

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE COMPLIANCE  
AUDIT OF SPECIFIC DIAGNOSIS CODES  
THAT KEYSTONE HEALTH PLAN EAST,  
INC. (H3952) SUBMITTED TO CMS**

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# *Office of Inspector General*

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## Report in Brief

Date: May 2023

Report No. A-03-20-00001

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 a higher risk for being miscoded, which may result in overpayments from CMS.

For this audit, we reviewed one MA organization, Keystone Health Plan East. Our objective was to determine whether selected diagnosis codes that Keystone submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

### How OIG Did This Audit

We sampled 270 unique enrollee condition and payment years (enrollee-years) with the high-risk diagnosis codes for which Keystone received higher payments for 2016 and 2017. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$746,012 for our sample.

## Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. (H3952) Submitted to CMS

### What OIG Found

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Keystone submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, for 205 of the 270 sampled enrollee-years, the medical records that Keystone provided did not support the diagnosis codes and resulted in \$550,391 in overpayments. As demonstrated by the errors in our sample, Keystone's policies and procedures to prevent, detect, and correct noncompliance with CMS program requirements could be improved. On the basis of our sample results, we estimated that Keystone received at least \$11.3 million in overpayments for 2016 and 2017.

### What OIG Recommends and Keystone Comments

We recommend that Keystone: (1) refund to the Federal Government the \$550,391 of 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; (3) continue its examination of existing compliance procedures to identify areas in which 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; and (4) ensure that it collects, for audits of risk adjustment data, medical records that comply with CMS requirements.

In written comments on our draft report, Keystone concurred with our third and fourth recommendations but did not fully agree with our findings and our first and second recommendations. Keystone provided additional information related to medical records it previously gave us.

After reviewing Keystone's comments and the additional information provided, we revised the number of enrollee-years in error from 207 to 205 for this final report. After we issued our draft report, CMS updated regulations for audits in its risk adjustment program to specify that extrapolated overpayments could only be recouped beginning with payment year 2018. Because our audit period covered payment years 2016 and 2017, we revised our first recommendation to specify a refund of only the overpayments for the sampled enrollee-years. We made no changes to our other recommendations. 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, gender, and health status of that individual. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources relative to healthier enrollees, who would be expected to require fewer health care resources. To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS.<sup>1</sup> We are auditing MA organizations because some diagnoses are at a 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 Keystone Health Plan East, Inc. (Keystone), a subsidiary of Independence Health Group, for contract number H3952 and focused on nine groups of high-risk diagnosis codes for payment years 2016 and 2017.<sup>3</sup>

### OBJECTIVE

Our objective was to determine whether selected diagnosis codes that Keystone 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, *Official Guidelines for Coding and Reporting*. The ICD is a coding system that is used by physicians and other health care providers to classify and code all diagnoses, symptoms, and procedures. Effective October 1, 2015, CMS transitioned from the ninth revision of the ICD Coding Guidelines (ICD-9-CM) to the tenth revision (ICD-10-CM). Each revision includes different diagnosis code sets.

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

<sup>3</sup> All subsequent references to "Keystone" in this report refer solely to contract number H3952.

fee-for-service 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 costs 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: (1) a base rate that CMS sets using bid amounts received from the MA organization and (2) 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 gender). 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 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.

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

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

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<sup>8</sup> During our audit period, CMS calculated risk scores based on the Version 22 CMS-HCC model.

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

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

### High-Risk Groups of Diagnoses

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

- *Acute stroke*: An enrollee received one acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim. In these instances, a diagnosis of history of stroke (which does not map to an HCC) typically should have been used.
- *Acute heart attack*: An enrollee received one diagnosis that mapped to either the HCC for Acute Myocardial Infarction or to the HCC for Unstable Angina and Other Acute Ischemic Heart Disease (Acute Heart Attack HCCs) on only one physician or outpatient claim during the service year but did not have an acute heart attack diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician or outpatient claim). In these instances, a diagnosis indicating a history of a myocardial infarction (which does not map to an HCC) typically should have been used.
- *Embolism*: An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or the HCC for Vascular Disease with Complications (Embolism HCCs) during the service year but did not have an anticoagulant medication dispensed on his or her behalf. An anticoagulant medication is typically used to treat an embolism. In these instances, a diagnosis of history of embolism (an indication that the provider is evaluating a prior acute embolism diagnosis, which does not map to an HCC) typically should have been used.
- *Vascular claudication*: An enrollee received one diagnosis related to vascular claudication (that mapped to the HCC for Vascular Disease) during the service year but had not received one of these diagnoses during the 2 preceding years and had medication dispensed on his or her behalf that is frequently dispensed for a diagnosis of

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<sup>10</sup> 42 CFR § 422.310(e) requires MA organizations (when undergoing an audit conducted by the Secretary) to submit medical records for the validation of risk adjustment data. For purposes of this report, we use the terms "supported" and "unsupported" to denote whether the reviewed diagnoses were supported by the medical records. If our audit determined that the diagnoses were supported, we used the term "validated" with respect to the associated HCC; if our audit determined that the diagnoses were unsupported, we used the term "unvalidated" with respect to the associated HCC.

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

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

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

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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 an individual is 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.

## Keystone Health Plan East, Inc.

Keystone is an MA organization based in Philadelphia, Pennsylvania. As of December 2017, Keystone provided coverage under contract number H3952 to 98,351 enrollees. For the 2016 and 2017 payment years (audit period), CMS paid Keystone approximately \$2.1 billion to provide coverage to its enrollees.<sup>12, 13</sup>

### HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of nine high-risk groups during the 2015 and 2016 service years, for which Keystone received increased risk-adjusted payments for payment years 2016 and 2017, respectively. Because enrollees could be classified into more than one high-risk group or could have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment year, which we refer to as “enrollee-years.”

We identified 7,599 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$18,524,218). We selected for audit a stratified random sample of 270 enrollee-years as shown in Table 1.

**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. Lung cancer	30
6. Breast cancer	30
7. Colon cancer	30
8. Prostate cancer	30
9. Major depressive disorder	30
<b>Total for All High-Risk Groups</b>	<b>270</b>

Keystone provided medical records as support for the selected diagnosis codes associated with all 270 enrollee-years. We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. For the HCCs that were not validated, if the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, or we

<sup>12</sup> The 2016 and 2017 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 Keystone and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

identified another diagnosis code (on CMS's system) that mapped to an HCC in the related disease-related group, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

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

Appendix A contains the details of our audit scope and methodology, Appendix C contains our statistical sampling methodology, Appendix D contains our sample results and estimates, and Appendix E contains the relevant Federal regulations.

## FINDINGS

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Keystone submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 65 of the 270 sampled enrollee-years, the medical records validated the reviewed HCC, or we identified another diagnosis code (on CMS's systems) that mapped to the HCC under review. However, for the remaining 205 enrollee-years, the diagnosis codes were not supported and the associated HCCs were therefore not validated. As a result, Keystone received \$550,391 in overpayments.

As demonstrated by the errors in our sample, the policies and procedures that Keystone had to detect and correct noncompliance with CMS program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that Keystone received at least \$11.3 million in overpayments for 2016 and 2017.<sup>14</sup> Because of Federal regulations that limit the use of extrapolation in Risk Adjustment Data Validation (RADV) audits for recovery purposes to payment years 2018 and forward, we are reporting the overall estimated overpayment amount but are recommending a refund of \$550,391 in overpayments for the sampled enrollee-years.<sup>15</sup>

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<sup>14</sup> Specifically, we estimated that Keystone received at least \$11,361,030 in overpayments. To be conservative, we estimate overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

<sup>15</sup> After we had issued our draft report, CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643 (Feb. 1, 2023)).

## FEDERAL REQUIREMENTS

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

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

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

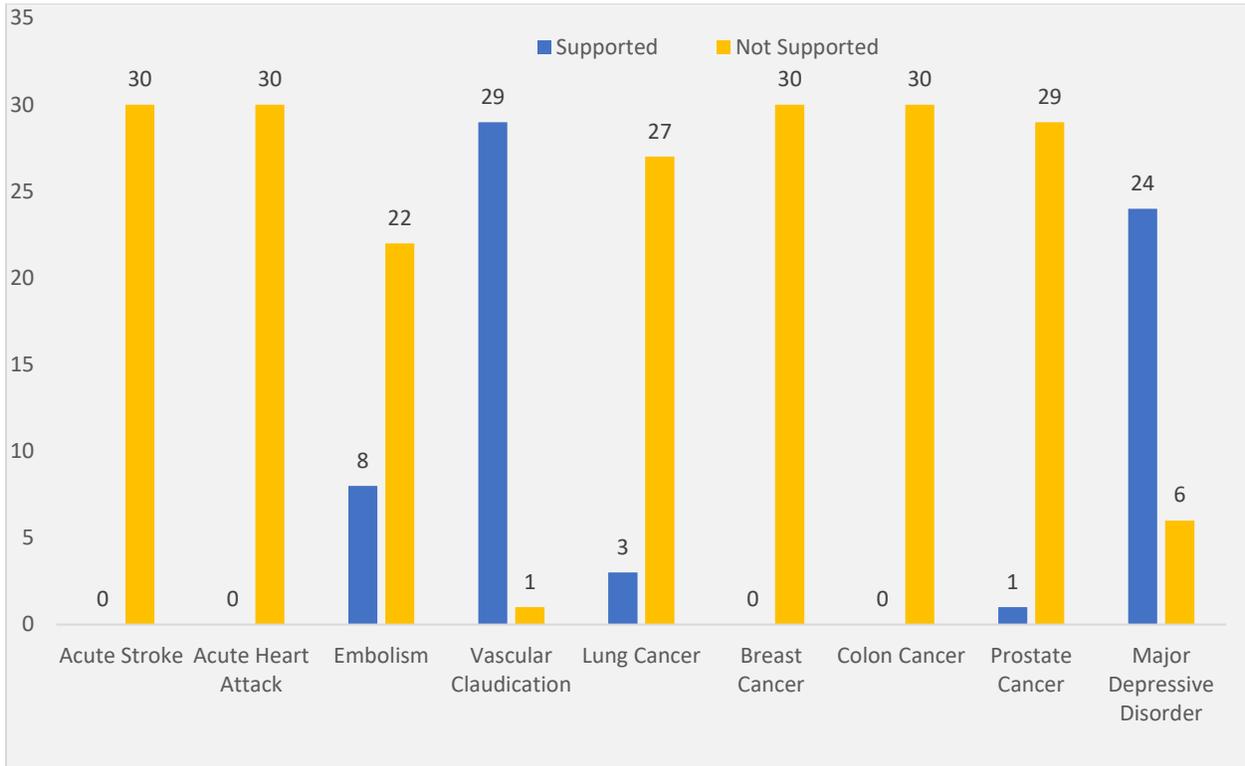
CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap. 7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7, § 40). The diagnosis must be coded according to the International Classification of Diseases, Clinical Modification, *Official Guidelines for Coding and Reporting* (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 KEYSTONE SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS**

Most of the selected high-risk diagnosis codes that Keystone submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. As shown in the figure on the following page, the medical records for 205 of the 270 sampled enrollee-years did not support the diagnosis codes. In these instances, Keystone should not have submitted the diagnosis codes to CMS and received the resulting overpayments.

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



### Incorrectly Submitted Diagnosis Codes for Acute Stroke

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

- For 18 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 noted that “there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC [for Ischemic or Unspecified Stroke] or a related HCC. There is mention of a history of a stroke [diagnosis] but no description of residuals or sequelae that should be coded.”<sup>16</sup> The history of stroke diagnosis code does not map to an HCC.

- For the remaining 12 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.

<sup>16</sup> Residuals or sequelae are lasting effects after the acute phase of an illness or injury has ended.

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

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and Keystone received \$68,770 in overpayments for these 30 sampled enrollee-years.

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

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

- For 14 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Acute Heart Attack HCC.

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

- For 10 enrollee-years, the medical records indicated in each case that the individual had an old myocardial infarction diagnosis, but the records did not justify a diagnosis that mapped to an Acute Heart Attack HCC at the time of the physician’s service.<sup>17</sup>

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

- For the remaining 6 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Acute Heart Attack HCC. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Keystone should not have received an increased payment for the submitted acute heart attack diagnosis but should have received a lesser increased payment for the other diagnosis identified.

As a result of these errors, the Acute Heart Attack HCCs were not validated, and Keystone received \$57,358 of overpayments for these 30 sampled enrollee-years.

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

## Incorrectly Submitted Diagnosis Codes for Embolism

Keystone incorrectly submitted diagnosis codes for embolism for 22 of 30 sampled enrollee-years. Specifically:

- For 10 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Embolism HCC.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Vascular Disease with Complications].”

- For 8 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not justify a diagnosis that mapped to an Embolism HCC at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of [the] HCC [for Vascular Disease with Complications]. There is documentation for a past medical history of a pulmonary embolism [diagnosis] that does not result in an HCC.”<sup>18</sup>

- For 2 enrollee-years, the medical records provided to support the reviewed HCC were not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner).<sup>19</sup> The data sources were computed tomography (CT) reports; therefore, the Embolism HCC was not validated.
- For the remaining 2 enrollee-years, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Vascular Disease with Complications]. There is documentation of abdominal aortic aneurysm [diagnosis] that results in [the] HCC [for Vascular Disease] which should have been assigned instead of the submitted HCC.”<sup>20</sup> Accordingly, Keystone should not have received an increased payment for the embolism diagnosis but should have received a lesser increased payment for the abdominal aortic aneurysm diagnosis.

As a result of these errors, the Embolism HCCs were not validated, and Keystone received \$57,263 of overpayments for these 22 sampled enrollee-years.

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<sup>18</sup> Pulmonary embolism is a blockage in one of the pulmonary arteries in the lungs.

<sup>19</sup> 42 CFR § 422.310(d)(3) and the Manual, chap. 7, §§ 40 and 120.1.

<sup>20</sup> Abdominal aortic aneurysm is a bulge or swelling in the aorta.

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

Keystone incorrectly submitted a diagnosis code for vascular claudication for 1 of the 30 sampled enrollee-years. Specifically, for 1 enrollee-year, the medical record did not support a diagnosis related to vascular claudication. For this 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in assignment of [the] HCC [for Vascular Disease].”

As a result of this error, the HCC for Vascular Disease was not validated, and Keystone received a \$2,294 overpayment for this sampled enrollee-year.

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

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

- For 10 enrollee-years, the medical records indicated in each case that the individual had previously had lung cancer, but the records did not support the lung cancer diagnosis at the time of the physician’s service.

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

- For 6 enrollee-years, the medical records provided to support the reviewed HCC were not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner). Four of the data sources were CT reports, and the remaining two data sources were x-ray reports; therefore, the HCC for Lung and Other Severe Cancers was not validated.
- For 6 enrollee-years, the medical records in each case did not support a lung cancer diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Keystone should not have received an increased payment for the submitted lung cancer diagnosis but should have received a lesser increased payment for the other diagnosis identified.
- For the remaining 5 enrollee-years, the medical records in each case did not support a lung cancer diagnosis.

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

As a result of these errors, the HCC for Lung and Other Severe Cancers was not validated, and Keystone received \$191,570 of overpayments for these 27 sampled enrollee-years.

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

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

- For 23 enrollee-years, the medical records indicated in each case that the individual had previously had breast cancer, but the records did not justify a breast cancer diagnosis at the time of the physician's service.

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

- For 4 enrollee-years, the medical records provided to support the reviewed HCC were not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner). The data sources were an x-ray report, a mammogram report, a radiology report, and a laboratory request; therefore, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated.
- For the remaining 3 enrollee-years, the medical records did not support a breast cancer 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 the assignment of [the] HCC [for Breast, Prostate, and Other Cancer and Tumors]. There was not enough documentation to support that the breast cancer was an active condition on this date of service."

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Keystone received \$46,626 of overpayments for these 30 sampled enrollee-years.

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

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

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

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation to support a diagnosis that results in [the] HCC [for Colorectal, Bladder, and Other Cancers]. There is documentation of a past medical history of colon cancer [diagnosis] that does not result in an HCC.”

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

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

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

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and Keystone received \$74,529 of overpayments for these 30 sampled enrollee-years.

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

Keystone incorrectly submitted diagnosis codes for prostate cancer for 29 of the 30 sampled enrollee-years. Specifically:

- For 24 enrollee-years, the medical records indicated in each case that the individual had previously had prostate cancer, but the records did not justify a prostate cancer diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of a diagnosis that results in [the] HCC [for Breast, Prostate, and Other Cancers and Tumors]. There is documentation of a past medical history of prostate cancer [diagnosis] that does not result in an HCC.”

- For 4 enrollee-years, the medical records did not support a prostate cancer diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is not enough documentation to support a diagnosis of prostate cancer as an active condition.”

- For the remaining 1 enrollee-year, the medical record provided to support the reviewed HCC was not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner). The data source was a laboratory data sheet;

therefore, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated.

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Keystone received \$38,779 of overpayments for these 29 sampled enrollee-years.

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

Keystone incorrectly submitted diagnosis codes for major depressive disorder for 6 of the 30 sampled enrollee-years. Specifically:

- For 5 enrollee-years, the medical records did not support a major depressive disorder 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 the assignment of [the] HCC [for Major Depressive, Bipolar, and Paranoid Disorders].”

- For the remaining 1 enrollee-year, the medical record provided to support the reviewed HCC was not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner). The data sources were a physical restraint/psychotropic review form, a prescription form, and medication records; therefore, the HCC for Major Depressive, Bipolar, and Paranoid Disorders was not validated.

As a result of these errors, the HCC for Major Depressive, Bipolar, and Paranoid Disorders was not validated, and Keystone received \$13,202 in overpayments for these 6 sampled enrollee-years.

### **Summary of Overpayments for Incorrectly Submitted Diagnosis Codes**

In summary and with respect to the nine high-risk groups covered by our audit, Keystone received \$550,391 in overpayments for the 205 sampled enrollee-years.

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

As demonstrated by the errors in our sample, the policies and procedures that Keystone had to prevent, detect, and correct noncompliance with CMS’s program requirements, as mandated by Federal regulations (42 CFR § 422.503(b)(4)(vi)), could be improved.

As part of its preventive measures, Keystone had compliance procedures to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. These procedures included a provider education program that was designed to promote

accurate diagnosis codes, including those in the nine high-risk groups we reviewed, for which Keystone provided instructions to its providers.

In addition, Keystone's compliance procedures included detection and correction techniques, which it used to perform routine internal medical reviews that compared diagnosis codes from a random sample of claims to the diagnoses that were documented on the associated medical records. For instances in which Keystone identified unsupported diagnosis codes on the claims, its procedures called for it to submit corrections to CMS. In 2019, Keystone expanded its procedures to include medical reviews that focused on selected diagnosis codes for acute stroke. According to Keystone officials, Keystone had completed one review of the selected diagnosis codes, and that review resulted in 85 percent of the reviewed codes not being validated. Keystone officials stated that Keystone will submit the corrections to CMS for these unvalidated diagnosis codes.

With regard to the errors identified in this report, Keystone officials also explained to us that Keystone relies on its providers to submit correct diagnosis codes on claims and that Keystone is taking additional measures to review the accuracy of these diagnosis codes.

For the 14 medical records that were determined to not be from acceptable data sources according to CMS coding guidelines, Keystone officials explained that they submitted them on the chance the medical reviewer might find support for the diagnosis code under review.

We acknowledge that Keystone's compliance procedures had measures designed to prevent and detect incorrect high-risk diagnosis codes. However, because we found that 205 of the 270 sampled enrollee-years were not supported by medical records, and based upon our discussions with Keystone officials, we conclude that these procedures could be improved.

## **KEYSTONE RECEIVED OVERPAYMENTS**

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Keystone received at least \$11.3 million in overpayments for these high-risk diagnosis codes for 2016 and 2017. (See Appendix D for our sample results and estimates).

Because of Federal regulations that limit the use of extrapolation in Risk Adjustment Data Validation (RADV) audits for recovery purposes, we are reporting the estimated overpayment amount but are recommending a refund of only the \$550,391 in overpayments that Keystone received for the 270 sampled enrollee-years.<sup>21</sup>

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<sup>21</sup> After we issued our draft report, CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643 (Feb. 1, 2023)).

## RECOMMENDATIONS

We recommend that Keystone Health Plan East, Inc.:

- refund to the Federal Government the \$550,391 in 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;
- continue its examination of existing compliance procedures to identify areas in which improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures; and
- ensure that it collects, for audits of risk adjustment data, medical records that comply with CMS requirements regarding appropriate data sources.

### KEYSTONE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Keystone concurred with our third and fourth recommendations but did not fully agree with our findings and our first and second recommendations. Specifically, Keystone did not agree with our findings for 22 of the 207 enrollee-years in error identified in our draft report and provided additional information as to why it believed that the medical records that it previously gave us validated the reviewed HCCs.<sup>22</sup> Further, Keystone did not agree with the conclusions related to our estimation of overpayments and did not agree with our first recommendation to refund estimated overpayments. In addition, Keystone stated that it did not have an obligation to perform reviews to identify similar instances of noncompliance and therefore did not agree with our second recommendation. With respect to our third and fourth recommendations, Keystone concurred with both recommendations and stated that it had established and improved its procedures to identify and correct errant diagnosis codes.

We reviewed the entirety of Keystone's comments and the additional information that it provided and, accordingly, reduced the number of enrollee-years in error from 207 to 205 and adjusted our calculation of overpayments for this final report. After we had issued our draft report, CMS updated Federal regulations for RADV audits to specify that extrapolated

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<sup>22</sup> Keystone submitted additional information for 27 enrollee-years. However, the information for 4 of those enrollee-years related to potential support for diagnoses that mapped to an HCC for a less severe manifestation of a related-disease groups. We had included these 4 HCCs in our calculations for our draft report. For the remaining enrollee-year, Keystone submitted information regarding a hemiparesis diagnosis (weakness on one side of the body caused by a stroke) that was already in CMS's systems and included in our calculations for the draft report. Thus, the additional information for the 5 enrollee-years did not impact our audit results for this final report.

overpayments could only be recouped beginning with payment year 2018 (footnote 15). Because our audit period covered payment years 2016 and 2017, we revised the amount in our first recommendation to reflect only the overpayments for the 205 sampled enrollee-years. We maintain that our other recommendations remain valid.

A summary of Keystone’s comments regarding the recommendations with which it did not agree follows, along with our responses. Keystone’s comments are included as Appendix F. We excluded the attachment (which Keystone identified as Appendix A in its comments) because it contains personally identifiable information. We are separately providing Keystone’s comments and the attachment in their entirety to CMS.

**KEYSTONE DID NOT AGREE WITH OUR FINDINGS FOR 22 ENROLLEE-YEARS**

**Keystone Comments**

Keystone did not agree with our findings for 22 sampled enrollee-years and provided additional information (including medical records and explanations) supporting its position that the HCCs were validated (footnote 22). Table 2 shows the breakdown of the 22 sampled enrollee-years by high-risk group.

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

<b>High-Risk Group</b>	<b>Number of Sampled Enrollee-Years</b>
Acute Stroke	1
Acute Heart Attack	14
Embolism	5
Lung Cancer	2
<b>Total for All High-Risk Groups</b>	<b>22</b>

**Office of Inspector General Response**

Our independent medical review contractor reviewed the additional information that Keystone provided for the 22 enrollee-years.

- For 20 of the 22 enrollee-years, our independent medical review contractor reaffirmed that the audited HCCs were not validated.
  - For 17 of the enrollee-years, our contractor did not find support for the audited HCC and reaffirmed that the HCCs were not validated.

For example, for 1 enrollee-year from the acute heart attack high-risk group, the contractor upheld its original decision upon reconsideration and noted, “There is documentation of a past medical history of a myocardial infarction which does not result in any HCC.”

- For 3 enrollee-years, our contractor did not find support for the audited HCC; however, our contractor did find support for a less severe manifestation of the disease in the related-disease group (acute heart attack and embolism). Because the audited HCCs were not validated, we continue to classify these enrollee-years as errors.
- For the remaining 2 enrollee-years, our independent medical review contractor found support for the audited HCCs and therefore reversed its original decision and validated the HCCs (embolism and lung cancer).

Accordingly, we revised our findings and reduced the total number of enrollee-years in error from 207 (as reported in our draft report) to 205.

## **KEYSTONE DID NOT AGREE WITH OUR OVERPAYMENT RECOMMENDATION THAT IT REFUND AN EXTRAPOLATED AMOUNT TO THE FEDERAL GOVERNMENT**

### **Keystone Comments**

Keystone stated that although it agreed with many of our findings related to medical record support, it did not agree with our conclusions in terms of an estimated overpayment or with our “recommendation to refund an estimated overpayment.” Keystone also noted that we and CMS “have inconsistent approaches to Medicare Advantage audits and overpayment determinations related to risk adjustment submissions.” These differences, according to Keystone, included documentation standards of review, statistical procedures, and methodologies to calculate “alleged overpayments.” In addition, Keystone noted that “there is no published authority or methodology for CMS to impose an extrapolation remedy.” Further, Keystone stated that it is probable that there will be legal challenges to our calculation and estimation of overpayments (including the application of a fee-for-service adjustment) in our other compliance audits of MA organizations. Finally, Keystone said our audit “advances important compliance objectives which are embraced but the findings do not legally require the processing the recommended estimated extrapolated overpayment.”

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

As stated above, we limited our final report recommendation to a recommendation that Keystone refund overpayments associated with the 205 sampled enrollee-years rather than an estimated amount (footnote 15). However, we believe that the results of our sampling, as well as our estimate of overpayments (Appendix D), provide a reasonable basis for our findings and conclusions.

Although our estimation 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. OIG is an independent oversight agency, and we are not required to mirror CMS’s estimation methodology. 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 provides a reasonably conservative estimate of the total amount overpaid to Keystone for the enrollee-years and time period covered in our sampling frame. Further, we note that this approach, which is routinely used by HHS for recovery calculations, results in a lower limit (the estimated overpayment) that is designed to be less than the actual overpayment amount 95 percent of the time.<sup>23</sup>

Additionally, 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>24</sup> As detailed in Appendix C, we properly executed a statistically valid 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.

With regard to Keystone’s comments about potential legal challenges to our overpayment calculations (including the application of a fee-for-service adjustment), we recognize that CMS—not OIG—is responsible for making operational and program payment determinations for the MA program and that any OIG audit findings and recommendations do not represent final determinations by CMS.<sup>25</sup> Further, we note that CMS stated (after we had issued our draft report) that it “will not apply an adjustment factor (known as an FFS Adjuster) in RADV audits.”<sup>26</sup>

Thus, we did not revise the amount in our first recommendation based on Keystone’s comments; rather, we revised the amount in response to the updated regulations that CMS published after we issued our draft report.

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<sup>23</sup> HHS has used the two-sided 90-percent confidence interval when calculating recoveries in both the Administration for Children and Families and Medicaid programs. See, for example, *New York State Department of Social Services*, DAB No. 1358, 13 (1992); and *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, for example, *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); and *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 17-18 (E.D.N.Y. 2012).

<sup>24</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>25</sup> Action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures. In accordance with 42 CFR § 422.311, which addresses audits conducted by the Secretary (including those conducted by OIG), if a disallowance is taken, MA organizations have the right to appeal the determination that an overpayment occurred through the Secretary’s RADV appeals process.

<sup>26</sup> 88 Fed. Reg.6643 (Feb.1, 2023).

## **KEYSTONE DID NOT AGREE WITH OUR RECOMMENDATION TO PERFORM ADDITIONAL REVIEWS FOR THE PERIODS BEFORE AND AFTER THE AUDIT PERIOD**

### **Keystone Comments**

Keystone did not agree with our second recommendation and stated that it did not have an obligation under the MA program to “undertake a similar audit as conducted by OAS.” However, Keystone stated that it would adhere to any CMS guidance and “will incorporate the complex risk issues identified . . . into enhancing its oversight program and provider education.”

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

We maintain the validity of our recommendation that Keystone 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. We believe that the error rate identified in our audit (205 of 270 sampled enrollee-years with unsupported diagnosis codes) (Appendix D) demonstrates that Keystone has compliance issues that need to be addressed. These issues may extend to periods of time beyond our audit scope.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

CMS paid Keystone \$2,093,081,653 to provide coverage to its enrollees for 2016 and 2017. We identified a sampling frame of 7,599 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2015 and 2016 service years. Keystone received \$124,634,128 in payments from CMS for these enrollee-years for 2016 and 2017. We selected for audit 270 enrollee-years with payments totaling \$4,562,906.

The 270 enrollee-years included 30 acute stroke diagnoses, 30 acute heart attack diagnoses, 30 embolism diagnoses, 30 vascular claudication diagnoses, 30 lung cancer diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, 30 prostate cancer diagnoses, and 30 major depressive disorder diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$746,012 for our sample.

We reviewed internal controls directly related to our audit objective. We reviewed Keystone's internal controls for ensuring that diagnosis codes it submitted to CMS were coded in accordance with Federal requirements.

We performed our audit from November 2019 through June 2022.

### METHODOLOGY

To accomplish our objective, we performed the following steps:

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

- 24 diagnosis codes for lung cancer,
  - 65 diagnosis codes for breast cancer,
  - 20 diagnosis codes for colon cancer,
  - 2 diagnosis codes for prostate cancer, and
  - 29 diagnosis codes for major depressive disorder.
- We used CMS’s systems to identify the enrollee-years on whose behalf providers documented the high-risk diagnosis codes. Specifically, we used extracts from CMS’s:
    - Risk Adjustment Processing System (RAPS) to identify enrollees who received high-risk diagnosis codes from a physician during the service years;<sup>27</sup>
    - Risk Adjustment System (RAS) to identify enrollees who received an HCC for the high-risk diagnosis codes;<sup>28</sup>
    - Medicare Advantage Prescription Drug system (MARx) to identify enrollees for whom CMS made monthly Medicare payments to Keystone, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C);<sup>29</sup>
    - Encounter Data System (EDS) to identify enrollees who received specific procedures;<sup>30</sup> and
    - Prescription Drug Event (PDE) file to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.<sup>31</sup>
  - We interviewed Keystone officials to gain an understanding of: (1) the policies and procedures that Keystone followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Keystone’s monitoring of those submissions to detect and correct noncompliance with Federal requirements.
  - We selected for audit a stratified random sample of 270 enrollee-years (Appendix C).

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<sup>27</sup> MA organizations use the RAPS to submit diagnosis codes to CMS.

<sup>28</sup> The RAS identifies the HCCs that CMS factors into each enrollee’s risk score calculation.

<sup>29</sup> The MARx identifies the payments made to MA organizations.

<sup>30</sup> The EDS contains information on each item (including procedures) and service provided to enrollees.

<sup>31</sup> The PDE file contains claims with prescription drugs that have been dispensed to enrollees through the Medicare Part D (prescription drug coverage) program.

- We used an independent medical review contractor to perform a coding review for the 270 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.<sup>32</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, and CMS systems, to calculate overpayments or underpayments (if any) for each enrollee-year. Specifically, we calculated:
  - a revised risk score in accordance with CMS’s risk adjustment program and
  - the payment that CMS should have made for each enrollee-year.
- For the nine high-risk groups covered by our audit, we estimated the total overpayment made to Keystone during the audit period.

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<sup>32</sup> Our independent medical review contractor used senior coders, all of whom possessed one or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS), Certified Coding Specialist – Physician-Based (CCS-P), Certified Professional Coder (CPC), and Certified Risk Adjustment Coder (CRC). RHITs have completed a 2-year degree program and have passed an American Health Information Management Association (AHIMA) certification exam. AHIMA also credentials individuals with CCS and CCS-P certifications, and the American Academy of Professional Coders credentials both CPCs and CRCs.

- We limited the total overpayment that we recommended for recovery to the sampled enrollee-years.<sup>33</sup>
- We discussed the results of our audit with Keystone 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> Federal regulations (42 CFR § 422.311(a)) state: “the Secretary annually conducts RADV audits to ensure risk-adjusted payment integrity and accuracy.” Recovery of improper payments from MA organizations will be conducted in accordance with the Secretary’s payment error extrapolation and recovery methodologies. CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years (88 Fed. Reg. 6643, 6655 (Feb. 1, 2023)).

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

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring Life &amp; Health Insurance Company, Inc. (Contract H4513) Submitted to CMS</i>	<a href="#"><u>A-07-19-01192</u></a>	3/28/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS</i>	<a href="#"><u>A-02-20-01008</u></a>	3/24/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS</i>	<a href="#"><u>A-09-21-03011</u></a>	3/16/2023
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Cigna-HealthSpring of Tennessee, Inc. (Contract H4454) Submitted to CMS</i>	<a href="#"><u>A-07-19-01193</u></a>	12/22/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BCBS of Rhode Island (Contract H4152) Submitted to CMS</i>	<a href="#"><u>A-01-20-00500</u></a>	11/16/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That California Physician’s Service, Inc. (Contract H0504) Submitted to CMS</i>	<a href="#"><u>A-09-19-03001</u></a>	11/10/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract R5826) Submitted to CMS</i>	<a href="#"><u>A-05-19-00039</u></a>	9/30/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (H3916) Submitted to CMS</i>	<a href="#"><u>A-03-19-00001</u></a>	9/29/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS</i>	<a href="#"><u>A-07-19-01195</u></a>	9/29/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes that Inter Valley Health Plan, Inc. (Contract H0545), Submitted to CMS</i>	<a href="#"><u>A-05-18-00020</u></a>	9/26/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS</i>	<a href="#"><u>A-09-20-03009</u></a>	9/13/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc., (Contract H1032) Submitted to CMS</i>	<a href="#"><u>A-04-19-07084</u></a>	8/29/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS</i>	<a href="#"><u>A-03-18-00002</u></a>	8/19/2022

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

## APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

### SAMPLING FRAME

Our sampling frame only included Keystone enrollees who: (1) were continuously enrolled in Keystone throughout all of the 2015 or 2016 service year and January of the following year, (2) were not classified as being enrolled in hospice or as having end-stage renal disease status at any time during 2015 or 2016 or in January of the following year, and (3) received a high-risk diagnosis during 2015 or 2016 that caused an increased payment to Keystone for 2016 or 2017, respectively.

We presented the data for these enrollees to Keystone for verification and performed an analysis of the data included in CMS's systems to determine whether the high-risk diagnosis codes increased CMS's payments to Keystone. We removed any enrollees whose managed care data could not be verified, and we classified the remaining individuals according to condition and payment year (enrollee-years). After we performed these steps, our finalized sample frame consisted of 7,599 enrollee-years.

### SAMPLE UNIT

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

### SAMPLE DESIGN AND SAMPLE SIZE

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

- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on only one physician claim during the service year but did not receive an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim (1,777 enrollee-years);
- a diagnosis (that mapped to an Acute Heart Attack HCC) on only one physician or outpatient claim during the service year but did not receive an acute heart attack diagnosis on a corresponding inpatient or outpatient hospital claim either 60 days before or 60 days after the physician claim (847 enrollee-years);
- a diagnosis (that mapped to an Embolism HCC) on only one claim during the service year but did not receive an anticoagulant medication dispensed on their behalf (538 enrollee-years);
- a diagnosis related to vascular claudication (that mapped to the HCC for Vascular Disease) on only one claim during the service year (a diagnosis that had not been documented during the 2 years that preceded the service year), but had medication for neurogenic claudication dispensed on their behalf (276 enrollee-years);

- a lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) on only one claim during the service year but did not receive surgical therapy, radiation treatments, or chemotherapy drug treatments related to the lung cancer diagnosis administered within a 6-month period before or after the diagnosis (237 enrollee-years);
- a breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one claim during the service year but did not receive surgical therapy, radiation treatments, or chemotherapy drug treatments related to the breast cancer diagnosis administered within a 6-month period before or after the diagnosis (1,177 enrollee-years);
- a colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) on only one claim during the service year but did not receive surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (358 enrollee-years);
- a prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) for an individual 74 years old or younger, on only one claim during the service year but did not receive surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (365 enrollee-years); and
- a major depressive disorder diagnosis (that mapped to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) on only one claim during the service year but did not have an antidepressant medication dispensed on their behalf (2,024 enrollee-years).

The specific strata are shown in Table 3.

**Table 3: Sample Design for Audited High-Risk Groups**

<b>Stratum (High-Risk Groups)</b>	<b>Frame Count of Enrollee-Years</b>	<b>CMS Payment for HCCs in Audited High-Risk Groups</b>	<b>Sample Size</b>
1 – Acute stroke	1,777	\$4,089,930	30
2 – Acute heart attack	847	1,684,828	30
3 – Embolism	538	1,433,774	30
4 – Vascular claudication	276	680,144	30
5 – Lung cancer	237	1,671,075	30
6 – Breast cancer	1,177	1,525,646	30
7 – Colon cancer	358	885,360	30
8 – Prostate cancer	365	485,408	30
9 – Major depressive disorder	2,024	6,068,053	30
<b>Total</b>	<b>7,599</b>	<b>\$18,524,218</b>	<b>270</b>

## **SOURCE OF RANDOM NUMBERS**

We generated the random numbers with the OIG, OAS, statistical software.

## **METHOD FOR SELECTING SAMPLE ITEMS**

We sorted the items in each stratum by the combination of the enrollee identifier and the payment year under review and then consecutively numbered the items in each stratum in the stratified sampling frame. After generating 270 random numbers according to our sample design, we selected the corresponding frame items for review.

## **ESTIMATION METHODOLOGY**

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

**APPENDIX D: SAMPLE RESULTS AND ESTIMATES**

**Table 4: Sample Details and Results**

<b>Audited High-Risk Group</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 Group (for Sampled Enrollee-Years)</b>	<b>Number of Sampled Enrollee-Years With Unvalidated HCCs</b>	<b>Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)</b>
1 – Acute stroke	1,777	\$4,089,930	30	\$68,770	30	\$68,770
2 – Acute heart attack	847	1,684,828	30	60,955	30	57,358
3 – Embolism	538	1,433,774	30	81,882	22	57,263
4 – Vascular claudication	276	680,144	30	75,020	1	2,294
5 –Lung cancer	237	1,671,075	30	214,588	27	191,570
6 –Breast cancer	1,177	1,525,646	30	46,626	30	46,626
7 –Colon cancer	358	885,360	30	74,529	30	74,529
8 –Prostate cancer	365	485,408	30	38,999	29	38,779
9 – Major depressive disorder	2,024	6,068,053	30	84,643	6	13,202
<b>Total</b>	<b>7,599</b>	<b>\$18,524,218</b>	<b>270</b>	<b>\$746,012</b>	<b>205</b>	<b>\$550,391</b>

**Table 5: Estimated Overpayments in the Sampling Frame  
(Limits Calculated for a 90-Percent Confidence Interval)**

Point Estimate	\$12,335,459
Lower Limit	11,361,090
Upper Limit	13,309,828

**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: KEYSTONE COMMENTS

1901 Market Street  
Philadelphia, PA 19103-1480



Mr. Stephen P. Fera  
Executive Vice President Public Affairs  
Keystone Health Plan East, Inc.  
1901 Market Street  
Philadelphia, PA 19103

August 25, 2022

### VIA OVERNIGHT AND ELECTRONIC MAIL

Ms. Nicole Freda  
Regional Inspector General for Audit Services  
Office of Audit Services, Region III  
801 Market Street, Suite 8500  
Philadelphia, PA 19107-3134

**Re: Report A-03-20-00001-Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. Submitted to CMS.**

Dear Ms. Freda:

Thank you for the opportunity to review and comment to the HHS OIG Office of Audit Service's (OAS) draft report entitled *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. Submitted to CMS*. We very much appreciate the courtesy, professionalism and diligence of the OAS audit staff in connection with the audit and believe the positive collaboration has benefitted and will improve our Medicare Advantage program for our enrollees.

On behalf of Keystone Health Plan East (Keystone) additional supplemental information is provided related to the medical record review findings. Keystone further asks for reconsideration of certain findings as noted below.

Keystone also provides limited commentary to the OIG's recommendations regarding the Medicare Advantage program obligations or responsibilities, which we believe is within the legal purview of CMS and subject to a much more complex assessment than the draft report and reliant methodology demonstrates. In the event CMS should determine an overpayment based on the OAS

Independence Blue Cross offers products directly, through its subsidiaries Keystone Health Plan East and QCC Insurance Company, and with Highmark Blue Shield. Independent Licensees of the Blue Cross and Blue Shield Association.

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Office of Audit Services, Region III  
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audit, extrapolated or otherwise, Keystone will present credible and appropriate legal challenges to the estimated overpayment. Keystone does not intend its response submission to the OAS draft audit to be construed as an admission of any liability or a waiver of any rights to seek full and appropriate administrative review of any CMS findings related to the OAS or any other program audit.

**I. Supplemental Medical Record Information for Select Enrollees and Related Findings.**

Keystone requests consideration of identified supplemental medical record information as attached and summarized below. We believe the supplemental information is important to the overall findings in the draft report and should change those findings in part. Specifically, Keystone has provided with this response additional supplemental medical records for six patients which substantiate and/or support some of the audited high-risk diagnoses. Additional supplied medical records for 21 patients support other related diagnoses to the audited diagnoses. *See* Appendix A to this response. We request that OAS take these supplemental materials into consideration and adjust the draft report findings accordingly.

**II. Keystone's Response to Report Recommendations.**

**1. Refund Estimated Extrapolated Overpayments.**

Keystone agrees with many of the findings related to medical record support for the specialized HCCs. Keystone does not agree with conclusions related to the findings in terms of an estimated and extrapolated overpayment or the recommendation to refund an estimated overpayment based on the OAS audit.

We note that CMS and the OIG have inconsistent approaches to Medicare Advantage audits and overpayment determinations related to risk adjustment submissions. These differences are well known and run the gamut from documentation standards of review to different statistical procedures to different methodologies for even calculating the core of alleged overpayments. These differences cannot be resolved in this compliance audit process; however, it is notable that based on current regulatory guidance and agency precedent, if CMS identified an actual overpayment, CMS would or should calculate any potential overpayment in a significantly different manner than the OAS methodology consistent with the complex structure of the Medicare Advantage program guidance for RADV audits and the legal fact there is no published authority or methodology for CMS to impose an extrapolation remedy.

It is also probable that an administrative legal challenge would embrace the positions pertaining to the assessment, calculation and extrapolation of coding errors presented by

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Regional Inspector General for Audit Services  
Office of Audit Services, Region III  
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Medicare Advantage contractors in similar OAS Medicare Advantage compliance audit reports, including challenges related to actuarial equivalence requirements in RADV audits and application of the fee-for-service (FFS) adjustment in determining any overpayment for coding errors and even the mathematical formula for extrapolation.

From Keystone's perspectives, the OAS compliance audit advances important compliance objectives which are embraced but the findings do not legally require the processing the recommended estimated extrapolated overpayment derived from this audit. Keystone will await the CMS determination consistent with recognized agency audit protocols and regulations.

**2. Identify Similar Instances of Non-Compliance Occurring before or after the Audit Period.**

Keystone will continue its extensive auditing program and focus on medical record support for diagnosis codes and will incorporate the complex risk issues identified in the OAS draft report into enhancing its oversight program and provider education. Keystone does not agree it has an obligation under the Medicare Advantage program to undertake a similar audit as conducted by the OAS for any period before 2015 or after 2016 dates of service, the service period of the audit. Keystone will adhere to any CMS guidance in this regard.

**3. Continue Examination of Existing Compliance Procedures and Enhance Policies and Procedures as Necessary.**

Keystone concurs with the OAS finding that it has substantial compliance policies and procedures in place and the recommendation to continue to enhance its risk management process to address the identified risk areas. Keystone has over 55 policies and procedures related to the Medicare Advantage program and undertakes significant auditing and provider education activities. It has established and improving procedures to identify errant codes and to process voids and deletes for risk adjustment submissions as a matter of routine course. Keystone believes its obligation outlined in Medicare Advantage regulations and CMS guidance to undertake reasonable efforts to detect and void the submission of errant information or data is fully met within its current program structure and that Keystone is in compliance with its obligations as a Medicare Advantage contractor.

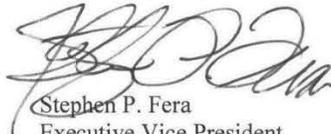
**4. Ensure collection of medical records for audit and risk adjustment data that complies with CMS requirements for appropriate data sources.**

Keystone concurs with this recommendation and will continue to improve its current and extensive process of medical record collection and review.

Nicole Freda  
Regional Inspector General for Audit Services  
Office of Audit Services, Region III  
August 25, 2022  
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Thank you again for the opportunity to review and comment to the draft report and for your consideration of Keystone's supplemental medical record information.

Very truly yours,



Stephen P. Fera  
Executive Vice President  
Public Affairs & Government Markets  
Keystone Health Plan East, Inc.

Enclosure-Submitted VIA Secure File Transfer  
Appendix A-Supplemental Medical Record Information Containing PHI

cc: Daniel Malis-HHS/OIG (via email)  
Craig Cohen-HHS/OIG (via email)  
Mitch Goldberg-Independence Blue Cross, Medicare Compliance Officer (via email)

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