DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

May 29, 2012

TO: Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: /Daniel R. Levinson/
Inspector General

SUBJECT: Risk Adjustment Data Validation of Payments Made to PacifiCare of Texas for Calendar Year 2007 (Contract Number H4590) (A-06-09-00012)

Attached, for your information, is an advance copy of our final report on risk adjustment data validation of payments made to PacifiCare of Texas (PacifiCare) for calendar year 2007 (contract number H4590). We will issue this report to Ovations, a business unit of PacifiCare, within 5 business days.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Brian P. Ritchie, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through email at Brian.Ritchie@oig.hhs.gov or Patricia Wheeler, Regional Inspector General for Audit Services, Region VI, at (214) 767-8414 or through email at Trish.Wheeler@oig.hhs.gov. Please refer to report number A-06-09-00012.

Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

OFFICE OF AUDIT SERVICES, REGION VI
1100 COMMERCE STREET, ROOM 632
DALLAS, TX 75242

May 30, 2012

Report Number: A-06-09-00012

Mr. Jack Larsen
CFO
Ovations
9701 Data Park Drive
Minnetonka, MN 55343

Dear Mr. Larsen:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *Risk Adjustment Data Validation of Payments Made to PacifiCare of Texas for Calendar Year 2007 (Contract Number H4590)*. We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at http://oig.hhs.gov.

If you have any questions or comments about this report, please do not hesitate to call me at (214) 767-8414, or contact Paul Garcia, Audit Manager, at (512) 339-3071 or through email at Paul.Garcia@oig.hhs.gov. Please refer to report number A-06-09-00012 in all correspondence.

Sincerely,

/Patricia M. Wheeler/
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Mr. Timothy P. Love
Acting Deputy Director
Center for Medicare
Centers for Medicare & Medicaid Services
Mail Stop C3-20-11
7500 Security Boulevard
Baltimore, MD 21244-1850

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

RISK ADJUSTMENT DATA VALIDATION OF PAYMENTS MADE TO PACIFICARE OF TEXAS FOR CALENDAR YEAR 2007 (CONTRACT NUMBER H4590)

Daniel R. Levinson
Inspector General

May 2012
A-06-09-00012

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC

at http://oig.hhs.gov

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

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 (beneficiaries). 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 CMS model and submit these diagnoses to CMS. CMS categorizes the diagnoses into groups of clinically related diseases called HCCs and uses the HCCs and 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.

PacifiCare of Texas (PacifiCare) is an MA organization owned by UnitedHealth Group. For calendar year (CY) 2007, PacifiCare had multiple contracts with CMS, including contract H4590, which we refer to as "the contract." Under the contract, CMS paid PacifiCare approximately $1.3 billion to administer health care plans for approximately 118,000 beneficiaries.

OBJECTIVE

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

SUMMARY OF FINDINGS

The diagnoses that PacifiCare submitted to CMS for use in CMS's risk score calculations did not always comply with Federal requirements. The risk scores calculated using the diagnoses that PacifiCare submitted for 57 of the 100 beneficiaries in our sample were valid. The risk scores for the remaining 43 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.

PacifiCare did not have written policies and procedures for obtaining, processing, and submitting diagnoses to CMS. Furthermore, PacifiCare's practices were not effective in 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). UnitedHealth Group officials stated that the providers were responsible for the accuracy of the diagnoses that PacifiCare submitted to CMS.

As a result of these unsupported and unconfirmed diagnoses, PacifiCare received $183,247 in overpayments from CMS. Based on our sample results, we estimated that PacifiCare was overpaid approximately $115,422,084 in CY 2007.

RECOMMENDATIONS

We recommend the following:

- PacifiCare should refund to the Federal Government $183,247 in overpayments identified for the sampled beneficiaries.

- PacifiCare should work with CMS to determine the correct contract-level adjustment for the projected $115,422,084 of overpayments. (This amount represents our point estimate. However, it is our policy to recommend recovery of overpayments at the lower limit of the 90-percent confidence interval, which is $82,129,887. See Appendix B.)

- PacifiCare should implement written policies and procedures for obtaining, processing, and submitting valid risk adjustment data.

- PacifiCare should improve its current practices to ensure compliance with Federal requirements.

PACIFICARE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, PacifiCare disagreed with our findings and said that our analysis, methodology, and projection were flawed. PacifiCare also stated that our audit results did not account for error rates inherent in Medicare fee-for-service (FFS) data, specifically the disparity between FFS claims data and FFS medical records data and its potential impact on MA payments. In addition, PacifiCare stated that we should have used the 2006 Participant Guide to evaluate PacifiCare's compliance with CMS's requirements. PacifiCare's comments appear in their entirety as Appendix D.

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. Because of the potential impact of these error rates on the CMS model we used to recalculate MA payments for the beneficiaries in our sample, we (1) modified one recommendation to have PacifiCare refund only the overpayments identified for the sampled beneficiaries rather than refund the projected overpayments and (2) added a recommendation that PacifiCare work with CMS to determine the correct contract-level adjustments for the projected 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 both the 2006 and 2007 Participant Guides and determined that there were no substantial differences in the criteria upon which our results were based. Nothing in PacifiCare's comments has caused us to change our findings or other recommendations.

TABLE OF CONTENTS

APPENDIXES

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.[1] MA organizations identify the diagnoses relevant to the CMS 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.[2]

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).

[1] Risk adjustment data also include health insurance claim numbers, provider types, and the from and through dates for the services.

[2] 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.

PacifiCare of Texas

PacifiCare of Texas (PacifiCare) is an MA organization owned by UnitedHealth Group. For CY 2007, PacifiCare had multiple contracts with CMS, including contract H4590, which we refer to as "the contract." Under the contract, CMS paid PacifiCare approximately $1.3 billion to administer health care plans for approximately 118,000 beneficiaries.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

Scope

Our review covered approximately $827 million of the CY 2007 MA organization payments that CMS made to PacifiCare on behalf of 62,987 beneficiaries. These payments were based on risk adjustment data that PacifiCare 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[3] and (2) had a CY 2007 risk score that was based on at least one HCC. We limited our review of PacifiCare's internal control structure to controls over the collection, processing, and submission of risk adjustment data.

We asked PacifiCare 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 gave PacifiCare the opportunity to submit an additional medical record for a second review.

We performed our fieldwork at UnitedHealth Group in Minnetonka, Minnesota, and at CMS in Baltimore, Maryland, from October 2008 through December 2009.

[3] We limited our sampling frame to continuously enrolled beneficiaries to ensure that PacifiCare 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 PacifiCare submitted supported the HCCs associated with the beneficiaries in our sample.

- We interviewed UnitedHealth Group officials to gain an understanding of PacifiCare'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 62,987 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 one HCC.

- We selected a simple random sample of 100 beneficiaries with 214 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 PacifiCare submitted to CMS associated with the beneficiary's HCC(s);

    - requested that PacifiCare provide us with documentation associated with an encounter that, in PacifiCare's judgment, best supported the HCC(s) that CMS used to calculate the beneficiary's risk score;

    - obtained PacifiCare's certification that the documentation provided represented "the one best medical record to support the HCC";[4] and

    - submitted PacifiCare's documentation and HCCs for each beneficiary to our medical review contractor for a first round of review and requested additional documentation from PacifiCare for a second round of review if the contractor

[4] 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 indicate 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).

found that documentation submitted during the first round did not support the HCCs.

- 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 objective.

FINDINGS AND RECOMMENDATIONS

The diagnoses that PacifiCare submitted to CMS for use in CMS's risk score calculations did not always comply with Federal requirements. The risk scores calculated using the diagnoses that PacifiCare submitted for 57 of the 100 beneficiaries in our sample were valid. The risk scores for the remaining 43 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.[5]

PacifiCare did not have written policies and procedures for obtaining, processing, and submitting diagnoses to CMS. Furthermore, PacifiCare's practices were not effective in ensuring that the diagnoses it submitted to CMS complied with the requirements of the 2006 and 2007 Participant Guides. UnitedHealth Group officials stated that providers were responsible for the accuracy of the diagnoses that PacifiCare submitted to CMS.

As a result of these unsupported and unconfirmed diagnoses, PacifiCare received $183,247 in overpayments from CMS. Based on our sample results, we estimated that PacifiCare was overpaid approximately $115,422,084 in CY 2007.

[5] 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.)

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, PacifiCare 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 43 sampled beneficiaries were invalid because the diagnoses that PacifiCare submitted to CMS were not supported, confirmed, or both. These diagnoses were associated with 58 HCCs. Appendix C shows the documentation error or errors found for each of the 58 HCCs. These errors were for unsupported diagnosis coding and unconfirmed diagnoses.

Unsupported Diagnosis Coding

The documentation that PacifiCare submitted to us for medical review did not support the diagnoses associated with 57 HCCs. The following are examples of HCCs that were not supported by PacifiCare's documentation.

- For one beneficiary, PacifiCare 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. However, the documentation that PacifiCare provided stated that the patient had complained of leg pain and difficulty walking. The documentation did not indicate that depression had affected the care, treatment, or management provided during the encounter.

- For a second beneficiary, PacifiCare submitted the diagnosis code for "peripheral vascular disease"(PVD). CMS used the HCC associated with PVD in calculating the beneficiary's risk score. However, the documentation that PacifiCare provided indicated that the patient's chief complaint on the date of service was pain in her right foot, which was caused by a heavy can that fell on her foot. The documentation did not mention PVD or indicate that PVD had affected the care, treatment, or management provided during the encounter.

- For a third beneficiary, PacifiCare submitted the diagnosis code for "malignant neoplasm of the brain, cerebrum, except for lobes and ventricles." CMS used the HCC associated with this diagnosis in calculating the beneficiary's risk score. However, the documentation that PacifiCare provided referenced benign prostatic hypertrophy. The documentation did not mention brain cancer or indicate that brain cancer had affected the care, treatment, or management provided during the encounter.

Unconfirmed Diagnoses

Three HCCs were unsupported because the diagnoses submitted to CMS were unconfirmed.

For example, for one beneficiary, PacifiCare submitted a diagnosis code for "chronic airway obstruction, not elsewhere classified." CMS used the HCC associated with this diagnosis in calculating the beneficiary's risk score. The documentation that PacifiCare submitted noted a "history of smoking with possible mild chronic obstructive pulmonary disease." Diagnoses that are "probable," "suspected," "questionable," or "working" should not have been coded.

CAUSES OF OVERPAYMENTS

During our audit period, PacifiCare did not have written policies and procedures for obtaining, processing, and submitting risk adjustment data to CMS. UnitedHealth Group officials informed us that PacifiCare had since developed written policies and procedures but had not implemented them as of December 2, 2009.

According to UnitedHealth Group officials, PacifiCare had practices, including error correction and chart validation, in place to ensure the accuracy of the diagnoses that it submitted to CMS:

- Error correction is an automated process designed to identify provider-submitted diagnosis codes that do not exist in the Coding Guidelines. UnitedHealth Group officials told us that 0.19 percent of the provider-submitted diagnosis codes were rejected by the automated process and manually corrected in CYs 2008 and 2009.

- Chart validation is a review of documentation to ensure that the diagnoses submitted to CMS are correctly coded. However, UnitedHealth Group officials stated that PacifiCare did not routinely use chart validation as a preventive practice but rather used it as a response to external auditors' requests for documentation that best supports the diagnoses already submitted to CMS.

As demonstrated by the significant error rate found in our sample, PacifiCare's practices were not effective in ensuring that the diagnoses submitted to CMS complied with the requirements of the 2006 and 2007 Participant Guides. UnitedHealth Group officials stated that providers were responsible for the accuracy of the diagnoses that PacifiCare submitted to CMS.

ESTIMATED OVERPAYMENTS

As a result of the unsupported and unconfirmed diagnoses in our sample, PacifiCare received $183,247 in overpayments from CMS. Based on our sample results, we estimated that PacifiCare was overpaid approximately $115,422,084 in 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.[6]

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

RECOMMENDATIONS

We recommend the following:

- PacifiCare should refund to the Federal Government $183,247 in overpayments identified for the sampled beneficiaries.

[6] 75 Fed. Reg. 19749 (April 15, 2010).

- PacifiCare should work with CMS to determine the correct contract-level adjustment for the projected $115,422,084[7] of overpayments.

- PacifiCare should implement written policies and procedures for obtaining, processing, and submitting valid risk adjustment data.

- PacifiCare should improve its current practices to ensure compliance with the Federal requirements.

PACIFICARE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, PacifiCare[8] disagreed with our findings and said that our analysis, methodology, and extrapolation were flawed. PacifiCare also stated that we did not account for error rates inherent in Medicare FFS data, specifically the disparity between FFS claims data and FFS medical records data and its potential impact on MA payments. In addition, PacifiCare stated that we should have used the 2006 Participant Guide to evaluate PacifiCare's compliance with CMS's requirements. PacifiCare's comments, which we summarize below, are included in their entirety as Appendix D.

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.[9] Therefore, because of the potential impact of these error rates on the CMS model we used to recalculate MA payments for the beneficiaries in our sample, we (1) modified one recommendation to have PacifiCare refund only the overpayments identified for the sampled beneficiaries rather than refund the projected overpayments and (2) added a recommendation that PacifiCare work with CMS to determine the correct contract-level adjustments for the projected 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 both the 2006 and 2007 Participant Guides and determined that there were no substantial differences in the criteria upon which our results were based. Nothing in PacifiCare's comments has caused us to change our findings or other recommendations.

[7] This amount represents our point estimate. However, it is our policy to recommend recovery of overpayments at the lower limit of the 90-percent confidence interval, which is $82,129,887. See Appendix B.

[8] The letterhead of the written comments is from Ovations, a business unit of UnitedHealth Group that merged with PacifiCare in 2005.

[9] 75 Fed. Reg. 19749 (April 15, 2010).

Random Sample

PacifiCare Comments

PacifiCare stated that our sample of 100 beneficiaries did not fully represent the 118,000 members enrolled in the contract or the 62,987 members who had a risk score based on at least 1 HCC during our audit period. PacifiCare said that because only 40 of the 70 HCCs that appeared in the population were represented in our audit sample, our sample did not accurately represent the population.

Office of Inspector General Response

Our sample size of 100 beneficiaries provided a fair and unbiased representation of the 62,987 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 30 HCCs not represented in our sample, 26 had a frequency of less than 1 percent of the sampling frame, and the remaining 4 had a frequency of less than 3 percent.

Audit Methodology

PacifiCare Comments

PacifiCare stated that we recommended a repayment amount using a methodology that has not been vetted by CMS and on which MA organizations have not had the opportunity to comment. PacifiCare further stated that we did not follow an established CMS methodology to calculate payment errors and that we did not adequately describe our payment calculation and extrapolation methodology and our basis for using that methodology. PacifiCare stated that our methodology must mirror a CMS methodology and that CMS has not determined a methodology.

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 (HHS) programs and operations. Accordingly, we do not always determine, nor are we required to determine, whether our payment error calculation and extrapolation methodology are consistent with CMS's methodology. We designed our review to determine whether diagnoses that PacifiCare submitted for use in CMS's risk score calculations complied with Federal requirements. In addition, we described our payment error calculation in the body of our report. We described our sample selection and estimated methodology in Appendixes A and B.

Hierarchical Condition Categories Derived From Medical Records

PacifiCare Comments

PacifiCare stated that using HCCs identified from medical records as inputs in computing payment errors was inappropriate because (1) HCCs derived from medical records are not the same as HCCs derived from claims data; (2) HCCs derived from medical records were not the appropriate input for the CMS model used to determine capitation payments; and (3) our audit results did not account for error rates inherent in Medicare FFS data, specifically the level of disparity between FFS claims data and FFS medical record data and its potential impact on MA payments.

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 methodology to recalculate the MA payments was appropriate because we used the CMS model to calculate PacifiCare'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 potential merit in further refining the calculation of payment errors that result from postpayment validation efforts.[10] Given the potential impact of this error rate on the CMS model 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 made an additional recommendation that PacifiCare work with CMS to determine the correct contract-level adjustments for the projected overpayments.

Centers for Medicare & Medicaid Services Model

PacifiCare Comments

PacifiCare stated that (1) while accurate for large populations, the CMS model was not designed to produce results for individual beneficiaries and (2) the confidence intervals we computed were understated. PacifiCare said that the CMS model was designed to make cost predictions for the average beneficiary in a relatively large subgroup and that the prediction for any individual beneficiary may be significantly in error. PacifiCare stated that the confidence interval reflects only the sampling variance in the overpayment (underpayment) amounts and does not incorporate uncertainty in the CMS model used to forecast expenditures for HCCs.

[10] 75 Fed. Reg. 19749 (April 15, 2010).

Office of Inspector General Response

Our use of the CMS model and supporting medical records was consistent with the method CMS used to compute PacifiCare'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 midpoint. Any attempt on our part to modify the CMS model to calculate PacifiCare's CY 2007 payments would have been speculative and beyond the scope of our audit.

Members Who Terminated Coverage or Changed Status

PacifiCare Comments

PacifiCare stated that we did not account for the differences between the sample population and the larger extrapolation population. Specifically, PacifiCare stated that we did not include members who moved to different plans or died during the 2007 payment year in the larger population. In addition, the larger population included beneficiaries whose status had changed during the payment year (e.g., transferred to institutions or started hospice care or dialysis). According to PacifiCare, determining an overpayment based on these members was inappropriate because their capitation payments were calculated using a different methodology from that used for the general membership.

Office of Inspector General Response

As we explain in Appendix A, we limited our population to the 62,987 beneficiaries who were continuously enrolled from January 2006 through January 2007 and had at least 1 HCC during the audit period.

Audit Processes and Standards

PacifiCare Comments

PacifiCare stated that the Office of Inspector General (OIG) was required by law and by our audit objective to follow CMS guidance and regulations governing Risk Adjustment Data Validation (RADV) audits in conducting this audit. PacifiCare said that we failed to follow CMS processes and, in doing so, exceeded our authority and arrived at inaccurate results that contradict CMS practices, stated policies, and methodologies. Also, PacifiCare stated that we should have used the 2006 Participant Guide to evaluate PacifiCare's compliance with CMS requirements.

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 HHS 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 PacifiCare submitted to CMS for use in CMS's risk score calculations complied with Federal requirements. Regarding CMS's 2006 Participant Guide, we did base 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 substantial differences in the criteria upon which our results were based.

Incidental Hierarchical Condition Categories

PacifiCare Comments

PacifiCare stated that we did not consider additional HCCs that were identified incidentally during the audit in accordance with CMS practices. Specifically, PacifiCare 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. PacifiCare added that it would have received credit for these HCCs under established CMS standards and practices.

Office of Inspector General Response

Our objective was to determine whether the diagnoses that PacifiCare 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.

Two Levels of Review

PacifiCare Comments

PacifiCare stated that our review of medical records did not include certain processes included in CMS's 2006 and 2007 Participant Guides. PacifiCare said that when conducting RADV audits, CMS contracts with two independent medical review contractors to conduct its medical reviews; OIG does not. During CMS medical reviews, one contractor conducts the initial medical review of medical records. Discrepancies identified by this contractor are subject to another review by a second contractor. PacifiCare added that the use of two contractors mitigates discrepancies and stated that our process did not provide the same procedural protections. In addition, PacifiCare stated that if OIG's review did not validate an HCC, it was included in a group from which a random sample of only 5 percent of the HCCs were chosen to be reviewed by a second medical reviewer.

Office of Inspector General Response

As stated previously, we did not design our review to be an RADV audit, and we are not required to follow CMS's RADV audit protocol. Although we did not have two independent contractors review PacifiCare'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, 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 PacifiCare to submit additional medical records. Any additional records PacifiCare provided went through the process described above.

Also, we accepted medical records PacifiCare 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. The random sample of 5 percent of HCCs PacifiCare cites was an additional random sample of all HCCs selected for review. This sample helped ensure accuracy and consistency with the results reported.

Physician Signature Attestations

PacifiCare Comments

PacifiCare stated that we did not follow CMS's audit methodology because we refused to accept physician signature attestations. PacifiCare added that, as a result, we identified 14 HCCs that were invalid, in whole or in part, 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, stated that documentation supporting the diagnosis must include an acceptable physician signature. However, pursuant to a 2010 change in Federal regulations (42 CFR § 422.311), we accepted attestations and revised our findings accordingly.

Individual Payment Adjustments

PacifiCare Comments

PacifiCare stated that neither the 2006 nor the 2007 Participant Guide discussed extrapolating "overpayments" to the contract level using risk-adjusted discrepancies discovered in an RADV audit. PacifiCare also stated that before the application of the pilot project,[11] CMS made payment adjustments only for those enrollees sampled.

[11] In July 2008, CMS announced a pilot project to more extensively audit MA organizations.

Office of Inspector General Response

As stated above, pursuant to the Inspector General Act of 1978, 5 U.S.C. App., our audits are intended to provide an independent assessment of HHS programs and operations. We modified our first recommendation to seek a refund only of the overpayments identified for the sampled beneficiaries. We made an additional recommendation that PacifiCare work with CMS to determine the correct contract-level adjustments for the projected overpayments.

Invalidated Hierarchical Condition Categories

PacifiCare Comments

PacifiCare stated that it had conducted its own review of the medical records from this review and concluded that at least 17 of the invalid HCCs were supported by the "one best medical record" submitted. PacifiCare stated that with the use of two levels of review (as afforded by CMS's RADV process), these HCCs would likely have been validated. PacifiCare also stated that it had evaluated each of the 44 beneficiaries who had 1 or more HCCs invalidated during the data collection period and that many of them were actually treated for the health conditions reported in the HCCs. PacifiCare stated that multiple records should be considered together when verifying a beneficiary's HCC.

Office of Inspector General Response

We ensured that our medical review contractor had an independent review process in place to provide two levels of review. We also accepted medical records provided by PacifiCare in addition to the "one best medical record" we initially requested to help validate HCCs. CMS developed the CMS model with inpatient, outpatient, and physician records used to support HCCs. Therefore, we accepted and reviewed only those types of records for CY 2006 dates of service.

Policies and Procedures

PacifiCare Comments

In response to our recommendation for improving its controls, PacifiCare stated that it largely used automated systems for obtaining, processing, and submitting diagnoses to CMS and that it had documented system protocols for processing data through its systems. Also, PacifiCare stated that it used the chart validation process as a validation tool for codes related to 2006 dates of service.

Office of Inspector General Response

PacifiCare officials explained to us that the automated systems were used only to verify the validity of the Coding Guidelines. In addition, PacifiCare officials told us that chart validation was not used routinely and was used only to validate diagnoses that PacifiCare received from providers that PacifiCare paid on a capitated basis.

APPENDIXES

APPENDIX A: SAMPLE DESIGN AND METHODOLOGY

SAMPLING FRAME

The sampling frame consisted of 62,987 beneficiaries on whose behalf the Centers for Medicare & Medicaid Services paid PacifiCare of Texas (PacifiCare) approximately $827 million in calendar year (CY) 2007. These beneficiaries (1) were continuously enrolled under contract H4590 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 62,987. 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
62,987	100	$1,143,851	43	$183,247

Estimated Value of Overpayments

(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	$115,422,084
Lower limit	82,129,887
Upper limit	148,714,281

APPENDIX C: DOCUMENTATION ERRORS IN SAMPLE

A	Unsupported diagnosis coding
B	Unconfirmed diagnosis

	Hierarchical Condition Category	A	B	Total Errors
1	Protein-Calorie Malnutrition	X		1
2	Vascular Disease	X		1
3	Major Depressive, Bipolar, and Paranoid Disorders	X		1
4	Vascular Disease	X		1
5	Congestive Heart Failure	X		1
6	Ischemic or Unspecified Stroke	X	X	2
7	Vascular Disease	X		1
8	Seizure Disorders and Convulsions	X		1
9	Diabetes With Renal or Periphery Circulatory Manifestation	X		1
10	Major Depressive, Bipolar, and Paranoid Disorders	X		1
11	Congestive Heart Failure	X	X	2
12	Polyneuropathy	X		1
13	Congestive Heart Failure	X		1
14	Diabetes With Neurologic or Other Specified Manifestation	X		1
15	Major Depressive, Bipolar, and Paranoid Disorders	X		1
16	Breast, Prostate, Colorectal and Other Cancers and Tumors	X		1
17	Polyneuropathy	X		1
18	Congestive Heart Failure	X		1
19	Congestive Heart Failure	X		1
20	Ischemic or Unspecified Stroke	X		1
21	Vascular Disease	X		1
22	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	X		1
23	Hip Fracture/Dislocation	X		1
24	Diabetes Without Complication	X		1
25	Diabetes With Renal or Periphery Circulatory Manifestation	X		1
26	Nephritis	X		1
27	Major Depressive, Bipolar, and Paranoid Disorders	X		1
28	Major Depressive, Bipolar, and Paranoid Disorders	X		1
29	Angina Pectoris/Old Myocardial Infarction	X		1
30	Breast, Prostate, Colorectal and Other Cancers and Tumors	X		1
31	Chronic Obstructive Pulmonary Disease	X		1
32	Diabetes With Ophthalmologic or Unspecified Manifestation	X		1
33	Ischemic or Unspecified Stroke	X		1
34	Diabetes With Neurologic or Other Specified Manifestation	X		1
35	Polyneuropathy	X		1
36	Chronic Obstructive Pulmonary Disease	X		1
37	Breast, Prostate, Colorectal and Other Cancers and Tumors	X		1
38	Congestive Heart Failure	X		1
39	Vascular Disease	X		1
40	Ischemic or Unspecified Stroke	X		1

	Hierarchical Condition Category	A	B	Total Errors
41	Chronic Obstructive Pulmonary Disease		X	1
42	Polyneuropathy	X		1
43	Specified Heart Arrhythmias	X		1
44	Vascular Disease	X		1
45	Chronic Obstructive Pulmonary Disease	X		1
46	Lung, Upper Digestive Tract, and Other Severe Cancers	X		1
47	Intestinal Obstruction/Perforation	X		1
48	Nephritis	X		1
49	Lymphatic, Head and Neck, Brain, and Other Major Cancers	X		1
50	Ischemic or Unspecified Stroke	X		1
51	Diabetes With Ophthalmologic or Unspecified Manifestation	X		1
52	Bone/Joint/Muscle Infections/Necrosis	X		1
53	Vascular Disease	X		1
54	Chronic Ulcer of Skin, Except Decubitis	X		1
55	Vascular Disease	X		1
56	Vascular Disease	X		1
57	Bone/Joint/Muscle Infections/Necrosis	X		1
58	Lymphatic, Head and Neck, Brain, and Other Major Cancers	X		1
	Total	**57**	**3**	**60**

APPENDIX D: PACIFICARE COMMENTS

OVATIONS
A UnitedHealth Group Company

September 10, 2010

Patricia Wheeler
Regional Inspector General for Audit Services
Office of Audit Services, Region VI
1100 Commerce Street, Room 632
Dallas, TX 75242

Dear Ms. Wheeler:

On behalf of PacifiCare of Texas, Inc. and its affiliate UnitedHealth Group (collectively "PacifiCare"), we are writing in response to the U.S. Department of Health and Human Services ("HHS"), Office of the Inspector General ("OIG"), draft report dated March 31, 2010 entitled "Risk Adjustment Data Validation of Payments made to PacifiCare of Texas for Calendar Year 2007 (Contract Number H4590)" (hereinafter, "Draft Report"). PacifiCare welcomes the opportunity to provide comments on the Draft Report before it is issued, and appreciates the dialogue and exchange of information the OIG has afforded PacifiCare during the audit process. However, PacifiCare strongly disagrees with the findings in the Draft Report and believes that the analysis, methodology, and extrapolation used by the OIG in its audit are flawed.

As you are aware, PacifiCare is one of the largest providers of Medicare Advantage ("MA") plans in the U.S., and has participated in the Medicare Part C program as either a Medicare+Choice plan or an MA plan since the inception of Medicare Part C. PacifiCare has worked with both the Centers for Medicare & Medicaid Services ("CMS") and the OIG on many occasions and has strived to be a valued business partner with the government to ensure the program's success. However, PacifiCare is concerned about the findings summarized in the Draft Report, which conclude that certain diagnoses that PacifiCare submitted to CMS for use in CMS's risk score calculations did not comply with the requirements of the CMS's *2007 Risk Adjustment Data Training for Medicare Advantage Participant Guide* (the "2007 Participant Guide"). The OIG determined that 62 risk scores for 44 members were invalid because (i) the

documentation did not support the associated diagnosis obtained from the coding used on the claims; (ii) the documentation did not include the provider's signature or credentials; or (iii) the diagnosis was uncertain based on the coding contained on the claims.

We believe that the OIG erred in its analysis and conclusion for several reasons, which we detail below, including:

- **The OIG's sample of 100 beneficiaries is not fully representative of beneficiaries among the 118,000 members of the plan, nor is it fully representative of the 63,000 members who had a risk score based on at least one HCC. Only 40 of the 70 HCCs that appear in the population are represented in the audit sample. As such, the OIG's extrapolation of invalidated diagnosis applies to 30 HCCs that appear in the population, but for whom no beneficiaries were audited.**

- **The underlying process of translating ICD-9 diagnosis codes reported on claims into HCCs (approach used for payment) versus employing validation contractors and a reconciliation process to review medical records (approach used in audit) will likely result in inconsistencies between HCCs derived from these two sources. HCCs determined from ICD-9 diagnosis codes reported on claims are likely to be different from HCCs derived from medical records and it is unreasonable to assume these two sources will result in the same HCCs. These differences are confirmed by examples of HCCs that are unsupported in the RADV audit of medical records, but are supported by multiple claim records by multiple providers. As a result, using this audit methodology to compute overpayments is fundamentally flawed and inappropriate.**

- **The OIG utilizes the CMS-HCC risk adjustment payment model (referred to as the "Pope model"[1/]) to audit the individual beneficiaries sampled from the population. The Pope model was not designed to make accurate predictions of capitation payments for individual records, rather it was designed so that on payments *on average* compensate for the risk over a large group of beneficiaries. Given the high forecasting error associated with this model as acknowledged by its authors,[2/] the variation between actual and forecasted expenditures for the OIG sample may differ significantly across random samples drawn from the population.**

- **The OIG did not follow CMS's audit methodology set forth in both the 2006 and 2007 Participant Guides to conclude that some of the diagnoses that PacifiCare submitted to CMS for risk score calculations were invalid.**

- **PacifiCare conducted its own review of the medical records that were the subject of this review, and concluded that many of the HCCs invalidated by OIG were, in fact, valid. At the very least, the OIG should correct the invalid HCCs and credit PacifiCare with the incidental HCCs documented in the submitted medical records before considering whether to issue a final report.**

[1/] 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):119141, Summer 2004.
[2/] Pope et al., (2004), p. 131.

Accordingly, we request that the OIG withhold finalizing its report or substantially revise it.[3/] In the alternative, we ask that the OIG attach these comments as an appendix to any final report issued. If OIG intends to finalize the report, we request that OIG keep the final report confidential. In addition to this response letter, PacifiCare reserves the right to submit supplemental materials either to the OIG or to CMS.

I. BACKGROUND

Congress created the Medicare+Choice program through the establishment of Medicare Part C as part of the Balanced Budget Act of 1997.[4/] Although private health plans had contracted with Medicare on a limited basis to provide services to eligible patients since the 1970s, the Medicare+Choice program was created to significantly increase the relationship between private health plans and Medicare. Prior to 1997, payments to health plans for managing Medicare recipients' health care were based on fee-for-service ("FFS") expenditures, adjusted by geographic areas and certain demographic factors (age, gender, working status, and Medicaid eligibility). Medicare+Choice began a transition from a demographic-based reimbursement model to a system using a patient's actual health status to estimate future health care costs.[5/]

In 2003, Congress revamped the Medicare Part C program through the creation of Medicare Advantage ("MA"). Under MA, health plans are reimbursed a capitated, risk-adjusted monthly fee for each enrollee based upon each patient's overall health. Enrollees are assigned a risk score that reflects their health status as determined from data submitted during the previous calendar year. MA's risk adjustment methodology relies on enrollee diagnoses, as specified by the International Classification of Disease, currently the Ninth Revision Clinical Modification guidelines ("ICD–9") to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee. Diagnosis codes are used to determine the risk scores, which in turn determine risk adjusted payments for enrollees.

The current risk adjustment model employed in adjusting MA plan payments is known as the CMS Hierarchical Condition Category ("CMS– HCC") model.[6/] The CMS-HCC 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. In 2007, a demographic

---

[3/] If the OIG substantially revises its report, PacifiCare requests the opportunity to review the modified draft before it is released.
[4/] Pub. L. No. 105-33.
[5/] Sherer R. The failure of Medicare+Choice. *Geriatric Times* 2003;4:4-5.
[6/] Pope et al., (2004).

data-only payment method was completely phased-out for MA plans, and 100 percent of each payment for an enrollee was risk-adjusted.[7/]

As CMS phased-in the application of health status risk adjustments from 2000 through 2007, and the financial impact of risk adjustment data became more significant and the complexities of the process became more apparent, CMS promulgated new rules regarding risk adjustment data collection. Prior to August 2008, MA organizations ("MAOs") received instruction regarding the submission of risk adjusted data through CMS's annual Participant Guides. For the 2007 plan year, where payments were made based on 2006 dates of services, MAOs relied primarily on the Participant Guide from 2006; the 2007 Participant Guide, which contained several changes from the 2006 Participant Guide, was not released until December 2007.

In August 2008, CMS codified the requirements regarding the submission of risk adjusted data that generally mirrored the obligations set forth in the Participant Guides.[8/] More recently, in April 2010, CMS finalized regulations governing its risk adjustment data validation ("RADV") dispute and appeals procedures, which in some instances formalized processes CMS had adopted in practice but had not established in regulation.[9/] This final rule also indicated CMS's intent to develop and release for public comment its RADV audit and extrapolation methodology, which is still under development.[10/] These dispute and appeals procedures recognize the complexity of the risk adjustment program and the need for clear methodologies and avenues for dispute resolution to be established.

Another significant development in the changing authorities governing risk adjustment data was CMS's announcement in July 2008 of a pilot project to more extensively audit MA organizations for payment year 2007 based on calendar year 2006 payment data.[11/] In this notice, CMS announced its intent to make contract-level payment adjustments using payment error findings from a sample of enrollees from selected contracts. This was a major change to CMS's RADV audit approach; it signaled for the first time CMS's intent to recover contract-level payments from MAOs. Prior to this initiative, payment adjustments were limited to enrollee-level adjustments for those enrollees sampled in the payment validation audit.[12/] In light of the potential impact of contract-level payment adjustments, CMS

[7/] CMS phased in the application of risk adjustments to payments from 2000 to 2007, with an increasing percentage of the monthly capitation payment subjected to risk adjustment each year. In 2007, 100 percent of payments to MAOs became risk-adjusted based on enrollee health status. 42 U.S.C. § 1395w–23(a)(1)(C).

[8/] 42 C.F.R. § 422.310; 73 Fed. Reg. 48757 (Aug. 19, 2008).

[9/] 75 Fed. Reg. 19678, 19806 (Apr. 15, 2010).

[10/] *Id.*

[11/] *See* CMS Memorandum, *Medical Record Request Instructions for the Pilot Calendar Year 2007 Medicare Part C Risk Adjustment Data Validation*, July 17, 2008.

[12/] 74 Fed. Reg. 56634, 54674 (Oct. 22, 2009). We note that, to our knowledge, CMS has not extrapolated payment errors at the contract-level for MAOs that have been subject to RADV audits as part of the pilot project.

developed several new policies. Importantly, CMS allowed MAOs selected for contract-level samples to submit physician-signature attestations for physician and outpatient medical records.[13/]

As demonstrated by these evolving authorities, there has been great flux in the development of risk adjustment data collection policies and regulations over the past few years. The OIG failed to consider this changing landscape and the complexities of risk adjusted payments in its audit and analysis. In addition, the OIG did not follow certain procedures that CMS applied to RADV audits for risk adjusted data collected during the data collection period. Detailed below are some of the specific factors that the OIG failed to consider when conducting the audit and calculating an alleged overpayment amount, and some examples where the OIG failed to follow CMS processes that results in inaccurate findings.

II. ERRONEOUS AUDIT AND EXTRAPOLATION METHODOLOGIES

Although the OIG asserts that it used generally accepted auditing standards, it did not. In conducting its audit and extrapolating an overpayment amount, the OIG disregarded several crucial aspects of risk adjustment payments that inappropriately biases the results and reflects an exaggerated alleged overpayment amount.

A. Statistically Valid Random Sample

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. The sample of 100 beneficiaries[14/] utilized by the OIG is not fully representative of beneficiaries among the 118,000 members enrolled in PacifiCare during the audit period, nor is it fully representative of the 63,000 members who had a risk score based on at least one HCC. Only 40 of the 70 HCCs that appear in the population are represented in the RADV audit sample. As such, the OIG's extrapolation of invalidated diagnosis applies to 30 HCCs that appear in the population, but for whom no beneficiaries were audited, and therefore is not an accurate representation of the population.

There are at least two ways that the sample could have been drawn to ensure representativeness. First, a larger sample would have a higher probability of drawing all of the HCCs that appear in the population during the relevant period. A sample size of 100 is too small to account for the tremendous diversity of the beneficiaries in the population.

Alternatively, the samples could have been stratified according to HCC. Stratification would have involved dividing the population into subgroups, one for each HCC in the population, and then

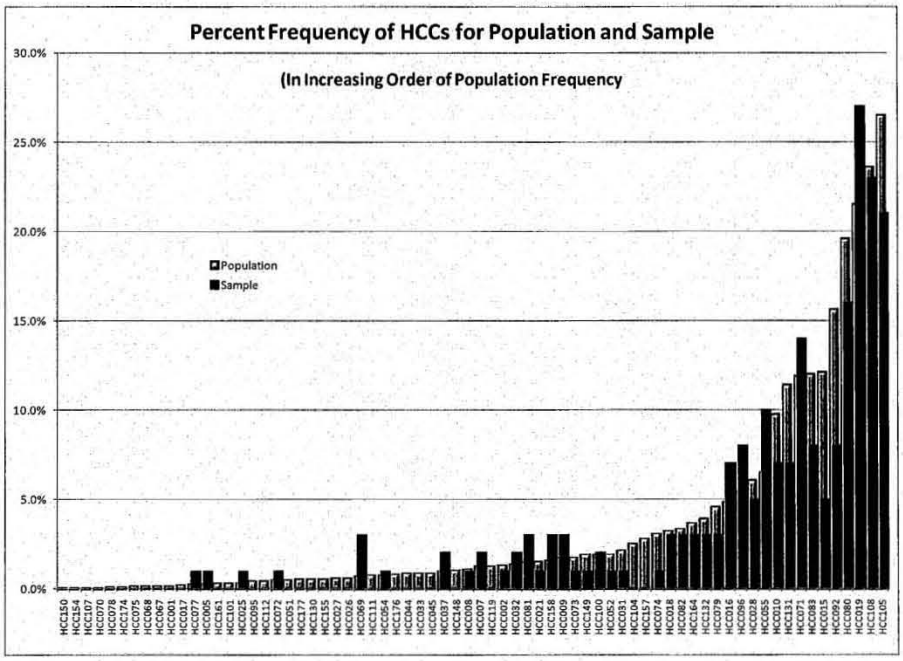
---

[13/] *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).

[14/] Under established CMS standards, CMS generally draws a sample of at least 200 members when conducting an RADV audit.

drawing a random sample of claims from each subgroup. There are a number of advantages to stratification, notably a reduction in sampling variance relative to a simple random sample. In addition, stratification is routinely employed for exactly the reasons suggested here: A simple random sample, particularly a small one, may not include enough of particular subgroups to ensure representativeness and reliable statistical inference. A stratified sample allows for oversampling of relevant subgroups, which are then reweighted according to their population frequency.

In this case, the sample could have been stratified so as to include at least one beneficiary for each of the 70 HCCs in the population to ensure that all of the relevant traits in the population are represented. Of course, a sample of 100 would produce many strata with only one observation, but again that is a reflection of the fact that a diverse population requires a larger sample in order to ensure representativeness. The fact that the total number of sample points (100) is not much larger than the number of proposed strata (70) is a strong indication that a sample size of 100 is inadequate for the population under study.



The chart above shows the frequency distribution among HCCs for both the population of 62,987 members with at least one HCC and in the audit sample. The match between the two distributions is generally poor, even among some of the HCCs that are more prevalent in the population. In particular, the current sample of 100 does not even account for a significant number of HCCs in the population – fully 30 HCCs are not represented in the sample.

Stratification would have ensured that the sample was more representative of the population. The OIG did not design the sample to account for the diversity of beneficiaries in the population, at least with regard to HCC. The lack of representativeness of the sample for the population in question significantly reduces the reliability of the extrapolated overpayment determinations.

B. OIG's Audit and Extrapolation Methodology Has No Grounding in CMS Policies and Procedures

Importantly, the OIG conducted this Audit, determined a payment error, determined an extrapolation methodology, and recommended a repayment amount using a methodology that has not been vetted by CMS and on which MAOs have not had the opportunity to comment. To date, CMS has only made enrollee-level adjustments for those enrollees sampled in an RADV audit under the 2006 and 2007 Participant Guides.[15/] On the heels of the new regulations that establish appeal rights for MAOs subject to RADV audits, and given the significance of contract-level adjustments, CMS has declared that it will implement three steps to ensure that the RADV process is transparent to audited MAOs and the public.[16/] First, CMS will incorporate an additional independent third party review to replicate and validate the payment determinations that result in CMS's error calculation. The independent third party will employ the same error-calculation criteria that will be used by CMS in preparing its initial error calculation. Second, CMS intends to publish its RADV methodology in "some type of CMS document - most likely a Medicare Manual, so that the public can review and provide comment as it deems necessary" before implementing.[17/] Third, CMS will describe CMS's RADV methodology in each audited organization's RADV Audit Report.[18/] In addition, CMS has recognized that there are complexities in validating risk adjusted payments and extrapolating discrepancies to the contract level,

---

[15/] 74 Fed. Reg. 56634, 54674 (Oct. 22, 2009). As discussed in Section I, CMS announced its intention to make contract-level payment adjustments using payment error findings from a sample of enrollees for those MAOs selected to participate in the RADV pilot project. CMS has not announced any extrapolation methodology and, to our knowledge, CMS has not extrapolated payment errors to the contract-level against MAOs that have been subject to RADV audits as part of the pilot project.

[16/] 75 Fed. Reg. 19678, 19746, 19753 (April 15, 2010).

[17/] *Id.*

[18/] 42 C.F.R. § 422.311(c)(3)(vi); 75 Fed. Reg. 19678, 19746, 19753 (April 15, 2010).

but has not yet revealed its methodology for doing so, and it is uncertain whether and when CMS will begin employing such measures.

The OIG's RADV process and payment calculation reflected in the Draft Report fails to comply with two important steps announced by CMS.

- The OIG did not follow an established CMS methodology to calculate payment errors. Indeed, CMS has not proposed any methodology for calculating Part C payment errors - certainly none on which PacifiCare has had an opportunity to comment. OIG's application of an extrapolation methodology is therefore both premature and inappropriate.
- Further, the OIG did not adequately describe its own payment calculation and extrapolation methodology - which must mirror the yet to be determined CMS methodology- in the Draft Report nor did it describe the bases for any such methodology.

The OIG's failure to follow CMS's procedures in conducting the Audit and the lack of detail regarding its payment calculation and extrapolation methodology result in a payment error calculation that is not only premature and inappropriate, but also imprecise and fails to provide enough detail so as to allow PacifiCare to challenge the OIG's findings. Until a payment error calculation and extrapolation methodology is released by CMS and the public has an opportunity to comment on such methodology, it is inappropriate for the OIG to recommend any contract-level adjustment.

C. The OIG's Audit Model Does Not Reflect CMS's Payment Model

Risk adjusted payments to MAOs are determined based on the health risks posed by individual beneficiaries. Each Medicare member is assigned an individual risk score, which is determined from historical health conditions. Specifically, CMS primarily utilizes ICD-9 codes submitted on by treating providers on claims in the previous year to compute the risk score and resulting payment for each individual for the current year. CMS has adopted a methodology that translates ICD-9s into Hierarchical Condition Categories (HCCs) by mapping the ICD-9s into Diagnostic Groups (DxGroups), which are subsequently mapped into Condition Categories (CCs) based on the CMS-HCC risk adjustment payment model.[19/] A set of hierarchical conditions are then imposed on the CCs to obtain HCCs. HCCs are computed as a function of ICD-9 codes, where various ICD-9 codes are mapped into Diagnostic Groups, CCs, and finally HCCs.

[19/] Pope et al., (2004).

CMS also commissioned the development of a statistical risk adjustment payment model to predict members' medical costs, which is used to determine MA risk adjusted payments. The model includes statistically estimated coefficients for HCCs, as well as gender, age, Medicaid/disabled indicators and interaction terms.[20/] CMS uses the functional form and coefficients from the statistical estimation process to compute capitation payment for each beneficiary.

In an effort to evaluate whether risk adjusted capitation amounts paid to MAOs are accurate, CMS uses a RADV audit process which, like the risk adjustment payment model, relies on the predictions from the Pope model. A sample of beneficiaries is selected from an MAO and specific contract, and CMS evaluates whether the payment HCCs assigned to each individual are supported by medical records from the previous year. MAOs must submit to CMS the "one best medical record" that supports each HCC.[21/]

One of the fundamental premises of this audit process is that HCCs derived from medical records should be equal to HCCs derived from claims submitted by treating providers, and differences between HCCs derived from medical records and HCCs derived from claims are "payment errors," and any overpayment must be refunded to CMS. However, we suggest that differences between HCCs derived from medical records and HCCs derived from claims are not payment errors, but rather are the results of two different inputs into the risk adjustment payment model: claims and medical records. Furthermore, since the payment model is estimated based on HCCs derived from claims, we believe it is inappropriate to use HCCs from medical records as model inputs to compute capitation amounts for the following two reasons:

1) **HCCs derived from medical records are not the same as HCCs derived from claims data**

During the OIG RADV audit, the OIG's validation contractors determined whether each HCC derived primarily from claims data submitted for each member was supported or not supported by the MAO-submitted "one best medical record." HCCs determined from claims submitted by treating providers are likely to be different from HCCs derived from validation contractors and medical records. Studies have shown that the diagnoses contained in medical records and diagnoses identified in claims are, in practice, inconsistent.[22/] This inconsistency, that is, the discrepancy between HCCs derived from claims data and HCCs derived from medical records, has been termed the "error rate" in the industry.

[20/] Pope et al., (2004).
[21/] Centers for Medicare & Medicaid Services: *CY2007 CMS Risk Adjustment Data Validation MA Organization Training*, PowerPoint Presentation, Baltimore, Maryland, October 23, 2009).
[22/] *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/.

HCCs identified from medical records are not likely to be equal to HCCs determined from claims data for two reasons. First, information contained in claims data is not equal to the information contained in medical records. Second, the process used to develop HCCs from medical records is different from the process used to determine HCCs from claims data.

In many instances, coding and medical records contain different information. Reasons include:

- Lack of documentation in either claims or medical records;
- ambiguities in coding specific conditions;
- errors in coding or medical record errors; or
- differences in interpretation of medical notes including lab results.

Discrepancies and errors in diagnosis codes are well documented (*See* Appendix A for a summary of research). CMS conducts regular coding audits and reports coding discrepancies and errors.[23/] Authors of the CMS-HCC risk adjustment payment model 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."[24/] Although efforts to reduce coding errors are important, errors are unlikely to ever be completely eliminated as long as coding includes human interpretation and judgment, and data entry.

In addition, the process of identifying HCCs from claims data is very different than the audit process. HCCs from claims are derived by mapping ICD-9s through diagnosis groups, condition categories, and applying hierarchies to arrive at HCCs, whereas HCCs derived from medical records are determined using verification contractors and a rule-based reconciliation process. These are very difference methods for determining HCCs and process differences are likely to account for inconsistencies in HCCs.

2) HCCs derived from medical records are not the appropriate input for the model to compute capitation payments

The statistical model developed to determine capitation payments was developed based on HCCs identified from ICD-9s.[25/] In statistical terms, the data generation process for HCCs derived from claims data is very different from the data generation process for HCCs derived from medical records. As a result, it is inappropriate to use one HCC methodology in a model developed for the other. Furthermore, there is no assurance that forecasted expenditures are accurate or even unbiased. ICD-9 errors and coding

[23/] See http://www.cms.gov/apps/er_report.
[24/] Pope et al., (2004), p. 121.
[25/] Pope et al., (2004).

patterns due to ambiguities and judgment are implicit in the model where HCCs are derived from claims data. As long as the errors and coding patterns are consistent between the model estimation data and the forecast period data, this model will continue to accurately forecast medical expenditures.

However, if CMS wishes to determine payments based on a statistical model where HCCs are derived from medical records, then a statistical model utilizing this framework should be developed from the ground up. This would require developing a sample of data using verification contractors and the reconciliation process to obtain HCCs from medical records. Estimation of a statistical model that uses HCCs derived from medical records as independent variables and medical expenditures as the dependent variable would be required. The functional form, including statistically significant HCCs, and the estimated coefficients would likely be different between the two models based on how HCCs were derived.

The precise relationship between HCCs derived from medical records and HCCs derived from claims data is not clear without further research. HCCs derived from medical records could be biased or unbiased with respect to HCCs derived from claims data. Further, even if HCCs derived from medical records is an imprecise, but unbiased estimate of HCCs derived from claims data, the CMS audit policies including (i) inability to introduce new HCCs, (ii) "one best medical record," and (iii) the exclusion of all beneficiaries with no HCCs from the audit would all result in a bias toward decreasing the number of HCCs and lower capitation payments. Given the inexact relationship between HCCs derived from medical records and HCCs derived from claims data and the one-sided implementation of the audit rules (i.e., elimination of all opportunities to increase number of HCCs), audits will almost always result in equal or fewer HCCs and equal or lower capitation payments.

3) The OIG's Model Does Not Account for FFS Disparity

CMS has 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.[26/] The OIG disregarded this important factor in reaching its conclusions. Unless and until CMS hones this process for determining "error rates," which it is considering, it is inappropriate for the OIG to recommend a contract-level payment amount. In particular, the audit and extrapolation methodologies employed in the OIG Audit are fundamentally at odds with the MA risk adjustment payment model. The MA risk adjustment model was developed using Medicare FFS claims data for the purpose of establishing "comparable" payments to MAOs intended to represent an actuarial estimate of the risk present in MAO plan membership relative to that of the Medicare FFS population.

[26/] 75 Fed. Reg. 19678, 19746, 19749 (April 15, 2010).

Given this correlation to FFS claims data, to achieve a fair and accurate result, the audit of MA risk adjustment data using a medical record review must take into account the circumstances of the underlying FFS data used to develop the model, specifically the recognized potential disparity between the diagnoses reported by providers on claims, which were used in developing the model, and those fully documented in medical records, which were not used in developing the model. To determine whether an MA organization's payments accurately reflect what would be paid to treat a FFS population based on the claims data submitted for the FFS population, the OIG needs to determine the level of disparity between the FFS claims data and the FFS medical record data, and the impact of translating that data in HCCs based on the claims data. The OIG audit results do not reflect such a comparison. Instead, the OIG recommends to adjust MA payments at the contract level based solely upon alleged coding errors in member medical records without any consideration of the extent to which these alleged "errors" or discrepancies are reflective of similar differences found in Medicare FFS.

D. The Risk Adjustment Payment Model Was Not Designed To Be Used to Make Predictions For Individual Beneficiaries

In the OIG audit, a sample of 100 beneficiaries was drawn from a population of 118,000 beneficiaries in PacifiCare of Texas. The audit included using medical records to either "support" or "not support" the existence of all HCCs for the sample of 100 beneficiaries. By using the "supported" HCCs, and employing the underlying statistically-developed risk adjustment payment model by Pope et al.,[27] the OIG recalculates MA payments for this sample. The recalculated expenditure is the amount that OIG suggests should have been paid to PacifiCare for the sample for CY 2007. The difference between this new value and what was paid is defined by OIG as overpayment (or underpayment). Subsequently, this difference is extrapolated to the population of 62,987 beneficiaries to compute the total overpayment.

While accurate for large populations, the model developed by Pope et al. to assign HCCs and predict costs was not designed to produce results for individual beneficiaries. The regression equations in the risk adjustment payment model can be used to determine the HCCs and make cost predictions for the *average* beneficiary in a relatively large subgroup, but there is substantial unexplained variation among beneficiaries not accounted for. The R-squared of the best model is under 13%, which is not surprising since the model is based on ICD-9 codes rather than individual medical records. The prediction for any individual beneficiary may be significantly in error. Inferences about the nature of specific elements of a population based solely upon aggregate statistics collected for the group to which those individuals belong is commonly known as the *ecological fallacy*. This fallacy assumes that individual members of a

[27] Pope et al.: Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model, *Health Care Financing Review* 25(4), 119-141, Summer 2004.

group have the *average* characteristics of the group at large. For example, if a particular group of people are measured to have a lower average income than the general population, it is an error to assume that *all* members of that group have lower income than the general population. For any given individual from that group, there is no way to know if that person has a lower than average income, average income, or above average income compared to the general population. In the same way, predictions made utilizing the Pope model should only be applied to large populations of beneficiaries to ensure that random but significant differences among beneficiaries which are not captured by ICD-9 codes do not produce predicted capitation payments that deviate dramatically from actual values. Indeed, in the Pope model, all of the comparisons of predictive accuracy are made for large subcategories of beneficiaries, and even then for some of those subgroups the model can under or overpredict by as much as 30 percent.[28/]

E. The Error Rate of the Risk Adjustment Payment Model Should Be Incorporated In Computing the Overpayment Confidence Interval

Another result of using the risk adjustment model as an audit tool is that the confidence intervals computed by the OIG auditor are understated, perhaps significantly. The OIG auditor computes a 90% confidence interval that reflects extrapolation from the sample of 100 audited beneficiaries to the population. However, this confidence interval reflects only the sampling variance in the overpayment (underpayment) amounts, and does not incorporate uncertainty due to the risk adjustment payment model used to forecast expenditures from HCCs. The aggregate error of this model, when applied to large populations, is small relative to the aggregate capitation payments. However, as with all statistical models used to predict future health expenditures based on past health conditions, the predictive accuracy of the model is relatively low for a small set of individuals. For a sample of 100, combining the forecast variability with the sampling variability will increase the confidence interval relative to that proposed by OIG.

Using the data in the OIG report appendix, the sample mean of the difference between payments based on ICD-9 derived from claims and payments based on ICD-9's derived from medical records is $1,997 and the sample standard deviation is $3,562. The 90% confidence interval for the population mean is $1,997 +/- $585.8. Extrapolating results gives the overpayment confidence interval of [$88,546,120, $162,988,333]. The 95% confidence interval is [$81,032,858, $170,501,946].

Details of these calculations and the replication (bootstrap) approach employed to obtain these results is described in Appendix B. Additional work is needed to identify the most appropriate methods for including model errors in the overpayment confidence interval. Although alternative approaches may be more appropriate, model errors should be explicitly considered when extrapolating audit results to the

[28/] Pope et al., (2004), Tables ES-3 through ES-6.

population. Furthermore, inclusion of model errors will result in a wider confidence interval for total overpayments. At a minimum, finalization of the report would be inappropriate without further analysis.

III. THE OIG FAILS TO ACCOUNT FOR MEMBERS WHO TERMINATED COVERAGE OR CHANGED STATUS

In the Draft Report, the OIG extrapolates alleged overpayments from the 100 member sample to the entire population of members who had at least one HCC and continuous enrollment from January 2006 through January 2007. However, this methodology does not account for differences between the sample population and the larger extrapolation population. For example, the OIG did not consider members who moved to different plans or passed away during the 2007 payment year in the larger population to which the alleged overpayment has been extrapolated. In addition, this membership includes beneficiaries whose status changed during the payment year (e.g., the members were transferred to institutions, hospice or dialysis). Extrapolation of an alleged overpayment to these members is inappropriate because their capitation payments are calculated using a different rate methodology than is used for the general membership. The OIG's methodology must account for these differences before proposing any extrapolation.

IV. ERRONEOUS AUDIT PROCESSES AND STANDARDS

The OIG is required, both by law[29/] and by the stated objective of its audit, to follow CMS's guidance and regulations governing RADV audits in conducting this audit. However, the OIG failed to follow CMS processes, and in doing so, exceeded its authority and arrived at inaccurate results that contradict CMS practices and stated policies and methodologies. To start with, the OIG should have used the 2006 Participant Guide as its benchmark against which to evaluate PacifiCare's compliance with CMS's requirements. Although the substance in the 2006 and 2007 Participant Guides are similar with respect to RADV audits, CMS afforded MAOs greater latitude pursuant to the guiding principle articulated in the 2006 Participant Guide in the submission of supporting medical record documentation than was granted in the 2007 Participant Guide. As noted above, the 2007 Participant Guide was not even published until December 2007, yet the OIG as applied it to medical records that were created in 2006 for purposes of this audit.

CMS provided the following flexibility to MAOs subject to RADV audits per the guiding principle reflected in the 2006 Participant Guide:

> The medical record documentation must show that the HCC diagnosis was assigned within the correct data collection period by appropriate provider type (hospital inpatient, hospital outpatient, and physician) as defined in the CMS instructions for

[29/] 5 U.S.C.A. App. 3, § 2.

> risk adjustment implementation. In addition, the diagnosis must be coded according to International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD-9-CM") Guidelines for Coding and Reporting. ***MA organizations will be allowed more flexibility, per the guiding principle, in the submission of supporting medical record documentation when responding to a medical record request.***[30/]

Some specific examples of how the OIG failed to follow CMS procedures include:

A. Incidental HCCs

The OIG failed to consider additional HCCs that were identified incidentally during the Audit in accordance with CMS practices. Although CMS's RADV process accounts for both underpayments and overpayments, the OIG did not take into consideration underpayments in the Draft Report. That is, CMS will credit MAOs with additional HCCs that are identified during the medical review as being documented in the medical record, but that had not originally been reported to CMS.[31/] PacifiCare's review of the medical records submitted to the OIG in support of the audited HCCs confirms that the medical records also support seventeen (17) incidental HCCs for certain members.[32/] Under established CMS standards and practices, PacifiCare would receive credit for these HCCs in evaluating the impact of any HCCs that OIG believes do not validate. Because the OIG has refused to consider these HCCs, its analysis is contrary to CMS standards and its results are inaccurate.

B. Two Levels of Review

The OIG denied PacifiCare certain processes provided in both the 2006 and 2007 Participant Guides. When conducting RADV audits, CMS contracts with two independent review contractors to conduct medical record reviews. The Initial Validation Contractor (IVC) facilitates the process and conducts the initial review of medical records. All identified discrepancies[33/] 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.[34/] The IVC

[30/] 2006 Participant Guide, 8.1.3. (***Emphasis added.***)
[31/] *Id.*
[32/] Please see TAB 1 in the spreadsheet attached at Appendix C with member-diagnosis level detail that explains why we believe PacifiCare should receive credit for certain incidental HCCs. Please note that the information contained in the attached spreadsheet is privileged and confidential, and protected from disclosure under the Freedom of Information Act, 5 U.S.C. § 522(c).
[33/] Data discrepancies can include coding discrepancies, invalid medical records, or missing information. See 2006 Participant Guide 8.2.5.1, 2007 Participant Guide 7.2.5.1.
[34/] 2006 Participant Guide, Section 8.1.6; 2007 Participant Guide, Section 7.1.6.

and SVC are blind to each other's findings.[35] CMS shares any plan level findings to the selected MAOs, which may include a response rate, data discrepancy rates, and risk adjustment discrepancy error rates.[36]

CMS's process for allowing two 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.* As such, a proper sampling design would dictate the inclusion of a sufficient number of claims for each auditor (so that possible errors in 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 did not provide PacifiCare with the same procedural protections. Instead, if an HCC did not did not validate under the OIG's review, it was included in a group from which only a 5% random sample was chosen to be reviewed by a second medical reviewer. Moreover, it is unclear whether or not this second reviewer was independent from the first or blinded as to the results of the first coder, as is the SVC that reviews discrepancies under CMS processes. The limited 5% review of risk adjustment discrepancies and the associated relationship between the OIG reviewers further brings into question the accuracy of the OIG's analysis and findings, as is evidenced by the conditions identified by PacifiCare that were in fact valid, discussed in Section IV below.

C. Physician Signature Attestations

The OIG did not follow CMS's audit methodology by refusing to accept physician signature attestations submitted by PacifiCare. The OIG determined that fourteen HCCs were invalid, in whole or in part, due to missing physician signatures or credentials. For the pilot project RADV audits, where payment errors could be extrapolated to the contract-level, CMS accepted physician-signature attestations for physician and outpatient medical records that show that the physician and other practitioners had the requisite signatures and credentials.[37] CMS permitted this additional information because it has recognized that "form over substance" errors should not be given as much weight as actual payment errors.[38] This was an important allowance for MAOs subject to the RADV pilot project, given the intention to make contract-level payment adjustments using payment error findings from the selected

---

[35] *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).

[36] 2006 Participant Guide, 8.2.6, 2007 Participant Guide, 7.2.6.

[37] *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).

[38] 75 Fed. Reg. 19678, 19749 (April 15, 2010).

sample. The financial impact of the adjustments was recognized by CMS and such attestations were required to avoid skewed, inaccurate results. Thus, at a minimum, the OIG should not recommend extrapolation of any alleged overpayment to the contract-level as part of this Audit where it does not accept such attestations.

D. Individual Payment Adjustments

Finally, and importantly, neither the 2006 nor the 2007 Participant Guides contemplate extrapolating "overpayments" to the contract level using risk adjusted discrepancies discovered in an RADV audit. Prior to the application of the pilot project, CMS made payment adjustments only for those enrollees sampled in the payment validation as part of its routine validation process. Thus, the OIG should not recommend extrapolation for any alleged overpayment to the contract-level as part of this Audit, as the explicit scope of the review is to determine compliance with the 2007 Participant Guide.

V. MANY OF THE CONDITIONS INVALIDATED BY THE OIG ARE VALID

In response to this audit, PacifiCare conducted its own review of the medical records that were the subject of this review and concluded that at least seventeen (17) of the OIG's invalidated HCCs were, in fact, supported by the "one best medical record" submitted to the OIG.[39/] If some of the procedural protections that CMS affords were in place, such as the use of two levels of review, we expect that these HCCs would have been validated.

Additionally, we not only reviewed the one best medical records that were submitted to the OIG for each of the 44 members who had one or more HCCs invalidated, but we also evaluated each of those member's records from the data collection period. We found that many of the members whose HCCs were audited and invalidated were actually treated for the health conditions for which HCCs were reported, regardless of the OIG's analysis. Through our review, for example, we found seven (7) diagnoses that were submitted to support a risk score were supported in records other than the one best medical record, often among a collection of several records, and perhaps from various providers.[40/] This highlights a common situation among members with a chronic disease, for whom a multiple records should be considered in the aggregate to verify the enrollee's HCC. Had the OIG followed the guiding

---

[39/] Please see TAB 2 in the spreadsheet attached as Appendix C with member-diagnosis level detail that explains why we believe PacifiCare should receive credit for these HCCs. Please note that the information contained in the attached spreadsheet is privileged and confidential, and protected from disclosure under the Freedom of Information Act, 5 U.S.C. § 522(c).

[40/] Please see TAB 4 in the spreadsheet attached as Appendix C with member-diagnosis level detail that explains why we believe PacifiCare should receive credit for these clinically justifiable HCCs. Please note that the information contained in the attached spreadsheet is privileged and confidential, and protected from disclosure under the Freedom of Information Act, 5 U.S.C. § 522(c).

principle articulated in the 2006 Participant Guide discussed above that granted MAOs greater flexibility in the submission of supporting medical record documentation, and had the OIG considered supplemental information in accordance with this guiding principle, the OIG would have determined that many of the invalidated HCCs were in fact adequately documented and conditions for which PacifiCare members were actually treated.

By way of example only, we have highlighted two members whose diagnoses have been invalidated by the OIG but for whom we have determined the patient's complete medical record supports the HCC:

(1) OIG Patient Number 54, Diabetes with Other Specified Manifestations

PacifiCare submitted the medical record of an encounter dated July 26, 2006 to support the diagnosis code of 250.80 (diabetes with other specified manifestations). The OIG found that the documentation supported the diagnosis of diabetes (code 250.0) but found that the medical chart notes were difficult to read and that the "manifestations" were not clearly documented.

PacifiCare disagrees with this assessment. The progress note from July 26, 2006 indicates that the patient was seen for a diabetes check up, and reflects that the patient had decreased glucose (indicated by a down arrow) with tremors. The plan of care included stopping the patient's Glipizide, an oral drug used to treat type 2 diabetes. Such a course of action is an appropriate response to hypoglycemia, which may be indicated by symptoms such as tremors, and is a well known serious reaction to Glipizide. Taken together, these symptoms reflect a "specified manifestation" in the ICD-9 tabular for the submitted diagnosis code.

(2) OIG Patient Number 68, Congestive Heart Failure

PacifiCare submitted a medical record from an emergency room visit on October 2, 2006 in support of diagnosis code 428.0 (Congestive heart failure, unspecified), among other diagnoses. The record indicated that the patient was seen for generalized weakness and pain below the waist with a past history of heart failure, high blood pressure, heart attack, heart failure, DVT, dysphagia, high cholesterol, and renal disease. The OIG determined that while it was likely that any of these past diagnoses could be assessed during part of a general overview of the patient's health, the physician did not specifically document any active treatment or assessment of these conditions at this visit. The OIG concluded that the presence of heart failure did not affect the care, treatment or the management provided at this encounter.

However, the order sheet from this date of service shows that the treating physician ordered a test for congestive heart failure, beta-natriuretic peptide (BNP), which returned dramatically elevated levels that strongly suggested congestive heart failure. Moreover, this patient's medical record documents earlier treatment for congestive heart failure during the reporting period. On March 1, 2006 and August 29, 2006 the patient was seen for persistent cough and weakness. On August 29th, this patient was treated with an increased dose of diuretic, a maneuver used for heart failure.

VI. POLICIES AND PROCEDURES

The Draft Report asserts that PacifiCare did not have written policies and procedures for obtaining, processing, and submitting diagnoses to CMS. As explained to the OIG during the audit, PacifiCare largely used automated systems for obtaining, processing, and submitting diagnoses to CMS. PacifiCare had documented system protocols for the processing of data through its systems.

The Draft Report also states that PacifiCare's practices were not effective at ensuring that the diagnoses submitted to CMS complied with the requirements of the Participant Guide. As indicated, we respectfully disagree with OIG's draft conclusions regarding whether the audited diagnosis codes were indicative of the medical conditions experienced by PacifiCare's members. PacifiCare's practices were sufficient to ensure that its submissions complied with the Participant Guide requirements.

The Draft Report indicates that PacifiCare did not routinely use chart validation as a preventative practice, but instead used it as a response to external auditors' requests for documentation. This statement is not accurate and suggests that the OIG misunderstood what it was told regarding chart validation. In its written response to OIG's questions, PacifiCare explained:

> A chart validation involved the review of a provider's patient charts to determine whether they supported certain codes that the provider had reported. We selected a provider for chart validation based principally on whether the provider's coding was unusually high compared to a national benchmark established by our risk adjustment system. The chart validation tested the provider's deviation from that benchmark. Codes found to be inaccurate or incomplete through chart validations were deleted.

This process was used as a validation tool of codes submitted related to 2006 dates of service.

In addition, PacifiCare implemented a number of provider education and outreach initiatives that stressed the importance of proper coding and documentation. PacifiCare shared with the OIG examples of these initiatives, including flyers that discussed symptoms of specific diagnoses such as depression and cancer to ensure that providers were not inappropriately assigning these ICD-9 codes, as well as

documents that were presented to network provider groups that emphasized the importance of accurate documentation.

VII. CONCLUSION

For the reasons stated above, PacifiCare respectfully disagrees with the OIG's findings and recommended extrapolation. Significantly, the OIG fails to account for the underlying complexities of risk adjustment payments in its audit methodology, and as a result, grossly overestimates an alleged overpayment amount. CMS's risk adjusted payments are not designed so that discrepancies found in information submitted to support risk scores can be extrapolated to the contract level. CMS has recognized that there are complexities in validating risk adjusted payments and extrapolating discrepancies to the contract level, but has not yet revealed or published its methodology for doing so. Thus, the OIG's recommendation to extrapolate any alleged overpayments is fundamentally flawed and inappropriate.

Moreover, our analysis of the alleged overpayment amount – using the calculation methodology used by the OIG – is reduced from $199,672 to approximately $106,000[41/] if the additional HCCs we have identified are considered. Notwithstanding our previously stated concerns regarding the validity of the OIG's sampling and extrapolation methodologies, the individual impact of each of these HCCs on the OIG's recommended extrapolation would be substantial, and the precision of the OIG's calculation of extrapolation falls significantly if the attached HCCs are considered. Accordingly, we urge the OIG to evaluate carefully each of these HCCs before issuing a final audit report in order to support the objectives of the audit to ensure that PacifiCare received accurate payments for the health status of its members.

We appreciate the opportunity to provide comments on the Draft Report, and welcome any questions or comments you may have about our response. In light of the points detailed above, we request that the OIG withhold its final report to allow CMS to address the issues raised in the Draft Report in the course of its developing RADV audit process. In the alternative, we ask that the OIG attach these comments as an appendix to any final report issued.

Please do not hesitate to e-mail me at tom_s_paul@uhc.com.

Sincerely,

Thomas S. Paul
Chief Executive Officer, Ovations

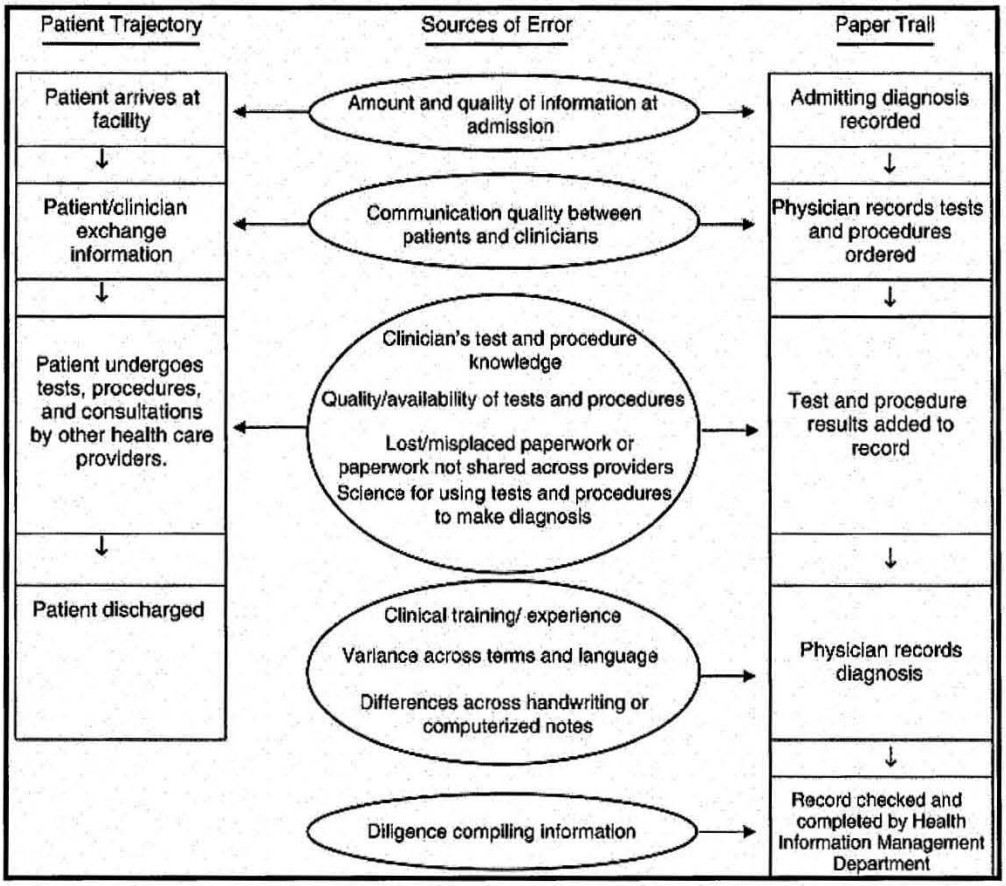
cc: Antigone Potamianos

[41/] This estimated overpayment amount could fluctuate slightly due to rounding and other arithmetic anomalies inherent in risk score calculations.

Appendix A

Research on Errors in Diagnosis Coding

A number of studies have evaluated coding accuracy, including coding ambiguities and errors. One such study developed a framework for characterizing errors as shown in the chart below. [42/]



[42/] 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/.

Research has also shown that errors in selecting the principal diagnosis may result from misunderstanding or misinterpreting a coding guideline, including failing to read encoder messages, inclusion and exclusion terms, and coding references during the coding process.[43/]

Common examples of incorrect principal diagnosis selection include:

- Coding a condition when a complication code should have been selected instead.
- Coding a symptom or sign rather than the definitive diagnosis.
- Assuming a diagnosis without definitive documentation of a condition.
- Coding from a discharge summary alone.
- Incorrectly applying the coding guidelines for principal diagnosis, especially in a situation where the coder selects the diagnoses when two or more diagnoses equally meet the definition of principal diagnosis.

Secondary diagnoses are frequently coded when they do not meet the criteria for reporting secondary diagnoses. Some of the "traps" in coding secondary diagnoses are found in physician documentation. Examples include use of the term "history of" for conditions that are currently under treatment, as well as for those that have been resolved prior to admission and misuse of terms. For example, "coagulopathy" is often documented when a patient on anticoagulant therapy has an expected prolonged prothrombin time, rather than a true coagulopathy. In addition, secondary diagnoses may be missed by coders who code from a discharge summary alone without reviewing all documentation.

[43/] Ruth Orcutt, Common Coding Errors and How to Prevent Them, Clinical Insights, June 2009, www.clinical-insights.com/resources-June09CodingErrors.html.

Appendix B

Identification of Confidence Intervals When Forecast Errors are Included

A. The OIG Methodology for Computing Overpayment Confidence Interval

The OIG computes the 90% confidence interval of the overpayments by applying the standard t-statistic methodology (the relevant value for 90% confidence with a sample size of 100 is 1.66). From Appendix C of the OIG Draft Report, overpayment amounts are shown for 44 of the 100 beneficiaries. The remaining 66 beneficiaries have zero overpayment. Using this data, the sample overpayment mean is $1,996.72 and variance is $12,686,696. The lower and upper bounds of the population mean of the overpayment is computed as $1,996.72 ± 1.66*[$12,686,696/(100-1)]^0.5, yielding a 90% confidence interval for the population mean of [$1,402.48, $2,590.97]. The overpayment confidence interval for the population is computed by multiplying the confidence interval for the population mean by 62,987 to yield [$88,546,120, $162,988,333].

B. Overpayment Confidence Intervals When Corrected to Include the Forecast Errors from the Pope Model

In computing this confidence interval, however, the OIG extrapolation incorrectly excludes the model errors from the CMS-HCC risk adjustment model.[44/] This model, as with all models that forecast future health expenditures based on current and past health conditions, exhibits significant forecast error. Although this error is small relative to total expenditures when the model is applied across large populations, the error is significant when the model is applied to a small set of beneficiaries. Given the high forecasting error associated with this model as acknowledged by its authors,[45/] the variation between actual and forecasted expenditures for the OIG sample may differ significantly across random samples drawn from the population.

The overpayment determined in the sample can be defined as:

1. $D_1 = (CP_{Medical\ Record} - CP_{claims}) + (e_{Medical\ Record})$

However, this calculation ignores the error introduced by the audit itself, since the predicted capitation amounts for individual records obtained from the Pope model are estimated with significant uncertainty. The following representation correctly accounts for both sources of uncertainty:

2. $D_2 = (CP_{Medical\ Record} - CP_{claims}) + (e_{Medical\ Record} - e_{claims})$.

[44/] Pope et al., (2004).
[45/] Pope et al., (2004), p. 131.

D_2 will have the same expected value as D_1, since the expected value of the overpayment remains unchanged from the OIG analysis (the expected value of the error terms are zero). However, D_2 has a significantly higher variance. To estimate the variance associated with D_2, a proxy for the error terms $e_{Medical\ Record}$ and e_{claims} is needed.

A statistical bootstrap approach was employed to incorporate forecast errors into the confidence interval of the overpayments. Proxies for the two error terms error terms $e_{Medical\ Record}$ and e_{claims} were developed from the population audited in the OIG analysis (contract H4590 and continuous enrollment January, 2006 through January 2007). Population members that continued to be members in December, 2007, and which did not utilize any capitated services were selected (n=23,666). Using the risk score for these members, and the medical expenditures for 2007, an estimate of the "national predicted average annual cost" was computed. This value was obtained where the risk factor multiplied by the national predicted average annual cost for all beneficiaries was equivalent to total medical expenditures for all beneficiaries. The proxy error for each observation was then generated by subtracting the forecasted expenditures (risk score times national predicted average annual cost) from the actual 2007 medical expenditures. This approach yielded and estimate of the variance of forecast errors of $813,846,784. Recall that this reflects only the population of members with at least one HCC.

***Method 1*: <u>Assume $e_{Medical\ Record}$ and e_{claims} are independent, and both have the distribution of the proxy errors computed above.</u>**

The bootstrap approach consisted of drawing 10,000 samples of 100 observations each. Each of the observations included a random draw of $(CP_{Medical\ Record} - CP_{claims})$ with replacement from the sample of 100 overpayments/ underpayments (including 66 zeros), and an independent separate random draw (with replacement) of each of $e_{Medical\ Record}$ and e_{claims} from the 23,666 proxy errors. In each observation, if a 0 was drawn for $(CP_{Medical\ Record} - CP_{claims}$, (i.e. one of the 66 observations with no adjustments), then $e_{Medical\ Record}$ and e_{claims} were also set to zero (no forecast error if no overpayment or underpayment amount). For each observation, D_2 was then computed.

By repeating the above steps, 10,000 samples of 100 observations each were obtained. The next step included computing the average D_2 for each of the 10,000 samples. By ordering the resulting 10,000 average values of D_2, the confidence interval was determined using the bootstrap percentiles, i.e. the 500th (5%) and 9,500th (95%) value of average D_2.

Under Method 1, where the two error terms are independent (i.e., the covariance term is zero), the resulting bootstrap-obtained confidence interval was [-$115,650,322, $372,809,489] versus the OIG reported confidence interval of [$88,546,120, $162,988,333]. This confidence interval, which includes

zero, suggests that the population variance is very high and the population overpayment is not statistically different from zero. A second option regarding the distributions of $e_{Medical\ Record}$ and e_{claims} are considered in Method 2.

***Method 2* – The forecast error terms are correlated, and the size of the error term is relative to the size of the forecasted overpayment (or underpayment).**

This implies that $e_{Medical\ Record}$ and e_{claims} are correlated, and that:

3. $e_{Medical\ Record} = (CP_{Medical\ Record} / CP_{claims}) * e_{claims}$

This method, although ad hoc, assumes that the size of the error term is relative to the size of the forecasted expenditure, a reasonable assumption. Furthermore, this method has an empirical basis since forecast errors were found to increase as the expected medical expenditure increased. By rearranging the terms in the above equations,

4. $(e_{Medical\ Record} - e_{claims}) = e_{claims} * (CP_{Medical\ Record} / CP_{claims} - 1)$.

This formulation implies that the forecast error introduced by the audit adjustment methodology is directly related to the overpayment, as a percent of the original payment. An identical bootstrap approach as Method 1 is used, except only one random draw of a forecast error term is needed. Again, in this case, if there was no overpayment, the error term is zero. Method 2 yielded a confidence interval of [$48,019,168, $192,972,591].

Additional methods might be proposed. Significant empirical work including obtaining variances of model parameters may be required to obtain an accurate confidence interval. In the end, however, including the model error will result in a wider confidence interval.

APPENDIX C "TAB 1" 9/10/2010

HCC Review - Incidental HCCs validated in sample
Pacificare of Texas CY 2007

	Sample #	Last Name	First Name	DOB	HIC	Incidental HCC Validated	ICD-9 Code Validated	Review Comments
1	H4590-002					16	250.60	Final submission DOS 12/8/2006 Page 2 supports that the patient was seen for follow up of small cell lung carcinoma. Physician states that patient has difficulty with ataxia and leg weakness bilaterally on presentation. The physician noted in the review of systems numbness and tingling of plantar aspect fairly chronic and associated with diabetic neuropathy (357.2, 250.60) thought to be non-progressive. Chronic condition assessed during office visit.
2	H4590-002					71	357.2	Folder 44 Final submission DOS 12/8/2006 Page 2 supports that th patient was seen for follow up of small cell lung carcinoma. Physician states that patient has difficulty with ataxia and leg weakness bilaterally on presentation. In the review of systems the physician noted numbness and tingling of plantar aspect fairly chronic and associated to diabetic neuropathy (357.2, 250.60) and the exam has no gross sensory deficit in the lower extremities. the chronic condition of diabetic neuropathy was assessed during visit and would code as an integral part of the visit.
3	H4590-009					105	440.0	Final submission DOS 4/6/2006 supports that hte patient was seen for follow up of cough and on page 3 440.0 aortic atherosclerosis noted in assessment/plan. Atherosclerotic changes noted on CT and patient is on statins. Blood pressure is at goal and patient is on Coumadin as unable to take Aspirin. We will continue therapy as patient asymptomatic. Condition was monitored and treated and would code as a chronic condition.
4	H4590-018					33	556.9	Final submission 4/24/2006 page 3-5 supports that the patient presented for Cardiomegaly, Ulcerative colitis and HTN. Ulcerative colitis (556.9) was addressed in the documentation and the patient is on Azulfidine for control and last surveillance scope was in 2003 for Ulcerative colitis in the assessment. Would offer as a chronic condition as it is being treated with medication per coding Guidelines.
5	H4590-027					83	412.0	Final submission DOS 10/2/2006 Page 2 supports that the patient presented to ER with complaint of weakness and wrist pain. Under history, physician circled heart attack, MI (412.0). EKG shows old RBBB. As old MI potentially related to presenting symptoms and EKG performed, would offer as a secondary diagnosis.
6	H4590-028					92	426.0	Final submission DOS 10/26/2006 documentation notes patient with complete heart block (426.0) treated with pacemaker; pacemaker evaluated during visit. Would offer as diagnosis per coding clinic that states although diagnosis of heart block not present still code as pacemaker was evaluated for functioning .
7	H4590-040					100	438.20	Final submission 8/14/2006 Page 2 supports 438.20 - CVA with right hemiparesis stable noted in A/P and exam. Would offer as a diagnosis due to coding guidelines that state would offer due to chronicity and the fact that it was assessed during the current visit.
8	H4590-044					80	429.1	Final submission DOS 1/9/2006, noted documentation of fatty heart with CAD (429.1) in OR report with patient undergoing a CABG and would add as a secondary diagnosis.
9	H4590-048					27	070.54	Final submission DOS 1/12/2006 Page 3 Chronic hepatitis C (070.54) monitored with lab (LFT). Would offer as diagnosis as current and being evaluated.

"TAB 2" 9/10/2010

HCC Review - Listing of HCCs from OIG-62 that were validated

Pacificare of Texas CY 2007

	Sample #	HCC	Last Name	First Name	DOB	HIC	ICD-9 Code	ICD-9 Code	ICD-9 Code	ICD-9 Code	Validated Submitted HCC?	Review Comments
1	H4590-004	55					296.90				Y	Late entry clarification documentation for DOS 5/26/2006 Page 2 supports that the patient complained of frequent urination and dysuria. A urine analysis was performed which was found to be negative. Diagnosis of overactive bladder made with Detrol LA given. The patient complained of a depressed mood due to family and work and the physician ordered Lexapro. Page 1 of the original submission states COPD, Mood D... (illegible) with urine analysis results noted and Detrol LA, Lexapro and Ceclor listed in the medications ordered. Credentials were noted on the "Attestation of Medical Record Authenticity" dated 12/23/08.
2	H4590-004	105					443.9				Y	Late entry clarification documentation Page 2 for DOS 10/17/2006 supports that the patient complained of lower leg pain, tender with exercise. Arterial Doppler studies were ordered, and the patient was ordered to continue to take aspirin. Additionally in the original visit documentation for DOS 10/17/2006 Page 2, the physician states claudication (443.9) under assessment. Credentials were noted on the "Attestation of Medical Record Authenticity" dated 12/23/08.
3	H4590-008	74					780.39				Y	Final submission DOS 8/31/06 Page 2 supports that the patient complained of left knee and leg pain. Under impression, the list of diagnoses included seizure disorder, hypertension, severe osteoarthritis. Plan included Lisinopril (hypertension), Phenytoin <no tab taking> (seizure disorder), aspirin daily increasing to 325 mg, Naproxen (osteoarthritis), and a plan to do labwork in November.

"TAB 2" 9/10/2010

HCC Review - Listing of HCCs from OIG-62 that were validated

Pacificare of Texas CY 2007

	Sample #	HCC	Last Name	First Name	DOB	HIC	ICD-9 Code	ICD-9 Code	ICD-9 Code	ICD-9 Code	Validated Submitted HCC?	Review Comments
4	H4590-010	15					250.40	250.42			Y	Final submission DOS 5/30/2006 Page 2 documentation supports that the patient presented to the hospital with shortness of breath and weakness. On Page 7 under the impression, acute renal failure likely clearing off secondary to diuresis is listed as number one along with the following comment "Would also need to consider component of diabetic neuropathy". It is suspected that neuropathy is a typo and should be nephropathy as diabetic neuropathy is also documented in list under impression. Additionally, DOS 3/6/2006 Page 2 supports that the patient was in for a visit for consult on labs and states DM type 2 with nephropathy and Chronic Renal Failure. It also states CHF stable, hypertensive heart disease stable, and old MI. Discussion included diet and weight loss with Avandia added to control DM. Therefore, would offer DM Type 2 with nephropathy as a valid diagnosis.
5	H4590-013	80					428.0				Y	Final submission DOS 10/11/2006 Page 3 supports that the patient presented with continuing complaints of soreness in her hips and neck. The patient has working diagnosis of CHF (428.0). Although the patient is not symptomatic at this time as determined by denying dyspnea, cough, wheezing or edema per documentation in the ROS, CHF should still be coded per Coding Guidelines as a secondary as it was assessed during the visit.

"TAB 2"

9/10/2010

HCC Review - Listing of HCCs from OIG-62 that were validated

Pacificare of Texas CY 2007

	Sample #	HCC	Last Name	First Name	DOB	HIC	ICD-9 Code	ICD-9 Code	ICD-9 Code	ICD-9 Code	Validated Submitted HCC?	Review Comments
6	H4590-018	80					425.4				Y	Final Submission DOS 4/24/2006 Page 3 supports that the patient presented for a second opinion regarding a diagnosis of cardiomegaly (425.4). Per the History on Page 3, the patient developed a cough and a chest x-ray suggested evidence of cardiomegaly. Under assessment on Page 5, the physician states history of cardiomegaly uncertain significance and patient with longstanding hypertension not controlled and dyspnea on exertion presumable on the basis of left ventricular dysfunction. The physician ordered resting EKG and Echocardiogram. Clarification on page 2 dated 1/6/2009 for DOS 4/24/2006 states CXR evidence of mild cardiomegaly and his echo showed left ventricle enlargement with hypertrophy and no clinical evidence of CHF. Per Outpatient coding guidelines, conditions found on diagnostic tests can be coded if documented by the physician providing care.
7	H4590-027	80					428.0	428.22	428.42		Y	2nd appeal documentation DOS 10/2/2006 Page 4, on ER documentation notes that patient had history of CHF (428.0). CHF is written again on the ER order sheet and a BNP was ordered which is a test specifically for determining if patient is with active CHF. Medication list on page 10 lists Lasix which is the treatment for CHF. Would offer as secondary diagnosis as it was assessed per Coding Guidelines.
8	H4590-029	38					714.9				Y	Final submission DOS 1/16/2006 patient presents for a follow up visit for Coumadin and prescription renewal. Page 6 states under diagnoses 714.9 polyarthropathy inflammatory. Would offer this specific diagnosis as documentation under plan states refill vicodin for arthritic pain of neck. Physician signature and credentials noted on "Attestation of Medical Record Authenticity" dated 12/22/08.

"TAB 2"

9/10/2010

HCC Review - Listing of HCCs from OIG-62 that were validated

Pacificare of Texas CY 2007

	Sample #	HCC	Last Name	First Name	DOB	HIC	ICD-9 Code	ICD-9 Code	ICD-9 Code	ICD-9 Code	Validated Submitted HCC?	Review Comments
9	H4590-038	19					250.00				Y	Final submission DOS 6/29/06 Page 3 ER physician documentation states patient had dizziness and fell on the wrought iron bench with contusion to head. Documentation states that patient has DM (250.00) noted in past medical history. Page 7 An accucheck was ordered which is specific for glucose level as well as chem 7. Would offer as a secondary diagnosis per coding guidelines for chronic condition as it was monitored with lab work.
10	H4590-041	55					296.30				Y	Final submission documentation for DOS 10/05/2006 Page 2 , states that the patient was very anxious with weight loss, poor appetite and inability to sleep. Diagnoses included depressive anxiety (300.4) and patient was given Fluoxitine. Clarification documentation on 12/26/2008 (Page 3) states that patient has major depressive disorder (296.30), and was given Fluoxitine.
11	H4590-045	83					413.9				Y	Final submission for DOS 10/3/2006 Page 3 supports that the patient was in the office for 6-month follow up, status post LAD with stent. Documentation on Page 2 states patient denies any angina and cardiac exam performed. Norvasc reduced due to mild edema noted on exam. Clarification dated 1/5/2009, Page 3 notes patient with known high grade residual diagonal lesion after treating with stent and had residual ischemia on thallium and blood pressure and angina controlled on Norvasc. May code diagnosis as it is still being treated per coding guidelines and is related to the present visit.
12	H4590-054	16					250.80				Y	Trumped by HCC 15 validated as incremental. Documentation on page 2 for DOS 7/26/2006 supports Diabetes with other specific manifestation (hypoglycemia) (250.80). Physician stopped medication Glipizide that patient was taking for diabetic blood sugar control. Clarification on 12/29/2008 states complications from DM include hypoglycemia, peripheral neuropathy (250.60), small vessel peripheral vascular disease (250.70) all with supporting exam.

"TAB 2" 9/10/2010

HCC Review - Listing of HCCs from OIG-62 that were validated

Pacificare of Texas CY 2007

	Sample #	HCC	Last Name	First Name	DOB	HIC	ICD-9 Code	ICD-9 Code	ICD-9 Code	ICD-9 Code	Validated Submitted HCC?	Review Comments
13	H4590-055	10					174.9				Y	Final submission DOS 2/28/2006 Page 3 states breast cancer (174.9) treated with lumpectomy, Tomoxifen and patient is currently on Evista. Breast exam performed and mammogram requested. Per documentation, patient was evaluated with a mammogram and treated with Evista which is used to prevent further breast cancer.
14	H4590-068	108					496				Y	Final submission DOS 5/14/2006 Page 2 anesthesia note documents a diagnosis of COPD (496) and that the patient needs oxygen at 3L/min per nasal cannula to retain O2 sat at 92%. 2nd Appeal documentation Page 8 consult note states under impression, she had some hypoxemia last night and in the operating room Page 35 physician's orders state Albuterol (respiratory treatment) every 6 hours as needed, pulse ox continuous (monitors oxygen level in blood), and on room air was 84% (below normal). Per inpatient coding guidelines, may code secondary chronic condition of COPD.
15	H4590-075	132					583.9				Y	Final Submission 10/6/2006 Page 3 patient presents for follow up and complaining of sinus drainage. Under assessment/plan the physician states DM and increased her DM medication as blood sugar was elevated, also noted was nephropathy (583.9) with the notation control BS. Lytes were stable which monitors the nephropathy. Nephropathy not directly linked to Diabetes; however, it is linked indirectly by noting the blood sugar needs to be controlled. Would offer the nephropathy as secondary diagnosis as it was monitored and treated with the increase in medication.
16	H4590-086	105					440.20	447.8	451.1	451.11	Y	Final Submission DOS 1/5/2006 Page 2, the physician documents in the history that the patient had intermittent claudication (443.9) and ischemic rest pain of legs and exam of extremities without Clubbing/Cyanosis/Edema which relates to the claudication. The diagnoses are related to presenting problem as the patient is awaiting knee replacement surgery and they are relevant. 443.9 is within the original HCC of 105.

"TAB 2" 9/10/2010

HCC Review - Listing of HCCs from OIG-62 that were validated

Pacificare of Texas CY 2007

	Sample #	HCC	Last Name	First Name	DOB	HIC	ICD-9 Code	ICD-9 Code	ICD-9 Code	ICD-9 Code	Validated Submitted HCC?	Review Comments
13	H4590-055	10					174.9				Y	Final submission DOS 2/28/2006 Page 3 states breast cancer (174.9) treated with lumpectomy, Tomoxifen and patient is currently on Evista. Breast exam performed and mammogram requested. Per documentation, patient was evaluated with a mammogram and treated with Evista which is used to prevent further breast cancer.
14	H4590-068	108					496				Y	Final submission DOS 5/14/2006 Page 2 anesthesia note documents a diagnosis of COPD (496) and that the patient needs oxygen at 3L/min per nasal cannula to retain O2 sat at 92%. 2nd Appeal documentation Page 8 consult note states under impression, she had some hypoxemia last night and in the operating room Page 35 physician's orders state Albuterol (respiratory treatment) every 6 hours as needed, pulse ox continuous (monitors oxygen level in blood), and on room air was 84% (below normal). Per inpatient coding guidelines, may code secondary chronic condition of COPD.
15	H4590-075	132					583.9				Y	Final Submission 10/6/2006 Page 3 patient presents for follow up and complaining of sinus drainage. Under assessment/plan the physician states DM and increased her DM medication as blood sugar was elevated, also noted was nephropathy (583.9) with the notation control BS. Lytes were stable which monitors the nephropathy. Nephropathy not directly linked to Diabetes; however, it is linked indirectly by noting the blood sugar needs to be controlled. Would offer the nephropathy as secondary diagnosis as it was monitored and treated with the increase in medication.
16	H4590-086	105					440.20	447.8	451.1	451.11	Y	Final Submission DOS 1/5/2006 Page 2, the physician documents in the history that the patient had intermittent claudication (443.9) and ischemic rest pain of legs and exam of extremities without Clubbing/Cyanosis/Edema which relates to the claudication. The diagnoses are related to presenting problem as the patient is awaiting knee replacement surgery and they are relevant. 443.9 is within the original HCC of 105.

"TAB 2"

9/10/2010

HCC Review - Listing of HCCs from OIG-62 that were validated
Pacificare of Texas CY 2007

	Sample #	HCC	Last Name	First Name	DOB	HIC	ICD-9 Code	ICD-9 Code	ICD-9 Code	ICD-9 Code	Validated Submitted HCC?	Review Comments
17	H4590-086	149					707.15				Y	Final submission DOS 10/18/2006 Page 2 documentation supports that the office visit was at a Podiatrist's office, and the main problem was an ulcer. Location of the ulcer is documented as R/L; therefore, unable to determine where on body the ulcer was located. Correct ICD-9 code for chronic ulcer of unspecified site is 707.9 which is within the original HCC of 149.

"TAB 3" 9/10/2010

Listing of HCCs from OIG-62 supported by Clinical Review

Pacificare of Texas CY 2007

	Sample #	HCC	Last Name	First Name	DOB	HIC	ICD-9 Code	ICD-9 Code	Clinical Comments
1	H4590-021	10					174.2		ICD-9 Code 174.2 (Malignant Neoplasm of Female Breast, Upper Inner Quadrant) was submitted 4/5/06. The OIG found that, "There is no evidence of active breast cancer." and, "The History of breast cancer would change the code to V10.3)." Review of the patient's medical record reveals that she is receiving ongoing evaluation. The patient had a left mastectomy with lymph node dissection with five lymph nodes positive in 2005. She subsequent underwent chemotherapy and radiation. All occurred in 1/2005. The patient was seen in for ongoing follow up of breast cancer. At that time a mammogram and CA 125 ordered to actively monitor for disease. The patient is only one year out from a cancer diagnosis with metastatic spread to lymph nodes and she is receiving ongoing follow up by an oncology physician.
2	H4590-025	71					356.9		ICD-9 code 356.9 (Hereditary and idiopathic peripheral neuropathy, unspecified) was submitted for the encounter on 2/20/06. The OIG found that the encounter indicated the patient presented for a cardiac evaluation due to left-sided numbness in arms, chest and entire torso above the waist, lasting 30 minutes before resolving. There was no evidence of an evaluation, clinical findings and/or treatment related to the ICD-9 code. Upon review of the documentation in the medical record, the 10/9/06 encounter by indicates a patient visit with "lower extremity pain" and "pain in both feet" in the HPI; "calf/leg pain" is circled in the ROS. Both these findings are consistent with a peripheral neuropathy. During the 3/16/06 encounter, documentation is present in the chief complaint and HPI of pain and numbness in both legs. The physical exam has documented a sensory deficit in the feet with slight decrease in pinprick. Evaluation is consistent with the work up for metabolic causes of neuropathy. The clinical record is consistent with the patient having a peripheral neuropathy.

"TAB 3" 9/10/2010
Listing of HCCs from OIG-62 supported by Clinical Review
Pacificare of Texas CY 2007

	Sample #	HCC	Last Name	First Name	DOB	HIC	ICD-9 Code	ICD-9 Code	Clinical Comments
3	H4590-054	71					357.9		The documentation submitted for the encounter on 2/7/2006 does not support ICD-9 code 357.9 (Inflammatory and toxic neuropathy, unspecified). The documentation included a nerve conduction study which was not interpreted by a physician, this is unacceptable documentation according to the RA Participant guide section 7.2.4.4. Upon review of the medical record, a nerve conduction study was performed on 2/7/2006 which was interpreted by The findings of this study were: "There is electrodiagnostic evidence…consistent with but not fully diagnostic of a sensory polyneuropathy…..This could be consistent with diabetic neuropathy." Upon query of the provider , clarification was obtained as to the patient's diagnoses. reply on 12/29/08 indicates that the patient has peripheral neuropathy of the distal extremities bilaterally.
4	H4590-057	105					440.0		ICD-9 code 440.0 (Atherosclerosis of aorta) was submitted for the encounter on12/15/2006. The OIG notes that the diagnosis is not documented/addressed in the patient's record of diagnoses. However, on a CT scan of the abdomen done at on 2/8/06, "Atherosclerotic changes are seen in the great vessels." Similar findings are found on a CT scan at on 2/10/06. Additionally, on a PET/CT scan on 1/3/06, "Extensive atherosclerotic vascular disease is again noted." Medical records from indicate abnormal pulses on 7/18/06, 9/19/06, 12/15/06. These finding are consistent with atherosclerosis of the aorta and the submitted ICD-9 code of 440.0.

"TAB 3" 9/10/2010

Listing of HCCs from OIG-62 supported by Clinical Review
Pacificare of Texas CY 2007

	Sample #	HCC	Last Name	First Name	DOB	HIC	ICD-9 Code	ICD-9 Code	Clinical Comments
5	H4590-065	71					357.9		ICD-9 code 357.9 (Inflammatory and toxic neuropathy, unspecified) was submitted for the encounter on 9/29/06. The OIG indicates that the record notes the patient presents with complaints of fatigue x 2 weeks. The member denies radiation of pain, swelling, redness, direct trauma, falls, tingling or numbness and has positive pedal pulses. The member is noted to have a history of neuropathy, however, no documentation to support this affected the care, treatment or management provided at this encounter. However, upon review of the documentation in the medical records for 9/29/06, the history documents that the patient "denies numbness/tingling" which is indicative that the physician is assessing the patient's neuropathy. The physician goes on to document a past medical history of a neuropathy and concludes with an assessment that the patient has a "Unspecified Inflammatory and Toxic Neuropathy" consistent with his clinical assessment. The clinical record therefore supports the utilization of ICD-9 code 357.9.
6	H4590-068	105					440.20	443.9	The OIG found that the documentation submitted for the encounter on 4/26/2006 does not support ICD-9 codes 440.20 (Atherosclerosis of the extremities, unspecified) or 443.9 (Peripheral vascular disease, unspecified). The physician documented "PVD" as one of five listed diagnosis, however, this diagnosis did not affect the care, treatment or management of patient at this encounter. However, upon review of the records of May 23, 2006 from the documentation indicates that the DP (dorsalis pedis) and PT (posterior tibialis) pulses are 0/4. The rating of 0/4 indicates that these pulses are absent. The physician furthermore diagnoses PVD under his assessment. The physician's plan indicates debridement of the nails. The clinical evaluation for and the presence of peripheral vascular disease impacts the care provided to this patient by this physician.

"TAB 3" 9/10/2010

Listing of HCCs from OIG-62 supported by Clinical Review
Pacificare of Texas CY 2007

	Sample #	HCC	Last Name	First Name	DOB	HIC	ICD-9 Code	ICD-9 Code	Clinical Comments
7	H4590-099	9					171.2		ICD-9 code 171.2 (Malignant Neoplasm of connective and other soft tissue of upper limb, including Shoulder) was submitted on 12/07/2006. The OIG has noted that there is no evidence of an evaluation, clinical findings and/or treatment related to the ICD-9 code. Upon review of the medical records, the patient was seen on 12/21/2006 by notes a left forearm lesion that was not healed and that appears to be a squamous cell carcinoma. This lesion was present on the previous visit of 12/7/2006. referred the patient to The patient was seen on 12/28.2006 by who noted a 1 cm ulcerated lesion of the left forearm. Local excision was planned. The clinical picture of a non-healing ulcer of several weeks duration is consistent with a malignancy. Per our coding experts, reference to the shoulder in the ICD-9 description is permissive, not mandatory. That is, the description of the code is for the upper limb to include the shoulder if involved.

"TAB 4"

9/10/2010

HCC Review - Alternative HCC validated for OIG-62
Pacificare of Texas CY 2007

	Sample #	HCC	Last Name	First Name	DOB	HIC	ICD-9 Code	Validated Submitted HCC	Validated Alternative ICD-9 Code	Validated Alternative HCC	Review Comments
1	H4590-081	96					436	N	Y - 438.20	Y - 100	Final submission, 7/26/2006 Page 9 supports that the patient did have a past history of a CVA with left sided hemiparesis noted in the history of present illness, past medical history and assessment (page 9-10). A more specific code for status post cerebrovascular disease with left sided hemiparesis is 438.20 which is within HCC 100.