA for two reasons. First, Congress delegated authority to the Inspector General, not the Secretary, under the IGA. Thus, the Secretary's new RADV audit rule does not apply to audits under the IGA. Second, the statutory authority for 42 C.F.R. part 422, subpart G is the SSA; the Inspector General has no authority to extrapolate under the relevant SSA provisions.[30]

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[28] *Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*, 79 Fed. Reg. 29844, 29934 (May 23, 2014) ("The Secretary (including the Office of Inspector General (OIG)—pursuant to OIG's authority under the Inspector General Act of 1978, 5 U.S.C. App.) clearly has the authority to conduct RADV audit activity.").

[29] New RADV Audit Rule, 88 Fed. Reg. at 6645 n.6.

[30] 42 C.F.R. § 422.300 (2021) ("This subpart is based on sections 1106, 1128J(d), 1853, 1854, and 1858 of the [Social Security] Act.").

Further, no statutory authority exists for OIG or CMS to calculate or extrapolate overpayments.[31] The Secretary has previously acknowledged that it does not have the authority to extrapolate by seeking a change in the statute to allow extrapolation,[32] but it has now switched tactics to circumvent the Congressional action necessary for the Secretary to extrapolate. The Secretary now argues that it has the authority to extrapolate because Congress has not expressly prohibited it.[33] However, an agency "may only take action that Congress has authorized"[34] and lack of Congressional action does not translate to a delegation of authority to an agency.

III. OIG's Use of Extrapolation Along with the Refusal to Apply an FFS Adjuster Is Arbitrary and Capricious.

A. The Use of Extrapolation Along with the Refusal to Apply an FFS Adjuster Is Arbitrary and Capricious Because OIG has Applied this New Methodology Retroactively.

In addition to OIG's lack of authority to extrapolate and despite the New RADV Audit Rule promulgated by CMS,[35] the use of extrapolation in this audit

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[31] 42 U.S.C. § 1395ddd(f)(3), which places limits on the use of extrapolation by program integrity contractors, does not apply to risk adjustment in the MA program. Although subsection (h)(9), sets forth special rules for the use of recovery audit contractors ("RACs") in the MA program, this subsection does not authorize the RACs to engage in program integrity activities related to MA risk adjustment.

[32] *See Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations for 2011: Hearings Before the H.R. Comm. on Appropriations*, 111th Cong. pt. 7, 14 (Mar. 4, 2010) (written statement of HHS Deputy Secretary William Corr); HHS & CMS, Fiscal Year 2011: Justification of Estimates for Appropriations Committees (2010), 177 (describing proposal that would "[c]larify in statute that CMS can extrapolate the error rate found in the risk adjustment validation (RADV) audits to the entire MA plan payment for a given year when recouping overpayments.").

[33] New RADV Audit Rule, 88 Fed. Reg. at 6651.

[34] *See Bais Yaakov of Spring Valley v. F.C.C.*, 852 F.3d 1078, 1082 (D.C. Cir. 2017) (citations omitted).

[35] Currently, an APA challenge to this rule is pending in the Northern District of Texas. *See Humana, Inc. v. Becerra*, No. 4:23-cv-909 (N.D. Tex.). In that case, Humana asserts "(1) the [New RADV Audit Rule] is arbitrary and capricious and contrary to law because it reverses CMS's prior policy on the FFS Adjuster without an adequate explanation, relying solely on legal justifications that misinterpret the Medicare statute; (2) CMS promulgated the [New RADV Audit Rule] without observance of procedure required by law; and (3) CMS acted contrary to law and abused its discretion in deciding to apply the new policy retroactively beginning in

along with the refusal to apply an FFS Adjuster is arbitrary and capricious because OIG has applied this new methodology retroactively.

The SSA prohibits the retroactive application of rules absent a significant public safety concern or other critical need.[36] Specifically the prohibition states:

> *A substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability* under this title *shall not be applied (by extrapolation or otherwise) retroactively* to items and services furnished before the effective date of the change, unless the Secretary determines that (i) such retroactive application is necessary to comply with statutory requirements; or (ii) failure to apply the change retroactively would be contrary to the public interest. [37]

OIG's new methodology for conducting MA audits is materially different from the CMS methodology that was in place when the MAOs—including Gateway—submitted bids for the years in question. Regardless of how OIG and CMS choose to label this new approach, it clearly represents a "substantive change."[38] The change effectively demands 100% accuracy of MAOs and has a significant potential impact on the reimbursement received by those plans for past years. Moreover, retroactive application is neither necessary to comply with statutory requirements nor in the public interest. In fact, the decision to not apply an FFS Adjuster is contrary to the design of the MA program as discussed above in Section I(E) and the use of extrapolation and the refusal to apply an FFS Adjuster is contrary to the public interest as discussed below in Sections III(B) and III(C). Given this, the SSA prohibits OIG's retroactive application of the approach.

B. The Refusal to Apply an FFS Adjuster Is Arbitrary and Capricious Because OIG and CMS have Failed to Provide Proper Justification for this Decision.

Although CMS has recently promulgated a final rule that does not require RADV audits and purportedly OIG audits to apply an FFS Adjuster, this decision is arbitrary and capricious, as CMS and OIG have not provided proper justification for this decision outside a flawed study criticized by many MAOs and other

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payment year 2018." Dkt. 44 at 29-30, Mot. for Summ. J., *Humana, Inc. v. Becerra*, No. 4:23-cv-909 (N.D. Tex. Oct. 7, 2024).

[36] 42 U.S.C. §1395hh(e)(1)(A).

[37] *Id.*

[38] CMS has disclaimed that this new approach to payment year 2018 forward is a retroactive application and has indicated that is believes even if it were a retroactive application, it would be necessary to meet statutory standards and would advance the public interest. New RADV Audit Rule, 88 Fed. Reg. at 6653. Gateway disagrees for the reasons stated above.

industry constituents.[39] CMS has acknowledged the need for an FFS Adjuster when performing extrapolated audits as far back as 2012.[40]

However, in the New RADV Audit Rule, CMS asserts that the D.C. Circuit's decision *UnitedHealthcare Insurance*—a case not about RADV or OIG audits, but about an entirely separate overpayment rule—supports its decision to not apply an FFS Adjuster to extrapolated audits.[41] Further, CMS argues that coding-intensity adjustment negates the need for an FFS Adjuster.[42] However, this reasoning is flawed and does not acknowledge what many industry experts have found: that the elimination of an FFS Adjuster disregards the requirement for actuarial equivalence between the MA program and traditional Medicare.[43]

C. The Decision to not Apply the FFS Adjuster Is Arbitrary and Capricious Because CMS Failed to Comply with the Notice-and-Comment Procedures when Promulgating the New RADV Audit Rule.

Additionally, OIG's decision to not apply an FFS Adjuster to this audit is arbitrary and capricious because CMS's New RADV Audit Rule eliminating the FFS Adjuster failed to comply with the notice and comment requirements under 42

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[39] *See, e.g.,* Anthem, Inc. Comments to Seema Verma, Re: CMS–4185–P: Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (Aug. 28, 2019), https://downloads.regulations.gov/CMS-2018-0133-0260/attachment_1.pdf; Pipich, R., *Medicare Advantage RADV FFS Adjuster: White paper*, Milliman, 24 (Aug. 23, 2019), https://us.milliman.com/en/insight/2019/Medicare-Advantage-RADV-FFS-adjuster.

[40] CMS, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level (Feb. 24, 2012), https://www.cms.gov/newsroom/fact-sheets/notice-final-payment-error-calculation-methodology-part-c-medicare-advantage-risk-adjustment-data.

[41] New RADV Audit Rule, 88 Fed. Reg. at 6644.

[42] *Id.* at 6656.

[43] *See, e.g.*, Anthem, Inc. Comments to Seema Verma, Re: CMS–4185–P: Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (Aug. 28, 2019), https://downloads.regulations.gov/CMS-2018-0133-0260/attachment_1.pdf; Pipich, R., *Medicare Advantage RADV FFS Adjuster: White paper*, Milliman, 24 (August 23, 2019), https://us.milliman.com/en/insight/2019/Medicare-Advantage-RADV-FFS-adjuster.

U.S.C. § 1395hh(b)(1).[44] CMS appears to heavily rest its final decision eliminating the FFS Adjuster on the reasoning in *UnitedHealthcare Insurance*—a case that was decided in 2021, years after CMS issued the proposed rule eliminating the FFS Adjuster in 2018. Thus, stakeholders, such as MAOs, have been denied the right to comment on the reasoning CMS has relied on in issuing the final rule. Therefore, the elimination of the FFS Adjuster has violated CMS's notice-and-comment requirements. In turn, OIG's refusal to apply an FFS Adjuster to this audit, based on CMS's reasoning, is arbitrary and capricious.

D. There Is No Mechanism for Release of Liability with Respect to Codes for which an MAO Makes Payment Based on Extrapolated Amounts.

Currently there is no CMS settlement process, of which Gateway is aware, for which an MAO that refunded an extrapolated amount would obtain a release from liability for errors relating to the same codes in subsequent audits, investigations, or other disputes. Thus, an MAO that refunds an extrapolated amount may continue to be liable for the same codes at issue in subsequent disputes, allowing CMS to "double-dip" on its recovery. This phenomenon is confirmed with CMS's recent press release regarding its "Aggressive Strategy to Enhance and Accelerate Medicare Advantage Audits." Neither OIG nor CMS comments on how extrapolated recoupments from OIG audits would be accounted for in CMS RADV audits.[45]

IV. OIG'S FOCUS ON "HIGH-RISK" CODES ALONG WITH ITS OTHER AUDIT METHODOLOGIES IS ARBITRARY AND CAPRICIOUS

A. OIG's Audit Methodology, Particularly Its Focus on High Risk Codes, Represents a Change in a Substantive Legal Standard and Should Not Have Been Adopted without Notice and Comment.

In adopting a new audit approach by focusing on "high-risk" codes that change from audit to audit, OIG did not engage the requisite notice and comment process. The "notice and comment" provision of the APA does not apply to the Medicare Act. However, in 1987, Congress enacted a notice and comment statute

[44] This subsection requires that "[b]efore issuing in final form any regulation under subsection (a), the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon." 42 U.S.C. § 1395hh(b)(1); *see also* Section IV(A) below.

[45] *See* CMS, CMS Rolls Out Aggressive Strategy to Enhance and Accelerate Medicare Advantage Audits (May 21, 2025), https://www.cms.gov/newsroom/press-releases/cms-rolls-out-aggressive-strategy-enhance-and-accelerate-medicare-advantage-audits.

specifically for Medicare. As the Supreme Court explained in *Azar v. Allina Health Services*:

> [T]he law requires the government to provide the public with advance notice and a chance to comment on any "rule, requirement, or other statement of policy" that "establishes or changes a substantive legal standard governing . . . the payment for services."[46]

The Court further noted that "[n]otice and comment gives affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes—and it affords the agency a chance to avoid errors and make a more informed decision."[47]

In the present case, OIG has adopted new substantive legal standards by performing audits that impose different standards from one audit to the next. For example, OIG has targeted different "high-risk" codes for different audits of MAOs.[48] Further, Gateway is unaware that OIG or CMS has specifically defined what constitutes a "high-risk" code.[49] This inconsistency and uncertainty is inappropriate given that these new standards did not go through the notice and comment process.

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[46] *Azar v. Allina Health Servs.*, 587 U.S. 566, 572 (2019) (quoting 42 U.S.C. § 1395hh(a)(2)). In *Azar v. Allina*, the government noted that, under the APA, "interpretive rules" do not require notice and comment and argued that the same should be true under the Medicare Act's notice and comment provision. *Id.* at 573. But the Court rejected this argument, holding that the notice and comment requirement under the Medicare Act was broader than under the APA and siding with the defendants, which argued that (i) under the Medicare Act, a "substantive legal standard" subject to the notice and comment requirement is one that "creates duties, rights and obligations," and (ii) CMS's adoption of a new approach required notice and comment (even though, in that case, the change was merely noted in a spreadsheet on the CMS website). *See id.* at 571-79.

[47] *Id.* at 582 (citation omitted).

[48] A chart summarizing recent OIG "high-risk" audits is attached as **Exhibit E**.

[49] In fact, OIG has acknowledged, "the methodology and approaches that we have used to identify high-risk diagnosis codes and calculate overpayments for our series of audits of MA organizations have evolved." HHS OIG, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc.*, (Contract Number H4461), A-02-20-01009, 22 (July 2022).

B. OIG's Audit Methodology Is Arbitrary and Capricious.

Agency actions can generally be set aside if they are "arbitrary and capricious."[50] Here, as detailed above, the various and changing standards and scope for audits targeting "high-risk" codes are arbitrary and capricious as they do not provide a set standard that an MAO can expect when planning for an OIG audit.

Although OIG did provide Gateway with a document entitled "Reviewer Qualifications and Review Methodology HHS/OIG/OAS Targeted Risk Adjustment Data Audits" that outlined the medical record reviewers' credentials and the review process, the medical record review contractor's identity should be disclosed so that the MAO can assess any conflicts of interest and evaluate the contractor's credentials, policies, procedures, and experience. OIG should also confirm that the coders performing the review were subject to inter-rater reliability ("IRR"), and if so, Gateway should have the ability to evaluate the results of such reviews.[51]

Moreover, Gateway asked several questions in follow-up to its Exit Conference in October 2024 regarding OIG's audit methodology that still have yet to be answered over six months later. Some of these include: (i) what OIG's process is for determining whether a condition is active or historical; (ii) whether OIG acknowledges that the gap between the audit period and the initiation of the audit creates significant validation issues; (iii) whether OIG acknowledges the extraordinary circumstances preventing Gateway from locating certain medical records due to the provider's incarceration; (iv) whether OIG can demonstrate actuarial equivalence in how it calculated the overpayment; (v) whether OIG agrees that a 100% coding accuracy rate is not required of MAOs; and (vi) whether OIG has performed similar targeted audits on FFS data. OIG's refusal to answer these questions and engage with Gateway in a discussion to resolve these issues is another example of how OIG's approach to conducting this audit is arbitrary and capricious. The answers to these questions would have provided Gateway with insight into how OIG conducted its review and views the underlying issues inherent in an audit of this type, equipping Gateway to better discuss the preliminary findings with OIG and allowing OIG to reach more fair and balanced audit findings. As the audited entity, Gateway has the right to understand all aspects of the approaches and methodologies OIG used to conduct this audit so that Gateway can appropriately contest any issues that may have arisen in that audit process. Without the answers to these questions, Gateway lacked the insight needed to address identified issues with this audit prior to the release of the draft report.

Additionally, OIG's audit approach is arbitrary and capricious for numerous reasons discussed above: OIG's failure to consider underpayments or to account

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[50] *See, e.g., Am. Clinical Lab'y Ass'n v. Becerra*, 40 F.4th 616, 624 (D.C. Cir. 2022).

[51] This information should be disclosed pursuant to the Data Quality Act. These issues likely affect Gateway's appeal rights under 42 C.F.R. § 422.311.

for errors in the FFS data and actuarial equivalence; its effective insistence on 100% accuracy despite the fact that both OIG and CMS have acknowledged that this is neither possible nor required; its extrapolation of results despite a lack of authority to do so; its retroactive application of a new audit methodology in violation of the SSA; its adoption of a new audit methodology without the opportunity for notice and comment; and its inconsistent application of approaches over time and from one MAO to the next without explanation.

V. OIG's Approach to Risk Adjustment Audits Could Negatively Impact the Medicare Advantage Program.

A. The MA Program Results in Improved Quality and Reduced Costs.

"The Congressional Budget Office (CBO) projects that the share of all Medicare beneficiaries enrolled in Medicare Advantage plans will rise to 62% by 2033."[52] MA plans are attractive to many beneficiaries because they are generally more affordable and offer more benefits than traditional Medicare. MA plans also manage chronic conditions better than traditional Medicare. A 2015 paper found that MA plans did better than traditional Medicare in managing diabetes.[53] Similarly, a 2017 study found that MA plans outperformed traditional Medicare on all 16 quality measures and four out of six patient experience measures.[54] In addition, a 2023 study showed that MA enrollees with certain chronic conditions had fewer inpatient stays and fewer emergency department visits than equivalent traditional Medicare beneficiaries.[55] There is also evidence of a spillover effect

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[52] *See* N. Ochieng, et al., *Medicare Advantage in 2023: Enrollment Update and Key Trends*, KFF (Aug. 9, 2023), https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-enrollment-update-and-key-trends/.

[53] *See* B. Landon et al., *A Comparison of Relative Resource Use and Quality in Medicare Advantage Health Plans Versus Traditional Medicare*, 21 Am. J. Manag. Care 559, 565 (2015), https://www.ajmc.com/view/a-comparison-of-relative-resource-use-and-quality-in-medicare-advantage-health-plans-versus-traditional-medicare.

[54] J. Timbie et al., *Medicare Advantage and Fee-for-Service Performance on Clinical Quality and Patient Experience Measures: Comparisons from Three Large States*, 52 Health Servs. Rsch. 2038, 2044 (2017), https://pmc.ncbi.nlm.nih.gov/articles/PMC5682140/.

[55] Avalere Health, *Analysis of Medicare Advantage Enrollee Demographics, Utilization, Spending, and Quality Compared to Fee-for-Service Medicare Among Enrollees with Chronic Conditions*, 15 (June 2023), https://bettermedicarealliance.org/wp-content/uploads/2023/06/BMA-MA_FFS-Outcomes-Among-Beneficiaries-with-Chronic-Conditions_FIN-1.pdf; *see also* E. DuGoff et al., *Quality, Health, and Spending in Medicare Advantage and Traditional Medicare*, 27 Am. J. of Manag. Care 395, 395 (2021), https://www.ajmc.com/view/quality-health-and-spending-in-medicare-advantage-

from MA that provides better quality outcomes to traditional Medicare patients because physicians tend to implement the same disease management and population health practices with all of their patients.[56]

B. OIG's Unpredictable Approach and Resulting Contract Offsets May Complicate the MA Bidding Process and Negatively Impact Benefit Packages and Premiums.

Each year an MAO must present a bid to CMS for each contracted health plan. The bid contains the essential cost and design elements necessary for the MAO to deliver the Parts A and B benefits, plus supplemental benefits to its members. In setting the bid prices and creating benefit packages, an MAO makes informed assumptions about the payments it will receive and retain from CMS.[57] In submitting its bids for services to be provided in 2018 and 2019, Gateway reasonably considered financial risk associated with repayment obligations that might result from CMS's standard RADV audit process. OIG adopted a completely new approach to audits, especially with respect to extrapolation, and has applied it retroactively to long closed contract years. Gateway could not have predicted this or taken it into account when it submitted bids and determined what benefits it could offer to its members for the years at issue in this audit.[58]

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and-traditional-medicare ("[M]ore than half of analyses found that MA beneficiaries experienced better quality of care, better health outcomes, and/or lower spending.").

[56] *See* B. Vabson et al., *Potential Spillover Effects on Traditional Medicare When Physicians Bear Medicare Advantage Risk*, 31 AM. J. MANAG. CARE 294, 300 (2025), https://www.ajmc.com/view/potential-spillover-effects-on-traditional-medicare-when-physicians-bear-medicare-advantage-risk.

[57] Significantly, under the Affordable Care Act ("**ACA**"), MAOs are required to spend at least 85% of the money they receive from the Medicare program on medical care — a percentage known as the Medical Loss Ratio ("**MLR**"). Plans that do not meet this MLR standard must return the difference between 85% and their MLR to the government. 42 C.F.R. § 422.2410(b) provides: "If CMS determines for a contract year that an MA organization has an MLR for a contract that is less than 0.85, the MA organization has not met the MLR requirement and must remit to CMS an amount equal to the product of the following: (1) The total revenue of the MA contract for the contract year. (2) The difference between 0.85 and the MLR for the contract year." MAOs design their benefits to ensure that at least 85% of the money they receive from the government is spent on patient care.

[58] CMS did not announce its intention to eliminate the FFS Adjuster until November 1, 2018, long after Gateway submitted its bid for the 2019 payment year on June 4, 2018.

Importantly, OIG's audit approach continues to change.[59] The uncertainty of additional future one-sided contract adjustments may inject unwarranted uncertainty into the benefit design process. OIG has conducted both beneficiary level and specific code-targeted audits; it has chosen different codes for different plans; it has recommended extrapolation in some audits but not others; and it has defined the categories audited differently in different audits.

Unpredictable contract adjustments caused by these audits, especially if OIG uses extrapolation as it intends to do in the future, are likely to, over time, increase premiums, decrease benefits, and harm the breadth and scope of the MA program and the beneficiaries that it serves. MAOs will need to revise their scope of benefits and their premiums to account for the uncertainty and higher overpayment amounts due to OIG's extrapolation and uncertain audit tactics. This could have a negative impact on both the overall cost of the Medicare program and the overall health of the Medicare population.[60]

C. OIG's Methodology Could Destabilize Value Based Contracting with Downstream Physician Practices.

OIG's methodology may unknowingly harm risk-bearing entities including primary care physician practices. MAOs increasingly contract with physicians and other clinicians through value- and risk-based contracts, which CMS has encouraged. In many of these arrangements, most operating margins, including risk-adjusted revenue, are paid directly to the providers. Depending on the particulars of the contract, if OIG attempts to retroactively recoup large sums from MAOs, these recoveries may impact, through recoupment, the providers themselves. This could present a significant financial challenge to provider practices, who do not carry or are not capable of booking large reserves.

VI. GATEWAY DISAGREES THAT CERTAIN CODES WERE INVALID.

As specifically outlined in a spreadsheet attached as **Exhibit F**, Gateway disagrees that 36 HCCs were invalidated based on the coding justification provided by OIG. Gateway respectfully requests that OIG review these HCCs again, and consider its analysis for validation of those HCCs, prior to issuing its Final Report.

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[59] *See* summaries of OIG audits attached as **Exhibit E**.

[60] *See* Better Medicare Alliance, *Understanding Medicare Advantage Payment & Policy Recommendations*, 13 (Sept. 2018), https://bettermedicarealliance.org/wp-content/uploads/2020/03/BMA_WhitePaper_MA_Bidding_and_Payment_2018_09_19-1.pdf ("[U]npredictabiity impacts efforts to make investments in innovation and care delivery programs that better meet the needs of Medicare Advantage enrollees and may negatively impact beneficiary cost sharing reductions or enhanced benefits.").

Additionally, Gateway validated two HCCs, which OIG did not validate, at a lower HCC than the audited HCC.[61]

Further, there were two HCCs for which member records were not available due to the provider being incarcerated; as a result, because their unavailability was beyond Gateway's control, they should be excluded from the OIG sample. OIG indicates in the Draft Report that Gateway should have provided certain documentation demonstrating "extraordinary circumstances" for these records in accordance with "Contract-Level Risk Adjustment Data Validation CMS Submission Instructions."[62] However, these instructions are specific to CMS audits and are not applicable to this audit conducted by OIG. Moreover, Gateway never received instructions regarding submission of such documentation in order to attempt to receive an extraordinary circumstance exception for these records. Gateway respectfully requests that it receive credit as an offset for these aforementioned HCCs as OIG finalizes its Final Report.

VII. Gateway Maintains an Effective Compliance and Monitoring Program But Cannot Reasonably Be Expected to Validate All Provider Diagnostic Codes in Encounter Data.

OIG recommended that Gateway (1) "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 (2) "take the necessary steps to enhance these procedures." Notably though, Gateway already has a robust compliance program. OIG acknowledges as much, stating:

> As part of its preventative measures, Gateway had compliance procedures designed to educate its providers on proper medical record documentation and reporting accurate diagnosis codes on claims. These outreach efforts included annual targeted provider webinars and a web-based provider portal in which Gateway leveraged data analytics to identify providers with coding accuracy gaps and provided targeted educational intervention to address those gaps. Gateway also provided guidance to specific providers on how to improve medical record documentation for key conditions such as embolism, cancer, stroke, and ulcers (including pressure ulcers).
>
> As part of its compliance policies and procedures, Gateway also had measures that it took to detect and correct incorrect diagnosis codes that its providers included on claims. Specifically, Gateway had internal coders, and it hired coding vendors to select and determine whether diagnosis codes on certain claims were supported in medical

[61] *See* Section I(D) and **Exhibit D**.

[62] Draft Audit Report at 18.

> records. For example, Gateway instructed coders to review 100 percent of claims that included a diagnosis that mapped to an HCC that had not been previously included in the enrollee's risk score. . . . Gateway also had a policy to submit corrections to CMS if the coder detected an unsupported diagnosis code. Gateway also had a quality assurance process by which it reviewed the results of each coder's reviews each month to ensure that the coders attained 95-percent accuracy.[63]

Notwithstanding these strong controls, OIG states without further analysis or support that, simply because some errors were found, Gateway's policies and procedures "could be improved."[64] Notably, though, OIG does not offer specific improvement recommendations. OIG cannot reasonably expect MAOs to achieve perfection, especially when measured by an audit specifically designed to identify one-sided errors. CMS provides MAOs broad discretion "to design their compliance plan structure to meet the unique aspects of each organization."[65] Gateway believes that its current compliance policies and auditing and monitoring activities more than comply with MA statutory and regulatory requirements. Moreover, OIG's audit included only data from 2018 and 2019 and, thus, has limited applicability to Gateway's current compliance policies and auditing and monitoring activities. Further, MAOs could only achieve OIG's requirement of 100% accuracy if MAOs undertook chart review for all submitted encounters, and even then, some determinations would likely still be challenged in an audit as diagnostic coding is an inherently subjective process. Gateway submitted over 5.6 million member diagnosis codes in service year 2018 to CMS for its MA members. Given this, reviewing every chart is simply not feasible. In fact, the cost and burden of reviewing all risk adjusted encounters would be prohibitive and would eliminate any efficiencies or savings under the MA program.

Moreover, OIG has recommended additional auditing of "high-risk" codes for payment years beyond the years subject to this audit. However, as noted above, Gateway's current compliance program and auditing and monitoring activities are robust, and such additional auditing is not required under CMS regulations. Further, OIG identifies no statutory authority allowing it to impose additional auditing requirements on MAOs. Lastly, Gateway has already been subject to multiple CMS audits in the years following the payment years at issue in this audit.

VIII. Conclusion

For the reasons stated above, Gateway requests that OIG withdraw its recommendations that Gateway (1) "refund to the Federal Government the $4.6 million of estimated net overpayments" (2) "identify, for the high-risk diagnoses

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[63] *Id.*

[64] *Id.*

[65] 65 Fed. Reg. at 40265.

included in this report, similar instances of noncompliance that occurred after our audit period and refund any resulting overpayments to the Federal Government" and (3) "continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures." Gateway will work with CMS to delete individual codes that Gateway determines were unsupported in the audit after OIG reconsiders the 36 HCCs that Gateway found to be supported in **Exhibit F**, the two HCCs that Gateway validated at a lower HCC than the audited HCC in **Exhibit D**, and the two HCCs for which member records were not available due to the provider being incarcerated.

Gateway welcomes the opportunity to discuss OIG's methodology and findings, as well as its proposed recommendations, and reserves all rights to challenge any current or revised recommendations.

Sincerely,

Melissa Anderson
Chief Risk & Compliance Officer
Highmark Inc.

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