

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**CIGNA HEALTHCARE OF  
ARIZONA, INC. (CONTRACT H0354),  
SUBMITTED MANY DIAGNOSES TO THE  
CENTERS FOR MEDICARE & MEDICAID  
SERVICES THAT DID NOT COMPLY WITH  
FEDERAL REQUIREMENTS FOR  
CALENDAR YEAR 2007**

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Inspector General

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# *Office of Inspector General*

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## EXECUTIVE SUMMARY

### BACKGROUND

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly capitated payments to MA organizations for beneficiaries enrolled in the organizations' health care plans. Subsections 1853(a)(1)(C) and (a)(3) of the Social Security Act require that these payments be adjusted based on the health status of each beneficiary. CMS uses the Hierarchical Condition Category (HCC) model (the CMS model) to calculate these risk-adjusted payments.

Under the CMS model, MA organizations collect risk adjustment data, including beneficiary diagnoses, from hospital inpatient facilities, hospital outpatient facilities, and physicians during a data collection period. MA organizations identify the diagnoses relevant to the model and submit them to CMS. CMS categorizes the diagnoses into groups of clinically related diseases called HCCs and uses the HCCs, as well as demographic characteristics, to calculate a risk score for each beneficiary. CMS then uses the risk scores to adjust the monthly capitated payments to MA organizations for the next payment period.

CIGNA Healthcare of Arizona, Inc. (CIGNA), is an MA organization. For calendar year (CY) 2007, CIGNA had one contract with CMS, contract H0354, which we refer to as "the contract." Under the contract, CMS paid CIGNA approximately \$328 million to administer health care plans for approximately 31,677 beneficiaries.

### OBJECTIVE

Our objective was to determine whether the diagnoses that CIGNA submitted to CMS for use in CMS's risk score calculations complied with Federal requirements.

### SUMMARY OF FINDINGS

The diagnoses that CIGNA submitted to CMS for use in CMS's risk score calculations did not always comply with Federal requirements. For 60 of the 100 beneficiaries in our sample, the risk scores calculated using the diagnoses that CIGNA submitted were valid. The risk scores for the remaining 40 beneficiaries were invalid because the diagnoses were not supported for one or both of the following reasons:

- The documentation did not support the associated diagnosis.
- The diagnosis was unconfirmed.

CIGNA's policies and procedures were not effective for ensuring that the diagnoses it submitted to CMS complied with the requirements of the *2006 Risk Adjustment Data Basic Training for Medicare Advantage Organizations Participant Guide* (the 2006 Participant Guide) and the *2007 Risk Adjustment Data Training for Medicare Advantage Organizations Participant Guide* (the 2007 Participant Guide). CIGNA's contracts required providers to submit accurate claims that

complied with all Medicare requirements, and CIGNA officials stated that they relied on providers to submit accurate diagnoses in their claims. However, providers often reported incorrect diagnoses as a result of data entry errors and reported diagnoses for conditions that did not exist at the time of beneficiaries' encounters.

As a result of these unsupported and unconfirmed diagnoses, CIGNA received \$151,453 in overpayments from CMS. Based on our sample results, we estimated that CIGNA received approximately \$28,353,516 in additional overpayments for CY 2007. This amount represents our point estimate less the total error amount for our sampled beneficiaries. The confidence interval for this estimate has a lower limit of \$20.7 million and an upper limit of \$36.3 million.

## **RECOMMENDATIONS**

We recommend the following:

- CIGNA should refund to the Federal Government \$151,453 in overpayments identified for the sampled beneficiaries.
- CIGNA should work with CMS to determine the correct contract-level adjustment for the additional \$28,353,516 of projected overpayments.
- CIGNA should improve its current policies and procedures to ensure compliance with Federal requirements.

## **CIGNA COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

### **Auditee Comments**

In written comments on our draft report and in followup communications, CIGNA disagreed with our findings and said that our analysis, methodology, and extrapolation were flawed. Specifically, CIGNA disagreed with results of our first and second medical reviews for 24 HCCs and gave us additional documentation (not previously provided) as to why the HCCs were supported. CIGNA stated that this documentation complied with CMS coding guidelines for seven HCCs.

CIGNA also stated that our model did not account for error rates inherent in Medicare fee-for-service (FFS) data, specifically the disparity between FFS claim data and FFS medical records data and the disparity's potential impact on MA payments. In addition, CIGNA said that we should have used the 2006 Participant Guide to evaluate CIGNA's compliance with CMS's requirements.

CIGNA stated that correcting errors made by our medical review contractor would reduce the extrapolated overpayment to approximately \$440,000.

## **Office of Inspector General Response**

Regarding the 24 HCCs for which CIGNA provided additional documentation, CIGNA stated that the medical records for 17 of the 24 HCCs were not coded according to CMS's coding guidelines, but added that CIGNA should be eligible for the associated risk adjustment payments because it could support the underlying diagnoses through other means. Because the documentation did not meet CMS's coding guidelines, we did not submit it to our medical review contractor. We submitted the documentation for the seven remaining HCCs to our medical review contractor for a third medical review and revised our findings accordingly.

Although an analysis to determine the potential impact of error rates inherent in FFS data on MA payments was beyond the scope of our audit, we acknowledge that CMS is studying this issue and its potential impact on audits of MA organizations. Therefore, because of the potential impact of these error rates on the CMS model that we used to recalculate MA payments for the beneficiaries in our sample, we (1) modified one recommendation to have CIGNA refund only the overpayments identified for the sampled beneficiaries rather than refund the estimated overpayments and (2) added a recommendation that CIGNA work with CMS to determine the correct contract-level adjustments for the estimated overpayments.

Regarding CMS's 2006 Participant Guide, we based our findings on criteria set forth in CMS's 2007 Participant Guide. After our review, we compared the data submission criteria in the 2006 and 2007 Participant Guides and determined that there were no substantive differences in the criteria upon which we based our results.

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# INTRODUCTION

## BACKGROUND

### Medicare Advantage Program

The Balanced Budget Act of 1997, P.L. No. 105-33, established Medicare Part C to offer beneficiaries managed care options through the Medicare+Choice program. Section 201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, revised Medicare Part C and renamed the program the Medicare Advantage (MA) program. Organizations that participate in the MA program include health maintenance organizations, preferred provider organizations, provider-sponsored organizations, and private fee-for-service (FFS) plans. The Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program, makes monthly capitated payments to MA organizations for beneficiaries enrolled in the organizations' health care plans (beneficiaries).

### Risk-Adjusted Payments

Subsections 1853(a)(1)(C) and (a)(3) of the Social Security Act require that payments to MA organizations be adjusted based on the health status of each beneficiary. In calendar year (CY) 2004, CMS implemented the Hierarchical Condition Category (HCC) model (the CMS model) to calculate these risk-adjusted payments.

Under the CMS model, MA organizations collect risk adjustment data, including beneficiary diagnoses, from hospital inpatient facilities, hospital outpatient facilities, and physicians during a data collection period.<sup>1</sup> MA organizations identify the diagnoses relevant to the model and submit them to CMS. CMS categorizes the diagnoses into groups of clinically related diseases called HCCs and uses the HCCs, as well as demographic characteristics, to calculate a risk score for each beneficiary. CMS then uses the risk scores to adjust the monthly capitated payments to MA organizations for the next payment period.<sup>2</sup>

### Federal Requirements

Regulations (42 CFR § 422.310(b)) require MA organizations to submit risk adjustment data to CMS in accordance with CMS instructions. CMS issued instructions in its *2006 Risk Adjustment Data Basic Training for Medicare Advantage Organizations Participant Guide* (the 2006 Participant Guide) that provided requirements for submitting risk adjustment data for the CY 2006 data collection period. CMS issued similar instructions in its *2007 Risk Adjustment Data Training for Medicare Advantage Organizations Participant Guide* (the 2007 Participant Guide).

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<sup>1</sup> Risk adjustment data also include health insurance claim numbers, provider types, and the from and through dates for the services.

<sup>2</sup> For example, CMS used data that MA organizations submitted for the CY 2006 data collection period to adjust payments for the CY 2007 payment period.

Diagnoses included in risk adjustment data must be based on clinical medical record documentation from a face-to-face encounter; coded according to the *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* (the Coding Guidelines); assigned based on dates of service within the data collection period; and submitted to the MA organization from an appropriate risk adjustment provider type and an appropriate risk adjustment physician data source. The 2006 and 2007 Participant Guides described requirements for hospital inpatient, hospital outpatient, and physician documentation.

### **CIGNA Healthcare of Arizona, Inc.**

CIGNA Healthcare of Arizona, Inc. (CIGNA), is an MA organization. For CY 2007, CIGNA had one contract with CMS, contract H0354, which we refer to as “the contract.” Under the contract, CMS paid CIGNA approximately \$328 million to administer health care plans for approximately 31,677 beneficiaries.

## **OBJECTIVE, SCOPE, AND METHODOLOGY**

### **Objective**

Our objective was to determine whether the diagnoses that CIGNA submitted to CMS for use in CMS’s risk score calculations complied with Federal requirements.

### **Scope**

Our review covered approximately \$210 million of the CY 2007 MA organization payments that CMS made to CIGNA on behalf of 18,821 beneficiaries. These payments were based on risk adjustment data that CIGNA submitted to CMS for CY 2006 dates of service for beneficiaries who (1) were continuously enrolled under the contract during all of CY 2006 and January of CY 2007<sup>3</sup> and (2) had a CY 2007 risk score that was based on at least one HCC. We limited our review of CIGNA’s internal control structure to controls over the collection, processing, and submission of risk adjustment data.

We asked CIGNA to provide us with the one medical record that best supported the HCC(s) that CMS used to calculate each risk score. If our review found that a medical record did not support one or more assigned HCCs, we provided CIGNA with the opportunity to submit an additional medical record for a second medical review.

We performed our fieldwork at CIGNA in Phoenix, Arizona, and at CMS in Baltimore, Maryland, from December 2008 through November 2009.

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<sup>3</sup> We limited our sampling frame to continuously enrolled beneficiaries to ensure that CIGNA was responsible for submitting the risk adjustment data that resulted in the risk scores covered by our review.

## Methodology

To accomplish our objective, we did the following:

- We reviewed applicable Federal laws, regulations, and guidance regarding payments to MA organizations.
- We interviewed CMS officials to obtain an understanding of the CMS model.
- We obtained the services of a medical review contractor to determine whether the documentation that CIGNA submitted supported the HCCs associated with the beneficiaries in our sample.
- We interviewed CIGNA officials to gain an understanding of CIGNA’s internal controls for obtaining risk adjustment data from providers, processing the data, and submitting the data to CMS.
- We obtained enrollment data, CY 2007 beneficiary risk score data, and CY 2006 risk adjustment data from CMS and identified 18,821 beneficiaries who (1) were continuously enrolled under the contract during all of CY 2006 and January of CY 2007 and (2) had a CY 2007 risk score that was based on at least 1 HCC.
- We selected a simple random sample of 100 beneficiaries with 314 HCCs. (See Appendix A for our sample design and methodology.) For each sampled beneficiary, we:
  - analyzed the CY 2007 beneficiary risk score data to identify the HCC(s) that CMS assigned;
  - analyzed the CY 2006 risk adjustment data to identify the diagnosis or diagnoses that CIGNA submitted to CMS associated with the beneficiary’s HCC(s);
  - requested that CIGNA provide us with the one medical record that, in CIGNA’s judgment, best supported the HCC(s) that CMS used to calculate the beneficiary’s risk score; and
  - obtained CIGNA’s certification that the documentation provided represented “the one best medical record to support the HCC.”<sup>4</sup>
- We submitted CIGNA’s documentation and HCCs for each beneficiary to our medical review contractor for a first medical review and requested additional documentation from

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<sup>4</sup> The 2006 Participant Guide, sections 8.2.3 and 8.2.3.1, and the 2007 Participant Guide, sections 7.2.3 and 7.2.3.1, required plans to select the “one best medical record” to support each HCC and indicated that the best medical record may include a range of consecutive dates (if the record is from a hospital inpatient provider) or one date (if the record is from a hospital outpatient or physician provider).

CIGNA for a second medical review if the medical review contractor found that documentation submitted during the first did not support the HCCs.<sup>5</sup>

- For HCCs that we questioned in our draft report with which CIGNA disagreed,<sup>6</sup> CIGNA provided additional information, which we submitted to our medical review contractor for a third review.
- For the sampled beneficiaries that we determined to have unsupported HCCs, we (1) used the medical review results to adjust the beneficiaries' risk scores, (2) recalculated CY 2007 payments using the adjusted risk scores, and (3) subtracted the recalculated CY 2007 payments from the actual CY 2007 payments to determine the overpayments and underpayments CMS made on behalf of the beneficiaries.
- We estimated the total value of overpayments based on our sample results. (See Appendix B for our sample results and estimates.)

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.

## FINDINGS AND RECOMMENDATIONS

The diagnoses that CIGNA submitted to CMS for use in CMS's risk score calculations did not always comply with Federal requirements. For 60 of the 100 beneficiaries in our sample, the risk scores calculated using the diagnoses that CIGNA submitted were valid. The risk scores for the remaining 40 beneficiaries were invalid because the diagnoses that CIGNA submitted were not supported for one or both of the following reasons:

- The documentation did not support the associated diagnosis.
- The diagnosis was unconfirmed.<sup>7</sup>

CIGNA's policies and procedures were not effective for ensuring that the diagnoses it submitted to CMS complied with the requirements of the 2006 Participant Guide and the 2007 Participant

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<sup>5</sup> For any HCC determined to be unsupported during either round of medical review, the medical review contractor subjected the HCC to another review by staff unaware of the first reviewer's determination. If the two reviewers disagreed, the contractor's medical director made the final determination.

<sup>6</sup> CIGNA disagreed with 24 of the 71 HCCs questioned in our draft report.

<sup>7</sup> The 2006 and 2007 Participant Guides state that physicians and hospital outpatient departments may not code diagnoses documented as "probable," "suspected," "questionable," "rule out," or "working." The Participant Guides consider these diagnoses as unconfirmed. (See section 5.4.2 of the 2006 Participant Guide and section 6.4.2 of the 2007 Participant Guide.)

Guide. CIGNA's contracts required providers to submit accurate claims that complied with all Medicare requirements, and CIGNA officials stated that they relied on providers to submit accurate diagnoses in their claims. However, providers often reported incorrect diagnoses as a result of data entry errors and reported diagnoses for conditions that did not exist at the time of beneficiaries' encounters.

As a result of these unsupported and unconfirmed diagnoses, CIGNA received \$151,453 in overpayments from CMS. Based on our sample results, we estimated that CIGNA was overpaid approximately \$28,353,516 in CY 2007.

## **FEDERAL REQUIREMENTS**

Regulations (42 CFR § 422.310(b)) state: "Each MA organization must submit to CMS (in accordance with CMS instructions) 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. CMS may also collect data necessary to characterize the functional limitations of enrollees of each MA organization." The 2007 Participant Guide, section 8.7.3, and the 2006 Participant Guide, section 7.7.3, state that "MA organizations are responsible for the accuracy of the data submitted to CMS."

Pursuant to section 2.2.1 of the 2007 and 2006 Participant Guides, risk adjustment data submitted to CMS must include a diagnosis. Pursuant to the 2007 Participant Guide, section 7.1.4, and the 2006 Participant Guide, section 8.1.3, the diagnosis must be coded according to the Coding Guidelines. Section III of the Coding Guidelines states that for each hospital inpatient stay, the hospital's medical record reviewer should code the principal diagnosis and "... all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received and/or length of stay. Diagnoses that relate to an earlier episode which have no bearing on the current hospital stay are to be excluded." Sections II and III of the Coding Guidelines state that "if the diagnosis documented at the time of discharge is qualified as 'probable,' 'suspected,' 'likely,' 'questionable,' 'possible,' or 'still to be ruled out,' code the condition as if it existed or was established."

Section IV of the Coding Guidelines states that for each outpatient and physician service, the provider should "[c]ode all documented conditions that coexist at the time of the encounter/visit, and require or affect patient care treatment or management." The Coding Guidelines also state that conditions should not be coded if they "... were previously treated and no longer exist. However, history codes ... may be used as secondary codes if the historical condition or family history has an impact on current care or influences treatment." Additionally, in outpatient and physician settings, uncertain diagnoses, including those that are "probable," "suspected," "questionable," or "working," should not be coded.

## **UNSUPPORTED HIERARCHICAL CONDITION CATEGORIES**

To calculate beneficiary risk scores and risk-adjusted payments to MA organizations, CMS must first convert diagnoses to HCCs. During our audit period, CIGNA submitted to CMS at least one diagnosis associated with each HCC that CMS used to calculate each sampled beneficiary's risk

score for CY 2007. The risk scores for 40 sampled beneficiaries were invalid because the diagnoses that CIGNA submitted to CMS were not supported, confirmed, or both. These diagnoses were associated with 59 HCCs. Appendix C shows the documentation error or errors found for each of the 59 HCCs. These errors were for unsupported diagnosis coding and unconfirmed diagnoses.

### **Unsupported Diagnosis Coding**

The documentation that CIGNA submitted to us did not support the diagnoses associated with 53 HCCs. For 4 of the 53 HCCs, our medical reviewer determined other diagnoses to be more appropriate. In these instances, the documentation supported HCCs that were different from those that CMS used in determining the beneficiaries' risk scores. The following are examples of HCCs that were not supported by CIGNA's documentation.

- For one beneficiary, CIGNA submitted the diagnosis code for “congestive heart failure, unspecified.” CMS used the HCC associated with this diagnosis in calculating the beneficiary's risk score. However, the documentation that CIGNA provided indicated that the beneficiary visited the physician because of knee pain. The documentation did not support the diagnosis of congestive heart failure.
- For a second beneficiary, CIGNA submitted the diagnosis code for “major depressive disorder, recurrent episode, moderate.” CMS used the HCC associated with this diagnosis in calculating the beneficiary's risk score. Although the documentation that CIGNA provided stated that the patient suffered from panic attacks and depression, the documentation did not distinguish between single or recurrent episodes; nor did it specify the onset, duration, or severity of the illness. The documentation supported a code for “depressive disorder, not elsewhere classified,” which does not have an associated HCC.
- For a third beneficiary, CIGNA submitted the diagnosis code for “venous embolism and thrombosis of the deep vessels of distal lower extremity.” CMS used the HCC associated with this diagnosis in calculating the beneficiary's risk score. However, the documentation that CIGNA provided indicated that the patient's chief complaint was lower extremity pain and circulatory concerns. According to the documentation, the venous Doppler ultrasound showed no evidence of venous embolism.

### **Unconfirmed Diagnoses**

Six HCCs were unsupported because the diagnoses submitted to CMS were unconfirmed. For example, for one beneficiary, CIGNA submitted a diagnosis code for “probable congestive heart failure.” CMS used the HCC associated with this diagnosis in calculating the beneficiary's risk score. The documentation that CIGNA submitted noted that the provider determined a diagnosis of “probable congestive heart failure” and ordered an echocardiogram for confirmation. The results were not interpreted by the ordering physician. According to the 2006 and 2007 Participant Guides, diagnoses that are “probable,” “suspected,” “questionable,” or “working” should not be coded.

## **CAUSES OF OVERPAYMENTS**

As demonstrated by the significant error rate found in our sample, CIGNA's policies and procedures were not effective for ensuring that the diagnoses it submitted to CMS complied with the requirements of the 2006 and 2007 Participant Guides. CIGNA's contracts required providers to submit accurate claims that complied with all Medicare requirements, and CIGNA officials stated that they relied on providers to submit accurate diagnoses in their claims. However, providers often reported incorrect diagnoses as a result of data entry errors and reported diagnoses for conditions that did not exist at the time of beneficiaries' encounters.

## **ESTIMATED OVERPAYMENTS**

As a result of the unsupported and unconfirmed diagnoses in our sample, CIGNA received \$151,453 in overpayments from CMS. Based on our sample results, we estimated that CIGNA received approximately \$28,353,516 in additional overpayments for CY 2007. However, while an analysis to determine the potential impact of error rates inherent in FFS data on MA payments was beyond the scope of our audit, we acknowledge that CMS is studying this issue and its potential impact on audits of MA organizations.<sup>8</sup>

Therefore, because of the potential impact of these error rates on the CMS model that we used to recalculate MA payments for the beneficiaries in our sample, we (1) modified one recommendation to have CIGNA refund only the overpayments identified for the sampled beneficiaries rather than refund the estimated overpayments and (2) added a recommendation that CIGNA work with CMS to determine the correct contract-level adjustments for the estimated overpayments.

## **RECOMMENDATIONS**

We recommend the following:

- CIGNA should refund to the Federal Government \$151,453 in overpayments identified for the sampled beneficiaries;
- CIGNA should work with CMS to determine the correct contract-level adjustment for the additional \$28,353,516<sup>9</sup> of projected overpayments.
- CIGNA should improve its current policies and procedures to ensure compliance with the Federal requirements.

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<sup>8</sup> 75 Fed. Reg. 19749 (April 15, 2010).

<sup>9</sup> This amount represents our point estimate of \$28,504,969 less our identified overpayments of \$151,453 for the sampled beneficiaries. The confidence interval for this estimate has a lower limit of \$20.7 million and an upper limit of \$36.3 million. See Appendix B.

## **CIGNA COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report and in followup communications, CIGNA disagreed with our findings and said that our analysis, methodology, and extrapolation were flawed. CIGNA also stated that our audit results did not account for error rates inherent in Medicare FFS data, specifically the disparity between FFS claim data and FFS medical records data and the disparity's potential impact on MA payments. In addition, CIGNA said that we should have used the 2006 Participant Guide to evaluate CIGNA's compliance with CMS's requirements.

CIGNA disagreed with the results of our first and second medical reviews for 24 HCCs and provided us with additional documentation (not previously provided) as to why the HCCs were supported. CIGNA stated that the medical records for 17 of the 24 HCCs were not coded according to CMS's coding guidelines, but added that CIGNA should be eligible for the associated risk adjustment payments because it could support the underlying diagnoses through other means. Because the documentation did not meet CMS's coding guidelines, we did not submit it to our medical review contractor. CIGNA stated, however, that the medical records for the seven remaining HCCs complied with CMS's coding guidelines. We submitted the documentation for the seven HCCs to our medical review contractor for a third medical review and revised our findings accordingly.

CIGNA stated that correcting errors made by our medical review contractor would reduce the extrapolated overpayment to approximately \$440,000.

CIGNA's comments on our draft are included as Appendix D. We excluded the attachments to the comments because they contained personally identifiable information.

Although an analysis to determine the potential impact of error rates inherent in FFS data on MA payments was beyond the scope of our audit, we acknowledge that CMS is studying this issue and its potential impact on audits of MA organizations.<sup>10</sup> Therefore, because of the potential impact of these error rates on the CMS model that we used to recalculate MA payments for the beneficiaries in our sample, we (1) modified one recommendation to have CIGNA refund only the overpayments identified for the sampled beneficiaries rather than refund the estimated overpayments and (2) added a recommendation that CIGNA work with CMS to determine the correct contract-level adjustments for the estimated overpayments.

Regarding CMS's 2006 Participant Guide, we based our findings on criteria set forth in CMS's 2007 Participant Guide. After our review, we compared the data submission criteria in the 2006 and 2007 Participant Guides and determined that there were no substantive differences in the criteria upon which we based our results.

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<sup>10</sup> 75 Fed. Reg. 19749 (April 15, 2010).

## **Centers for Medicare & Medicaid Services Model**

### *CIGNA Comments*

CIGNA stated that the CMS payment model should not be used as an audit tool to compute payment errors because (1) the determination of HCCs for payment is not equivalent to audit evaluation of HCCs from medical records, (2) the CMS model was not designed to produce results for individual members on audit, and (3) use of the CMS model for audit requires a substantial adjustment to the applicable statistical confidence level.

### *Office of Inspector General Response*

According to section 6.5 of the 2007 Participant Guide and section 5.5 of the 2006 Participant Guide, reported diagnoses must be supported with medical record documentation. We used medical records as inputs to support HCCs because medical records must support the diagnoses that were used to assign the HCCs.

Our use of the CMS model and supporting medical records was consistent with the method that CMS used to compute CIGNA's monthly contract-level capitation payments. We agree that the CMS model is designed to make a cost prediction for the average beneficiary in a subgroup, and we have never asserted that the payments we recalculated after adjusting the risk scores based on validated HCCs were any more or less accurate for a given beneficiary than what the CMS model was designed to predict.

CMS officials told us that capitated payments made to MA plans for individual beneficiaries are fixed and have never been retroactively adjusted. We estimated the overpayment amount using the point estimate (Appendix B). Any attempt on our part to modify the CMS model to calculate CIGNA's CY 2007 payments would have been speculative and beyond the scope of our audit.

## **Random Sample**

### *CIGNA Comments*

CIGNA stated that our sample of 100 beneficiaries did not fully represent the 18,821 members who had a risk score based on at least 1 HCC during our audit period. CIGNA said that because only 47 of the 69 HCCs that appeared in the population were represented in our audit sample, our sample did not accurately represent the population. CIGNA also stated that our failure to include 13,400 beneficiaries (who did not have an HCC) skewed "... the audit results in favor of a higher alleged overpayment amount."

### *Office of Inspector General Response*

Our sample size of 100 beneficiaries provided a fair and unbiased representation of the 18,821 members in our sampling frame.

A random sample is not required to contain one or more items from every subgroup within a sampling frame because a very small HCC subgroup would have only a small probability of inclusion in the sample. Of the 22 HCCs not represented in our sample, all had a frequency of less than 1 percent of the sampling frame.

Our objective was to determine whether the diagnoses that CIGNA submitted to CMS for use in CMS's risk score calculations complied with Federal requirements. Beneficiaries who did not have diagnoses originally reported to CMS were outside the scope of our audit.

## **Audit Methodology**

### *CIGNA Comments*

CIGNA stated that the extrapolation of the payment error to the entire membership of enrollees with one HCC is not warranted in routine risk adjustment data validation (RADV) audits. Specifically, CIGNA stated that there is no precedent for extrapolation under Medicare managed care. CIGNA cited three previous audits for which we selected a statistical random sample but did not recommend that the managed care plan refund extrapolated overpayments.

CIGNA also said that our extrapolation should be limited to instances in which plans have exhibited a sustained level or pattern of errors and that "... [t]here has been no suggestion of such a level or pattern in this audit." CIGNA added that "[i]t is unfair and inappropriate to seek contract-level extrapolated payment adjustments for the first year that payments to Medicare Advantage organizations were 100 [percent] risk-adjusted."

In addition, CIGNA stated that we should await further CMS guidance on adjustments intended to correct significant deficiencies in the RADV audit methodology. Specifically, CIGNA stated that any audit of the Medicare Advantage risk data must take into account the circumstances of the underlying Medicare FFS data used to develop the model.

### *Office of Inspector General Response*

Pursuant to the Inspector General Act of 1978, 5 U.S.C. App., our audits are intended to provide an independent assessment of U.S. Department of Health and Human Services programs and operations. Accordingly, we do not always determine, nor are we required to determine, whether our payment calculation and extrapolation methodology are consistent with CMS's methodology.

The three audits to which CIGNA referred, in which we selected a statistical random sample but did not recommend that the managed care plans refund extrapolated overpayments, used different audit methodologies. Accordingly, we made recommendations to recover overpayments in accordance with our policies and procedures for those audits.

For our audit of CIGNA, we designed our review to determine whether diagnoses that CIGNA submitted for use in CMS's risk score calculations complied with Federal requirements. In

addition, we describe our payment error calculation and extrapolation methodology in Appendixes A and B.

Our methodology to recalculate the MA payments was appropriate because we used the CMS model to calculate CIGNA's monthly contract-level capitation payments. An analysis to determine the potential impact of error rates inherent in Medicare FFS data on MA payments was outside the scope of this audit. However, in its Final Rule, "Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," CMS stated that there may be merit in further refining the calculation of payment errors that result from postpayment validation efforts.<sup>11</sup> Given the potential impact of this error rate on the CMS model that we used to recalculate MA payments, we modified our first recommendation to seek a refund only for the overpayments identified for the sampled beneficiaries. We also added a recommendation that CIGNA work with CMS to determine the correct contract-level adjustments for the estimated overpayments.

### **Departure From 2006 and 2007 Participant Guides**

#### *CIGNA Comments*

CIGNA stated that our review of medical records did not include certain processes included in CMS's 2006 and 2007 Participant Guides.

CIGNA stated that the independent medical reviewers should have included a physician to assess whether any clinical factors may have changed the outcome in certain cases. CIGNA added that to facilitate the audit process, it should have been given the identity of our medical reviewer because medical record chart review is often a subjective process.

CIGNA said that when conducting RADV audits, CMS contracts with two independent medical review contractors to conduct its medical reviews but that we did not. During CMS medical reviews, one contractor facilitates the process and conducts the initial medical review of medical records. Discrepancies identified by this contractor are subject to another review by a second contractor. CIGNA added that the use of two contractors mitigates discrepancies and said that our process did not provide the same procedural protections.

In addition, CIGNA said that we should have used the 2006 Participant Guide to evaluate CIGNA's compliance with CMS's requirements.

Further, CIGNA stated that we should follow the CMS appeals process that would have allowed CIGNA to provide additional medical record documentation to our medical reviewers. The 2006 and 2007 Participant Guides require MA organizations to submit a clearly documented reason for disagreement with medical review findings.

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<sup>11</sup> 75 Fed. Reg. 19749 (April 15, 2010).

### *Office of Inspector General Response*

We are not required by law to follow CMS guidance and regulations governing RADV audits. Pursuant to the Inspector General Act of 1978, 5 U.S.C. App., our audits are intended to provide an independent assessment of U.S. Department of Health and Human Services programs and operations. We did not perform an RADV audit pursuant to the guidelines that CMS established in its 2006 and 2007 Participant Guides. Those reviews are a CMS function. We designed our review to determine whether diagnoses that CIGNA submitted for use in CMS's risk score calculations complied with Federal requirements.

Regarding CMS's 2006 Participant Guide, we based our findings on criteria set forth in CMS's 2007 Participant Guide. After our review, we compared the data submission criteria in both the 2006 and 2007 Participant Guides and determined that there were no substantive differences in the criteria upon which we based our results.

Although we did not have two independent contractors review CIGNA's medical record documentation, we ensured that our medical review contractor had an independent review process in place. If the initial medical reviewer identified discrepancies, another medical reviewer, independent of the initial review and unaware of the first reviewer's determination, performed a second review. If the results of both reviews differed, the contractor's medical director made the final determination. If we found that medical records did not support one or more assigned HCCs, we asked CIGNA to submit additional medical records. Any additional records CIGNA provided went through the process described above.

Also, we accepted medical records CIGNA provided in addition to the "one best medical record." All HCCs that were not validated during the initial medical review were subjected to the second medical review described above.

### **Physician Signature Attestations**

#### *CIGNA Comments*

Our draft report included a finding regarding missing physician signatures or credentials. CIGNA stated that we should follow CMS's methodology of allowing physician signature attestations to address any discrepancies due solely to missing or illegible physician signatures or credentials in the documentation. CIGNA added that, as a result, we identified four HCCs that were invalid because they did not have physician signatures and credentials.

### *Office of Inspector General Response*

We did not initially accept physician attestations because the 2007 Participant Guide, section 7.2.4.5, and the 2006 Participant Guide, section 8.2.4.4, state that documentation supporting the diagnosis must include an acceptable physician signature. However, in keeping with a 2010 change in Federal regulations (42 CFR § 422.311), we accepted attestations and revised our findings accordingly.

## **Limitations and Overreliance on Physician Coding Accuracy**

### *CIGNA Comments*

CIGNA stated that CMS’s methodology of limiting MA organizations to specific types of medical records for risk adjustment purposes is too restrictive and ignores other sources that would validate an HCC. CIGNA also said that it disagreed with CMS’s “one best medical record requirement” for validation purposes. CIGNA added that some of the HCCs identify chronic health care conditions that are not curable but that will not necessarily be diagnosed or even noted on every medical record. CIGNA stated that the 2006 and 2007 Participant Guides recognize the usefulness of alternative data sources and said that we should accept these sources for risk adjustment purposes.

### *Office of Inspector General Response*

As stated previously, we did not design our review to be a RADV audit, and we are not required to follow CMS’s RADV audit protocol. Our use of the CMS payment model and supporting medical records was consistent with the method that CMS used to compute CIGNA’s monthly contract-level capitation payments. We also accepted medical records provided by CIGNA in addition to the “one best medical record” required by the 2006 and 2007 Participant Guides to help validate HCCs. CMS developed the payment model with inpatient, outpatient, and physician records that are used to support HCCs. Therefore, we accepted and reviewed only those types of records for CY 2006 dates of service. Regarding alternative data sources, the sections of the 2006 and 2007 Participant Guides to which CIGNA referred prohibit MA organizations from substituting alternative data sources for diagnoses from a hospital or physician.

## **Additional Hierarchical Condition Categories**

### *CIGNA Comments*

CIGNA stated that, contrary to CMS practice, we did not consider additional HCCs that were identified incidentally during the audit. Specifically, CIGNA said that we did not credit it for HCCs that had been documented in the medical records and identified during the medical review but not reported to CMS. CIGNA added that it would have received credit for these HCCs under established CMS standards and practices. Further, CIGNA stated that we made explicit representations to include “underpayments” (for incidental HCCs) in our audit and then later retracted those representations.

### *Office of Inspector General Response*

Our objective was to determine whether the diagnoses that CIGNA submitted to CMS for use in CMS’s risk score calculations complied with Federal requirements. Additional diagnoses that were not originally reported to CMS were outside the scope of our audit. Further, we did not retract our representation regarding underpayments, but rather clarified that we did not consider additional HCCs within the scope of our audit.

## **Invalidated Hierarchical Condition Categories**

### *CIGNA Comments*

CIGNA said that our process should include "... a full, fair and independent review by a second, qualified [medical review contractor] of the Plan's position as to each of the 28 HCC discrepancies and the additional HCC documentation and other information provided by the Plan."

CIGNA stated that it had conducted its own review of the 28 medical records and concluded that 24 of the HCCs invalidated by our medical record review contractor were supported by medical record documentation. CIGNA provided us with additional documentation (not previously provided) as to why the HCCs were supported. CIGNA categorized the disputed HCCs into 2 groups: additional documentation that complied with CMS coding guidelines (7 HCCs) and additional documentation that did not meet coding guidelines but in which the clinical assessment supported the appropriateness of the diagnosis (17 HCCs).

For the remaining four HCCs, CIGNA stated that a physician attestation was provided to resolve discrepancies.

### *Office of Inspector General Response*

We accepted and evaluated the additional documentation that CIGNA provided for the 24 HCCs. In cases when CIGNA stated that the documentation met CMS coding guidelines, we submitted the additional documentation to our medical review contractor for a third medical review. We accepted the additional inpatient, outpatient, and physician records with CY 2006 dates of services to help validate seven HCCs that met CMS coding guidelines and for which our medical review contractor did not find support during the first two medical reviews. For the third medical review, our medical review contractor followed the same protocol used during each of the first two reviews. Our medical review contractor found support in this additional documentation that validated three of the seven HCCs. We revised our findings accordingly.

We did not submit the documentation to our medical reviewers for the 17 HCCs that, as CIGNA stated, did not comply with coding guidelines.

As previously discussed, we accepted attestations and revised our findings accordingly.

## **Policies and Procedures**

### *CIGNA Comments*

In response to our recommendation for improving its controls, CIGNA stated that it had processes in place designed to prevent and detect coding errors for 2006 data submissions. CIGNA also stated that it has education and audit programs "... in its effort to assure that provider documentation and coding fully support the ... codes submitted by [CIGNA] to CMS

for risk adjustment.” CIGNA requested that this recommendation be removed from the final report.

*Office of Inspector General Response*

We continue to recommend that CIGNA improve its current policies and procedures. CIGNA officials stated that they relied on providers to submit accurate diagnoses in their claims. However, providers often reported incorrect diagnoses as a result of data entry errors and reported diagnoses for conditions that did not exist at the time of beneficiaries’ encounters.

# **APPENDIXES**

## **APPENDIX A: SAMPLE DESIGN AND METHODOLOGY**

### **SAMPLING FRAME**

The sampling frame consisted of 18,821 beneficiaries on whose behalf the Centers for Medicare & Medicaid Services paid CIGNA Healthcare of Arizona, Inc. (CIGNA), approximately \$210 million in calendar year (CY) 2007. These beneficiaries (1) were continuously enrolled under contract H0354 during all of CY 2006 and January of CY 2007 and (2) had a CY 2007 risk score that was based on at least one Hierarchical Condition Category.

### **SAMPLE UNIT**

The sample unit was a beneficiary.

### **SAMPLE DESIGN**

We used a simple random sample.

### **SAMPLE SIZE**

We selected a sample of 100 beneficiaries.

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

We used Office of Inspector General, Office of Audit Services, statistical software to generate the random numbers.

### **METHOD OF SELECTING SAMPLE ITEMS**

We consecutively numbered the sample units in the sampling frame from 1 to 18,821. After generating 100 random numbers, we selected the corresponding frame items.

### **ESTIMATION METHODOLOGY**

We used Office of Inspector General, Office of Audit Services, statistical software to estimate the total value of overpayments.

## APPENDIX B: SAMPLE RESULTS AND ESTIMATES

### Sample Results

Sampling Frame Size	Sample Size	Value of Sample	Number of Beneficiaries With Incorrect Payments	Value of Overpayments
18,821	100	\$1,111,970	40	\$151,453

### Estimated Value of Overpayments

*(Limits Calculated for a 90-Percent Confidence Interval)*

Point estimate	\$28,504,969
Lower limit	20,700,567
Upper limit	36,309,371

**APPENDIX C: DOCUMENTATION ERRORS IN SAMPLE**

<b>A</b>	Unsupported diagnosis coding
<b>B</b>	Unconfirmed diagnosis

	<b>Hierarchical Condition Category</b>	<b>A</b>	<b>B</b>	<b>Total Errors</b>
1	Mechanical Complication of Cardiac Device, Implant, and Graft Due to Heart Valve Prosthesis	X		1
2	Rheumatoid Arthritis	X		1
3	Peripheral Vascular Disease, Unspecified	X		1
4	Unspecified Intestinal Malabsorption	X	X	2
5	Malignant Neoplasm of Small Intestine, Including Duodenum, Colon, Unspecified	X		1
6	Congestive Heart Failure, Unspecified	X		1
7	Other Specified Peripheral Vascular Diseases, Other, and Venous Embolism and Thrombosis of Deep Vessels of Proximal Lower Extremity	X	X	2
8	Nephritis and Nephropathy, Not Specified as Acute or Chronic, in Diseases Classified Elsewhere	X		1
9	Septic Shock	X		1
10	Occlusion or Cerebral Arteries, Cerebral Artery Occlusion, Unspecified	X		1
11	Venous Embolism and Thrombosis of Deep Vessels of Distal Lower Extremity	X		1
12	Atherosclerosis of the Extremities With Intermittent Claudication and Peripheral Vascular Disease, Unspecified	X		1
13	Diabetes With Renal Manifestations, Type II or Unspecified Type, Not Stated as Uncontrolled	X		1
14	Congestive Heart Failure, Unspecified	X	X	2
15	Malignant Neoplasm of Colon, Splenic Flexure	X		1
16	Esophageal Varices With Bleeding	X		1
17	Atherosclerosis of Aorta	X		1
18	Diabetes With Neurological Manifestations, Type II or Unspecified Type, Uncontrolled	X		1
19	Polyneuropathy in Diabetes	X		1
20	Major Depressive Disorder, Single Episode, Unspecified	X		1
21	Secondary Malignant Neoplasm of Respiratory and Digestive Systems, Lung	X		1
22	Anterior Horn Cell Disease, Unspecified	X		1
23	Hypoxemia and Acute Respiratory Failure	X		1

	<b>Hierarchical Condition Category</b>	<b>A</b>	<b>B</b>	<b>Total Errors</b>
24	Acute Myocardial Infarction, Unspecified Site, Subsequent Episode of Care	X		1
25	Atrial Fibrillation	X		1
26	Diabetes Mellitus Without Mention of Complication, Type II or Unspecified Type, Not Stated as Uncontrolled	X		1
27	Cauda Equina Syndrome With Neurogenic Bladder	X		1
28	Congestive Heart Failure, Unspecified	X		1
29	End-Stage Renal Disease	X		1
30	Hypoxemia	X		1
31	Malignant Neoplasm of Prostate	X		1
32	Chronic Airway Obstruction, Not Elsewhere Classified	X		1
33	Major Depressive Disorder, Single Episode, Moderate	X		1
34	Cerebral Artery Occlusion, Unspecified, With Cerebral Infarction	X		1
35	Chronic Kidney Disease, Unspecified	X		1
36	Epilepsy, Unspecified, Without Mention of Intractable Epilepsy	X		1
37	Major Depressive Disorder, Recurrent Episode, Moderate	X		1
38	Chronic Airway Obstruction, Not Elsewhere Classified	X		1
39	Other Primary Cardiomyopathies	X		1
40	Acute Myocardial Infarction of Other Anterior Wall, Initial Episode of Care	X		1
41	Unspecified Immunity Deficiency	X		1
42	Acute but Ill-Defined Cerebrovascular Disease	X		1
43	Chronic Airway Obstruction, Not Elsewhere Classified	X		1
44	Decubitus Ulcer, Elbow	X		1
45	Cerebral Artery Occlusion, Unspecified, With Cerebral Infarction	X		1
46	Intermediate Coronary Syndrome	X		1
47	Congestive Heart Failure, Unspecified	X	X	2
48	Other Disorders of Arteries and Arterioles, Stricture of Artery and Phlebitis and Thrombophlebitis, of Deep Vessels of Lower Extremities, Other	X	X	2
49	Other Disorders of Pancreatic Internal Secretion, Other Specified Disorders of Pancreatic Internal Secretions	X		1
50	Chronic Airway Obstruction, Not Elsewhere Classified	X		1
51	Pathologic Fracture of Vertebrae	X	X	2
52	Major Depressive Disorder, Recurrent Episode, Unspecified	X		1
53	Cardiac Dysrhythmias, Paroxysmal Supraventricular Tachycardia	X		1
	Total	53	6	59

**APPENDIX D: CIGNA COMMENTS**

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November 29, 2010

**VIA OVERNIGHT MAIL**

Patrick J. Cogley  
Regional Inspector General  
for Audit Services  
Department of Health and Human Services  
Office of Inspector General  
Office of Audit Services  
Region VII  
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**Re: Draft Audit Report No. A-07-10-01082  
Risk Adjustment Data Validation of Payments Made to CIGNA HealthCare  
of Arizona, Inc. for Calendar Year 2007 (Contract H0354)**

Dear Mr. Cogley:

We are in receipt of the above-referenced draft report on the risk adjustment data validation (“RADV”) audit of CIGNA HealthCare of Arizona, Inc. (the “Plan”) for calendar year 2007 (the “Draft Report”). We appreciated the opportunity to meet with you and other representatives from the Office of Inspector General (“OIG”) Office of Audit Services on September 21, 2010 to discuss the Plan’s concerns regarding the OIG’s audit and the Draft Report. This letter together with the attached exhibits and additional documentation being provided constitute the Plan’s response to the Draft Report’s preliminary findings and recommendations (the “Response”). For all of the reasons stated below, the Plan does not concur with the two recommendations made in the Draft Report.

## I. INTRODUCTION

The Draft Report indicates that the OIG provides auditing services for the Department of Health and Human Services (“HHS”) and that “[t]hese assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.” A key objective of risk adjusted payments to Medicare Advantage organizations is to encourage the provision of coverage to chronically ill Medicare beneficiaries who require a higher level of care than the average Medicare beneficiary.<sup>1</sup> However, the OIG audit process to date has accomplished neither of these goals and instead, has achieved quite the opposite. The flaws in the methodology and processes used by the OIG in performing the audit have resulted in Draft Report findings and a recommended adjustment that are erroneous, exaggerated, inequitable and inconsistent with the goals of the risk adjustment payment methodology.<sup>2</sup>

The Draft Report is based on an audit sample of only 100 Plan members out of the approximately 32,260 total Plan members enrolled during that time frame. Of those 100 members, the Draft Report makes findings with respect to 43 members and a recommended payment adjustment of \$23,635,074 on an extrapolated basis. The Plan does not concur with this recommendation. That the OIG could arrive at an adjustment of such magnitude based on 43 members is unfathomable. While there is always an inherent risk that monthly payments from CMS will be insufficient to cover the costs incurred in providing coverage to Medicare members,

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<sup>1</sup> In OIG Report No. A-05-00-00015, the OIG reported that “[r]isk adjustment factors will produce payments that more closely reflect the costs of providing care and reduce the disincentive to enroll sicker beneficiaries.”

<sup>2</sup> The goal of risk adjustment is to pay Medicare Advantage organizations “accurately and fairly by adjusting payment for enrollees based on demographic and health status.” 2006 Risk Adjustment Data Basic Training for Medicare Advantage Organizations Participant Guide (the “2006 Participant Guide”) at p. 1-1. In addition, the goal of the Centers for Medicare and Medicaid Services (“CMS”) in selecting the CMS-Hierarchical Condition Category (“HCC”) risk adjustment model was “to select a clinically sound risk adjustment model that improved payment accuracy **while minimizing the administrative burden on MA organizations.**” *Id.* at p. 1-4 (emphasis added). The logic of the Draft Report suggests that the only way to avoid an extrapolated amount of the magnitude at issue here would be to conduct a review of underlying medical records supporting each diagnosis code billed by a provider. As the Plan processes over one million claims per year (excluding pharmacy), such a review would not serve to minimize the Plan’s administrative burden.

Medicare Advantage organizations address that risk during the bid process by developing a bid that reflects the organization's best estimate of its anticipated health care costs in providing coverage to its members during that year. No Medicare Advantage organization, when pricing its bid for the 2007 contract year, could reasonably have anticipated that three years later, the OIG would recommend an unsupported retroactive payment adjustment of the size at issue in this audit, using the flawed methodology described in this Response. The Plan's objections are not a self-serving attempt to retain amounts to which it is not entitled. Rather, the Plan's objections reflect legitimate concerns regarding the government's recommendation for retroactive payment adjustments based on data and an audit methodology that are flawed.

Furthermore, applying retrospective adjustments to Medicare Advantage organization's risk scores undermines the actuarial soundness of the Medicare Advantage bidding and payment process. Retroactive contract-level adjustments based on the alleged lack of support for every physician-submitted diagnosis is totally inconsistent with the Medicare Advantage bidding process wherein a Medicare Advantage organization's supplemental benefits, member premiums, program savings, payments, and targeted margins are based on assumptions and methodologies known at the time the bid is prepared and submitted to CMS in the preceding June for the upcoming contract year (i.e., June 2006 for 2007 contract year). This is demonstrated by the example set forth in Exhibit 1.

## **II. BACKGROUND ON RISK ADJUSTMENT PAYMENT METHODOLOGY AND RISK ADJUSTMENT DATA VALIDATION AUDITS**

Congress created the Medicare+Choice program through the establishment of Medicare Part C as part of the Balanced Budget Act of 1997 (the "BBA").<sup>3</sup> Although private health plans had contracted with Medicare on a limited basis to provide services to eligible beneficiaries since the 1970s, the Medicare+Choice program was created to significantly increase the relationship between private health plans and Medicare. Prior to the BBA, payments to health plans for managing Medicare beneficiaries' health care were based on fee-for-service ("FFS")

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<sup>3</sup> Pub. L. No. 105-33.

expenditures, adjusted by geographic area and certain demographic factors (e.g., age, gender, working aged status, and Medicaid eligibility). Medicare+Choice began a transition from a demographic-based payment model to a model that uses a member's actual health status to estimate future health care costs.<sup>4</sup>

In 2003, Congress revamped the Medicare Part C program through the creation of the Medicare Advantage or "MA" program. Under the MA program, health plans are paid a capitated, risk-adjusted monthly fee for each member based upon the member's overall health. Medicare members are assigned a risk score that reflects their health status as determined from data submitted during the previous calendar year. The risk adjustment methodology utilizes diagnosis codes as specified by the International Classification of Disease, currently the Ninth Revision Clinical Modification guidelines ("ICD-9"), to determine members' risk scores, which are used to prospectively adjust capitation payments.

The current risk adjustment model employed in adjusting Medicare Advantage organizations' payments is known as the CMS-HCC payment model.<sup>5</sup> The CMS-HCC payment model (also referred to as the "Pope Model") categorizes ICD-9 codes into disease groups called Hierarchical Condition Categories or "HCCs." Each HCC includes diagnosis codes that are related clinically and have similar cost implications. Different values are assigned to each HCC relative to other HCCs based on an assessment of the underlying Medicare FFS expenses over a large population associated with each HCC's constellation of ICD-9 codes. Effective for the 2007 contract year, the demographic-adjusted payment methodology was completely phased out for Medicare Advantage organizations, with the result that 100% of each monthly payment for a Medicare Advantage member is risk-adjusted.<sup>6</sup>

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<sup>4</sup> Sherer, R., *The Failure of Medicare+Choice*, Geriatric Times 2003; 4:4-5.

<sup>5</sup> Pope, G.C., Kautter, J., Ellis R.P., et al., *Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model*, Health Care Financing Review 25(4):119-141, Summer 2004.

<sup>6</sup> 42 U.S.C. § 1395w-23(a)(1)(C).

As CMS phased in the health status risk adjustments over the period from 2000 through 2006, the financial impact of risk adjustment data became more significant and the complexities of the process increasingly apparent. CMS provided instructions to Medicare Advantage organizations regarding the submission of risk adjustment data through its annual Participant Guides.<sup>7</sup> The 2008 Participant Guide differed from the prior Participant Guides in at least one significant respect and to the disadvantage of Medicare Advantage organizations. The 2008 Participant Guide eliminated the ability of Medicare Advantage organizations to submit, on appeal and in support of the HCC payment received, the breadth of medical record documentation previously permitted under the 2006 and 2007 Participant Guides.<sup>8</sup>

In another development important to this Response, in July 2008, CMS announced a pilot project to more extensively audit Medicare Advantage organizations for payment year 2007 based on calendar year 2006 dates of service.<sup>9</sup> In its notice, CMS announced its intent to make contract-level payment adjustments using extrapolated payment error findings based on a sample of members from each Medicare Advantage organization selected for audit. This was a major change to CMS' RADV audit approach and signaled for the first time CMS' intent to recover contract-level payments from Medicare Advantage organizations. Prior to the pilot project, payment adjustments were limited to member-level adjustments for those members sampled in

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<sup>7</sup> For the 2007 calendar year, CMS payments were made based on 2006 dates of service. Accordingly, Medicare Advantage organizations relied on the 2006 Participant Guide to train providers how to code diagnoses and to submit ICD-9 codes to CMS in 2006. The 2007 Participant Guide, upon which the OIG incorrectly relied in performing this audit, was not released until December 2007.

<sup>8</sup> Compare 2006 Participant Guide at p. 8-19 and 2007 Participant Guide at p. 7-21 to 2008 Participant Guide at pp.7-21 and 22. Specifically, the 2006 and 2007 Participant Guides allow Medicare Advantage organizations to submit additional clinical documentation if the reviewers find that the one best medical record does not support the HCC. The 2008 Participant Guide eliminated the right to submit additional documentation, leaving Medicare Advantage organizations with only the right to dispute the reviewers' finding that the one best medical record did not support the HCC. The OIG has represented both on page 1 of the Draft Report and in comments made to the Plan during the September 21, 2010 meeting that it does not intend to apply the subsequently-issued and more restrictive 2008 Participant Guide to this 2007 payment year audit but rather, the 2007 version of the Participant Guide.

<sup>9</sup> See CMS Memorandum, *Medical Record Request Instructions for the Pilot Calendar Year 2007 Medicare Part C Risk Adjustment Data Validation*, July 17, 2008.

the payment validation audit.<sup>10</sup> CMS did make one significant accommodation to Medicare Advantage organizations in view of the potential impact of contract-level payment adjustments pursuant to the pilot and subsequent RADV audits -- CMS allowed Medicare Advantage organizations to submit physician attestations for physician and outpatient hospital records that were missing or had illegible physician signatures and/or credentials.<sup>11</sup>

Most recently, in April 2010, CMS finalized a regulation governing its RADV dispute and appeals procedures.<sup>12</sup> CMS incorporated into its regulations the “one best medical record” standard and other limitations on acceptable documentation that Medicare Advantage organizations may submit to support an HCC. However, in the preamble to the final rule, CMS indicated its intent to develop and release for public comment its RADV audit and extrapolation methodology. Significantly, this methodology has not yet been released (see discussion in Section V.B, below).<sup>13</sup> It is anticipated that this further guidance will go far towards correcting inequities that currently exist in the OIG audit process as described in this Response.

CMS has given varying degrees of consideration to issues negatively impacting Medicare Advantage organizations related to the development of risk adjustment data collection and validation policies and regulations over the past few years.<sup>14</sup> However, in assessing the accuracy

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<sup>10</sup> 74 Fed. Reg. 54634, 54674 (Oct. 22, 2009). To the Plan’s knowledge, CMS has not yet released any RADV audit report wherein CMS extrapolated payment errors to the contract level.

<sup>11</sup> See “MA and Part D Data: Who, What, Where, and How,” page 11 (Tom Hutchinson, 9/15/09 Slide Presentation to America’s Health Insurance Plans (“AHIP”)); See also, 75 Fed. Reg. 19678, 19742 (April 15, 2010).

<sup>12</sup> 75 Fed. Reg. 19678 (April 15, 2010) (codified at 42 C.F.R. §§ 422.2 and 422.311).

<sup>13</sup> *Id.* at 19746 (CMS “intend[s] to publish its RADV methodology in some type of public document—most likely, a Medicare Manual, so that the public can review and provide comment as it deems necessary. Finally, to ensure that audited organizations understand how their RADV error rate was calculated, as indicated in our proposed rule, we further intend to describe our RADV methodology in each audit.”)

<sup>14</sup> In a 2008 rulemaking, CMS expanded the data that it could collect for risk adjustment purposes to include data regarding each item and service provided to a Medicare Advantage plan member in order to improve the accuracy of risk adjustment payments. See 73 Fed. Reg. 48434 (August 19, 2008). According to the preamble, “once encounter data for MA enrollees are available, CMS would have beneficiary-specific information on the utilization of services of MA plan enrollees. These data could be

(continued...)

of CMS risk-adjusted payments to the Plan in the 2007 contract year, the OIG has entirely failed to consider the complexities of the risk adjustment payment system or to follow the procedures CMS has indicated are important to the fair conduct of RADV audits.

### **III. THE PLAN'S CONCERNS WITH THE DRAFT REPORT'S FINDINGS AND RECOMMENDATIONS**

Sections IV and V below describe major flaws in the OIG's RADV audit methodology, including application of the CMS-HCC payment model to this audit without an appropriate confidence level adjustment, inadequate sampling techniques, and proceeding without the benefit of forthcoming CMS guidance on an appropriate adjustment to be applied. Any decision to proceed further with the audit's current recommendations based on such faulty logic renders the OIG audit process indefensible.

Even if these substantive audit deficiencies are overlooked, Sections VI and VII go on to detail that the findings of the OIG's unidentified Medical Review Contractor ("MRC") regarding the specific 60 HCCs which form the basis for the OIG's extrapolation include significant errors. The Draft Report identifies 60 discrepancies<sup>15</sup> out of the 314 audited HCCs for 43 of the 100 members in the audit sample. According to the Draft Report, these alleged discrepancies resulted in an overpayment to the Plan of \$169,341 for the 43 members and a staggering estimated total overpayment to the Plan of \$23,635,074 when extrapolated over the 18,821 Plan members with at least one HCC.

However, as further outlined in Exhibits 2 and 3, these findings are to a large extent erroneous and accordingly the Plan is entitled to offset a considerable amount from the contract-level adjustment recommended in the Draft Report. Specifically, the Plan has validated 28 of the

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(continued)

used to calibrate the CMS-HCC risk adjustment models using MA patterns of diagnoses and expenditures." *Id.* at 48651.

<sup>15</sup> The Fact Sheet provided by the OIG at the November 2009 exit interview identified 59 HCC discrepancies. In December 2009, the OIG provided the Plan with an additional HCC discrepancy, for a total of 60 as indicated in the Draft Report.

60 alleged HCC discrepancies. Seven (7) HCCs met coding guidelines in effect on the date of service, seventeen (17) HCCs are supported by clinical assessment of the appropriateness of the diagnosis coded, and four (4) HCCs have been resolved by physician attestations as are allowed by CMS RADV procedures. Correcting for these 28 HCCs reduces the alleged \$169,341 sample error by \$69,026 to \$100,314 and reduces the alleged \$23.6 million extrapolated error amount by approximately \$11.8 million to \$11.7 million on a contract-level basis. Further, the Plan has identified nine (9) additional HCCs for the sampled members which the Plan had not previously reported and which were not identified by the OIG or its MRC,<sup>16</sup> despite the fact that the OIG expressly represented to the Plan that it would consider such underpayments in its findings and results.<sup>17</sup> Correcting for these 9 additional HCCs and two (2) disease interaction errors made by the OIG as described in Exhibit 5 further reduces the alleged sample error by another \$28,675 and reduces the alleged extrapolated error by another \$6.5 million on a contract level basis.<sup>18</sup>

Accordingly, even if the fatal flaws in the OIG's methodology identified below are disregarded, correction of the MRC's errors in reviewing the 60 HCCs and then offsetting the additional HCC underpayments as promised would together reduce the alleged overpayment on a member level by \$97,702 to \$71,639 and reduce the alleged extrapolated overpayment by \$18,333,970 to approximately \$5.2 million.

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<sup>16</sup> See Sections VII, VIII and Exhibit 3 for a detailed discussion of these four categories of HCCs.

<sup>17</sup> See Exhibit 4, which is the OIG's Entrance Conference Agenda for the audit. The agenda provides that the OIG "will also consider underpayments in our results." The OIG's subsequent retraction at the September 21, 2010 meeting of its explicit representation that the audit would take underpayments into account is discussed in Section V.I.D of this Response.

<sup>18</sup> In two cases, the payment adjustments calculated by the OIG for alleged HCC discrepancies reflected incorrect computations of disease interactions that comprise the CMS-HCC payment model. In one example, the OIG indicated that an error existed for a disease interaction that never impacted the member in the first place. Put another way, the OIG incorrectly assigned a disease interaction to the member for purposes of its analysis and then disallowed the disease interaction in the repayment calculation. These errors are corrected in the dollar adjustments described here and in Exhibit 2. Correcting for these two errors, reduces the extrapolated adjustment amount by over \$1.1 million. See Exhibit 5.

#### **IV. THE OIG RADV AUDIT METHODOLOGY IS FATALLY FLAWED**

Although the OIG asserts in its Draft Report that it used generally accepted auditing standards, it did not. As discussed in this Section IV, in conducting its audit and extrapolating an overpayment amount, the OIG disregarded several crucial aspects of risk adjustment and therefore biased the results and grossly exaggerated the alleged overpayment amount.

##### **A. The CMS-HCC Payment Model Should Not Be Used as an Audit Tool**

###### **1. Determination of HCCs for Payment is Not Equivalent to Audit Evaluation of HCCs from Medical Records**

Differences between HCCs derived from ICD-9 codes in claims or encounter data that are used by CMS for payment (“Payment HCCs”) and HCCs subsequently derived from medical records upon audit (“Audit HCCs”) are not payment errors, but are the result of two different inputs into the CMS-HCC payment model. *See* Exhibit 6.

First, the process of identifying Payment HCCs from ICD-9 codes is very different than the process of identifying HCCs from review of the underlying medical records for audit. Payment HCCs (used by CMS for 2007 payments) were derived by mapping ICD-9s through diagnosis groups, then condition categories, and applying hierarchies to arrive at HCCs. However, under the OIG RADV Audit HCC process, a sample of 100 members was selected and a determination made as to whether each Payment HCC assigned to each member was supported by “one best medical record” from the previous year. To the extent that the OIG MRC medical record review did not support the same Payment HCC assigned based on the submitted claim or encounter data, a payment error was identified. These very different processes for determining HCCs likely account for much of the inconsistency found between HCCs determined for payment and HCCs examined upon audit.

Second, information contained in ICD-9 codes is not equal to the information contained in the underlying medical records. Studies have shown that the diagnosis codes contained in

claims or encounter forms are inconsistent with diagnoses contained in medical records.<sup>19</sup> This inconsistency between Payment HCCs derived from ICD-9 codes in claims or encounter data and Audit HCCs derived from medical records is recognized in the industry.<sup>20</sup> There are a number of reasons why Payment HCCs are not equal to Audit HCCs. As noted above, the process used to determine HCCs from ICD-9 codes is different from the process used to develop HCCs from medical records. Further, coding and medical records in many cases contain different information. Reasons for this are many, and may include the lack of documentation in either claims or medical records; ambiguities in coding specific conditions; errors in coding or medical records; or differences in interpretation of medical notes, including lab results. Discrepancies and errors in diagnosis codes are well documented; indeed, CMS conducts regular coding audits and reports coding discrepancies and errors.<sup>21</sup> In fact, the authors of the CMS-HCC payment model themselves acknowledged the presence of judgment in coding and coding errors: “Concern about the quality of diagnostic reporting is the greatest in physician offices, where the diagnoses have not heretofore affected payment, and recording of diagnoses is less rigorously practiced than in hospitals.”<sup>22</sup>

Finally, even if Audit HCCs is an imprecise, but unbiased estimate of Payment HCCs, then the restrictive audit procedures used by the OIG in its audit of the Plan, including (i) inability of the Plan to introduce previously unreported HCCs, (ii) “one best medical record,” and (iii) excluding all Plan members with no HCCs from the audit, would result in a bias toward decreasing the number of HCCs and lower capitation payments. Given the inexact relationship between Audit HCCs and Payment HCCs and the one-sided audit rules listed above, OIG RADV audits will almost always result in equal or fewer HCCs and equal or lower capitation payments.

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<sup>19</sup> See e.g., Measuring Diagnoses: ICD Code Accuracy, Health Service Research 2005 October; 40 (5 Pt 2): 1620–1639. This article can be obtained at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1361216/>.

<sup>20</sup> *Id.*

<sup>21</sup> Semiannual reports are available at [http://www.cms.gov/apps/er\\_report](http://www.cms.gov/apps/er_report). According to the Medicare Fee-For-Service Improper Payments Report for November 2009, for example, improper coding contributed to a national error rate of 7.8%.

<sup>22</sup> Pope, *supra* at note 5, p. 121.

In sum, there are a number of reasons why HCCs determined from ICD-9 codes are not equal to HCCs identified from medical records. Although efforts to reduce coding errors are important, errors are unlikely to ever be completely eliminated as long as coding involves human interpretation, judgment and data entry.

2. The CMS-HCC Payment Model was Not Designed to Produce Results for Individual Members on Audit

The CMS-HCC payment model was developed to assign HCCs and predict costs over large populations. It was not designed to produce results for individual members. The model is used to take Medicare FFS data and from that data, determine the HCCs and make cost predictions for the average member with those particular HCCs in a relatively large subgroup. However, this average cost prediction does not accurately represent the costs associated with any one individual with a particular HCC or constellation of HCCs. There is substantial, unexplained variation among individual members with the same HCCs that is not accounted for. The CMS-HCC payment model simply was not designed to make accurate predictions of capitation payments as to any one individual member. Nevertheless, the OIG has used the CMS-HCC payment model as an audit tool to calculate a member-specific payment adjustment for each of the 43 members, and to then extrapolate the member-specific adjustments back out again across a diverse membership which to a significant extent, has a different set of HCCs. (See Exhibit 7).

This statistical error is referred to as an *ecological fallacy*, which is the erroneous assumption that individual members of a group have the *average* characteristics of the group at large. It is simply not accurate to make inferences about the nature of specific elements of a population based solely upon aggregate statistics collected for the group to which those individuals belong. Predictions made using the CMS-HCC payment model should only be applied to large populations of beneficiaries to ensure that random but significant differences among beneficiaries that are not captured by ICD-9 codes do not produce predicted capitation payments that deviate dramatically from actual values. Indeed, in the CMS-HCC payment model, all of the comparisons of predictive accuracy are made for large subcategories of

beneficiaries. Even as to some of those subgroups, the model can under or overpredict by as much as 30%.<sup>23</sup>

The inaccuracy of the OIG's methodology is apparent when one considers that the Plan's actual 2007 costs in providing coverage to the 43 members exceeded CMS capitation payments to the Plan for the same 43 members by over **\$525,000**, and actual 2007 costs for all 100 sampled members exceeded CMS payments to the Plan for those members by over **\$800,000**. (See Exhibit 8.) According to the OIG, "[t]he implementation of risk adjustment to the [Medicare managed care] payment system should lessen the disparity between Medicare payments and individual beneficiaries' medical costs."<sup>24</sup> The Plan's analysis shows that, even with risk adjustment, there is a significant disparity between costs incurred to cover chronically ill beneficiaries and CMS risk-adjusted payments for those members. This disparity is substantially expanded by the OIG's recommended retroactive contract-level payment adjustment.

3. Use of the CMS-HCC Payment Model for Audit Requires a Substantial Adjustment to the Applicable Statistical Confidence Level

As discussed above, it is inappropriate to use the CMS-HCC payment model as an audit tool. If used as such, a significant adjustment to the confidence interval computed by the OIG is required. The predictive accuracy of the CMS-HCC payment model is not that high even in predicting total aggregate capitation payments over large subpopulations of the data.<sup>25</sup> Thus, it is not surprising that the predictive accuracy of the model is low when applied to a very small sample such as the 100 members sampled in this audit.

To arrive at the estimated overpayment in this case, the OIG computed a standard 90% confidence interval based on the extrapolation of the results from the sample of 100 audited members to the population. The OIG's payment request is based on the lower bound of this

<sup>23</sup> Pope, *supra* at note 5, , Tables ES-3 through ES-6.

<sup>24</sup> OIG Memorandum enclosing OIG Report No. A-05-00-00015 at p. 2.

<sup>25</sup> The authors also devote significant sections of their report to discussions of the accuracy and in particular validation of the CMS-HCC payment model vis-à-vis several large subsets of the data. (See Pope, *supra* at note 5, Section 4.7, pp. 4-13 to 4-20).

confidence interval, to account for an estimate with high variability. However, the OIG calculation includes only the variance which arises from the fact that a sample rather than the full population was audited (“sampling variability”). The OIG’s analysis is incomplete because it overlooks the crucial fact that *the audit process itself* is based on a “regression model.” A regression model is a statistical tool used to model relationships between multiple variables based on a set of data and an underlying model of how the variables interact. The CMS-HCC model is really no different conceptually than any other regression model used to make predictions.

For example, one might consider a regression model which attempts to predict how much a particular drug lowers blood pressure, based on the weight of the patient. Even if such a model were estimated with a large set of underlying data on patients treated with the drug, the predictions would vary considerably due to other factors (such as gender and age) as well as the underlying variability in blood pressure (which can fluctuate throughout the day based on activity level). The high variability in the underlying data leads to a model whose predictions are more imprecise, which in turn requires wider confidence intervals around those predictions.

In the case of the CMS-HCC payment model, the underlying regression models utilize dozens of predictive variables, most related to various categorizations of diseases.<sup>26</sup> The CMS-HCC payment model can underpredict or overpredict significantly, even for large subsets containing thousands of patients.<sup>27</sup>

In order to assess the uncertainty of the CMS-HCC payment model as applied to the Plan and then translate that uncertainty into a further appropriate adjustment to the confidence levels

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<sup>26</sup> In chapter 5, *Diagnosis-Based Risk Adjustment Models*, the authors of the CMS-HCC payment model state: “In this chapter, we use the Medicare 1996/1997 5 percent sample analytic data described in Chapter 2 to estimate, develop, refine, and evaluate DCG/HCC prospective diagnosis-based risk adjustment models. A series of regression models are fit to the data, modified to enhance clinical credibility, and examined for their performance as risk adjustment models. We calculate measures of predictive accuracy of models at the individual level and for significant subgroups of Medicare beneficiaries.” The estimated coefficients and other summary statistics for the baseline model are contained in Pope, *supra* at note 5, Tables 4.1 and 4.2, pp. 4-25 and 4-26).

<sup>27</sup> Pope, *supra* at note 5, Table 4.8, pp. 4-55 to 4-57.

applied by the OIG, the Plan used the approach outlined in detail in Exhibit 9. The calculations outlined in Exhibit 9 result in a lower level confidence bound of \$12,727,724 which is much less than the OIG-reported lower confidence bound of \$23,572,284. Assuming that the Plan prevails on its arguments that the MRC's alleged HCC discrepancies are erroneous, the resulting lower confidence bound would be **negative \$4,012,472** -- significantly less than the lower confidence bound of \$5,238,314 described in Exhibit 9 at p. 4 (which includes only sampling variability and excludes the variability in the CMS-HCC payment model.) This lower confidence bound, which is less than zero, clearly demonstrates that the variance in the health status of the 18,821 Plan members from whom the sample was drawn is very high and supports a determination in this case that the overpayment is not different from zero.

Although statistical experts might propose different ways to obtain a more precise measure of the additional variance introduced into this RADV audit through the use of the CMS-HCC payment model, in the end, there can be no doubt that any adjustment made to the regression model in this case to account for the variability inherent in the CMS-HCC payment model will necessarily result in a lower confidence bound, and it is more than likely a significant reduction.

**B. The OIG Audit Sample is Not Fully Representative of the Member Population**

For the reasons summarized above, the CMS-HCC payment model should not be used as an audit tool without a significant adjustment to the confidence level. The flawed results produced by this approach and by failure to apply the anticipated CMS adjustment factor (see discussion in Section V.B) are further exacerbated by the flaws in the sampling and extrapolation methodology used by the OIG in this audit.

In order for the results of an audit sample to be reliably extrapolated to the population, the sample itself must be both random and representative of the population.<sup>28</sup> There are at least

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<sup>28</sup> See *Protestant Memorial Medical Center, Inc. v. Department of Public Aid*, 295 Ill. App. 3d 249; 255-256, 692 N.E.2d 861 (Ill. App. Ct. 1998) (A statistically valid sample must be composed of three criteria:

(continued...)

two ways that the sample should have been drawn to ensure representativeness. First, a larger sample would have had a higher probability of drawing all of the HCCs that were present among the Plan's membership during the relevant period. A sample size of 100 is simply too small. (Under established CMS standards, CMS generally draws a sample of at least 200 members when conducting a RADV audit.) The 100-member sample drawn by OIG was not fully representative of the 18,821 Plan members who had a risk score based on at least one HCC. Only 47 of the 69 HCCs that appear in this population are represented in the OIG audit sample. As such, the OIG's extrapolation applies to 22 HCCs that appear in the Plan population, but for whom no Plan members with these corresponding HCCs were audited by the OIG. Therefore, the small 100-member audit sample used in this case is not an accurate representation of the Plan members with a risk score based on at least one HCC. (See Exhibit 7.)

Second, the sample could have been stratified according to HCC by dividing the population into a subgroup for each HCC in the population and then drawing a random sample of diagnosis codes from each subgroup. Specifically, the audit sample could have been stratified so as to include at least one member for each of the 69 HCCs in the population to ensure that all of the relevant traits in the population were represented. Stratification would have ensured that the sample was more representative of the Plan membership with at least one HCC. Unlike OIG, it is our understanding that CMS does stratify its RADV audit samples. The lack of representativeness of the audit sample further and significantly reduces the reliability of the OIG's extrapolated overpayment determinations. (See Exhibit 7.)

The inadequacy of the OIG's sampling methodology and the adverse and unfair impact of extrapolation are demonstrated by the following example. Three (3) of the 100 members sampled were assigned to the same Plan contracted provider (Inspiris). Inspiris is responsible for the Plan's institutionalized members. Plan membership assigned to Inspiris in the OIG sample of

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(continued)

randomness, efficiency, and representativeness. If the basic underlying selection of a sample does not meet these three criteria, then no matter how sound the statistical methods applied are, the result is useless and invalid upon extrapolation.)

100 members was less than 1% (186/18,821), yet 3% of the 100 sampled members were assigned to this provider. In addition, the three Inspiris members accounted for 19 of the 314 OIG-sampled HCCs -- over 6% of the HCCs sampled. Thus, members assigned to this provider were over-represented in the audited sample. Moreover, these three audited members reflected 6 errors, accounting for 10% of the errors identified by OIG. The OIG extrapolated the HCC discrepancies associated with this provider over the entire 18,821 Plan member population that had at least one HCC. By post-stratifying the sample by Inspiris versus non-Inspiris members, the sample estimates can be reweighted from the two groups according to their population frequency while still providing a statistically reliable estimate. The effect of treating the Inspiris members as a separate stratum reduces the alleged overpayment by approximately \$900,000.

**V. THE OIG RADV AUDIT SHOULD BE DISCONTINUED UNTIL CMS HAS ACTED**

The OIG has conducted this audit, determined a payment error, extrapolated that payment error to the entire Plan membership having at least one HCC, and recommended a contract-level repayment amount, all without CMS having yet implemented the methodology that it will use for Medicare Advantage organizations and on which Medicare Advantage organizations have not had the opportunity to comment. For the reasons described below, the OIG's actions are inappropriate and premature.

**A. Extrapolation is Not Warranted in Routine RADV Audits**

1. There is No Precedent for Extrapolation under Medicare Managed Care

CMS and OIG audits of Medicare Advantage organizations (and predecessor Medicare managed care contractors) have historically resulted in recommended repayments as to the specific errors and members identified in the audit and have not been extrapolated to require repayment on a contract-level basis. During the Plan's September 21, 2010 meeting with the OIG, the OIG disagreed with this statement and sought to distinguish its prior audits of Medicare managed care plans where member level refunds were recommended from the OIG's RADV audit of the Plan. According to the OIG, prior OIG audits of institutionalized status payments to Medicare health plans reviewed all institutionalized status payments (as opposed to a sample)

made to the audited plan on behalf of members believed to satisfy the institutionalized status criteria. As a result, member level findings were appropriate in those audits.

However, the Plan's position – not the OIG's -- is borne out by a review of prior OIG audits, including the following:<sup>29</sup>

- In OIG Report No. A-05-94-00053, the OIG reviewed a random sample of 100 beneficiaries whom the audited plan had classified as institutionalized. The OIG determined that 15 of 100 beneficiaries did not meet applicable criteria for institutionalized status payments and that the plan was overpaid \$93,252 for the 15 beneficiaries. “On the basis of the sample, [the OIG projected] that at least \$861,615 of overpayments were made” to the plan. However, the OIG’s recommendations were that the plan refund the member level overpayments of \$93,252, and “review the balance of the institutionalized beneficiary universe to identify and refund additional overpayments, which [the OIG] estimate[s] to total at least \$861,615.”
- In OIG Report No. A-05-01-00070, the OIG determined that the audited plan received overpayments totaling \$11,089 for 13 beneficiaries out of “a statistical sample of 100 Medicare beneficiaries, reported as institutionalized” and, based on the OIG’s sample results, the OIG estimated that the plan received Medicare overpayments of \$98,689 for beneficiaries incorrectly reported as institutionalized. The OIG recommended that the plan refund the \$11,089 and review the balance of the institutionalized universe (890 beneficiaries) to identify and refund the additional overpayments, which the OIG had estimated to be \$98,689.

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<sup>29</sup> Other examples of OIG audit reports where member level adjustments were made include: OIG Report Nos. A-09-01-00056, A-03-00-00010, and A-03-98-00034.

- In OIG Report No. A-06-06-00104, the OIG reviewed whether the encounter data submitted by the audited plan were valid and accurate. The OIG “statistically selected” 100 beneficiary enrollment months, and determined that the risk factors CMS assigned to 13 beneficiaries were based on inpatient stays for which providers incorrectly coded the principal diagnoses. For the 13 beneficiaries, the OIG determined that the plan had received overpayments for 6 beneficiaries and underpayments for 3 beneficiaries. Using the OIG’s statistical software, the OIG estimated the amount of erroneous payments in the audit universe to be \$50,000 in overpayments. Despite identifying overpayments to the audited plan, the OIG’s recommendations did not include repayment of any amount. Instead, the OIG recommended that the plan:
  - Strengthen internal controls to ensure that providers maintain medical records;
  - Insert into provider contracts provisions that promote the accurate recording of encounter data; and
  - Train providers to code diagnoses accurately.

Thus, contrary to the OIG’s recollection as expressed at the September 21, 2010 meeting, OIG audit report precedent is to make member level adjustments only -- even when the OIG has calculated an extrapolated overpayment. Furthermore, where an extrapolated overpayment has been calculated by the OIG, the OIG has used the extrapolated amount as part of its recommendation that the audited plan engage in its own review and refund additional overpayments that the plan may subsequently identify. The Draft Report in this case goes considerably and unjustifiably beyond existing OIG precedent and should be modified accordingly.

## 2. Extrapolation Should be Limited to Sustained Errors

In addition, precedent under the Medicare program for the use of extrapolation involves situations where there is a sustained or high level of payment error.<sup>30</sup> In a prior ruling,<sup>31</sup> CMS (then the Health Care Financing Administration or “HCFA”) determined that HCFA and its Medicare contractors may use statistical sampling to project overpayments to providers and suppliers when claims are voluminous and reflect a pattern of erroneous billing or overutilization and when a case-by-case review is not administratively feasible.

In the context of CMS-HCC payment model risk-adjusted capitation rather than fee-for-service claim payments, the issue becomes whether the Plan has exhibited a sustained level or pattern of erroneous or otherwise inappropriately excessive diagnosis code submissions. There has been no suggestion of such a level or pattern in this audit. The Plan has simply had the financial misfortune of being randomly selected by the OIG for audit. Moreover, while it may not be administratively feasible for the OIG to review the medical record documentation underlying all of the Plan’s members with at least one HCC, a review of more than 100 records is not only feasible, but required, particularly where the OIG is conducting RADV audits of only a few Medicare Advantage organizations. In fact, in prior audits of Medicare managed care plans, the OIG audited the entire universe of relevant members. These prior OIG audits contradict the OIG’s use of such a small audit sample of 100 Plan members with at least one

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<sup>30</sup> See 42 U.S.C. § 1395ddd(f)(3) (A Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that - (A) there is a sustained or high level of payment error; or (B) documented educational intervention has failed to correct the payment error.

<sup>31</sup> HCFA Ruling No. HCFAR-86-1 (Feb. 20, 1986).

HCC to make a contract level repayment recommendation for a universe of approximately 18,821 members.<sup>32</sup>

### 3. Other Problems with Extrapolation

According to the CMS Medicare Program Integrity Manual,

The size of the sample (i.e., the number of sampling units) will have a direct bearing on the precision of the estimated overpayment, but it is not the only factor that influences precision. The standard error of the estimator also depends on (1) the underlying variation in the target population, (2) the particular sampling method that is employed (such as simple random, stratified, or cluster sampling), and (3) the particular form of the estimator that is used (e.g., simple expansion of the sample total by dividing by the selection rate, or more complicated methods such as ratio estimation). **It is neither possible nor desirable to specify a minimum sample size that applies to all situations.**<sup>33</sup>

During the September 21, 2010 meeting, OIG representatives vigorously defended the OIG audit sampling methodology, claiming that the methodology has been upheld by the courts on a number of occasions. Since that meeting, the Plan has attempted to identify a single court decision that has validated the OIG's audit sampling methodology. The Plan has yet to identify any such decision.

Further, in the relatively recent world of CMS-HCC payment model risk-adjusted capitation, it is equally unfair to extrapolate audit results based on ever-changing and retroactively-applied rules regarding what documentation can be used to validate a risk-adjusted payment. (How is a Medicare Advantage organization supposed to train a provider to bill using a coding rule that has not yet been created?) Retroactive application of increasingly narrow rules

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<sup>32</sup> See e.g., OIG Report No. A-09-00-00103 (OIG audited all 380 members for whom the plan received Medicaid special status payments); OIG Report No. A-07-02-00150 (OIG audited all 220 members for whom the plan received enhanced institutionalized status payments); and OIG Report No. A-07-03-00151 (OIG audited all 772 members for whom the plan received enhanced institutionalized status payments).

<sup>33</sup> Cited in *John v. Sebelius*, 2010 U.S. Dist. LEXIS 107854, \*9 (E.D. AK 2010) (emphasis added).

regarding what constitutes acceptable documentation in support of an HCC is fundamentally an unfair and inequitable approach, as further described in Section VII.

Extrapolation, if used, should be phased in over a period of time (i.e., the percentage of the extrapolated payment adjustment increasing each year until 100% extrapolation is implemented), with rules applicable to medical record review implemented on a prospective basis only. The CMS-HCC payment model was phased in over a period of several years, with 100% risk adjustment commencing in 2007. It is unfair and inappropriate to seek contract-level extrapolated payment adjustments for the first year that payments to Medicare Advantage organizations were 100% risk-adjusted.

In sum, extrapolation without a legitimate underlying concern as to sustained levels or patterns of diagnosis submission errors is unprecedented and inappropriate as to any Medicare Advantage organization. The Plan is a case in point. It is currently the number-one CMS star-rated plan in Maricopa County and has been a highly-regarded Medicare managed care plan for nearly 40 years. If the OIG publicly releases its unfounded recommendation that CMS recoup an alleged “overpayment” of the magnitude stated in the Draft Report, it is quite an understatement to say that the public perception of the Plan will be negatively impacted when the Plan’s only mistake was its immense misfortune of being randomly selected for this OIG RADV audit.

**B. The OIG RADV Audit is Premature and OIG Should Await Further CMS Guidance on Adjustments Intended to Correct Significant Deficiencies in RADV Audit Methodology**

It is significant to note that to date, CMS has not issued any RADV audit findings that extrapolate error rates on a contract-level basis, and has made only member-level adjustments in RADV audits. One of the principal reasons for this is that CMS is working to remedy the following concern.

To achieve a fair and accurate result, any audit of Medicare Advantage risk-adjusted data must take into account the circumstances of the underlying Medicare FFS data used to develop the model. The Medicare Advantage risk-adjusted payment model was developed using Medicare FFS claims data for the purpose of establishing “comparable” payments to Medicare Advantage organizations. These payments are intended to represent an actuarial estimate of the

risk present in Medicare Advantage organization plan membership relative to that of the Medicare FFS population.

The diagnosis data used by CMS to develop the risk scores for the HCC payment methodology is from Medicare FFS claims, which the Plan understands has a significant error rate. Medicare Advantage organizations cannot reasonably be expected to have a lower error rate than Medicare FFS since the same physicians submit claims under both programs. Extrapolated payment adjustments should be used, if ever, for Medicare Advantage organizations that have particularly high rates of unsupported diagnoses compared to unsupported Medicare FFS diagnoses upon which the CMS-HCC risk score data are based.<sup>34</sup>

It is our understanding that CMS intends to address this concern and avoid penalizing Medicare Advantage organizations for this error rate. CMS is currently working on the development of this FFS adjustment factor and perhaps other adjustments as well. In the preamble to its April 15, 2010 final rule, CMS declared its intent to ensure that the RADV process is transparent to audited Medicare Advantage organizations and the public.<sup>35</sup> CMS has expressly recognized that it is necessary to “refine the error rate calculation” to account for any error rates inherent in Medicare FFS data that affect MA error rates.<sup>36</sup> Under the CMS approach as the Plan understands it, Medicare Advantage organizations would be held accountable only for their specific error rate, i.e., the audited error rate that exceeds the FFS error rate.

CMS has statutory authority to administer the Medicare Advantage program in accordance with rules that it promulgates. *See* 42 U.S.C. §§ 1302(a), 1395w-27(b) and 1395hh(a)(1). CMS rules are entitled to deference. *See Fed. Express Corp. v. Holowecki*, 552 U.S. 389 (2008). Until a payment error calculation and extrapolation methodology is released by

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<sup>34</sup> The need for a FFS adjustment factor could potentially be eliminated once CMS, consistent with its August 19, 2008 rulemaking, has Medicare Advantage member-specific utilization data that could be used to recalibrate the CMS-HCC risk adjustment models.

<sup>35</sup> 75 Fed. Reg. 19678 at 19746 and 19753.

<sup>36</sup> *Id.* at 19746 and 19749.

CMS and the public has an opportunity to comment on such methodology, it is inappropriate for the OIG to proceed with recommending a contract-level adjustment using its current methodology.

**VI. THE PLAN IS ENTITLED TO A SECOND INDEPENDENT AND QUALIFIED MRC REVIEW**

Even if one were to disregard the deficiencies in the OIG RADV audit methodology described above, the OIG process is subject to additional challenges that the CMS process is not. The Plan believes that, if not discontinued for the reasons described above, the OIG audit process should be pended until CMS has released further guidance on adjustments to its RADV audit methodology and until there is a full, fair and independent review by a second, qualified MRC of the Plan's position as to each of the 28 HCC discrepancies and the additional HCC documentation and other information provided by the Plan. This independent MRC review should further apply the correct and appropriate documentation and review standards, as described below.<sup>37</sup> Finally and consistent with the 2006 and 2007 Participant Guides and in order to assure a clear understanding of the Plan Medical Director's clinical discussions and records for each disputed HCC attached to this Response, the Plan specifically requests that a physician be among the MRC reviewers "to assess whether any clinical factors may change the outcome".<sup>38</sup>

**A. The Plan was Denied Access to the Original OIG MRC and is Entitled to Review of That MRC's Findings by a Second, Independent MRC**

1. The Plan Was Not Told the Identity of or Permitted to Interact With the MRC

The OIG engaged an MRC for the purpose of determining whether the medical record documentation provided by the Plan to the OIG supported the reported diagnoses and resulting

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<sup>37</sup> Government Auditing Standards provide at § 8.36 that, in preparing a final audit report, "the auditors should modify their report as necessary if they find the comments valid and supported with sufficient, appropriate evidence."

<sup>38</sup> 2006 Participant Guide at p. 8-19; 2007 Participant Guide at p. 7-21.

HCC scores for the 100 sampled members. The OIG acknowledged to Plan staff that the OIG did not have the internal expertise to perform the review itself.<sup>39</sup> While the Plan may not object to the OIG's use of a contractor, the Plan does object to the "secrecy" surrounding the MRC. Specifically, the OIG would not provide the Plan with the name of the MRC or the credentials of the MRC's reviewers and, most significantly, the OIG would not allow the Plan to have any discussions with the MRC reviewers during the course of the audit.

The Plan does not understand why the OIG would not identify the MRC or allow MRC and Plan staff to interact during the audit process. Without knowing who the MRC was, the Plan was unable to evaluate whether the MRC's participation in this audit created any real or potential conflict of interest.<sup>40</sup> Furthermore, interaction between Plan and MRC staff would have facilitated the audit process, particularly as medical record chart review is oftentimes a subjective process. In fact, for 24 of the HCCs invalidated by the reviewers Category 1 (Coding) and Category 2 (Clinical), the Plan believes that the medical record documentation it submitted complies with CMS requirements and ICD-9 Coding Guidelines and/or that the applicable medical record documentation clinically supports the reported HCC.<sup>41</sup> A resolution with respect to these 24 HCCs could have been achieved before the Draft Report was issued, had discussions between Plan staff and the MRC reviewers been allowed. Such interaction could have also compensated for the OIG audit staff's lack of experience in this area.

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<sup>39</sup> Government auditing standards require that the audit staff possess adequate professional competence for the tasks required. *See* Government Auditing Standards at § 3.40. The audit staff should also possess a general knowledge of the environment in which the audited entity operates and the subject matter under review. *Id.* at § 3.43.

<sup>40</sup> Government Auditing Standards at § 3.02 provide that "[i]n all matters relating to the audit work, the audit organization and the individual auditor, whether government or public, must be free from personal, external, and organizational impairments to independence, and must avoid the appearance of such impairments of independence."

<sup>41</sup> *See* Section VIII; Exhibit 3.

2. The MRC Was Released by OIG Before the MRC Considered the Plan's Material Challenges to the MRC's Findings

On October 30, 2009 and prior to the audit exit conference in November 2009, the OIG provided the Plan with a "Part C Error Matrix" and Summary created by the MRC and requested that the Plan be prepared to discuss the alleged HCC discrepancies during the exit conference. Just prior to the November 2009 exit conference, the OIG further presented the Plan with a "Fact Sheet" that summarized the MRC's findings, which included 59 HCC discrepancies. It was at this point that the Plan was told that the extrapolated overpayment alleged by OIG exceeded \$23.6 million. In December 2009, the OIG provided the Plan with an additional HCC discrepancy (for a total of 60 as indicated in the Draft Report) and asked the Plan for its response, which the Plan provided. It is the Plan's understanding that shortly thereafter, the OIG released the MRC.

The OIG next told the Plan that the Draft Report would likely be issued in February 2010. However, by April 2010, the Draft Report had still not been issued and the Plan was hopeful that the delay was due to the OIG's efforts to engage a second MRC. On April 20, 2010 and pursuant to the OIG's April 15, 2010 request, the Plan submitted a more detailed response to the MRC's Error Matrix and Summary. Subsequent to the Plan's submission, the OIG informed the Plan that none of the additional information provided by the Plan would be considered for purposes of the Draft Report. Instead, on April 26, 2010, the OIG simply returned the same, unchanged version of the Part C Error Matrix and Summary from October 30, 2009, which was based exclusively on the original MRC's initial findings. Given the OIG's delay in issuing the Draft Report, the OIG should have retained a second and independent MRC to consider the Plan's April 20, 2010 submission before issuing the Draft Report.

The OIG's release of its MRC and the OIG's failure to retain a second independent MRC before the Plan submitted this Response to the Draft Report suggest that the Plan's responses to

the Draft Report's findings regarding specific HCCs may not be evaluated by a qualified reviewer before the final audit report is issued.<sup>42</sup>

3. The Plan is Entitled to an Independent MRC Review Before Any Final  
OIG Report is Issued

Principles of fundamental fairness dictate that the OIG should have identified the MRC and the Plan should have been allowed to review and discuss the MRC's preliminary findings with the MRC reviewers. This is particularly true given that the OIG released the MRC before it informed the Plan that the MRC's HCC discrepancy findings, when extrapolated, would result in a staggering recommended repayment amount in excess of \$23.6 million. Having missed that opportunity, the OIG should have retained the services of a second, independent MRC to review the Plan's revised April 20, 2010 Error Matrix and Summary submission, which the OIG specifically requested that the Plan provide, before it released its Draft Report in June 2010 (which the Plan had understandably further researched and supplemented after being told the amount of the recommended adjustment the OIG was going to make).

Having missed that opportunity as well, the OIG is compelled at this point in the process to retain a second, independent MRC to review the Plan's submissions before the OIG issues any final report.<sup>43</sup> This review should include the review of the findings of the original MRC, the information submitted by the Plan to OIG on April 20, 2010 pursuant to the OIG's request, the additional HCCs that the Plan identified in the audited sample that OIG represented it would consider, but did not, and the HCC information contained in this Response.

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<sup>42</sup> At the September 21, 2010 meeting, the OIG stated its intent to retain an MRC to review the Plan's response. However, as of the date of the Plan's Response, the OIG has yet to retain the MRC. Furthermore, the OIG has declined the Plan's request for assurances that the second MRC will be a separate firm independent of the first MRC. The OIG made clear at the meeting that it does not intend to reveal the identity of any second MRC or its coding staff and stated that it is unlikely the OIG will permit the Plan to interact with the second MRC. The OIG did allow the Plan an additional sixty (60) days beyond the original September 27, 2009 due date to submit this Response including further information for MRC review and OIG's consideration.

<sup>43</sup> The Plan welcomes the additional MRC review described by the OIG at the September 21, 2010 meeting, which the Plan hopes will be a comprehensive, independent and interactive review.

Government Auditing Standards provide at § 8.36 that in preparing a final audit report, “the auditors should modify their report as necessary if they find the comments valid and supported with sufficient, appropriate evidence.” OIG by its own admission is not qualified to evaluate the validity or sufficiency of the HCC arguments presented by the Plan without a second independent and qualified MRC review. Further, under HCFAR-86-1, the Plan must be given a full opportunity to demonstrate that the overpayment determination is wrong. If individual cases within the sample are determined to be erroneous, the amount of projected overpayment must be modified. This full opportunity should include the opportunity for the Plan to present its arguments regarding the HCCs challenged and the additional HCCs directly to a second independent and qualified MRC, and the opportunity to respond to any questions raised by the MRC or its physician.

In sum, the law is clear that the use of sampling and extrapolation can be arbitrary and capricious if the audited party is not given an opportunity to rebut the initial determination of overpayment.<sup>44</sup> In this audit, the OIG has the responsibility to ensure that it is on firm ground with respect to its evaluation of and findings regarding the clinical support underlying the HCCs that serve as the basis for the extrapolated adjustment amount. As any OIG final report ultimately issued may become a public document, the Plan believes the OIG must take all reasonable steps to assure its report is accurate and not to issue a report that misrepresents the Plan’s compliance with CMS requirements and contains an unsupported and erroneous recommendation that the Plan owes the federal government a refund of tens of millions of dollars.

**B. A Second MRC Review is Consistent with Rights Provided by CMS**

As the OIG RADV audit process does not allow the Plan to formally appeal adverse audit findings before a final audit report is issued and becomes an inaccurate public document, the

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<sup>44</sup> Use of sampling and extrapolation can be arbitrary and capricious if the audited party is not given an opportunity to rebut the initial determination of overpayment. *See Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982).

OIG should treat this Response consistently with the CMS RADV audit process as set forth in the 2006 and 2007 Participant Guides, and allow for two independent levels of review and the submission of additional documentation as discussed in Section VII.A.

When conducting RADV audits, CMS contracts with two independent review contractors to conduct medical record reviews.<sup>45</sup> The Initial Validation Contractor (“IVC”) facilitates the process and conducts the initial review of medical records. All discrepancies<sup>46</sup> identified by the IVC are subject to a second, independent medical record review by the Second Validation Contractor (“SVC”) to confirm the discrepancy. The SVC receives any discrepant medical records from the IVC, confirms risk adjustment discrepancies that are identified by the IVC, and implements an appeals process.<sup>47</sup> The IVC and SVC are blind to each other’s findings.<sup>48</sup> CMS shares any plan level findings with the selected Medicare Advantage organization, which findings may include a response rate, data discrepancy rates, and risk adjustment discrepancy error rates.<sup>49</sup>

The CMS process for allowing two independent levels of review mitigates discrepancies due to inter-rater reliability. That is, for any particular coder, there will be errors in the subjective interpretations of the individual claims. In practice, *different coders may reach different conclusions with regard to the same claim.*<sup>50</sup> As such, a proper sampling design would dictate the inclusion of a sufficient number of claims for each auditor (so that possible errors in

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<sup>45</sup> See 2006 Participant Guide at p. 8-1; 2007 Participant Guide at p. 7-1.

<sup>46</sup> Data discrepancies can include coding discrepancies, invalid medical records, or missing information. See 2006 Participant Guide at p. 8-17; 2007 Participant Guide at p. 7-19.

<sup>47</sup> 2006 Participant Guide at p. 8-5; 2007 Participant Guide at p. 7-6.

<sup>48</sup> See “Risk Adjustment Data Validation (RADV) and Prescription Drug Event Data Validation Program Overview” (Tom Hutchinson Slide Presentation, accessed at [http://www.iceforhealth.org/podcast/20100113\\_02\\_ICEConf2009\\_1ERiskAdjDataVal.pdf](http://www.iceforhealth.org/podcast/20100113_02_ICEConf2009_1ERiskAdjDataVal.pdf)).

<sup>49</sup> 2006 Participant Guide at p. 8-18; 2007 Participant Guide at p. 7-20.

<sup>50</sup> In fact, the OIG has acknowledged that “experts can disagree as to how a claim should be coded.” OIG Report No. A-06-06-00104 at p. 6.

the subjective interpretation of claims reviewed by that auditor are averaged out) and the use of multiple coders (so that the normal expected variation among auditors is averaged out).

However, the OIG has not yet provided the Plan with these procedural protections. As the Draft Report indicates at footnote 4, the OIG did not utilize two independent review contractors. Rather, the OIG utilized a single MRC that provided unsupported HCC determinations made by the **MRC staff** during the first medical review to **other staff** for a second review. The associated relationship between the OIG reviewers is an additional basis for challenging the accuracy of the OIG's findings and recommendations. The second MRC review should include two **independent** levels of review consistent with the CMS process.

**VII. OIG AND THE SECOND MRC SHOULD APPLY DOCUMENTATION AND OTHER REQUIREMENTS IN EFFECT FOR THE AUDITED PLAN YEAR TO ADVANCE THE ACCURACY OF RISK-ADJUSTED PAYMENTS**

**A. The Standards in Effect For the Plan Year Audited**

In order to mitigate distortion of any extrapolated amount and to assure the fairness of its process, the OIG should instruct its second MRC to apply the standards for review that were in effect at the time the services were rendered. The standards in effect for the 2006 dates of service at issue included principally the CMS 2006 Participant Guide, which was in effect until replaced in December 2007 with the CMS 2007 Participant Guide, as well as CMS guidance adopted for the 2007 RADV pilot project.<sup>51</sup>

Both the 2006 and 2007 CMS Participant Guides provide for an appeal process that allows Medicare Advantage organizations to “offer a different interpretation of the ICD-9 code assignment based on ICD-9 Coding Clinic Guidelines.”<sup>52</sup> In addition, Medicare Advantage organizations can “**provide additional medical record documentation to support their appeal. Thus, each appeal must include, at a minimum: - A clearly documented reason for**

<sup>51</sup> At the September 21, 2010 meeting, the OIG informed the Plan that the OIG would apply the standards in effect for the 2006 dates of service in reviewing the Plan's Response.

<sup>52</sup> 2006 Participant Guide at p. 8-19; 2007 Participant Guide at p. 7-21.

**disagreement with the medical review finding; and/or - Additional medical record documentation to support the reason for appeal.”<sup>53</sup>** Under the 2006 and 2007 Participant Guides, Medicare Advantage organizations are not limited to disputing whether the one best medical record does or does not validate the HCC.

Based on this review standard, the second MRC is not limited to a review of only the “one best medical record” or limited by other more recent unfairly limiting and retroactively-applied documentation requirements. The second MRC should appropriately consider the Plan’s concerns in the breadth of documentation deemed acceptable.

There are legitimate concerns regarding current risk adjustment data submission and validation processes. The risk adjustment payment methodology and risk adjustment audit system must each accurately capture the operational aspects and assumptions that make up CMS payments to Medicare Advantage organizations. Otherwise, Medicare Advantage organizations will be unfairly and inappropriately penalized for errors that are outside of their control. For the same reason, the OIG and the second MRC should allow physician attestations to address any discrepancies solely due to missing or illegible physician signatures or credentials in the medical record documentation.<sup>54</sup> Included with this Response, are four physician attestations that the Plan obtained on the CMS-required form.

Set forth below is a discussion of why the OIG should instruct its second MRC to follow the above documentation guidance as well as accept physician attestations that CMS has allowed Medicare Advantage organizations to use since the 2007 RADV pilot project.<sup>55</sup> Had the OIG conducted an independent review that sought valid clinical support for HCCs in light of the goals of risk-adjusted payments, more HCCs would have been appropriately validated. We request

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<sup>53</sup> *Id.* (emphasis added).

<sup>54</sup> The Plan understands from its September 21, 2010 meeting with the OIG that the OIG is considering accepting physician attestations to address missing or illegible physician signatures or credentials.

<sup>55</sup> CMS subsequently adopted the use of a physician attestation in its April 15, 2010 final rule. *See* 75 Fed. Reg. at 19807 (promulgated at 42 C.F.R. § 422.311(c)).

that the OIG consider the Plan's concerns and recommendations in preparing its final audit report and in making any recommendations to CMS regarding the risk adjustment data submission and validation processes.

**B. Current Acceptable Sources of Medical Records Are Too Limited And Overly Reliant on Physician Coding Accuracy**

CMS' limitations on the sources of acceptable medical records that a Medicare Advantage organization may submit for risk adjustment purposes are too restrictive and ignore other valid sources that would support a diagnosis and validate an HCC or are also valid predictors of members' future health care costs. The current restrictions are in direct conflict with CMS' stated goals of improving payment accuracy while minimizing administrative burdens on Medicare Advantage organizations.

If the government wants to ensure accurate HCCs are assigned to Medicare Advantage members, then they should not unduly restrict the documentation that can be submitted to verify the diagnosis coding. This is particularly true given that the CMS-HCC model is dependent upon the accurate and complete diagnosis coding and documentation practices of physicians. CMS' own guidance recognizes the fact that physicians are incentivized to bill by procedure code not diagnosis code because they are paid by procedure:

[The CMS-HCC] module emphasizes physician documentation and reporting of diagnosis codes. Historically, physician reimbursement in fee-for-service is primarily based on procedures or services rather than diagnoses, and physicians are very familiar with documentation guidelines for procedures and services. **Physicians generally are not as familiar with diagnosis codes and their associated documentation guidelines as they are with procedure coding rules. The [CMS-HCC] models depend upon accurate diagnosis coding, which means that physicians must fully understand and comply with documentation and coding guidelines for reporting diagnoses.**<sup>56</sup>

The risk adjustment process is flawed because Medicare Advantage organizations do not and cannot control the underlying medical documentation. While the Plan trains and educates

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<sup>56</sup> 2006 Participant Guide at p. 5-2 (emphasis added); 2007 Participant Guide at p. 6-2.

physicians on proper coding and documentation, the fact remains that it is the physicians who control the underlying medical documentation.<sup>57</sup> Since only about one quarter of all Medicare beneficiaries are enrolled in Medicare Advantage plans, enforcing the coding and documentation requirements only on Medicare Advantage organizations will not likely change the coding and documentation practices of physicians. Furthermore, while medical record reviews and audits by the Plan help to identify coding errors and deficiencies in documentation practices, it is unrealistic and impractical for the government to expect Medicare Advantage organizations to review medical records for every encounter submitted. It is also contrary to one of the stated goals of risk adjustment – to minimize the administrative burdens on Medicare Advantage organizations. The Plan currently processes approximately one million medical claims / encounters per year (excluding pharmacy).

To address the over-reliance on physician coding and documentation practices, the RADV process should allow alternative sources of information to confirm that a member has a particular condition and to validate an HCC. HCCs identify chronic health care conditions that generally are not curable, such as diabetes, congenital heart disease, chronic kidney disease and peripheral vascular disease. These chronic conditions are always present for affected patients, but will not necessarily be diagnosed or even noted on every medical record. Despite this, the RADV process precludes submission of anything but a single medical record, even when the balance of the member's medical record or other records would validate the HCC. CMS' own guidance recognizes the usefulness of "alternative data sources," such as diagnostic data and pharmacy records, in validating diagnoses.<sup>58</sup> The OIG should take the additional step to accept alternative data sources for risk adjustment purposes.<sup>59</sup>

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<sup>57</sup> See Section IX for a discussion of the Plan's training, education and audit programs.

<sup>58</sup> See 2006 Participant Guide at p. 3-10; 2007 Participant Guide at p. 3-11.

<sup>59</sup> The following are examples of HCCs that are fully supported by alternative data sources: H0354-037/HCC 55; H0354-040/HCC 79; H0354-045/HCC 79; H0354-047/HCC 10; H0354-090/HCC 108; and H0354-097/HCC 92. See Exhibit 3.

Further complicating the data submission process are changing CMS requirements regarding acceptable records. These changing requirements make it difficult for Medicare Advantage organizations to develop and implement policies and procedures as well as provider training. One example of changing CMS requirements is diagnostic radiology. Diagnostic radiology was an acceptable physician specialty for dates of service occurring in 2003 through 2005. However, CMS eliminated diagnostic radiology as an acceptable risk adjustment physician specialty beginning with 2006 dates of services. Two of the HCC discrepancies in the Draft Report are supported by radiology reports.<sup>60</sup>

**C. The One Best Medical Record Rule Is Inconsistent with the Medical Documentation Practices of Providers**

The Plan also disagrees with the one best medical record requirement for risk adjustment validation purposes. Multiple records are often needed to verify the accuracy of the HCCs of Medicare members.<sup>61</sup> This may be a reason why CMS allowed additional medical record documentation to be submitted for risk adjustment validation purposes under the 2006 and 2007 Participant Guides. Furthermore, there may not be a single medical record that verifies every HCC. For example, the records of several specialists, including but not limited to, an ophthalmologist or an optometrist, may be needed to validate an HCC such as a diagnosis of diabetes with eye complications. Moreover, as CMS has acknowledged, pharmacy records and prescription drug data can verify many conditions such as congestive heart failure and other chronic conditions.<sup>62</sup> Hospital records may also shed light on a member's condition whenever the medical record itself is not sufficiently clear.<sup>63</sup>

The one best medical record approach is flawed because it leads to false negatives. Medicare members who have valid HCCs may not need to see a physician during the data

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<sup>60</sup> See H0354-033/HCC 105 and H0354-077/HCC 108 in Exhibit 3.

<sup>61</sup> See H0354-094/HCC 159 in Exhibit 3.

<sup>62</sup> See 2006 Participant Guide at p. 3-10; 2007 Participant Guide at p. 3-11.

<sup>63</sup> See H0354-040/HCC 79 in Exhibit 3.

collection period, while others may only see a physician during the data collection period for something that is not specifically related to the HCC diagnosis. Under the one best medical record requirement, there would be no acceptable medical record support for these members' HCCs.<sup>64</sup>

The purpose of medical documentation is to document the patient's condition and treatment as necessary for clinical purposes. Under standard documentation practices, there is no requirement that a patient's underlying diagnosis be "re-documented" in every record every year. In fact, in the case of chronic conditions, the diagnosis will often not be noted each and every year following the initial diagnosis. Whether such chronic conditions are recorded depends on the care sought and the treatment rendered during the relevant encounter. The fact that the condition was not re-documented does not mean that the condition was not taken into account during the encounter. Moreover, the failure to re-document an underlying medical condition does not mean that the condition has "gone away." However, under CMS requirements, Medicare Advantage organizations are precluded from submitting a record from a prior or subsequent year containing the relevant diagnosis to substantiate the HCC, or a sworn statement from the physician that the member had the relevant condition during the data collection period. This is an unreasonable and unwarranted limitation. Furthermore, this limitation is contrary to the goal of determining whether the individual actually had the condition identified by the HCC and ensuring that payments to Medicare Advantage organizations accurately reflect their members' health status.<sup>65</sup>

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<sup>64</sup> The OIG invalidated H0354-068/HCC 80 as unsupported. This member had congestive heart failure ("CHF") that was appropriately documented in medical records in 2005 and 2008, but not in 2006. Obviously, the member had CHF in 2006. Nevertheless, the Draft Report invalidated the HCC.

<sup>65</sup> See 42 U.S.C. §§ 1395w-23(a)(1)(C) and (3).

**D. Additional HCCs for the Audited Members and Resulting CMS Underpayments to the Plan Must Be Included in the Audit's Findings and Recommendations**

As previously referred to in Section III, the OIG has retracted its representation on the Entrance Conference Agenda that underpayments to the Plan would be taken into account as part of the audit. Specifically, the OIG informed the Plan that “[d]iagnoses that were not included on the original submissions to CMS that were identified as a result of subsequent medical review are outside the scope of our review.” The OIG’s statement directly contradicts the explicit representations made to the Plan during the audit that the OIG will “consider underpayments in [its] results.”

Separate from the explicit representation the OIG made that it would consider underpayments, underpayments clearly are within the scope of the audit as set forth on the same Entrance Conference Agenda: “We will validate the risk scores for samples of Medicare Part C beneficiaries who were enrolled under CIGNA Healthcare of Arizona, Inc’s. (CIGNA) contract (H0354) during calendar year 2006.” The “Methodology” set forth on the agenda provided that that the OIG would “calculate the total amount of errors in [its] sample and project those results to the population” as well as “also consider underpayments in [its] results.” A risk score can be erroneous because it is too high **or low**. Both types of errors are within the scope of the OIG audit.

The OIG’s refusal to consider additional HCCs is particularly objectionable given the extrapolation of the OIG’s findings with respect to the sampled members to the entire universe of Plan members with at least one HCC. The fact that the OIG could arrive at a recommended refund in excess of \$23.6 million based on HCC discrepancies for 43 members and refuse to consider potential offsets for those members is arbitrary and capricious.

Other OIG audits of Medicare managed care plans have taken underpayments into account in their findings. For example, the audit objectives of OIG Report No. A-06-06-00104 “were to determine whether the encounter data CMS used as the basis for the 2003 monthly payments made on behalf of beneficiaries enrolled in [the audited plan] were valid and accurate.” Specifically, the OIG determined whether:

- The encounter data met the definition of “valid encounter data” that the OIG developed from CMS guidance;
- CMS used the correct diagnoses when assigning beneficiaries’ risk factors; and
- Medical records supported the encounter data.

The audit objectives of OIG Report No. A-06-06-00104 are nearly identical to those of the OIG’s audit of the Plan. However, in the previous audit, the “OIG determined the effect of the discrepancies between medical records and coded diagnoses on beneficiaries’ risk factors and calculated overpayments **and underpayments**. Why the OIG would not follow the same approach in the Plan’s audit is inexplicable.

Furthermore, the OIG’s refusal to consider underpayments among the audited sample is contrary to the purposes of risk adjustment generally and of RADV audits specifically. The OIG’s refusal is also contrary to CMS risk adjustment validation procedures. Both the 2006 and 2007 Participant Guides provide that “the purpose of risk adjustment data validation is to ensure risk adjusted payment integrity and accuracy . . . A payment adjustment may **increase or decrease** the risk adjusted payment . . .”<sup>66</sup> For example, both the 2006 and 2007 Participant Guides instruct Medicare Advantage organizations that CMS may find that a record submitted by the organization pursuant to data validation could contain “clinical information that result in risk adjustment ICD-9 codes that were not previously submitted to CMS.”<sup>67</sup>

Thus, the OIG should instruct the second MRC to review the Plan documentation for unreported HCCs and corresponding underpayments to the Plan.

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<sup>66</sup> 2006 Participant Guide at pp. 8-18 and 19; 2007 Participant Guide at 7-20 (emphasis added).

<sup>67</sup> 2006 Participant Guide at p. 8-10; 2007 Participant Guide at p. 7-11.

### **VIII. THE DRAFT REPORT CONTAINS ERRONEOUS DISCREPANCY FINDINGS**

Set forth in Exhibit 3 are the HCC discrepancies that the Plan disputes.<sup>68</sup> The Plan has categorized the disputed HCCs as follows:

- Category 1 (7 HCCs): The documentation provided by the Plan meets the coding guidelines.
- Category 2 (17 HCCs): The documentation provided by the Plan does not meet coding guidelines but the clinical assessment supports the appropriateness of the diagnosis.
- Category 3 (4 HCCs): A physician attestation was provided to resolve the discrepancy.

In addition, the Plan has identified nine (9) HCCs applicable to the sampled members that should have been captured for the 2006 reporting period but were not, and were not identified by the OIG in its findings. (See Category 4.) With respect to these nine HCCs, the Plan has obtained signed and credentialed documentation from the treating physician that accurately reflects the patient's diagnosis under the physician's assessment. See Exhibit 3.

### **IX. THE PLAN'S POLICIES AND PROCEDURES**

The second and final recommendation in the Draft Report is that the Plan "improve its current policies and procedures to ensure compliance with the requirements of the Participant Guide."

The Plan already provided a great deal of information to the OIG in September 2009 in response to the OIG's eleven (11) "Contract H0354 Risk Adjustment Process Questions." A copy of the Plan's responses to those questions (without the supporting materials) is attached as Exhibit 10. Included in the documentation produced at that time were copies of all Plan policies "relevant to obtaining, processing and submitting" risk adjustment data for the audit period at issue, and the Plan's then-current quality assurance policies and procedures relating to the risk

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<sup>68</sup> Supporting documentation is also being provided separate from the narratives included in Exhibit 3.

adjustment process, including information, instructions and training given by the Plan to its providers.

In addition to these previously-provided materials, the Plan has summarized below various process improvements, education and audit programs currently used by the Plan in its ongoing effort to assure that provider documentation and coding fully support the ICD-9 codes submitted by the Plan to CMS for risk adjustment. Specifically, the Plan, through its multi-specialty medical group practice (Cigna Medical Group or "CMG") has implemented the following programs to assure appropriate documentation, coding and reporting of HCC diagnosis codes:

#### Process Improvement Programs

- Physician Visit Aids
- Electronic Health Record Implementation
- Plan Member Outreach
- Coder-Shadowed Physician Visits
- Review for Diagnosis Coding Accuracy Prior to Submission
- Review of Diagnosis Coding Accuracy Post Submission

#### Physician Education Programs

- Mandatory Annual Documentation and Coding Training
- Periodic Physician Training
- Monthly Coding Newsletters
- Intense Audio Coding Training

#### Audit Programs

- Medical Record Audits for Expiring Diagnoses
- Medical Record Audits Targeting Diagnosis Errors
- Annual Reverse (Retroactive) Audits
- Annual Back-End Audits
- Metrics and Performance Audits

The foregoing process improvement, physician education and audit programs are described below.

**A. Process Improvement Programs**

1. Physician Visit Aids (referred to internally as the “Purple Paper” process). A Visit Aid (printed on purple paper for ease of identification) has been developed for physician use that is generated when a Plan member presents for his/her appointment at a CMG medical office. This aid identifies the member’s current and prior year captured medical condition(s) and codes and is used by the physician to determine the completeness and accuracy of those conditions/codes. Also incorporated into the visit aid are “suspected” or potential diagnosis codes that may have been missed, which are identified by a data analysis of the Plan member’s durable medical equipment, laboratory and prescription drug utilization. This listing of possible additional codes prompts the physician to assess the appropriateness of coding for these conditions as well. For example, if a Plan member is on home oxygen, the diagnosis of Chronic Respiratory Failure is put on the Visit Aid for the physician to assess and confirm during an examination. The Visit Aid tool has led to improved medical outcomes for Plan members by proactively identifying disease conditions requiring physician follow-up during a scheduled office visit. *See Exhibit 10.A.1.*

2. Electronic Health Record (“EHR”) Implementation. CMG has implemented an EHR which has functionality built in to identify HCC diagnosis codes for provider code choice. The Visit Aid is being into the EHR to increase physicians’ ability to assess expiring and suspected diagnoses during the office visit with Plan members. Various triggers and alerts have been placed in the EHR that require physicians to assess a diagnosis before they can move to the next screen in a member’s medical record. *See Exhibit 10.A.2.*

3. Plan Member Outreach. Plan members who have not received medical services in the current calendar year are identified monthly. Members are contacted and an annual physical examination appointment with their primary care physician is scheduled. This allows the physician to assess for expiring codes, as well as identify new codes based on use of the Visit Aid described above. Alerts are placed on the Visit Aid. An example of such an alert is: “the patient had an acute MI [myocardial infarction] in the prior year, document and code for old MI.” In addition, all newly-enrolled Plan members are contacted within the first month of

enrollment to schedule an initial primary care physician (“PCP”) assessment and conduct a thorough review of the patient’s history and medical needs.

4. Coder-Shadowed Physician Visits. Under this program, coders “shadow” PCPs by using the Visit Aid to create notes that are given to PCPs prior to their annual physical examinations of Plan members. All member annual exams are included in the scope of this project. Coders assist PCPs in documenting and coding patient encounters accurately. To prepare for the actual visit, coders review patient clinical history and supply the PCPs with diagnoses data and information on documentation appropriateness for all currently-existing chronic conditions identified from the patient’s clinical history. *See Exhibit 10.A.4.*

5. Review for Diagnosis Coding Accuracy Prior to CMS Submission. Before the Plan submits ICD-9 codes to CMS for risk adjustment, senior clinicians and certified professional coders review medical record documentation underlying claims / encounter data to assure the coding is accurate. Currently, 100% of all CMG adult medicine provider records and claims /encounter data are reviewed before the Plan submits ICD-9 codes to CMS. A two-step approach to this ICD-9 coding review is used. First, a coder validates the physician’s medical record documentation. Any code found to be lacking documented support undergoes a second review by a senior nurse auditor. If the error is confirmed, the code is deleted from the CMS submission.

#### **B. Physician Education Programs**

In order to further improve HCC diagnosis capture processes and ensure that the entire CMG organization is aware of the importance of appropriate diagnosis coding, a comprehensive physician education program has been developed that includes the following components:

1. Mandatory Annual Documentation and Coding Training. This training is conducted annually to communicate code changes, documentation requirements, deleted codes, and any new coding policies that have been created or changed in the previous year. All CMG physicians are required to complete the training at least annually. These formal coding training sessions provide education regarding guidelines for documentation and coding with real-time examples. At the end of all sessions, a test is given to the physicians to assess their

understanding of the material and feedback is given to each physician. Physicians receive follow-up one-on-one supplemental training sessions with a coder when necessary. *See Exhibit 10.B.1.*

2. Periodic Physician Training. In addition to the mandatory annual training, the coding team presents regular coding topics at monthly PCP meetings, quarterly specialty care meetings, and medical executive and medical center leadership team meetings. Various metrics are shared at these meetings, including diagnosis capture rate statistics, potential expiring code information and guidance on frequent coding error. Numerous specialty-specific education programs have also been developed. The programs provide not only a basic understanding of the Medicare Advantage payment methodology and CMS requirements, but also specific working examples, tailored to the area of expertise of each physician team.

3. Physician Education Subgroup. A physician education subgroup has developed training for physician back-office nursing staff to assure that all clinical resources are focused on the accurate and efficient capture of ICD-9 diagnosis codes in real-time. During this process, educational opportunities for coders, providers, and back office staff are identified. Training programs are designed based on real-life documentation and coding errors and focuses on ways to improve physician clinical documentation and encourage the review of all pertinent information, including applicable lab results, radiology reports, and other related documentation that would assist in the patient assessment for the final documented medical record note. Physicians and staff are constantly reminded that medical record documentation must indicate that the diagnoses are being Monitored, Evaluated, Assessed/Addressed, or Treated (“MEAT”). *See Exhibit 10.B.3.*

4. Monthly Coding Newsletters. Monthly newsletters are sent to physicians and emphasize the need for accuracy in documentation and coding and provide examples of ways to improve clinical documentation using the MEAT format. The Plan publishes Monthly Coding Newsletters that dedicate an entire section on accurate HCC documentation and coding with examples for physician use. *See Exhibit 10.B.4.*

5. Intense Audio Coding Training. Experienced HCC coders provide real-time and recorded training with emphasis on correct documentation and coding. This training is

conducted for physicians and their nursing staff, and for all new physician hires. *See* Exhibit 10.B.5.

**C. Audit Programs**

1. Medical Record Audits for Expiring Diagnoses. The focus of chart reviews for process audits is on “expiring” ICD-9 codes (meaning the underlying diagnosis is becoming a historic rather than current diagnosis). CMG has a team of certified professional coders who conduct retrospective chart audits on patients with expiring codes to determine if physician documentation continues to support reporting the diagnosis to CMS. These individuals are able to capitalize on their knowledge of ICD-9 codes and appropriate physician documentation and are specifically trained to assure that codes are appropriately reported. The coders review thousands of Plan member medical charts to determine if all documented codes have been accurately captured and to assure that only codes supported by appropriate documentation are reported to CMS. Recaptured codes and inappropriately-reported codes are submitted to CMS for retroactive payment adjustment. Ongoing audits of charts, physician documentation and coding performance are required to ensure the accuracy and completeness of coding efforts.

2. Medical Record Audits Targeting Diagnosis Errors. These audits are performed up to three times a year by senior CMG clinicians, certified professional coders, and nurses who are certified professional coders. The purpose of the audits is to determine the validity of the codes submitted and to identify opportunities for provider education on documentation and diagnosis coding. For each audit, a sample of 100 patient visit records is pulled which contain certain frequently-used ICD-9 codes shown to have a higher diagnosis coding error rate, based on prior reviews. Logic-based system searches are conducted to identify members with the ICD-9 codes to be audited. As an example of this type of review, one audit focused on coding diabetes in connection with foot care services (a type of service not uncommon for diabetic patients). The audit identified that patient appointment schedulers were giving all physicians with upcoming appointments for foot care services information on how to appropriately code for diagnosis of diabetes, which resulted in higher incidence of incorrect coding for that diagnosis. As a result of that audit, the source of the coding error was identified, the claims were corrected,

and CMS was informed of the incorrect diagnosis codes. Other diagnoses given priority for audit have included:

- Chronic Kidney Disease
- Old Myocardial Infarction
- Chronic Obstructive Pulmonary Disorder
- Chronic Respiratory Failure
- Cancers

3. Annual Reverse (Retroactive) Audits. These audits are conducted by the Plan to assess the accuracy of ICD-9 codes previously submitted to CMS. The audits are designed to identify coding errors that have led or could lead to CMS overpayments. The reverse audit process focuses on those ICD-9 codes that prior review has shown are most frequently billed in error. After a thorough review of the accuracy of documentation and coding, any ICD-9 codes submitted to CMS in error are reported to CMS for payment adjustment. *See* Exhibit 10.C.3.

4. Annual Back-End Audits. These audits are conducted by the Plan to identify documentation supporting codes previously missed and not submitted by the Plan to CMS for risk adjustment purposes. Logic-based system searches of claims data are conducted to identify those members with diagnosis codes submitted in the previous year, but not the current year. This information is used to conduct a review of missed diagnosis codes that should have been submitted for risk adjustment for that time period. Information identified showing ICD-9 codes were not previously submitted to CMS for risk adjustment is sent to CMS as a resubmission.

5. Metrics and Performance Audits. A multi-disciplinary team (HCC Diagnosis Team) meets bi-monthly to review performance metrics and develop action plans to improve HCC documentation and diagnosis capture.

Based on the Plan's implementation of all of the foregoing process improvement, physician educational and audit programs, the Plan does not concur with the Draft Report's second recommendation and requests that the recommendation not be included in any final audit report issued by the OIG.

## X. CONCLUSION

The Plan respectfully disagrees with the Draft Report's findings and recommendations and requests that the OIG discontinue its RADV audit. At a minimum, the Plan requests that the OIG postpone the audit process pending further guidance from CMS and a review performed by a second, independent MRC.

The statistically invalid methodology used by the OIG to arrive at its recommendation that the Plan repay over \$23.6 million in alleged overpayments for contract year 2007 is erroneous, unwarranted and undermines the principal objective of the CMS-HCC payment model, which is to compensate Medicare Advantage organizations more accurately for the higher coverage needs of chronically ill Medicare beneficiaries. The inaccuracy of this methodology is perhaps most clearly demonstrated by the fact that, in contract year 2007, the Plan sustained a loss of over \$800,000 in providing coverage to the 100 Plan members sampled by the OIG.

The recalculation of the Plan's risk scores and application of a contract-level adjustment on a retroactive basis undermine the Medicare Advantage bidding and payment process. At a minimum, the Plan was entitled to advance notice of the government's intent to use the flawed methodology at issue here so that the Plan could have evaluated back in 2006 whether or not it would remain in the Medicare Advantage program.

The methodology used to conduct this audit is fatally flawed and statistically invalid for at least the following reasons:

- The RADV audit process, based on the CMS-HCC payment model, fails to recognize that the process used to determine HCCs for risk-adjusted payment is not the same as the process used to determine upon audit whether the "one best medical record" supports the HCC. The MRC's failure to account for differences in these processes resulted in the erroneous invalidation of nearly half of the HCCs, as evidenced by the Plan Medical Director's analyses of the OIG's alleged HCC "errors." *See* Exhibit 3. These summaries make clear that the Plan members at issue had the diagnosis that supported the HCC that was the basis for the risk-adjusted payment to the Plan. Removing these erroneous discrepancies from the Draft Report reduces the alleged extrapolated "overpayment" by approximately \$11.8 million.

- The failure to include over 13,400 (of 32,260) Plan members with no HCCs in the audit population is an additional factor skewing the audit results in favor of a higher alleged overpayment amount.

- The OIG's retraction of its prior representation to the Plan that it would consider additional HCCs within the audited sample to offset its results deprives the Plan of a further reduction of \$6.5 million to the alleged overpayment amount. If all HCC review errors are considered, **the OIG's recommended adjustment figure of \$23.6 million is reduced to \$5.2 million.** See Exhibit 3.

- The CMS-HCC payment model (which pays a set capitation amount for an individual based on cost predictions made over a large population of individuals with the same assigned HCCs) is highly inaccurate when used to audit payments for a small sample size. Capitation paid for one individual based on his/her HCC(s) bears virtually no relationship to the actual cost of coverage for that particular individual. The confidence interval used by the OIG accounts only for the small sample size relative to the population sampled and completely fails to account for the high degree of uncertainty caused by the application of the CMS-HCC payment methodology logic to this audit. In fact, the Plan can demonstrate that the confidence interval adjustment required by use of this methodology is so significant that the lower confidence bound may well result in a **2007 underpayment by CMS to the Plan.**

- The OIG failed to apply other basic statistical principles which CMS has followed in its own RADV audits, including use of a sample size twice that used by the OIG in its RADV audit of the Plan and use of a stratified sampling process to ensure a representative sample.

- The OIG failed to take into account the impending CMS RADV audit adjustment methodology. This adjustment is necessary to account for the error rate in Medicare fee-for-service claims data upon which the CMS-HCC risk adjustment factors are based.

If OIG's reconsideration of the issues outlined above does not result in the Plan's requested discontinuation of this audit, then the audit process should at least be pended until there has been a full, fair and independent review by a second qualified MRC of the HCC discrepancies and the additional documentation and information provided by the Plan in this

Response. Any further draft or final OIG report should reflect that the review conducted by the second MRC applied the correct documentation and review standards, and incorporated the CMS adjustment factor once it is released.

Finally, consistent with OIG precedent, any recommended payment adjustment should be limited to the results of the audit sample and not extrapolated.

\* \* \* \* \*

Please do not hesitate to contact us regarding any matter contained in this Response.

Sincerely,



Kristi Thomason  
VP, Medicare Administration

Enclosures

**List of Exhibits**

Exhibit 1	Analysis: Comparison of Plan Bids and CMS Payment With and Without Prospective Audit Adjustment
Exhibit 2	Adjustments Due to Errors in Review by MRC
Exhibit 3	Disputed HCC Discrepancies and Additional HCCs
Exhibit 4	OIG Entrance Conference Agenda
Exhibit 5	Analysis: Impact of OIG Disease Interaction Errors
Exhibit 6	Analysis: Determination of HCCs for Payment is Not Equivalent to Audit Evaluation of HCCs from Medical Records
Exhibit 7	Chart: Percent Frequency of HCCs for Population and Sample
Exhibit 8	Analysis: CMS Revenue Received Compared to Medical Expense incurred for OIG Sampled Members
Exhibit 9	Analysis: Forecast Variances for Risk Adjustment Payment Model Not Considered in Confidence Interval
Exhibit 10	Plan Process Improvement, Physician Education and Audit Programs