

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE COMPLIANCE  
AUDIT OF SPECIFIC DIAGNOSIS CODES  
THAT HIGHMARK SENIOR HEALTH  
COMPANY (H3916) SUBMITTED TO CMS**

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# ***Office of Inspector General***

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## Report in Brief

Date: September 2022  
Report No. A-03-19-00001

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



### Why OIG Did This Audit

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations according to a system of risk adjustment that depends on the health status of each enrollee. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources than to healthier enrollees, who would be expected to require fewer health care resources. To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS. Some diagnosis codes are at higher risk for being miscoded, which may result in overpayments from CMS. For this audit, we reviewed one MA organization, Highmark Senior Health Company.

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

### How OIG Did This Audit

We sampled 226 unique enrollee condition and payment years (enrollee-years) with the high-risk diagnosis codes for which Highmark received higher payments for 2015 and 2016. We limited our review to the portion of the payments that were associated with these high-risk diagnosis codes, which totaled \$801,166.

## Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (H3916) Submitted to CMS

### What OIG Found

With respect to the six high-risk groups covered by our audit, most of the selected diagnosis codes that Highmark submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 160 of the 226 sampled enrollee-years, the diagnosis codes were not supported in the medical records.

These errors occurred because the policies and procedures that Highmark had to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. As a result, the Hierarchical Condition Categories (diagnosis code groupings based on similarity of clinical characteristics, severity, and cost implications) for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Highmark received at least \$6.2 million of net overpayments for 2015 and 2016.

### What OIG Recommends and Highmark Comments

We recommend that Highmark: (1) refund to the Federal Government the \$6.2 million of estimated net overpayments; (2) identify, for the high-risk diagnoses included in the report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and (3) continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure 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.

In written comments on our draft report, Highmark disagreed with our findings and recommendations. Highmark provided additional information for two medical records that it said substantiated specific Hierarchical Condition Categories. Highmark also questioned our audit and statistical sampling methodologies and stated that it had a robust compliance program. After reviewing Highmark's comments and the additional information provided, we revised our findings and recommendations as appropriate. We maintain that our methodologies were reasonable and properly executed.

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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, sex, and health status of that individual. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources relative to healthier enrollees, who would be expected to require fewer health care resources. To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS.<sup>1</sup> We are auditing MA organizations because some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS.<sup>2</sup> Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 29 major depressive disorder diagnoses into 1 group.) This audit covered Highmark Senior Health Company (Highmark) for contract number H3916 and focused on six groups of high-risk diagnosis codes for payment years 2015 and 2016.<sup>3</sup>

### OBJECTIVE

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

### BACKGROUND

#### Medicare Advantage Program

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

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<sup>1</sup> Providers code diagnoses using the International Classification of Diseases (ICD), Clinical Modification (CM), *Official Guidelines for Coding and Reporting* (ICD Coding Guidelines). The ICD is a coding system that is used by physicians and other health care providers to classify and code all diagnoses, symptoms, and procedures. Effective October 1, 2015, CMS transitioned from the ninth revision of the ICD Coding Guidelines (which we refer to as "ICD-9" in this report) to the tenth revision (which we refer to as "ICD-10" in this report). Each revision includes different diagnosis code sets.

<sup>2</sup> See Appendix B for related Office of Inspector General reports.

<sup>3</sup> All subsequent references to "Highmark" in this report refer solely to contract number H3916.

fee-for-service (FFS) program.<sup>4</sup> Beneficiaries who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

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

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

### **Risk Adjustment Program**

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

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

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

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

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

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

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

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

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

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

For enrollees who have certain combinations of HCCs (in either the Version 12 model or the Version 22 model), 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 (in the Version 12 model) for an enrollee that map to the HCCs for acute stroke, acute myocardial infarction, and chronic obstructive pulmonary disease, CMS assigns a separate factor for this disease interaction. By doing so, CMS increases the enrollee's risk score for each of the three 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 for providing coverage to enrollees expected to require more health care resources.

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

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<sup>8</sup> CMS transitioned from one HCC payment model to another during our audit period. As part of this transition, for 2015, CMS calculated risk scores based on both payment models. CMS refers to these models as the Version 12 model and the Version 22 model, each of which has unique HCCs. CMS blended the two separate risk scores into a single risk score that it used to calculate a risk-adjusted payment. Accordingly, for 2015, an enrollee's blended risk score is based on the HCCs from both payment models. For 2016, CMS calculated risk scores based on the Version 22 model.

sequestration reduction.<sup>9</sup> CMS uses diagnosis codes that it receives from MA organizations to determine which HCCs should be used in calculating enrollee risk scores. If medical records do not support these diagnosis codes, the HCCs are not validated. Unvalidated HCCs cause enrollee risk scores to be overstated, which results in improper payments (overpayments) from CMS to MA organizations. Conversely, if medical records support diagnosis codes that MA organizations do not submit to CMS, enrollee risk scores may be understated, which may also result in improper payments (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 six high-risk groups:<sup>10</sup>

- *Acute stroke*: An enrollee received one acute stroke diagnosis (which maps to the HCC for Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim. A diagnosis of history of stroke (which does not map to an HCC) typically should have been used.
- *Acute heart attack*: An enrollee received one diagnosis that mapped to either the HCC for Acute Myocardial Infarction or to the HCC for Unstable Angina and Other Acute Ischemic Heart Disease (Acute Heart Attack HCCs) on only one physician claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician's claim). A diagnosis for a less severe manifestation of a disease in the related-disease group typically should have been used.
- *Embolism*: An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease With Complications (Embolism HCCs) during the service year but did not have an anticoagulant medication dispensed on his or her behalf. An anticoagulant medication is typically used to treat an embolism. A diagnosis of history of embolism (an indication that the provider is evaluating a prior acute embolism diagnosis, which does not map to an HCC) typically should have been used.
- *Vascular claudication*: An enrollee received one diagnosis related to vascular claudication (which maps to the HCC for Vascular Disease) during the service year but had medication dispensed on his or her behalf that is frequently dispensed for a

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<sup>9</sup> Budget sequestration refers to automatic spending cuts that occurred through the withdrawal of funding for certain Federal Government programs, including the MA program, as provided in the Budget Control Act of 2011 (BCA) (P.L. No. 112-25 (8-2-2011)). Under the BCA, the sequestration of mandatory spending began in April 2013.

<sup>10</sup> Unless otherwise specified, the HCCs described in this report have the same name under both the Version 12 and Version 22 models.

diagnosis of neurogenic claudication.<sup>11</sup> In these instances, the vascular claudication diagnoses may not be supported in the medical records.

- *Major depressive disorder:* An enrollee received one major depressive disorder diagnosis (which maps to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) during the service year but did not have an antidepressant medication dispensed on his or her behalf. In these instances, the major depressive disorder diagnoses may not be supported in the medical records.
- *Potentially mis-keyed diagnosis codes:* An enrollee received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition (which mapped to a possibly unvalidated HCC). For example, ICD-9 diagnosis code 250.00 (which maps to the HCC for Diabetes Without Complication) could be transposed as diagnosis code 205.00 (which maps to the HCC for Metastatic Cancer and Acute Leukemia and, in this example, would be unvalidated). Using an analytical tool that we developed, we identified 832 scenarios in which diagnosis codes mis-keyed because of data transposition or other data entry errors could have resulted in the assignment of an unvalidated HCC.

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

### **Highmark Senior Health Company**

Highmark is an MA organization based in Pittsburgh, Pennsylvania. As of December 31, 2016, Highmark provided coverage under contract number H3916 to approximately 208,600 enrollees. For the 2015 and 2016 payment years (audit period),<sup>12</sup> CMS paid Highmark approximately \$3.6 billion to provide coverage to its enrollees.<sup>13</sup>

### **HOW WE CONDUCTED THIS AUDIT**

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of the six high-risk groups during the 2014 and 2015 service years, for which Highmark received increased risk-adjusted payments for payment years 2015 and 2016, respectively. Because enrollees could be classified in more than one high-risk group or have high-risk diagnosis codes documented in more than 1 year, we classified these individuals

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<sup>11</sup> Vascular claudication and neurogenic claudication are different diagnoses. Vascular claudication is a condition that can result in leg pain while walking and is caused by insufficient blood flow. Neurogenic claudication is a condition that can also result in leg pain but is caused by damage to the neurological system, namely the spinal cord and nerves.

<sup>12</sup> The 2015 and 2016 payment year data were the most recent data available at the start of the audit.

<sup>13</sup> All of the payment amounts that CMS made to Highmark and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

according to the condition and the payment year, which we refer to as “enrollee-years.” We identified 4,232 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$11.2 million). We selected for audit a sample of 226 enrollee-years, which comprised: (1) a stratified random sample of 150 (out of 4,156) enrollee-years for the first 5 high-risk groups and (2) 76 enrollee-years for the remaining high-risk group.

Table 1 details the number of sampled enrollee-years for each high-risk group.

**Table 1: Sampled Enrollee-Years**

| High-Risk Group                           | Number of Sampled Enrollee-Years |
|---|----------------------------------|
| 1. Acute stroke                           | 30                               |
| 2. Acute heart attack                     | 30                               |
| 3. Embolism                               | 30                               |
| 4. Vascular claudication                  | 30                               |
| 5. Major depressive disorder              | 30                               |
| <b>Total for Stratified Random Sample</b> | <b>150</b>                       |
| 6. Potentially mis-keyed diagnosis codes  | 76                               |
| <b>Total for All High-Risk Groups</b>     | <b>226</b>                       |

Highmark provided medical records as support for the selected diagnosis codes associated with the 218 of 226 enrollee-years.<sup>14</sup> We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. If the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

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

<sup>14</sup> Highmark could not locate any medical records for 8 enrollee-years.

## FINDINGS

With respect to the six high-risk groups covered by our audit, most of the selected diagnosis codes that Highmark submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 66 of the 226 sampled enrollee-years, either the medical records validated the reviewed HCCs, or we identified another diagnosis code (on CMS's systems) that mapped to the HCC under review. However, for the remaining 160 enrollee-years, the diagnosis codes were not supported in the medical records.

These errors occurred because the policies and procedures that Highmark had to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. As a result, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Highmark received at least \$6.2 million of net overpayments for 2015 and 2016.<sup>15</sup>

### FEDERAL REQUIREMENTS

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

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

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

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<sup>15</sup> Specifically, we estimated that Highmark received at least \$6,227,005 (\$5,897,209 for the statistically sampled groups plus \$329,796 for the group of potentially mis-keyed diagnosis codes) of net overpayments. To be conservative, we recommend recovery of 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.

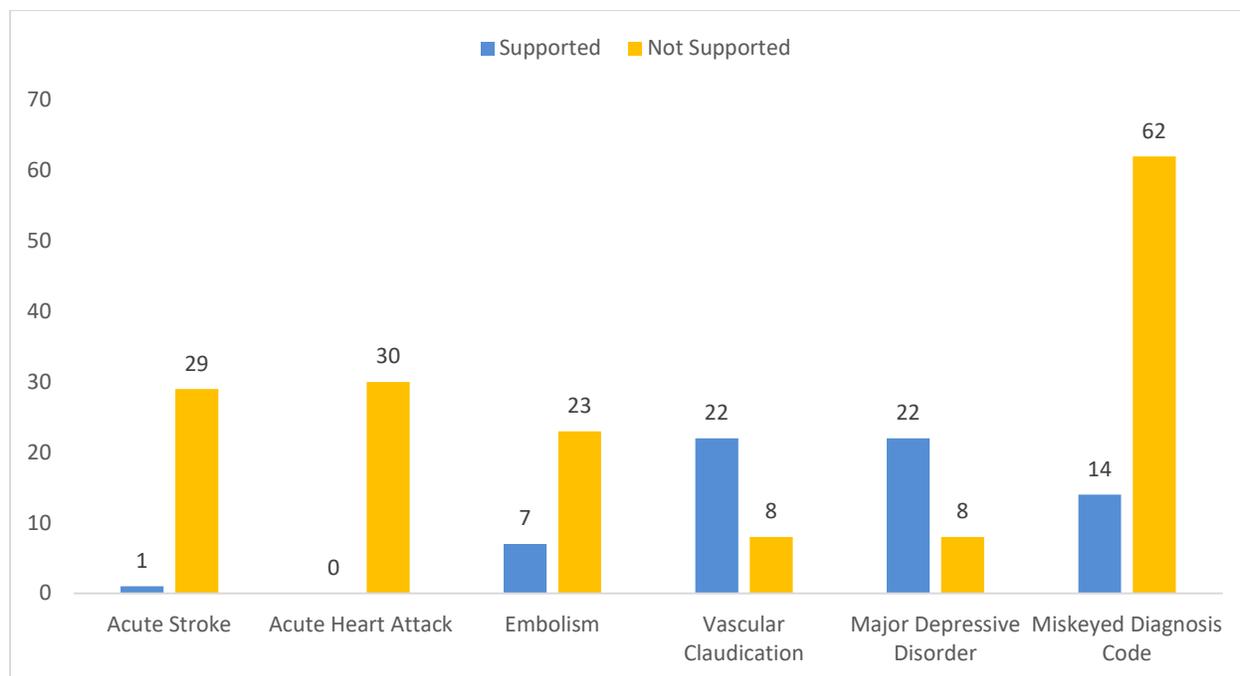
according to the ICD Coding Guidelines (42 CFR § 422.310(d)(1) and 45 CFR §§ 162.1002(b)(1) and (c)(2)-(3)). Further, the MA organizations must implement procedures to ensure that diagnoses come only from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities,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

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

**MOST OF THE SELECTED HIGH-RISK DIAGNOSIS CODES THAT HIGHMARK SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS**

Most of the selected high-risk diagnosis codes that Highmark submitted to CMS for use in CMS’s risk adjustment program did not comply with Federal requirements. As shown in the figure below, the medical records for 160 of the 226 sampled enrollee-years did not support the diagnosis codes. In these instances, Highmark 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

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

- For 27 enrollee-years, the medical records did not support an acute stroke diagnosis:

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

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no evidence of an acute stroke or any related condition that would result in an assignment of the [reviewed] HCC. There is mention of a history of a stroke [diagnosis] but no description of residuals or sequelae<sup>16</sup> that should be coded."

- For 9 enrollee-years, the medical records did not contain sufficient information to support an acute stroke diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that "Based on review of the medical record/s submitted, there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC or a related HCC. The patient was seen in an office setting with no support that the condition occurred at the time of the visit."

- For 1 enrollee-year, Highmark submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiplegia<sup>17</sup> (which was supported in the medical records). This error caused an underpayment.

For this enrollee-year, the independent medical review contractor did not find support for an acute stroke but noted that "[t]here is mention of hemiplegia as a late effect of [a] cerebral vascular accident."

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

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<sup>16</sup> Sequelae is a condition following or occurring as a consequence of another condition or event.

<sup>17</sup> Hemiplegia is defined as total or partial paralysis of one side of the body that results from disease of or injury to the motor centers of the brain.

As a result of these errors, the HCCs for Ischemic or Unspecified Stroke were not validated, and Highmark received \$62,261 of net overpayments for these 29 sampled enrollee-years.

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

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

- For 17 enrollee-years, the medical records did not support either an acute myocardial infarction diagnosis or a diagnosis of a less severe manifestation of the related-disease group.
  - For example, for 1 enrollee-year, the medical review contractor noted that “there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of [the] HCC [for Acute Myocardial Infarction]. The diagnosis is not documented on this date of service.”
- For 13 enrollee-years, the medical records did not support an acute myocardial infarction diagnosis. However, we identified support for a diagnosis of a less severe manifestation of the related-disease group:
  - For 8 enrollee-years, which occurred in payment year 2015, we identified support for an old myocardial infarction diagnosis,<sup>18</sup> which mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Highmark should not have received an increased payment for the acute myocardial infarction diagnosis but should have received a lesser increased payment for the old 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 assignment of [diagnosis] that translates to the assignment of [the] HCC [for Acute Heart Attack] however, there is documentation of old [myocardial infarction].”

- For 4 enrollee-years, which occurred in payment year 2016, we identified support for an old myocardial infarction diagnosis which did not map to an

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<sup>18</sup> An “old myocardial infarction” is a distinct diagnosis that represents a myocardial infarction that occurred more than 4 weeks previously, has no current symptoms directly associated with that myocardial infarction, and requires no current care.

HCC.<sup>19</sup> Accordingly, Highmark should not have received an increased payment for acute myocardial infarction.

- For the remaining 1 enrollee-year, the medical review contractor stated that “Based on review of the medical record/s submitted for this HCC, there is no documentation of a diagnosis that results in [the] HCC [for Unstable Angina and Other Acute Ischemic Heart Disease]. There is documentation of chronic stable angina<sup>[20]</sup> (diagnosis code) which results in [the] HCC [for Angina Pectoris] and should have been assigned instead of a diagnosis that maps to the submitted HCC.” Accordingly, Highmark should have received a lesser increased payment for the chronic stable angina diagnosis.

As a result of these errors, the Acute Heart Attack HCCs were not validated, and Highmark received \$51,208 of overpayments for these 30 sampled enrollee-years.

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

Highmark incorrectly submitted diagnosis codes for embolism for 23 of 30 sampled enrollee-years. Specifically:

- For 12 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not justify an embolism diagnosis at the time of the physician’s service.
  - For example, for 1 enrollee-year, the independent medical review contractor noted that “Based on review of the medical record/s submitted for this HCC, there is no documentation of any condition that will result in assignment of an ICD-9-CM code that translates to the assignment of [the] HCC [for Vascular Disease]. There is documentation of a past medical history of deep venous thrombosis [diagnosis]<sup>[21]</sup> which does not result in an HCC.”
- For 10 enrollee-years, the medical records did not contain sufficient information to support an embolism diagnosis.
  - For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of [a diagnosis] code that translates to the assignment of [the] HCC

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<sup>19</sup> In contrast to the enrollee-years that occurred in payment year 2015 (for which CMS used the Version 12 model), for payment year 2016, CMS used only the Version 22 model, which did not include an HCC for Old Myocardial Infarction, to calculate risk scores (footnote 8).

<sup>20</sup> Chronic stable angina is defined as discomfort in the chest region due to poor blood flow through the blood vessels in the heart.

<sup>21</sup> Deep vein thrombosis is a blood clot in a major vein that usually develops in the legs or pelvis.

[for Vascular Disease with Complications]. Condition is not documented with active/current support.”

- For the remaining 1 enrollee-year, Highmark 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 Highmark received \$70,372 of overpayments for these 23 sampled enrollee-years.

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

Highmark incorrectly submitted diagnosis codes for vascular claudication for 8 of 30 sampled enrollee-years. Specifically:

- For 6 enrollee-years, the medical records did not support a vascular claudication diagnosis.
  - For example, for 1 enrollee-year, the independent medical review contractor stated that “Based on review of the medical record/s submitted for this HCC, there is no documentation of any condition that will result in assignment of an ICD-9-CM code that translates to the assignment of [the] HCC [for Vascular Disease].”
- For the remaining 2 enrollee-years, Highmark could not locate any medical records to support the vascular claudication diagnosis; therefore, the Vascular Claudication HCC was not validated.

As a result of these errors, the HCCs for Vascular Disease were not validated, and Highmark received \$18,691 of overpayments for these 8 sampled enrollee-years.

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

Highmark incorrectly submitted diagnosis codes for major depressive disorder for 8 of 30 sampled enrollee-years. Specifically:

- For 7 enrollee-years, the medical records did not support a major depressive disorder diagnosis.<sup>22</sup>
  - For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in

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<sup>22</sup> The 7 enrollee-years include 1 enrollee-year that the independent medical review contractor classified as an illegible record. We requested additional information for this illegible record but did not receive any additional documentation. As stated in 42 CFR § 482.24(c)(1), all patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided.

assignment of [a diagnosis] code that translates to the assignment of [the] HCC [for Major Depressive, Bipolar, and Paranoid Disorders]. The provider has documented [a diagnosis of depressive disorder, not elsewhere classified] in the assessment section of the note which does not result in an HCC.”

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

As a result of these errors, the HCCs for Major Depressive, Bipolar, and Paranoid Disorders were not validated, and Highmark received \$24,138 of overpayments for these 8 sampled enrollee-years.

### **Potentially Mis-Keyed Diagnosis Codes**

Highmark submitted potentially mis-keyed diagnosis codes for 62 of 76 enrollee-years. In each of these cases, the beneficiaries associated with these enrollee-years received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition. Specifically:

- For 48 enrollee-years, the medical records did not support the diagnosis for the unrelated condition; therefore, Highmark submitted to CMS unsupported diagnosis codes that mapped to unvalidated HCCs.
  - For example, for 1 enrollee-year, Highmark submitted to CMS 31 diagnosis codes for coronary artery disease (414.00) and only one diagnosis code for dissection of aorta (441.00). The independent medical review contractor noted “there is no documentation of any condition that would result in the assignment of [the] HCC [for Vascular Disease with Complications]. There is documentation of coronary artery disease [diagnosis] which does not result in an HCC and should have been assigned instead of a diagnosis that maps to the submitted HCC.”
- For 12 enrollee-years, the medical records did not support the diagnosis code submitted to CMS; however, we found support for a different diagnosis code that mapped to an HCC for a less severe manifestation of the related-disease group.
  - For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of a diagnosis that results in [the] HCC [for Vascular Disease with Complications]. There is documentation . . . which results in [the] HCC [for Vascular Disease] and should have been assigned instead of a diagnosis that maps to the submitted HCC.” Accordingly, Highmark should not have received an increased payment for the Vascular Disease with Complications HCC but should have received a lesser increased payment for the Vascular Disease HCC.

- For the remaining 2 enrollee-years, Highmark could not locate any medical records to support the potentially mis-keyed diagnosis code; therefore, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated.

Appendix F summarizes the 62 HCCs that were not validated (Table 5) and the additional HCCs that were supported for the 12 enrollee-years (Table 6).

As a result of these errors, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated, and Highmark received \$329,796 in overpayments for these 62 sampled enrollee-years.

### **THE POLICIES AND PROCEDURES THAT HIGHMARK USED TO PREVENT, DETECT, AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS COULD BE IMPROVED**

The errors we identified occurred because the policies and procedures that Highmark 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.

Highmark 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. These procedures included routine internal medical reviews to compare diagnosis codes from a sample of claims to the diagnosis codes that were documented on the associated medical records. These internal medical reviews targeted diagnosis codes from certain high-risk groups such as acute stroke, acute heart attack, and embolism. If Highmark detected compliance problems, it corrected the reviewed claims and expanded its review to other claims not initially selected. The results of these internal medical reviews were used to develop provider educational materials that informed providers of high-risk diagnosis areas. The educational materials highlighted coding errors identified during Highmark's internal reviews and provided additional guidance to providers on how to avoid these errors. Despite the internal medical reviews and educational materials, the diagnosis codes for 160 of the 226 sampled enrollee-years were not supported by the medical records; therefore, Highmark's compliance procedures, with regard to high-risk diagnosis areas, could be improved.

### **HIGHMARK 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 Highmark received at least \$6,227,005 of net overpayments (\$5,897,209 for the statistically sampled high-risk groups plus \$329,796 for the group of potentially mis-keyed diagnosis codes) in 2015 and 2016 (Appendix D).

## RECOMMENDATIONS

We recommend that Highmark Senior Health Company:

- refund to the Federal Government the \$6,227,005 of estimated net overpayments;
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
- continue its examination of existing compliance procedures to identify areas where improvements can be made to ensure 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.

### HIGHMARK COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Highmark disagreed with our findings and recommendations. Although Highmark did not specifically disagree with 159 of the 161 enrollee-years identified in our draft report as not having medical records to support the associated diagnosis codes, Highmark disagreed with our findings for the remaining 2 enrollee-years and provided additional information explaining why it believed that either the associated HCC was validated or an HCC for a less severe manifestation of the related disease group was validated.

Highmark stated that we used an audit methodology that was inconsistent with the fundamentals of MA program payment, we incorrectly changed our audit methodology without going through a notice-and-comment process, and our methodology was unpredictable and could have a negative effect on the MA program. Highmark also stated that we do not have the authority to extrapolate and there is no adequate mechanism for repayment of extrapolated amounts. In addition, Highmark stated that our findings and recommendations effectively require providers to attain 100 percent accuracy and that it disagrees with our suggestion that its compliance program is inadequate. Highmark requested that we withdraw all of our recommendations.

After reviewing Highmark's comments and the additional information it provided, we reduced the number of enrollee-years in error from 161 to 160 and adjusted our calculation of estimated net overpayments. Accordingly, we reduced our first recommendation from \$6,314,074 to \$6,227,005 for this final report. We did not make any changes to our second and third recommendations.

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

## HIGHMARK DISAGREED WITH OUR FINDINGS FOR 2 ENROLLEE-YEARS

### Highmark Comments

Highmark did not agree with our findings for two of the sampled enrollee-years and stated that we “failed to recognize alternative [diagnosis] codes identified in the medical record that should have been submitted to CMS instead of the selected codes.” Specifically:

- For one enrollee-year, Highmark explained why it believed it should receive credit for the HCC for Old Myocardial Infarction instead of an Acute Heart Attack HCC. Highmark stated that a previously provided medical record “clearly indicated the patient had ‘recently’ suffered from a myocardial infarction. ICD9 coding guidelines allowed the coding of an acute myocardial infarction (AMI) for up to eight weeks after the initial event.; [sic] ICD10 (effective October of 2015) permits coding four weeks after an AMI. Although the note did not explicitly state how ‘recently’ the infarction had occurred, [the Office of Inspector General (OIG)] should have credited Highmark for . . . (Old Myocardial Infarction).”
- For the other enrollee-year, Highmark explained why it believed a Vascular Claudication HCC should be validated. Highmark stated that a previously provided medical record supported a diagnosis of atherosclerosis.<sup>23</sup> Highmark stated that although it submitted a code for Peripheral Vascular Disease<sup>24</sup> and acknowledged that the code was not supported by the submitted medical record, “(Atherosclerosis), which maps to the same HCCs, was supported by the medical record. The diagnosis was noted in the abdominal CT scan image findings that were specifically ‘reviewed and assessed’ by the physician. Specifically, the note reads, ‘Atherosclerotic calcifications, abdominal aorta and iliac arteries.’ ICD coding guidelines permit diagnoses from diagnostic imaging as long as the provider has noted a review of the findings.”

### Office of Inspector General Response

Our independent medical review contractor reviewed the medical records that Highmark referred to in its comments as well as the explanations that Highmark provided for these two enrollee-years and agreed with Highmark’s statements regarding the HCCs that should be validated:

- For the first enrollee-year, the independent medical review contractor found support for an old myocardial infarction diagnosis but did not find support for the HCC for Unstable Angina and Other Acute Ischemic Heart Disease. Thus, this enrollee-year remains classified as an error. However, Highmark should not have received an increased payment for the acute myocardial infarction diagnosis but should have

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<sup>23</sup> Atherosclerosis is a disorder in which arteries become clogged or narrowed due to abnormal fat deposits.

<sup>24</sup> Peripheral Vascular Disease is a narrowing, blockage, or spasms in a blood vessel.

received a lesser increased payment for the old myocardial infarction. Accordingly, we updated the overpayment amount for this enrollee-year; this update did not change the number of errors in the Acute Heart Attack high-risk group section.

- For the second enrollee-year, the independent medical review contractor stated that “There is documentation of atherosclerotic calcification of abdominal aorta [diagnosis code] which results in the [HCC] for [Vascular Disease] on the additional noted date of service.” We reclassified this HCC as validated and updated the Vascular Claudication high-risk group section.

Accordingly, we reduced the number of sampled enrollee-years in error from 161 (in our draft report) to 160 and reduced the associated monetary recommendation.

## **HIGHMARK STATED THAT OUR AUDIT METHODOLOGY IS INCONSISTENT WITH THE FUNDAMENTALS OF MEDICARE ADVANTAGE PAYMENT**

### **Highmark Comments**

Highmark stated that our audit methodology was not consistent with the fundamentals of MA program payment. Specifically, Highmark said that “any inquiry in MA designed to determine whether an improper payment has occurred must take into account all potential errors that affect payment, including undercoding and overcoding.” Highmark stated that our audit methodology did not consider “instances of potential undercoding, or underpayments, in the [MA organization’s] data” and the impact of errors in FFS data (that CMS used to determine payments). Highmark said that if we had taken these points into consideration, we “would not have had a basis upon which to calculate and extrapolate an overpayment.”

Highmark stated that any audit of improper payments “must determine whether, on average, across all codes for all members, the plan received a larger (or smaller) payment than it should have.” Highmark stated that we did not account for underpayments in a meaningful way in our methodology and did not establish an overall underpayment rate because we chose, and audited, codes for which there was a likely error in the Government’s favor and not codes for which there was a likely error in the MA organization’s favor. Highmark said that it conducted a limited analysis of unsubmitted codes for certain chronic conditions and “used a targeted approach, similar to OIG’s, selecting conditions that, in its experience, are often undercoded by providers.” Highmark stated that it calculated \$11.1 million in underpayments from this limited exercise and also said that we “should allow [MA organizations] to offset any alleged overpayments with evidence of underpayments.” Further, Highmark stated that its coders reviewed the medical records it provided to us for this audit and found 36 new, unique codes for the same patients in the same year. Highmark stated that in a typical Risk Adjustment Data Validation (RADV) audit, CMS would offset the overpayments with these underpayments and that “It is particularly unclear” why we did not do so for this audit.

Highmark also stated that we did not account for the fact that the same types of coding errors are present in the FFS data that CMS uses to calculate the payments that it makes to MA

organizations. Highmark stated that “It is widely recognized that individual providers often submit inaccurate and non-comprehensive diagnosis data.” Highmark said that CMS has argued that the FFS data still leads to appropriate overall reimbursement for MA organizations because errors (overpayments and underpayments) tend to offset one another. Highmark noted that CMS has argued that an “FFS adjuster” is not needed in the context of a RADV audit, but Highmark also said that others have criticized this conclusion. Highmark also said that an FFS adjuster for this audit (of selected diagnosis codes) would have to be higher than that of a RADV audit. Highmark stated that we “selected coding patterns most likely to have high rates of overcoding and ignored the other side of the equation (underpayments).” Highmark also said that because we “did not consider the errors in the FFS data, [our] audit methodology and results are inaccurate.”

Finally, Highmark said that the Social Security Act requires that CMS pay MA organizations “in a way that ensures ‘actuarial equivalence’ with what CMS would have paid to provide care for the same beneficiaries under traditional Medicare.” Highmark stated that our “audit approach, which does not consider underpayments or 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 beneficiaries” and that our approach is “inconsistent with the actuarial equivalence requirement.”

### **Office of Inspector General 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. We do not agree that we have to consider the impact of errors in FFS data when calculating estimated net overpayments. Further, we do not agree that we have to consider, in our calculation of estimated net overpayments, all potential overpayments and underpayments for every diagnosis code submitted for every enrollee. It was beyond the scope of our audit to identify: (1) all possible diagnosis codes that Highmark could have submitted on behalf of the sampled enrollee-years, and (2) enrollees for whom Highmark did not submit any risk-adjusted diagnosis codes.

With regard to Highmark’s comment that we did not consider the impact of errors in FFS, our audit methodology correctly applied CMS requirements to properly identify the overpayment amount associated with unsubstantiated HCCs for each sample item. We used the results of the independent medical review contractor’s coding review to determine which high-risk HCCs were not substantiated. Consistent with our methodology, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments. We followed the requirements of CMS’s risk adjustment program to determine the payment that CMS should have made for each sampled enrollee-year. We used the overpayments and underpayments identified for each enrollee-year to determine our estimated net overpayment amount.

Although our approach was generally consistent with the methodology CMS uses in its RADV audits, it did not mirror CMS’s approach in all aspects, nor did it have to. We recognize that CMS is responsible for making operations and program payment determinations for the MA program, including the application of any FFS adjuster requirements. CMS has not issued any requirements that compel us to reduce our net overpayment calculations. If CMS deems it appropriate to apply an FFS adjuster, it will adjust our overpayment finding by whatever amount it determines necessary. Thus, we believe that the steps that we followed for this audit provide a reasonable basis for our findings and recommendations, including our estimation of net overpayments.

## **HIGHMARK STATED THAT OUR AUDIT APPROACH VIOLATED STATUTORY AND REGULATORY REQUIREMENTS**

### **Highmark Comments**

Highmark stated that our approach violated statutory and regulatory requirements. Specifically, Highmark stated that our audit methodology is new and materially different from the CMS methodology that was in place when MA organizations submitted bids for the years covered by our audit. According to Highmark, this difference is a “substantive change” that demands 100-percent “accuracy of [MA organizations] and has a significant potential impact on the reimbursement received by those [MA organizations] for past years.” According to Highmark, the Social Security Act “prohibits the retroactive application of rules absent a significant public safety concern or other critical need” and “prohibits OIG’s retroactive application of this approach.”

Highmark also said that “[i]n adopting a new audit approach, OIG did not engage the requisite notice and comment process.” In this regard, Highmark cited a decision from the Supreme Court case *Azar v. Allina Health Services* that provides the public with advance notice to comment on any rule, requirement, or other statement of policy. Highmark stated that we “adopted new substantive legal standards by performing audits that impose different standards from one audit to the next and different standards than those that CMS has historically utilized in the context of its RADV audits. This is inappropriate given that these new standards did not go through the notice and comment process.”

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

Our audit did not violate statutory or regulatory requirements. The Inspector General Act of 1978 (IG Act), 5 U.S.C. App., provides OIG with independent authority to provide oversight of the Department’s programs through audits and investigations. As such, we conduct our audits in accordance with generally accepted government auditing standards, which require that audits be planned and performed so as to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions. As a result, OIG’s audits do not represent a “retroactive application of rules absent a significant public safety concern or other critical need.” Instead, these audits represent OIG’s exercise of its central statutory authorities under the IG Act as an independent oversight entity. Accordingly, we are not recommending the

application of any new statutory or regulatory or other type of requirements; thus, the criteria cited by Highmark that prohibit retroactivity are not applicable to this audit.

In addition, we disagree that our audit methodology represents a change in substantive legal standard and should not have been adopted without notice and comment. Our audit approach was generally consistent with the methodology used by CMS in its RADV audits; however, it did not mirror CMS's approach in all aspects, nor did it have to. Moreover, the criteria that we used for this audit does not represent a substantive change, or retroactive application of rules; these are the Federal requirements that CMS has put in place to govern the MA program.

## **HIGHMARK STATED THAT OUR APPROACH WAS UNPREDICTABLE AND COULD HAVE A NEGATIVE EFFECT ON THE MEDICARE ADVANTAGE PROGRAM**

### **Highmark Comments**

Highmark stated that our methodology is unpredictable and could have a negative effect on the MA program. Specifically, Highmark stated that our "audit approach is arbitrary and capricious for numerous reasons," including "its inconsistent application of approaches over time and from one [MA organization] to the next without explanation."

Highmark stated that "In submitting its bids for services to be provided in 2014 and 2015, Highmark reasonably considered financial risk associated with repayment obligations that might result from CMS's standard RADV audit process." Because our current audit process was applied to closed contract years, Highmark stated that "Unpredictable contract adjustments caused by these audits may, over time, increase premiums, decrease benefits, and harm the breadth and scope of the MA program. This could have a negative impact on both the overall cost of the Medicare program and the overall health of the Medicare population."

Highmark also stated that our audit approach continues to change and noted the differences in what our audits targeted in seven other audits of MA organizations. Highmark stated that the "uncertainty of additional future one-sided contract adjustments may inject unwarranted uncertainty into the benefit design process."

Finally, Highmark stated that our audit methodology "may unknowingly harm risk-bearing entities including primary care physician practices. . . . Depending on the particulars of the contract, if OIG attempts to retroactively recoup large sums from [MA organizations], 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."

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

We do not agree that our audit methodology was arbitrary and capricious. Our audit is intended to provide an independent assessment of Department of Health and Human Services (HHS) programs and operations in accordance with the IG Act. Our mission is to provide

objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve. By identifying errors, we strive to ensure the efficiency and integrity of the MA program and promote the effective delivery of services to Highmark and its affiliated providers' members. With regard to Highmark's comment that our methodology may harm risk-bearing entities, including primary care physician practices, the interactions that Highmark has with downstream entities is beyond the scope of our audit.

## **HIGHMARK STATED THAT WE DO NOT HAVE THE AUTHORITY TO EXTRAPOLATE**

### **Highmark Comments**

Highmark stated that, "While OIG has the independent authority to conduct audits to ensure accurate payment, it does not have the authority to extrapolate its findings under Medicare Part C." Highmark further stated that, "The [Social Security Act] provides qualified authority to extrapolate only to Medicare contractors conducting audits on behalf of CMS under Medicare Parts A and B (traditional Medicare). The statute permits contractors to extrapolate error rates identified so long as there is evidence to show that there is: (1) a sustained or high level of payment error; and (2) documented evidence that educational interventions (by the government) failed to correct the payment error." In addition, Highmark noted that CMS does not use extrapolation in its RADV audits and that CMS has proposed but not implemented the use of extrapolation. Highmark quoted CMS as saying in 2018 that its proposed rule would "**establish** that extrapolation would be utilized as a valid part of audit authority in Part C, as it has been historically a normal part of auditing practice throughout the Medicare program." According to Highmark, this statement is "a clear acknowledgement that there is currently no authority to extrapolate under MA even for CMS, let alone OIG." Further, Highmark stated that "even if extrapolation were appropriate (which it is not), OIG's use of a two-sided 90% confidence interval to calculate the extrapolated repayment amount was not appropriate. A better approach would be to use a lower bound of a 99% confidence interval, which is what CMS does in its RADV audits."

Expanding on this point, Highmark stated that "OIG is not a Medicare contractor" and "OIG never calculated an actual 'improper' payment error because it did not consider overall payments made to Highmark for its MA population or take into account FFS errors." In addition, Highmark stated that it "is aware of no means by which it could refund extrapolated amounts to CMS."

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

We do not agree with Highmark's comments regarding extrapolation. Extrapolation has long been recognized as a permissible method of calculating overpayments in Medicare. Highmark relied on 42 U.S.C. section 1395ddd(f)(3) to say that we do not have the authority to extrapolate. However, no statutory 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.<sup>25</sup> The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.<sup>26</sup> We properly executed our statistical sampling methodology in that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

OIG is an independent and objective oversight unit of HHS. Our policy is to recommend recovery at the lower limit of a two-sided 90-percent confidence interval. We believe that the lower limit of a two-sided 90-percent confidence interval provided a reasonably conservative estimate of the total amount overpaid to Highmark for the enrollee-years and time period covered in our sampling frame. This approach, which is routinely used by HHS for recovery calculations,<sup>27</sup> results in a lower limit (the estimated overpayment amount to refund) that is designed to be less than the actual overpayment total 95 percent of the time. Action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with CMS's policies and procedures.

## **HIGHMARK STATED THAT WE ARE EFFECTIVELY REQUIRING PROVIDERS TO ATTAIN 100 PERCENT ACCURACY AND THAT IT HAS AN EFFECTIVE COMPLIANCE PROGRAM**

### **Highmark Comments**

Highmark stated that OIG's audit approach would hold MA organizations to a "standard of perfection" which is "inconsistent with previous acknowledgments by both CMS and OIG that 100% accuracy in the data [MA organizations] submit to CMS is not possible or required." Highmark further stated that "CMS regulations require that an [MA organization] 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'." Highmark concluded

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<sup>25</sup> See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at \*26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at \*17 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

<sup>26</sup> See *John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at \*34-35 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634-37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at \*17 (S.D. Fla. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at \*13 (S.D. Tex. 2012).

<sup>27</sup> For example, HHS has used the two-sided 90-percent confidence interval when calculating recoveries in both the Administration for Child and Families and Medicaid programs. See e.g., *New York State Department of Social Services*, HHS Departmental Appeals Board (DAB) No. 1358, 13 (1992); *Arizona Health Care Cost Containment System*, DAB No. 2981, 4-5 (2019). In addition, HHS contractors rely on the one-sided 90-percent confidence interval, which is less conservative than the two-sided interval, for recoveries arising from Medicare FFS overpayments. See e.g., *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634-37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 17-18 (E.D.N.Y. 2012).

that “It is unreasonable for OIG to effectively hold [MA organizations] 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.”

Further, Highmark stated it has a “robust compliance program,” which it continually refines. Highmark stated that we acknowledged Highmark’s compliance program, and, while we indicated that the program could be improved, did not offer specific improvement recommendations. Highmark further stated that CMS provided broad discretion to MA organizations “to design their compliance plan structure to meet the unique aspects of each organization.” Highmark stated that MA organizations “could only achieve OIG’s requirement of 100% accuracy if [MA organizations] undertook chart review for all submitted encounters. Highmark submits over 7.5 million claims to CMS annually 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.” Highmark concluded that its current compliance policies and auditing and monitoring activities more than comply with MA statutory and regulatory requirements and that it therefore believes that our third recommendation should be withdrawn.

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

We do not agree with Highmark’s interpretation of our audit approach as requiring MA organizations to have 100 percent data accuracy. Our objective was developed to review specific diagnoses. We recognize that MA organizations have the latitude to design their own compliance programs and recognize that CMS applies a best “knowledge, information, and belief” standard when MA organizations certify the volume of data submitted for the CMS risk adjustment program.

However, Federal regulations at 42 CFR section 422.503(b)(4)(vi) state that MA organizations must “implement effective measures that prevent, detect, and correct noncompliance with CMS’ program requirements.” Further, these regulations specify that an MA organization “must at a minimum, include [certain] core requirements,” which include “an effective system for routine monitoring and identification of compliance risks [including] internal monitoring and audit and, as appropriate, external audits to evaluate . . . compliance with CMS requirements and the overall effectiveness of the compliance program.”

While we acknowledge Highmark 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 160 of the 226 sampled enrollee-years were not supported by the medical records. In addition, three of the areas we reviewed (Acute Stroke, Acute Heart Attack, and Embolism) accounted for 51 percent (82 of 160 sample errors) of the errors we found. Improving 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 third recommendation is valid.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

CMS paid Highmark \$3,551,632,114 to provide coverage to its enrollees for 2015 and 2016. We identified a sampling frame of 4,232 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2014 and 2015 service years. Highmark received \$68,663,268 in payments from CMS for these enrollee-years for 2015 and 2016. We selected for audit 226 enrollee-years with payments totaling \$4,413,571.

The 226 enrollee-years included 30 acute stroke diagnoses, 30 acute heart attack diagnoses, 30 embolism diagnoses, 30 vascular claudication diagnoses, 30 major depressive disorder diagnoses, and 76 potentially mis-keyed diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$801,166 for our sample.

We reviewed internal controls directly related to our audit objective. Specifically, we reviewed Highmark's internal controls for ensuring that the diagnosis codes it submitted to CMS were coded in accordance with Federal requirements. We performed our audit from April 2019 through January 2022.

### METHODOLOGY

To accomplish our objective, we performed the following steps:

- We reviewed applicable Federal laws, regulations, and guidance.
- We discussed with CMS program officials the Federal requirements that MA organizations should follow when submitting diagnosis codes to CMS.
- We identified, through data mining and discussions with medical professionals at a Medicare administrative contractor, diagnosis codes and HCCs that were at high risk for noncompliance. We also identified the diagnosis codes that potentially should have been used for cases in which the high-risk diagnoses were miscoded.
- We consolidated the high-risk diagnosis codes into specific groups, which included:
  - 6 diagnosis codes for acute stroke,
  - 35 diagnosis codes for acute heart attack,
  - 58 diagnosis codes for embolism,
  - 4 diagnosis codes for vascular claudication, and
  - 29 diagnosis codes for major depressive disorder.

- We developed an analytical tool that identified 832 scenarios in which either ICD-9 or ICD-10 diagnosis codes, when mis-keyed into an electronic claim because of a data transposition or other data entry error, could result in the assignment of an incorrect HCC to an enrollee’s risk score. For each of the 832 occurrences, the tool identified a potentially mis-keyed diagnosis code and the likely correct diagnosis code. Accordingly, we considered the potentially mis-keyed diagnosis codes to be high risk.
- We used CMS’s systems to identify the enrollee-years on behalf of which providers documented the high-risk diagnosis codes. Specifically, we used extracts from CMS’s:
  - Risk Adjustment Processing System (RAPS)<sup>28</sup> to identify enrollees who received high-risk diagnosis codes from a physician during the service years,
  - Risk Adjustment System (RAS)<sup>29</sup> to identify enrollees who received an HCC for the high-risk diagnosis codes,
  - Medicare Advantage Prescription Drug System (MARx)<sup>30</sup> to identify enrollees for whom CMS made monthly Medicare payments to Highmark before applying the budget sequestration reduction for the relevant portions of the service and payment years (Appendix C),
  - Encounter Data System (EDS)<sup>31</sup> to identify enrollees who received specific procedures, and
  - Prescription Drug Event (PDE) file<sup>32</sup> to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.
- We interviewed Highmark officials to gain an understanding of: (1) the policies and procedures that Highmark followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Highmark’s monitoring of those diagnosis codes to identify and detect noncompliance with Federal requirements.
- We selected for audit a sample of 226 enrollee-years that included: (1) a stratified random sample of 150 enrollee-years and (2) 76 enrollee-years as identified by our analytical tool.

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<sup>28</sup> MA organizations use the RAPS to submit diagnosis codes to CMS.

<sup>29</sup> The RAS identifies the HCCs that CMS factors into each enrollee’s risk score calculation.

<sup>30</sup> The MARx identifies the payments made to MA organizations.

<sup>31</sup> The EDS contains information on each item (including procedures) and service provided to an enrollee.

<sup>32</sup> The PDE file contains claims with prescription drugs that have been dispensed to enrollees through the Medicare Part D (prescription drug coverage) program.

- We used an independent medical review contractor to perform a coding review for 218 of the 226 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.<sup>33, 34</sup>
- The independent medical review contractor’s coding review followed a specific process to determine whether there was support for a diagnosis code and the associated HCC:
  - If the first senior coder found support for the diagnosis code on the medical record, the HCC was considered validated.
  - If the first senior coder did not find support on the medical record, a second senior coder performed a separate review of the same medical record:
    - If the second senior coder also did not find support, the HCC was considered to be not validated.
    - If the second senior coder found support, then a physician independently reviewed the medical record to make the final determination.
  - If either the first or second senior coder asked a physician for assistance, the physician’s decision became the final determination.
- We used the results of the independent medical review contractor to calculate overpayments or underpayments 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 Highmark during the audit period.
- We discussed the results of our audit with Highmark 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.

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<sup>33</sup> Our independent medical review contractor used senior coders all of whom possessed one or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS), Certified Coding Specialist – Physician-Based (CCS-P), Certified Professional Coder (CPC), and Certified Risk 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.

<sup>34</sup> Highmark could not locate any medical records for 8 enrollee-years.

**APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS**

| <b>Report Title</b>  | <b>Report Number</b>                 | <b>Date Issued</b> |
|--|--------------------------------------|--------------------|
| <i>Medicare Advantage Compliance Audit of Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3917)</i>                             | <a href="#"><u>A-09-20-03009</u></a> | 9/13/2022          |
| <i>Medicare Advantage Compliance Audit of Diagnosis Codes That WellCare of Florida, Inc. (Contract H1032) Submitted to CMS</i>                         | <a href="#"><u>A-04-19-07084</u></a> | 8/29/2022          |
| <i>Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS</i>               | <a href="#"><u>A-03-18-00002</u></a> | 8/19/2022          |
| <i>Medicare Advantage Compliance Audit of Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS</i>                        | <a href="#"><u>A-02-20-01009</u></a> | 7/18/2022          |
| <i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health Network (Contract H1961) Submitted to CMS</i>                   | <a href="#"><u>A-06-18-05002</u></a> | 5/25/2022          |
| <i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS</i>                        | <a href="#"><u>A-01-19-00500</u></a> | 2/14/2022          |
| <i>Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS</i>                                  | <a href="#"><u>A-07-17-01169</u></a> | 2/3/2022           |
| <i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS</i>           | <a href="#"><u>A-02-18-01029</u></a> | 1/5/2022           |
| <i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS</i>                   | <a href="#"><u>A-07-19-01188</u></a> | 11/5/2021          |
| <i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS</i>   | <a href="#"><u>A-07-17-01173</u></a> | 10/28/2021         |
| <i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS</i> | <a href="#"><u>A-07-19-01187</u></a> | 5/21/2021          |
| <i>Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS</i>                                     | <a href="#"><u>A-07-16-01165</u></a> | 4/19/2021          |
| <i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS</i>       | <a href="#"><u>A-02-18-01028</u></a> | 2/24/2021          |

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

## APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

### SAMPLING FRAME

We identified Highmark enrollees who: (1) were continuously enrolled in Highmark throughout all of the 2014 or 2015 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 2014 or 2015 or in January of the following year, and (3) received a high-risk diagnosis during 2014 or 2015 that caused an increased payment to Highmark for 2015 or 2016, respectively.

We presented the data for these enrollees to Highmark 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 Highmark. After we performed these steps, our finalized sampling frame consisted of 4,232 enrollee-years.

### SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2015 or 2016.

### SAMPLE DESIGN

The design for our statistical sample comprised of five strata of enrollee-years that had:

- an acute stroke diagnosis (which maps to the HCC for Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim (1,362 enrollee-years),
- a diagnosis that mapped to an Acute Heart Attack HCC on only one physician claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician claim (1,012 enrollee-years),
- a diagnosis that mapped to an Embolism HCC on one claim during the service year but for which an anticoagulant medication was not dispensed (498 enrollee-years),
- a vascular claudication diagnosis (which maps to the HCC for Vascular Disease) on one claim during the service year but for which medication was dispensed for neurogenic claudication (646 enrollee-years), or
- a major depressive disorder diagnosis (which maps to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) on one claim during the service year but for which antidepressant medication was not dispensed (638 enrollee-years).

The specific strata are shown in Table 2 on the following page.

**Table 2: Sample Design for Audited High-Risk Groups**

| <b>Stratum<br/>(High-Risk Groups)</b> | <b>Frame Count of<br/>Enrollee-Years</b> | <b>CMS Payment for HCCs<br/>in Audited High-Risk<br/>Groups*</b> | <b>Sample<br/>Size</b> |
|---------------------------------------|--|--|------------------------|
| 1 – Acute stroke                      | 1,362                                    | \$3,572,730  | 30                     |
| 2 – Acute heart attack                | 1,012                                    | 2,311,468  | 30                     |
| 3 – Embolism                          | 498                                      | 1,537,107  | 30                     |
| 4 – Vascular claudication             | 646                                      | 1,585,493  | 30                     |
| 5 – Major depressive disorder         | 638                                      | 1,798,997  | 30                     |
| <b>Total – First Five Strata</b>      | <b>4,156</b>                             | <b>\$10,805,795</b>  | <b>150</b>             |

\*Rounded to the nearest whole dollar amount.

After we selected the 150 enrollee-years, we identified an additional group of 76 enrollee-years that represented individuals who received 1 of the 832 potentially mis-keyed diagnosis codes (which mapped to a potentially unvalidated HCC) and multiple instances of diagnosis codes that were likely keyed correctly. Thus, we selected for audit a total of 226 enrollee-years.

#### **SOURCE OF RANDOM NUMBERS**

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

#### **METHOD FOR SELECTING SAMPLE ITEMS**

We sorted the items in each stratum by enrollee identifier and payment year and then consecutively numbered the items in each stratum in the stratified sampling frame. After generating 150 random numbers according to our sample design, we then selected the corresponding frame items for review. We also selected all 76 items from the potentially mis-keyed group.

#### **ESTIMATION METHODOLOGY**

We used the OIG, OAS, statistical software to estimate the total amount of net overpayments to Highmark 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. We also identified the net overpayment associated with each of the 76 potentially mis-keyed diagnosis codes and added the sum of those amounts to the estimate for the statistical sample to obtain the total net overpayments.

**APPENDIX D: SAMPLE RESULTS AND ESTIMATES**

**Table 3: Sample Results**

| <b>Audited High-Risk Groups</b>     | <b>Frame Size</b> | <b>CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)</b> | <b>Sample Size</b> | <b>CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)</b> | <b>Number of Sampled Enrollee-Years With Unvalidated HCCs</b> | <b>Net Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)</b> |
|-------------------------------------|-------------------|---|--------------------|--|---|--|
| 1 – Acute Stroke                    | 1,362             | \$3,572,730   | 30                 | \$71,630   | 29  | \$62,261   |
| 2 – Acute Heart Attack              | 1,012             | 2,311,468   | 30                 | 66,321   | 30  | 51,208   |
| 3 – Embolism                        | 498               | 1,537,107   | 30                 | 88,055   | 23  | 70,372   |
| 4 – Vascular Claudication           | 646               | 1,585,493   | 30                 | 71,425   | 8   | 18,691   |
| 5 – Major Depressive Disorder       | 638               | 1,798,997   | 30                 | 77,952   | 8   | 24,138   |
| <b>Total – First Five Strata</b>    | <b>4,156</b>      | <b>\$10,805,795</b>   | <b>150</b>         | <b>375,383</b>   | <b>98</b>   | <b>\$226,670</b>   |
| 6 – Potentially Mis-Keyed Diagnoses | 76                | \$425,783   | 76                 | \$425,783  | 62  | \$329,796  |
| <b>Totals – All Strata</b>          | <b>4,232</b>      | <b>\$11,231,578</b>   | <b>226</b>         | <b>\$801,166</b>   | <b>160</b>  | <b>\$556,466</b>   |

**Table 4: Estimated Net Overpayments in the Sampling Frame  
(Limits Calculated at the 90-Percent Confidence Level)**

|                | <b>Estimated Net Overpayment for Statistical Sample</b> | <b>Overpayment for Potentially Mis-Keyed Diagnosis Group</b> | <b>Total Estimated Net Overpayments</b> |
|----------------|---|--|---|
| Point Estimate | \$6,638,029   | \$329,796  | \$6,967,825                             |
| Lower Limit    | 5,897,209   | 329,796  | 6,227,005                               |
| Upper Limit    | 7,378,849   | 329,796  | 7,708,645                               |

**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: DETAILS OF POTENTIALLY MIS-KEYED DIAGNOSIS CODES**

**Table 5: Potentially Mis-Keued Diagnosis Codes and Associated Overpayments**

| Number of Enrollee-Years | One Diagnosis for a Condition (Determined To Be Incorrect) |  | Multiple Diagnoses for a Condition (Not Reviewed) |   | Overpayment |
|--------------------------|--|--|---|---|-------------|
|                          | Diagnosis Code   | Diagnosis Code Description   | Diagnosis Code                                    | Diagnosis Code Description  |             |
| 9                        | 205.00   | Acute myeloid leukemia, without mention of having achieved remission | 250.00  | Diabetes mellitus without mention of complications, type II or unspecified type | \$153,129   |
| 9                        | 441.00   | Dissection of aorta, unspecified site                                | 414.00  | Coronary atherosclerosis of unspecified type of vessel, native or graft         | 19,570      |
| 8                        | 441.01   | Dissection of aorta, thoracic  | 414.01  | Coronary atherosclerosis of native coronary artery                              | 19,878      |
| 7                        | 482.0  | Pneumonia due to Klebsiella pneumonia                                | 428.0   | Congestive heart failure, unspecified   | 37,121      |
| 5                        | E32.9  | Disease of thymus, unspecified                                       | F32.9   | Major depressive disorder, single episode                                       | 11,490      |
| 3                        | 433.01   | Occlusion and stenosis of basilar artery with cerebral infarction    | 433.10  | Occlusion and stenosis of carotid artery without mention of cerebral infarction | 8,812       |
| 3                        | 714.9  | Unspecified inflammatory polyarthropathy                             | 174.9   | Malignant neoplasm of breast (female), unspecified                              | 9,872       |
| 3                        | 850.2  | Concussion with moderate loss of consciousness                       | 805.2   | Closed fracture of thoracic vertebra without mention of spinal cord injury      | 4,527       |
| 2                        | 174.9  | Malignant neoplasm of breast (female), unspecified                   | 714.9   | Unspecified inflammatory polyarthropathy  | 3,322       |
| 2                        | 200.00   | Reticulosarcoma, unspecified site, extranodal and solid organ sites  | 250.00  | Diabetes mellitus without mention of complications, type II or unspecified type | 7,898       |

| Number of Enrollee-Years | One Diagnosis for a Condition (Determined To Be Incorrect) |  | Multiple Diagnoses for a Condition (Not Reviewed) |   | Overpayment      |
|--------------------------|--|--|---|---|------------------|
|                          | Diagnosis Code   | Diagnosis Code Description   | Diagnosis Code                                    | Diagnosis Code Description  |                  |
| 2                        | 250.00   | Diabetes mellitus without mention of complications, type II or unspecified type              | 205.00  | Acute myeloid leukemia, without mention of having achieved remission                      | 1,873            |
| 2                        | 250.10   | Other specified diabetes mellitus with ketoacidosis without coma                             | 205.10  | Chronic myeloid leukemia, without mention of having achieved remission                    | 4,139            |
| 2                        | 402.01   | Malignant hypertensive heart disease with heart failure                                      | 402.10  | Benign hypertensive heart disease without heart failure                                   | 7,476            |
| 1                        | 205.02   | Acute myeloid leukemia, in relapse   | 250.02  | Diabetes mellitus without mention of complication, type II or unspecified, uncontrolled   | 20,623           |
| 1                        | 249.20   | Secondary diabetes mellitus with hyperosmolarity, not stated as uncontrolled, or unspecified | 294.20  | Dementia, unspecified, without behavioral disturbance                                     | 3,027            |
| 1                        | 441.2  | Thoracic aneurysm without mention of rupture   | 414.2   | Chronic total occlusion of coronary artery  | 2,847            |
| 1                        | 710.3  | Dermatomyositis  | 170.3   | Malignant neoplasm of ribs, sternum, and clavicle   | 1,628            |
| 1                        | 996.56   | Mechanical complication due to peritoneal dialysis catheter                                  | 996.65  | Infection and inflammatory reaction due to other genitourinary device, implant, and graft | 12,564           |
| <b>62</b>                |  |  |   |   | <b>\$329,796</b> |

**Table 6: Hierarchical Condition Categories That Were Not Validated and Hierarchical Condition Categories for a Less Severe Manifestation of the Related-Disease Group That Were Supported**

| <b>Count of Enrollee-Years</b> | <b>More Severe Hierarchical Condition Category That Was Not Validated</b> | <b>Less Severe Hierarchical Conditional Category That Was Supported*</b> |
|--------------------------------|---|--|
| 11                             | Vascular Disease with Complications                                       | Vascular Disease   |
| 1                              | Diabetes with Acute Complications   | Diabetes without Complication  |

\*Unless otherwise indicated, the definitions were the same in both Version 12 and Version 22.

## APPENDIX G: HIGHMARK COMMENTS



April 1, 2022

### BY EMAIL

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-03-19-00001 of  
Highmark Senior Health Company (H3916)**

Dear Ms. Freda and Mr. Cohen,

Highmark Senior Health Company (“**Highmark**”) 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 February 2022 entitled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Highmark Senior Health Company (H3916) Submitted to CMS* (the “**Draft Report**”). Highmark and its affiliated companies are non-profit licensees of the Blue Cross Blue Shield Association. Highmark offers HMO and PPO Medicare Advantage (“**MA**”) products in Pennsylvania, New York, West Virginia, and Delaware. In the most recent Medicare Star Ratings, all of Highmark’s plans scored either 4.5 or 5 out of a possible 5 stars. In the J.D. Power study of overall customer satisfaction with MA plans, Highmark ranked first in 2020 and second in 2021.

Highmark respectfully disagrees with OIG’s findings and requests that OIG withdraw its recommendations that Highmark refund the government \$6.3 million in extrapolated “overpayments” for the years covered by the audit; identify similar instances of “overpayments” in other years and refund the corresponding amounts; and enhance its compliance procedures.

As discussed in more detail below, Highmark requests that OIG withdraw its recommendations for several reasons. First, OIG did not take into consideration all elements of an “improper payment,” focusing only on alleged overpayments to Highmark and ignoring underpayments to Highmark and errors in the fee-for-service (“**FFS**”) data on which MA payment rates are based. Second, extrapolation is not appropriate because OIG does not have the authority to extrapolate and there is no adequate mechanism for repayment of extrapolated amounts. Moreover, OIG’s imposition of its new audit approach retroactively and without the proper notice and comment process violates statutory and regulatory requirements. Additionally, these unpredictable and inconsistent audits have potential devastating effects to the MA program ranging from plan participation to, most importantly, beneficiary harm. Lastly, Highmark has a robust compliance program, which it continually refines. Highmark disagrees with OIG’s suggestion that the findings of this audit demonstrate that Highmark’s compliance program is inadequate.

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LHP-004 (R4-14)

**I. OIG’S AUDIT METHODOLOGY IS INCONSISTENT WITH THE FUNDAMENTALS OF MEDICARE ADVANTAGE PAYMENT.**

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

The MA program uses a global capitated payment model developed by the Centers for Medicare & Medicaid Services (“CMS”) that relies on FFS data from the traditional Medicare program to determine the value of coefficients used for payment. 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, including undercoding and overcoding, as well as errors in the FFS data, and the resultant effect on CMS’s total *overall* payment to the MA Organization (“MAO”). OIG’s findings, upon which it bases the extrapolated demand, do not take into account: (i) instances of potential undercoding, or underpayments, in the MAO’s 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, it would not have had a basis upon which to calculate and extrapolate an overpayment.

**B. OIG Did Not Account for Underpayments, Which, When Evaluated, More Than Offset the Alleged Overpayments.**

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: “Unvalidated HCCs cause enrollee risk scores to be overstated, which results in improper payments (overpayments) from CMS to MA organizations. Conversely, if medical records support diagnoses codes that MA organizations do not submit to CMS, enrollee risk scores may be understated, which may also result in improper payments (underpayments).”<sup>1</sup> While OIG acknowledges that underpayments also constitute an improper payment, it does not account for them in any meaningful way in its methodology.<sup>2</sup> 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.

To demonstrate the potential error in OIG’s approach, Highmark performed a limited analysis of certain chronic conditions that were likely to have existed during 2014 and 2015 but not submitted to CMS. Highmark used a targeted approach, similar to OIG’s, selecting conditions that, in its experience, are often undercoded by providers – diabetes mellitus with complications (“DM”), chronic kidney disease (“CKD”), and chronic obstructive pulmonary disease

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<sup>1</sup> Draft Report at 4.

<sup>2</sup> Where OIG found that the HCC in question was not supported but that a different HCC should have been assigned, that change was incorporated into the calculation. This was the only way in which OIG accounted for codes that should have been submitted but were not.

(“COPD”).<sup>3</sup> Highmark focused on members who had one of these diagnoses submitted in a prior and/or subsequent year but not in either 2014 or 2015. Highmark selected a random sample from the universe identified for which medical records were readily available. Experienced coders reviewed the associated medical records.<sup>4</sup>

After a quality assurance process that included two levels of review, Highmark identified an undercoding rate between 7% and 10%, depending on the diagnosis code. This resulted in an underpayment amount of approximately \$18,100 identified in the samples reviewed. To replicate OIG’s approach, Highmark then extrapolated from this amount, using OIG’s methodology. Highmark calculated \$11.1 million in underpayments from this limited exercise. This amount more than offsets the \$6.3 million in alleged overpayments. Significantly, Highmark reviewed only three conditions. If Highmark had evaluated the undercoding associated with additional conditions, the underpayments found, presumably, would have been even more significant.

To be clear, Highmark is not suggesting that CMS now pay Highmark 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.<sup>5</sup>

**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 should include consideration of underpayments related to all patients and all medical records, and not be limited to those patients and records that are the subject of the audit. OIG did not do this, and in fact, did not even consider underpayments in the medical records submitted in connection with the audit. This approach departs from CMS Risk Adjustment Data Validation (“RADV”) audits. OIG disregarded all instances of undercoding shown in the medical records reviewed unless the code replaced the targeted diagnosis code.

Highmark coders reviewed the medical records submitted to OIG and identified a total of 36 new, unique codes for the same patient in the same year, with a value of \$82,486. Of these codes, 19 were associated with a medical record that validated a targeted condition. These 19 codes

<sup>3</sup> The following table shows the Hierarchical Condition Categories (“HCCs”) and International Classification of Disease (“ICD”) codes for these conditions. Version 12 (“V12”) of the HCCs was used through 2014. Version 22 (“V22”) was incorporated into the risk adjustment model beginning in 2014. The ICD system of diagnoses codes switched from version 9 (“ICD9”) to version 10 (“ICD10”) on October 1, 2015.

| Condition | V12 HCC | V22 HCC     | ICD9           | ICD10        |
|-----------|---------|-------------|----------------|--------------|
| DM        | 18      | 18          | 250.1x- 250.9x | E11.1x-E11.8 |
| CKD       | n/a     | 136 and 137 | 585.3-585.5    | N18.3-N18.5  |
| COPD      | 108     | 111         | 496            | J44.x        |

<sup>4</sup> The Highmark 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.

<sup>5</sup> 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.

have a value of \$39,026, which CMS would offset in a typical RADV. As noted above, the appropriate approach would be to fully credit *any* offsetting underpayments. It is particularly unclear why OIG would not credit underpayments to the same extent that CMS does in its RADV audits.

**D. OIG Made Two 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, we included a financial impact of the resulting HCC (if any) in our calculation of overpayments.” For instance, OIG noted, “Highmark submitted an acute stroke diagnosis code (which was not supported in the medical records) instead of a diagnosis code for hemiplegia (which was supported by the medical records). This error caused an underpayment.”<sup>6</sup>

However, there were two instances in which OIG failed to recognize alternative codes identified in the medical record that should have been submitted to CMS instead of the selected codes. In Sample 82, Highmark submitted ICD-9 410.72 (Sub endocardial Infarction, Subsequent), which triggered V12HCC 82. The medical record provided in support of the code was a cardiac catheterization procedure note, which clearly indicated the patient had “recently” suffered from a myocardial infarction. ICD9 coding guidelines allowed coding of an acute myocardial infarction (AMI) for up to eight weeks after the initial event.; ICD10 (effective October of 2015) permits coding four weeks after an AMI. Although the note did not explicitly state how “recently” the infarction had occurred, OIG should have credited Highmark for ICD-9 412 (Old Myocardial Infarction), which, in 2014, mapped to HCC 83.

In Sample 128, one of the codes submitted was ICD-9 443.9 (Peripheral Vascular Disease (“PVD”)), which maps to V12HCC 105/ V22HCC 108. While PVD was not supported by the medical record provided to OIG, ICD-9 440.0 (Atherosclerosis), which maps to the same HCCs, was supported by the medical record. The diagnosis was noted in the abdominal CT scan image findings that were specifically “reviewed and assessed” by the physician. Specifically, the note reads, “Atherosclerotic calcifications, abdominal aorta and iliac arteries.” ICD coding guidelines permit diagnoses from diagnostic imaging as long as the provider has noted a review of the findings.

**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 non-comprehensive diagnosis data. Although coding continues to improve, FFS providers 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 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%.<sup>7</sup>

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<sup>6</sup> Draft Report at 9.

<sup>7</sup> 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.”).

CMS has argued 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.<sup>8</sup> Thus, CMS has argued that there is no need for an “FFS Adjuster” in the context of RADV audits. Notably, others have criticized this conclusion. For instance, a Milliman white paper concluded that CMS’s analysis was faulty and that, in fact, a FFS Adjuster is necessary.<sup>9</sup>

Even if CMS was correct, in that underpayments and overpayments cancel one another *overall*, this would not negate the need for OIG to take the error rate in the FFS data into account in the present audit. 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 FFS Medicare patients. CMS then uses the same FFS data to set the co-efficient values for specific HCCs, which factor into MAO payments. Thus, the payments to MAOs already take into account the fact that a large number of the codes submitted in these situations are likely to be unsupported.<sup>10</sup> Further, the amount of a 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.<sup>11</sup>

In this audit, OIG searched for specific coding patterns in which the diagnosis was unlikely to be supported. 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.<sup>12</sup>

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<sup>8</sup> *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 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.”).

<sup>9</sup> Pipich, R., *Medicare Advantage RADV FFS adjuster: White paper*, Milliman (August 23, 2019).

<sup>10</sup> 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 co-efficient 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 to underpayment to the MAOs.

<sup>11</sup> For example, OIG identified members diagnosed with Major Depressive Disorder who had no related medication. OIG found that in these instances, the diagnosis was not supported by the medical record in 22 of 30 instances (or 73% 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 Highmark’s data. If the errors occur with the same frequency in both the FFS and the MA data, then Highmark would be underpaid if it were required to remit these amounts back to CMS.

<sup>12</sup> 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.” OIG, *Risk Adjustment Data Validation of Payments Made to PacifiCare of California for Calendar Year 2007* (Contract Number H0543), A-09-09-00045, ii-iii (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. 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.<sup>13</sup> 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.”<sup>14</sup> 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.”<sup>15</sup> Similarly, OIG has stated that the requirement that an MAO certify the accuracy of data “does not constitute an absolute guarantee of accuracy.”<sup>16</sup>

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.

**G. OIG’s Audit Approach Would Result in a Violation of the Actuarial Equivalence Requirement.**

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.<sup>17</sup> 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 underpayments or errors

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<sup>13</sup> Similarly, in *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. Nov. 1, 2021), the D.C. Circuit recently held that: “*Nothing in the Overpayment Rule obligates insurers to audit their reported data*...the Rule only requires insurers to refund amounts they know were overpayments, i.e., payments they are aware lack support in a beneficiary’s medical records. That limited scope does not impose a self-auditing mandate.” *Id.* at 884 (emphasis added).

<sup>14</sup> 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.”).

<sup>15</sup> Health Care Financing Administration (“HCFA”), Department of Health and Human Services (“HHS”), *Medicare Program, Medicare+Choice Program*, 65 Fed. Reg. 40,170, 40,268 (June 29, 2000) (emphasis added).

<sup>16</sup> HHS, OIG, *Publication of the OIG’s Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans*, 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999) (emphasis added).

<sup>17</sup> 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 (January 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.”).

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. This is inconsistent with the actuarial equivalence requirement.

## **II. EVEN IF THE AUDIT HAD IDENTIFIED IMPROPER PAYMENTS, EXTRAPOLATION FROM OIG’S FINDINGS WOULD BE INAPPROPRIATE.**

### **A. OIG Lacks the Authority to Extrapolate.**

While OIG has the independent authority to conduct audits to ensure accurate payment, it does not have the authority to extrapolate its findings under Medicare Part C. The SSA provides qualified authority to extrapolate only to *Medicare contractors* conducting audits on behalf of CMS *under Medicare Parts A and B* (traditional Medicare). The statute permits contractors to extrapolate error rates identified so long as there is evidence to show that there is: (1) a sustained or high level of payment error; and (2) documented evidence that educational interventions (by the government) failed to correct the payment error.<sup>18</sup>

First, OIG is not a Medicare contractor. Moreover, there is no comparable statutory authority provided to OIG under Medicare Part C. Similarly, we are not aware of any rulemaking or public notice that purports to grant OIG the ability to adjust payment via extrapolation under MA.

Second, although OIG might argue that there is a high level of payment error revealed by its sample, this is untrue for the reasons discussed above. OIG never calculated an actual “improper” payment error because it did not consider overall payments made to Highmark for its MA population or take into account FFS errors.

Third, CMS has yet to impose extrapolation in its own RADV audits. In 2012, CMS attempted to incorporate extrapolation into its methodology for payment recoveries related to RADV audits but, as CMS has noted, “it has never been implemented.” . . . In 2018, CMS proposed a revised RADV audit methodology, which included the use of extrapolation.<sup>19</sup> CMS stated: “In this proposed rule, we would, based on longstanding case law and best practice from HHS and other federal agencies, *establish* that extrapolation would be utilized as a valid part of audit authority in Part C, as it has been historically a normal part of auditing practice throughout the Medicare program.”<sup>20</sup> This is a clear acknowledgement that there is currently no authority to extrapolate under MA even for CMS, let alone OIG. CMS has yet to issue a final rule regarding RADV methodology and extrapolation. However, CMS continues with RADV audits, most recently for payment years 2014 and 2015, and has explicitly stated that it would “not seek to recover on any extrapolated basis until the rule is final.”<sup>21</sup>

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<sup>18</sup> 42 U.S.C. § 1395ddd(f)(3).

<sup>19</sup> 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\*](#), 83 Fed. Reg. 54,982 (Nov. 1, 2018).

<sup>20</sup> *Id.* at 54,984 (emphasis added).

<sup>21</sup> *Id.* at 55,039 n.26.

It may be OIG's position that its results are not final and that OIG itself is not "requiring" extrapolation or a repayment. We note that OIG is careful not to suggest that its audits are a final agency determination and instead suggests that MAOs work with CMS on remediation. This sidesteps the practical implications for MAOs that receive a letter from an enforcement agency instructing them to re-open a closed contract period and make payment adjustments to CMS.<sup>22</sup>

**B. There Is No Mechanism for Correcting Diagnostic Data Associated With Extrapolated Amounts.**

Highmark is aware of no means by which it could refund extrapolated amounts to CMS. Currently, CMS requires MAOs to correct diagnostic data by issuing "delete files" to CMS. The financial amount associated with the diagnosis codes deleted is then reconciled against future payments for that contract. It is impossible to issue delete files based on an extrapolated number, as OIG proposes. CMS has yet to provide any guidance on how an MAO, in response to an OIG audit, is supposed to reconcile extrapolated amounts with the government. Further, there is currently no CMS settlement process, of which Highmark 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.

**III. OIG'S APPROACH VIOLATES STATUTORY AND REGULATORY REQUIREMENTS.**

**A. The SSA Prohibits OIG From Imposing Its New Approach Retroactively.**

The SSA prohibits the retroactive application of rules absent a significant public safety concern or other critical need.<sup>23</sup> OIG has argued in another audit report that because its new audit methodology is not a "statutory or regulatory requirement," it is not subject to this prohibition.<sup>24</sup> However, the prohibition is broader than that:

*A substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that (i) such retroactive application is necessary to comply with statutory requirements; or (ii) failure to apply the change retroactively would be contrary to the public interest.*<sup>25</sup>

OIG's new methodology for conducting MA audits is materially different from the CMS methodology that was in place when the MAOs submitted bids for the years in question. Regardless of how OIG chooses to label this new approach, it clearly represents a "substantive

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<sup>22</sup> Moreover, even if extrapolation were appropriate (which it is not), OIG's use of a two sided 90% confidence interval to calculate the extrapolated repayment amount was not appropriate. A better approach would be to use a lower bound of a 99% confidence interval, which is what CMS does in its RADV audits. Had OIG used the same confidence interval that CMS uses, the extrapolated repayment amounts would have been lower.

<sup>23</sup> 42 U.S.C. §139hh(e)(1)(A).

<sup>24</sup> [Healthfirst Audit](#) at 18.

<sup>25</sup> 42 U.S.C. §139hh(e)(1)(A).

change.” 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. Given this, the SSA prohibits OIG’s retroactive application of the approach.

**B. OIG’s Audit Methodology Represents a Change in a Substantive Legal Standard and Should Not Have Been Adopted without Notice and Comment.**

In adopting a new audit approach, OIG did not engage the requisite notice and comment process. The “notice and comment” provision of the Administrative Procedures Act (“APA”) does not apply to the Medicare Act. However, in 1987, Congress enacted a notice and comment statute 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.”<sup>26</sup>

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.”<sup>27</sup>

In the present case, OIG has adopted new substantive legal standards by performing audits that impose different standards from one audit to the next and different standards than those that CMS has historically utilized in the context of its RADV audits. This is inappropriate given that these new standards did not go through the notice and comment process.

**C. OIG’s Audit Methodology Is Arbitrary and Capricious.**

Agency actions can generally be set aside if they are “arbitrary and capricious.”<sup>28</sup> OIG’s audit approach is arbitrary and capricious for numerous reasons discussed above: OIG’s failure to consider underpayments or to account 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.

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<sup>26</sup> *Azar v. Allina Health Services*, 139 S.Ct. 1804 (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. 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).

<sup>27</sup> *Id.* at 1816.

<sup>28</sup> *See, e.g., Lead Indus. Ass’n, Inc. v. Env’t Prot. Agency*, 647 F.2d 1130, 1146 (D.C. Cir. 1980).

#### **IV. 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 has forecast that by 2029, 47% of Medicare beneficiaries will be enrolled in MA plans.<sup>29</sup> 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.<sup>30</sup> Similarly, a 2017 study found that MA plans outperformed traditional Medicare on all 16 quality measures and four out of six patient experience measures.<sup>31</sup> In addition, a 2018 study showed that MA enrollees with certain chronic conditions had 23% fewer inpatient stays and 33% fewer emergency department visits than equivalent traditional Medicare beneficiaries.<sup>32</sup> There is also evidence of a spillover effect from MA that saves money on traditional Medicare because physicians tend to implement the same disease management and population health practices with all of their patients.<sup>33</sup>

##### **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.<sup>34</sup> In submitting its bids for services to be provided in 2014 and 2015, Highmark 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 and has applied it retroactively to long closed contract years. Highmark could not have predicted this or

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<sup>29</sup> See KFF, [Medicare Advantage](#) (June 6, 2019).

<sup>30</sup> Landon et al., [A Comparison of Relative Resource Use and Quality in Medicare Advantage Health Plans Versus Traditional Medicare](#), AJMC (August 18, 2015).

<sup>31</sup> Timbie et al., [Medicare Advantage and Fee-for-Service Performance on Clinical Quality and Patient Experience Measures](#), 52 Health Services Research 2038 (2017).

<sup>32</sup> Avalere Health, [Medicare Advantage Achieves Cost-Effective Care and Better Outcomes for Beneficiaries with Chronic Conditions Relative to Fee-for-Service Medicare](#) (July 2018).

<sup>33</sup> Johnson et al., [Recent Growth In Medicare Advantage Enrollment Associated With Decreased Fee-For-Service Spending In Certain US Counties](#), Health Affairs Vol. 35, No. 9 (Sept. 2016); Timbie et al., [Medicare Advantage and Fee-for-Service Performance on Clinical Quality and Patient Experience Measures](#), 52 Health Services Research 2038 (2017).

<sup>34</sup> 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 CFR § 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.

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.

Importantly, OIG’s audit approach continues to change.<sup>35</sup> 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.<sup>36</sup> For instance, in the Essence audit, OIG defined the high-risk category for Major Depressive Disorder as consisting of a diagnosis of Major Depressive Disorder on only one or two claims in a year, rather than several claims in a year.<sup>37</sup> In other audits, it has defined this same high-risk category as consisting of a diagnosis of Major Depressive Disorder without an anti-depressant medication dispensed.

Unpredictable contract adjustments caused by these audits may, over time, increase premiums, decrease benefits, and harm the breadth and scope of the MA program. This could have a negative impact on both the overall cost of the Medicare program and the overall health of the Medicare population.

<sup>35</sup> See summaries of OIG audits, below:

| Plan                        | Date of Plan’s Response to Draft Audit | Date of Final OIG Audit Report | What the Audit Targeted | Errors Found (thousands) | Extrapolated Amounts (millions) | Service Years    |
|-----------------------------|--|--------------------------------|-------------------------|--------------------------|---------------------------------|------------------|
| <a href="#">Essence</a>     | 2019 (Mar. 11)                         | 2019 (Apr.)                    | 2 categories            | \$159                    | <i>None</i>                     | 2012, 2013, 2014 |
| <a href="#">Humana</a>      | 2019 (Dec. 6)                          | 2021 (Apr.)                    | 200 <i>enrollees</i>    | \$249                    | \$197.7                         | 2014             |
| <a href="#">Coventry</a>    | 2020 (Aug. 20)                         | 2021 (Oct.)                    | 6 categories            | \$549                    | <i>None</i>                     | 2013, 2014, 2015 |
| <a href="#">Anthem</a>      | 2020 (Oct. 16)                         | 2021 (May)                     | 7 categories            | \$354                    | \$3.47                          | 2014, 2015       |
| <a href="#">BCBSM</a>       | 2021 (Feb. 1)                          | 2021 (Feb.)                    | 7 categories            | \$668                    | \$14.5                          | 2014, 2015       |
| <a href="#">UPMC</a>        | 2021 (May 26)                          | 2021 (Nov.)                    | 10 categories           | \$681                    | \$6.4                           | 2014, 2015       |
| <a href="#">Tufts</a>       | 2021 (Sept. 16)                        | 2022 (Feb.)                    | 7 categories            | \$536                    | \$3.8                           | 2014, 2015       |
| <a href="#">Healthfirst</a> | 2021 (Oct. 18)                         | 2022 (Jan.)                    | 7 categories            | \$517                    | \$5.2                           | 2014, 2015       |
| Highmark                    | Draft report - Feb. 1, 2022            |                                | 6 categories            | \$560                    | \$6.3                           | 2014, 2015       |

<sup>36</sup> OIG’s approach differs not only from one audit to the next but also from CMS’s approach. Most obviously, CMS’s RADV audits use a more representative sample of diagnosis codes rather than targeting just codes with a high risk of error. Additionally, as noted above, when extrapolating, CMS uses a lower bound of a 99% confidence interval instead of the two sided 90% confidence interval used by OIG. Further, in the coding review, CMS uses a two level review process, whereas OIG uses a three level review process in which a physician makes the determination if the second level reviewer disagrees with the first level reviewer. This raises concerns not only because it differs from CMS’s approach, but also because the physician is unlikely to be a certified coder and because it suggests that the review process may be taking into account whether the clinical diagnosis was appropriate, which CMS has indicated is not to play any role in determining the appropriateness of a diagnosis code. See CMS, [ICD-10-CM Official Guidelines for Coding and Reporting FY 2019](#), at 13 (effective Oct. 1, 2018) (“The assignment of a diagnosis code is based on the provider’s diagnostic statement that the condition exists. The provider’s statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis.”).

<sup>37</sup> [Essence Audit](#) at 3.

**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 capable of booking large reserves.

**V. HIGHMARK MAINTAINS AN EFFECTIVE COMPLIANCE AND MONITORING PROGRAM BUT CANNOT REASONABLY BE EXPECTED TO VALIDATE ALL PROVIDER DIAGNOSTIC CODES IN ENCOUNTER DATA.**

OIG recommended that Highmark (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, Highmark already has a robust compliance program. OIG acknowledges as much, stating:

Highmark 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. These procedures included routine internal medical reviews to compare diagnosis codes from a sample of claims to the diagnosis codes that were documented on the associated medical records. These internal medical reviews targeted diagnosis codes from certain high-risk groups such as acute stroke, acute heart attack, and embolism. If Highmark detected compliance problems, it corrected the reviewed claims and expanded its review to other claims not initially selected. The results of these internal medical reviews were used to develop provider educational materials that informed providers of high-risk diagnosis areas. The educational materials highlighted coding errors identified during Highmark’s internal reviews and provided additional guidance to providers on how to avoid these errors.<sup>38</sup>

Notwithstanding these strong controls, OIG states that because errors were found, Highmark’s policies and procedures “could be improved.” 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.”<sup>39</sup> Highmark 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 2014 and 2015 and, thus, has limited

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<sup>38</sup> Draft Report at 14.

<sup>39</sup> Health Care Financing Administration (“HCFA”), Department of Health and Human Services (“HHS”), Medicare Program, *Medicare+Choice Program*, 65 Fed. Reg. 40,170, 40,265.

applicability to Highmark's current compliance policies. Further, MAOs could only achieve OIG's requirement of 100% accuracy if MAOs undertook chart review for all submitted encounters. Highmark submits over 7.5 million claims to CMS annually 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.

## **VI. CONCLUSION**

For the reasons stated above, Highmark requests that OIG withdraw its recommendations that Highmark "(1) refund to the Federal Government the \$6.3 million ... (2) identify ... similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments ... and (3) continue its examination of its existing compliance procedures ... and take the necessary steps to enhance those procedures." Highmark will work with CMS to delete individual codes that Highmark determines were unsupported in the audit.

Highmark 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/*

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Carolyn Duronio, Chief Legal Officer and Secretary, Highmark Health  
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