Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

RISK ADJUSTMENT DATA VALIDATION OF PAYMENTS MADE TO PACIFICARE OF CALIFORNIA FOR CALENDAR YEAR 2007 (CONTRACT NUMBER H0543)

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Daniel R. Levinson
Inspector General

November 2012
A-09-09-00045

Office of Inspector General

https://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 https://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. 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 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.

PacifiCare of California (PacifiCare) is an MA organization owned by UnitedHealth Group. For calendar year (CY) 2007, PacifiCare had multiple contracts with CMS, including contract H0543, which we refer to as "the contract." Under the contract, CMS paid PacifiCare approximately $3.6 billion to administer health care plans for approximately 344,000 beneficiaries. Our review covered approximately $2.3 billion of the payments that CMS made to PacifiCare on behalf of 188,829 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. For 55 of the 100 beneficiaries in our sample, the risk scores calculated using the diagnoses that PacifiCare submitted were valid. The risk scores for the remaining 45 beneficiaries were invalid because the diagnoses were not supported by the documentation that PacifiCare provided.

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 diagnoses, PacifiCare received $224,388 in overpayments from CMS. Based on our sample results, we estimated that PacifiCare was overpaid approximately $423,709,068 in CY 2007. (This amount represents our point estimate. The confidence interval for this estimate has a lower limit of $288 million and an upper limit of $559 million. See Appendix B.)

RECOMMENDATIONS

We recommend the following:

- PacifiCare should refund to the Federal Government $224,388 in overpayments identified for the sampled beneficiaries.

- PacifiCare should work with CMS to determine the correct contract-level adjustment for the estimated $423,709,068 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 Federal requirements.

PACIFICARE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, PacifiCare disagreed with our findings and our recommendation that it refund the identified overpayments. PacifiCare said that our analysis, methodology, and projection were flawed. PacifiCare stated that our audit results did not account for error rates inherent in Medicare fee-for-service (FFS) data, specifically the disparity between FFS claim data and FFS medical records data and its potential impact on MA payments. PacifiCare also stated that we should have used the 2006 Participant Guide to evaluate its compliance with CMS's requirements. In addition, PacifiCare stated that we did not follow CMS's audit methodology when we refused to accept physician signature attestations. Lastly, PacifiCare disagreed with the results of our first and second medical reviews for 22 HCCs and, for 12 of these HCCs, provided us with additional documentation and/or new information on documentation previously provided as to why the HCCs were supported. PacifiCare's comments are included in their entirety as Appendix D.

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

overpayments and (2) added a recommendation that PacifiCare work with CMS to determine the correct contract-level adjustments for the estimated overpayments.

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

We did not initially accept physician attestations. However, pursuant to a 2010 change in Federal regulations, we accepted attestations and revised our findings accordingly. For the 12 HCCs for which PacifiCare provided additional documentation and information, we submitted the documentation and information to our medical review contractor for a third medical review and revised our findings accordingly.

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 California

PacifiCare of California (PacifiCare) is an MA organization owned by UnitedHealth Group. For CY 2007, PacifiCare had multiple contracts with CMS, including contract H0543, which we refer to as "the contract." Under the contract, CMS paid PacifiCare approximately $3.6 billion to administer health care plans for approximately 344,000 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 $2.3 billion of the CY 2007 MA organization payments that CMS made to PacifiCare on behalf of 188,829 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 medical review.

We performed our fieldwork at UnitedHealth Group in Minnetonka, Minnesota, and at CMS in Baltimore, Maryland, from December 2008 through November 2011.

[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 188,829 beneficiaries who (1) were continuously enrolled under the contract during all of CY 2006 and January of CY 2007 and (2) had a CY 2007 risk score that was based on at least 1 HCC.

- We selected a simple random sample of 100 beneficiaries with 262 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 the one medical record 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 medical review and requested additional documentation from PacifiCare for a second medical 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 review did not support the HCCs.

- For some of the draft report findings with which it disagreed,[5] PacifiCare provided additional documentation and/or information, which we submitted to our medical review contractor for a third review.

- For the sampled beneficiaries that we determined to have unsupported HCCs, we (1) used the medical review results to adjust the beneficiaries' risk scores, (2) recalculated CY 2007 payments using the adjusted risk scores, and (3) subtracted the recalculated CY 2007 payments from the actual CY 2007 payments to determine the overpayments and underpayments CMS made on behalf of the beneficiaries.

- We estimated the total value of overpayments based on our sample results. (See Appendix B for our sample results and estimates.)

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit 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. For 55 of the 100 beneficiaries in our sample, the risk scores calculated using the diagnoses that PacifiCare submitted were valid. The risk scores for the remaining 45 beneficiaries were invalid because the diagnoses were not supported by the documentation provided by PacifiCare.

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 diagnoses, PacifiCare received $224,388 in overpayments from CMS. Based on our sample results, we estimated that PacifiCare was overpaid approximately $423,709,068 in CY 2007.

[5] Of the 22 HCCs that PacifiCare disagreed with, we accepted physician signature attestations that validated 5 HCCs and submitted 12 HCCs for a third medical review. PacifiCare did not provide any new documentation or information on the remaining five HCCs.

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 45 sampled beneficiaries were invalid because the diagnoses that PacifiCare submitted to CMS were not supported. These diagnoses were associated with 77 unsupported HCCs, shown in Appendix C.

For 11 of the 77 HCCs, other diagnoses were determined to be more appropriate. In these instances, the documentation supported HCCs that were different from those that CMS used in determining the beneficiaries' risk scores. The following are examples of HCCs that were not supported by the documentation that PacifiCare submitted to us for medical review:

- For one beneficiary, PacifiCare submitted the diagnosis code for "spinocerebellar disease, other cerebellar ataxia."[6] CMS used the HCC associated with this diagnosis in calculating the beneficiary's risk score. However, the documentation that PacifiCare provided described an evaluation for fever and cough. The documentation did not mention cerebellar ataxia or indicate that cerebellar ataxia had affected the care, treatment, or management provided during the encounter.

- For a second beneficiary, PacifiCare submitted the diagnosis code for "malignant neoplasm of the prostate." CMS used the HCC associated with this diagnosis in calculating the beneficiary's risk score. However, the documentation that PacifiCare provided appeared to describe suture removal and left shoulder bursitis/tendonitis. The documentation did not mention prostate cancer or indicate that prostate cancer had affected the care, treatment, or management provided during the encounter.

- For a third beneficiary, PacifiCare submitted the diagnosis code for "unspecified septicemia" (commonly referred to as "blood poisoning"). CMS used the HCC associated with this diagnosis in calculating the beneficiary's risk score. However, the documentation that PacifiCare provided noted that the patient was admitted for a "left total knee revision arthroplasty." The documentation did not mention blood poisoning or indicate that blood poisoning had affected the care, treatment, or management provided during the encounter.

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.

[6] Spinocerebellar ataxia is a genetically inherited disorder characterized by abnormal brain function.

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 diagnoses in our sample, PacifiCare received $224,388 in overpayments from CMS. Based on our sample results, we estimated that PacifiCare was overpaid approximately $423,709,068 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.[7]

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

RECOMMENDATIONS

We recommend the following:

- PacifiCare should refund to the Federal Government $224,388 in overpayments identified for the sampled beneficiaries.

- PacifiCare should work with CMS to determine the correct contract-level adjustment for the estimated $423,709,068[8] 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 Federal requirements.

[7] 75 Fed. Reg. 19749 (April 15, 2010).

[8] This amount represents our point estimate. The confidence interval for this estimate has a lower limit of $288 million and an upper limit of $559 million. See Appendix B.

PACIFICARE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, PacifiCare[9] disagreed with our findings and our recommendation that it refund the identified overpayments. PacifiCare said that our analysis, methodology, and projection were flawed. PacifiCare stated that our audit results did not account for error rates inherent in Medicare FFS data, specifically the disparity between FFS claim data and FFS medical records data and its potential impact on MA payments. PacifiCare also stated that we should have used the 2006 Participant Guide to evaluate its compliance with CMS's requirements. In addition, PacifiCare stated that we did not follow CMS's audit methodology when we refused to accept physician signature attestations. Lastly, PacifiCare disagreed with the results of our first and second medical reviews for 22 HCCs and, for 12 of these HCCs, provided us with additional documentation and/or new information on documentation previously provided as to why the HCCs were supported. PacifiCare's comments, which we summarize below, are included in their entirety as Appendix D.

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

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

We did not initially accept physician attestations. However, pursuant to a 2010 change in Federal regulations, we accepted attestations and revised our findings accordingly. For the 12 HCCs for which PacifiCare provided additional documentation and information, we submitted the documentation and information to our medical review contractor for a third medical review and revised our findings accordingly.

Random Sample

PacifiCare Comments

PacifiCare stated that our sample of 100 beneficiaries did not fully represent the 344,000 members enrolled in the contract or the 188,829 members who had a risk score based on at least 1 HCC during our audit period. PacifiCare said that because (1) only 49 of the 70 HCCs that

[9] The letterhead of the written comments is from United Healthcare Medicare & Retirement. Medicare & Retirement is one of six businesses operated by UnitedHealth Group, which owns PacifiCare.

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

appeared in the population were represented in our audit sample, (2) the risk adjustment factor (RAF) sample mean was not statistically equal to the RAF population mean, and (3) the average number of HCCs per member in the sample was higher than in the population, 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 188,829 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 21 HCCs that PacifiCare stated were not represented in our sample, 19 had a frequency of less than 1 percent of the sampling frame and the remaining 2 had a frequency of less than 2 percent.

In addition, because there are many combinations of 100 beneficiaries that could have been selected from our sampling frame, the RAF mean and average number of HCCs per member in the sample would not necessarily, and most likely would not, equal the RAF mean and average number of HCCs per member in the sampling frame. However, this does not mean that the sample is not a valid random sample. By definition, a random sample is representative of the sampling frame regardless of the differences between the RAF mean and average number of HCCs in the sample versus the sampling frame.

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 estimation 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 claim 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 claim 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 merit in further refining the calculation of payment errors that result from postpayment validation efforts.[11] Given the potential impact of this error rate on the CMS model that we used to recalculate MA payments, we modified our first recommendation to seek a refund only for the overpayments identified for the sampled beneficiaries. We made an additional recommendation that PacifiCare work with CMS to determine the correct contract-level adjustments for the estimated overpayments.

Centers for Medicare & Medicaid Services Model

PacifiCare Comments

PacifiCare stated that (1) although accurate for large populations, the CMS model was not designed to produce results for individual beneficiaries and (2) the confidence intervals that 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.

[11] 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 that 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 in the larger population members who moved to different plans or died during the 2007 payment year. 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 188,829 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 for use in CMS's risk score calculations complied with Federal requirements. Regarding CMS's 2006 Participant Guide, we based our findings on criteria set forth in CMS's 2007 Participant Guide. After our review, we compared the data submission criteria in both the 2006 and 2007 Participant Guides and determined that there were no substantial differences in the criteria upon which our results were based.

Stratification of Sample

PacifiCare Comments

PacifiCare stated that we did not follow CMS's example in conducting RADV audits by stratifying our sample. PacifiCare stated that stratification would have ensured that the sample was both random and representative of the population.

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. Furthermore, although we did not stratify our sample, it was randomly selected. By definition, any random sample is representative of the sampling frame.

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.

Physician Signature Attestations

PacifiCare Comments

PacifiCare stated that we did not follow CMS's audit methodology when we refused to accept physician signature attestations. PacifiCare added that, as a result, we identified nine 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,[12] CMS made payment adjustments only for those enrollees sampled.

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 estimated overpayments.

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.

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

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 independent review 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.

Policies and Procedures

PacifiCare Comments

PacifiCare disagreed with our finding that it did not have written policies and procedures in place for obtaining, processing, and submitting diagnoses to CMS. 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. PacifiCare also stated that it used the chart validation process as a validation tool for codes related to CY 2006 dates of service. In addition, PacifiCare stated that it strives to ensure that its practices ensure compliance with the requirements of the Participant Guide.

Office of Inspector General Response

PacifiCare officials explained to us that the automated systems were used only to verify the validity of the diagnosis codes; however, these systems do not validate the diagnoses. According to the RADV process described in the 2006 Participant Guide, validating a diagnosis submitted to CMS requires a review of the medical records. During our fieldwork, PacifiCare officials told us that the review of medical records was not routinely performed and was used only to validate diagnoses that PacifiCare received from providers that PacifiCare paid on a capitated basis. Moreover, PacifiCare did not have any written policies and procedures on review of medical records to ensure the validity of diagnoses submitted to CMS.

Invalidated Hierarchical Condition Categories

PacifiCare Comments

In an appendix to its comments, PacifiCare included a list of 22 HCCs that it believed should have been supported by the medical records provided. PacifiCare stated that it had conducted its

own review of the medical records from this review and concluded that at least six 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 50 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. In addition, after the issuance of our draft report, PacifiCare provided additional documentation that was not provided to us during the first two medical reviews and new information on documentation previously provided as to why certain HCCs were supported.

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.

We accepted and evaluated the additional documentation and new information that PacifiCare provided with its comments on our draft report. In cases when (1) PacifiCare provided new documentation or (2) PacifiCare provided a new explanation as to why the documentation validated the selected HCC, we submitted the additional documentation to our medical review contractor for a third medical review. We accepted the additional inpatient, outpatient, and physician records with CY 2006 dates of services to help validate the 12 HCCs with which PacifiCare disagreed during the first two medical reviews. For the third medical review, our contractor followed the same protocol used during each of the first two reviews. Our contractor found that the additional information supported and validated 6 of the 12 HCCs. We revised our findings accordingly.

APPENDIXES

APPENDIX A: SAMPLE DESIGN AND METHODOLOGY

SAMPLING FRAME

The sampling frame consisted of 188,829 beneficiaries on whose behalf the Centers for Medicare & Medicaid Services paid PacifiCare of California (PacifiCare) approximately $2.3 billion in calendar year (CY) 2007. These beneficiaries (1) were continuously enrolled under contract H0543 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 the 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 188,829. After generating 100 random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the 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
188,829	100	$1,383,411	45	$224,388

Estimated Value of Overpayments
(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	$423,709,068
Lower limit	288,232,331
Upper limit	559,185,805

APPENDIX C: UNSUPPORTED HIERARCHICAL CONDITION CATEGORIES IN SAMPLE

	Hierarchical Condition Category
1	Chronic Obstructive Pulmonary Disease
2	Spinal Cord Disorders/Injuries
3	Angina Pectoris/Old Myocardial Infarction
4	Inflammatory Bowel Disease
5	Breast, Prostate, Colorectal, and Other Cancers and Tumors
6	Breast, Prostate, Colorectal, and Other Cancers and Tumors
7	Chronic Obstructive Pulmonary Disease
8	Septicemia/Shock
9	Intestinal Obstruction/Perforation
10	Disorders of Immunity
11	Major Depressive, Bipolar, and Paranoid Disorders
12	Spinal Cord Disorders/Injuries
13	Nephritis
14	Breast, Prostate, Colorectal, and Other Cancers and Tumors
15	Major Depressive, Bipolar, and Paranoid Disorders
16	Aspiration and Specified Bacterial Pneumonias
17	Decubitus Ulcer of Skin
18	Major Depressive, Bipolar, and Paranoid Disorders
19	Vascular Disease
20	Breast, Prostate, Colorectal, and Other Cancers and Tumors
21	Diabetes With Renal or Periphery Circulatory Manifestation
22	Lymphatic, Head and Neck, Brain, and Other Major Cancers
23	Diabetes Without Complication
24	Diabetes With Ophthalmologic or Unspecified Manifestation
25	Breast, Prostate, Colorectal, and Other Cancers and Tumors
26	Diabetes With Renal or Peripheral Circulatory Manifestation
27	Angina Pectoris/Old Myocardial Infarction
28	Ischemic or Unspecified Stroke
29	Major Depressive, Bipolar, and Paranoid Disorders
30	Diabetes Without Complications
31	Parkinson’s and Huntington’s Diseases
32	Unstable Angina and Other Acute Ischemic Heart Disease
33	Renal Failure
34	Unstable Angina and Other Acute Ischemic Heart Disease
35	Nephritis
36	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease
37	Angina/Pectoris/Old Myocardial Infarction
38	Breast, Prostate, Colorectal, and Other Cancers and Tumors
39	Drug/Alcohol Dependence
40	Seizure Disorders and Convulsions
41	Acute Myocardial Infarction
42	Polyneuropathy

	Hierarchical Condition Category
43	Diabetes Without Complication
44	Unstable Angina and Other Acute Ischemic Heart Disease
45	Diabetes With Neurologic or Other Specified Manifestation
46	Diabetes Without Complication
47	Diabetes With Ophthalmologic or Unspecified Manifestation
48	Schizophrenia
49	Ischemic or Unspecified Stroke
50	Major Head Injury
51	Hip Fracture/Dislocation
52	Breast, Prostate, Colorectal, and Other Cancers and Tumors
53	Major Depressive, Bipolar, and Paranoid Disorders
54	Breast, Prostate, Colorectal, and Other Cancers and Tumors
55	Renal Failure
56	Lymphatic, Head and Neck, Brain, and Other Major Cancers
57	Diabetes With Renal or Periphery Circulatory Manifestation
58	Major Depressive, Bipolar, and Paranoid Disorders
59	Congestive Heart Failure
60	Ischemic or Unspecified Stroke
61	Nephritis
62	Breast, Prostate, Colorectal, and Other Cancers and Tumors
63	Diabetes With Ophthalmologic or Unspecified Manifestation
64	Vascular Disease
65	Major Complication of Medical Care and Trauma
66	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease
67	Diabetes With Neurologic or Other Specified Manifestation
68	Diabetes With Neurologic or Other Specified Manifestation
69	Lymphatic, Head and Neck, Brain, and Other Major Cancers
70	Major Complications of Medical Care and Trauma
71	Cardio-Respiratory Failure and Shock
72	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease
73	Major Depressive, Bipolar, and Paranoid Disorders
74	Diabetes With Renal or Peripheral Circulatory Manifestation
75	Diabetes With Acute Complications
76	Diabetes Without Complication
77	Renal Failure

APPENDIX D: PACIFICARE COMMENTS

Lori Ahlstrand
Regional Inspector General for Audit Services
Office of Audit Services, Region IX
90-7th Street, Suite 3-650
San Francisco, CA 94103

Dear Ms. Ahlstrand:

On behalf of PacifiCare of California, 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 July 22, 2010 entitled "Risk Adjustment Data Validation of Payments made to PacifiCare of California for Calendar Year 2007 (Contract Number H0543)" (hereinafter, "Draft Report"). PacifiCare welcomes the opportunity to comment on the Draft Report before a final report is issued, and appreciates the additional time the OIG has given PacifiCare to submit these comments. 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 90 HCCs for 50 members were invalid because (i) the documentation did not support the associated diagnosis, or (ii) the documentation did not include the provider's signature.

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 344,000 members of the plan, nor is it fully representative of the 188,829 members who had a risk score based on at least one HCC. Only 49 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 21 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 beneficiaries, 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.**

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.

[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.

[3/] If the OIG substantially revises its report, PacifiCare requests the opportunity to review the modified draft before it is released.

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 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

---

[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).
[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).

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 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

---

[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.
[13/] *See* "MA and Part D Data: Who, What, Where, and How," slide 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).

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. RESPONSES TO THE OIG'S RECOMMENDATIONS

A. PacifiCare Disagrees with the OIG's Recommendation that PacifiCare Refund $356,324,030 in Alleged Overpayments

1. 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 344,000 members of the population, nor is it fully representative of the 188,829 members who had a risk score based on at least one HCC. Only 49 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 21 HCCs that appear in the population, but for whom no beneficiaries were audited, and therefore is not an accurate representation of the population.

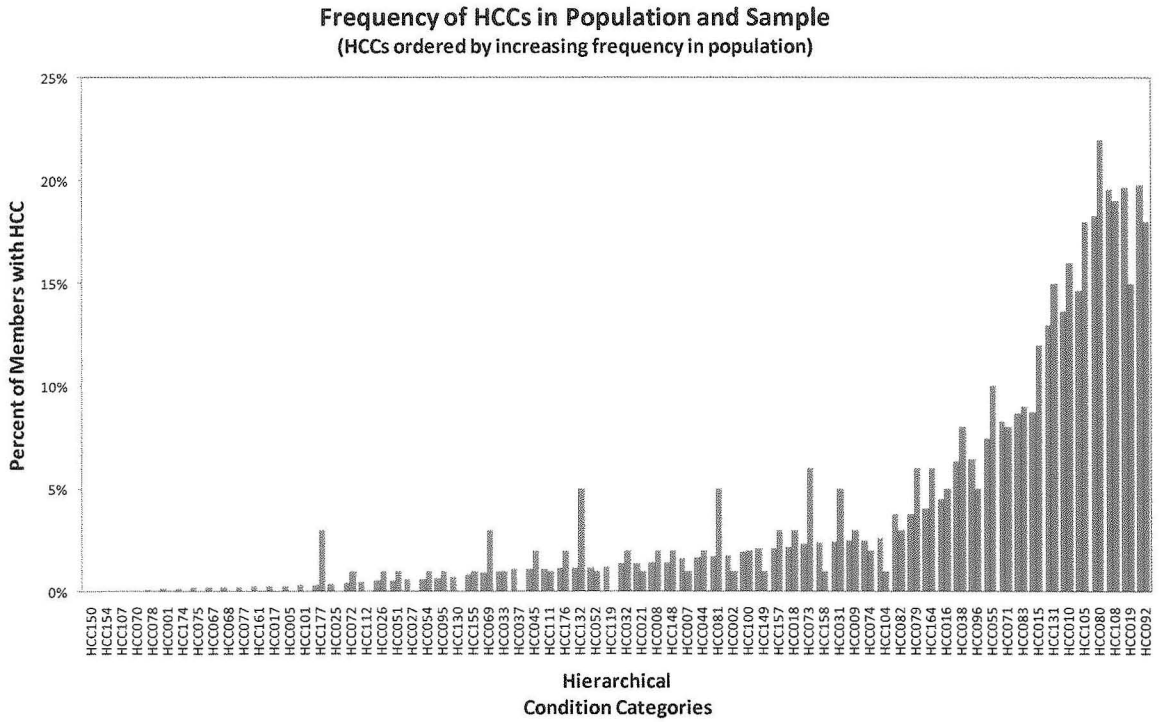
There are at least two ways that the sample could have been drawn to ensure representativeness. First, a larger sample would have a higher probability of drawing all of the HCCs that appear in the population during the relevant period. A sample size of 100 is too small to account for the tremendous diversity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

Alternatively, the samples could have been stratified, just as CMS stratifies its sample population as discussed in more detail below. Stratification would have involved dividing the population into subgroups, for example one for each HCC in the population, and then 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

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

allows for oversampling of relevant subgroups, which are then reweighted according to their population frequency.

In this case, the sample could have been stratified 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 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 188,829 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 21 HCCs are not represented in the sample.

Moreover, a comparison of the OIG's sample as compared to the sample frame used by OIG for its audit (i.e., PacifiCare's population) shows that the OIG's random sample is not statistically valid:

- **The Average Risk Adjustment Factor (RAF) Sample Mean Is not Representative of the Population.** The average RAF for all members in the sample is 1.64, but the average

RAF for all the members in the population is 1.46. Using the sample mean, population variance, and standard normal z statistic, the 90% confidence interval for the RAF population mean is (1.48, 1.80), indicating that the actual population mean is not within in the confidence interval. This indicates that the RAF sample mean is not statistically equal to the RAF population mean, and the sample is not representative of the sample frame with respect to RAF.[15/]

- **The Average Number of HCCs Per Member in the Sample is Higher than the Average Number of HCCs in the Population.** The average number of HCCs per member in the sample is 2.61, whereas the average number of HCCs per member in the population is 2.33. Based on the average number of HCCs per member in the sample, the variance of number of HCCs per member in the population, and the standard normal z-statistic, the 90% confidence interval of the average number of HCCs in the population is (2.31, 2.90). Although the 90% confidence interval includes the population mean at the extreme low end of the interval (the probability of drawing a sample with a mean of 2.61 or greater is 5.8%), the higher number of HCCs per member in the sample is consistent with the high average RAF in the sample versus the population. This suggests that the sample is not representative of the population with respect to RAF and number of HCCs. Coupled with the statistically significantly higher RAF of the sample, even if the sample overpayment has been determined accurately, extrapolation of the overpayment to the population is not accurate, and will result in a significant overstatement of the population overpayment.[16/]

Stratification would have ensured that the sample was more representative of the population. As discussed in the section below, stratification with respect to RAF would have ensured that the RAF in the sample was representative of the population. In addition, the OIG did not design the sample to account for the diversity of beneficiaries in the population 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 and determined a payment error using a methodology that fails to follow CMS procedures. When CMS conducts RADV audits, it employs stratified

[15/] *See* the attached Appendix A for additional analysis.
[16/] *Id.*

proportional sampling. Eligible members are ranked from lowest to highest risks scores, and the sample frame is divided into thirds to establish low, medium, and high RAF strata with an equal number of randomly selected members in each strata of the sample.[17/] The enrollee sample weight is then computed as a total number of enrollees in the eligible population stratum divided by the number of sample enrollees for that stratum.[18/] Presumably, CMS employs this methodology to ensure that the audit sample is both random and representative of the population with respect to RAF. As discussed above, it is important for the sample to be both random and representative of the population in order for the results of an audit sample to be reliably extrapolated to the population.

PacifiCare's analysis of the sample shows that OIG did not follow CMS's sampling methodology. After the population is ranked by RAF, 25 members were taken from the lowest 1/3 of the population, 34 members from the medium RAF stratum, and 38 members from the high RAF stratum.[19/] If the OIG had followed stratified proportional sampling, the sample would have had approximately 33 observations from each of the stratum.

In addition, the OIG recommends 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.[20/] 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.[21/] 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

---

[17/] *See* "Sampling Analysis and Payment Error Estimates," slide 103 (Lateefa Hughes, October 23, 2009 slide presentation entitled "Presentation CY 2007 CMS Risk Adjustment Data Validation MA Organization Training").

[18/] *Id.*

[19/] Three members in the sample were hospice beneficiaries as of January 1, 2007 and therefore were not subject to the risk adjustment model. As a result, the RAF for these members is zero.

[20/] 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.

[21/] 75 Fed. Reg. 19678, 19746, 19753 (April 15, 2010).

implementing.[22/] CMS has recognized that there are complexities in validating risk adjusted payments and extrapolating discrepancies to the contract level, but has not yet revealed its methodology for doing so, and it is uncertain whether and when CMS will begin employing such measures. Third, CMS will describe CMS's RADV methodology in each audited organization's RADV Audit Report.[23/]

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 fails to provide enough detail about its methodology 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 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, based on the Pope model, 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.[24/] A set of hierarchical conditions are then imposed on the CCs to

---

[22/] *Id.*
[23/] 42 C.F.R. § 422.311(c)(3)(vi); 75 Fed. Reg. 19678, 19746, 19753 (April 15, 2010).
[24/] Pope et al., (2004).

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.

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.[25/] CMS uses the functional form and coefficients from the statistical estimation process to compute the 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.[26/]

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 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

---

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

[26/] Centers for Medicare & Medicaid Services: *CY2007 CMS Risk Adjustment Data Validation MA Organization Training*, PowerPoint Presentation, Baltimore, Maryland, October 23, 2009).

are, in practice, inconsistent.[27/] 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.

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 B for a summary of research). CMS conducts regular coding audits and reports coding discrepancies and errors.[28/] 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." [29/] 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 different 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-9 codes found in claims.[30/] In statistical terms, the data generation process for HCCs

---

[27/] *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/.
[28/] See http://www.cms.gov/apps/er_report.
[29/] Pope et al., (2004), p. 121.
[30/] Pope et al., (2004).

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 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.

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.[31/] 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

[31/] 75 Fed. Reg. 19678, 19746, 19749 (April 15, 2010).

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.

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 adjusting 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.

3) *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 188,829 beneficiaries in PacifiCare of California. 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.,[32/] 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 188,829 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%, and as a result, the

---

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

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 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 over predict by as much as 30 percent. [33/]

d. 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.

The OIG used a bootstrap methodology to estimate the 90% confidence interval for the total sample frame overpayment. This approach used estimated errors from the risk adjustment payment model, and the sample overpayments of 100 members from Appendix C in the draft report. Under specific conditions of the error terms in the risk adjustment payment models, the overpayment confidence

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

interval is estimated to be (-$120M, $1,137M) (details provided in Appendix C). This confidence interval on the total overpayment is significantly wider than ($356M, $652M), which was reported in the OIG draft. Including the model error terms in addition to overpayments suggests that the estimated total overpayment can be highly inaccurate.

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 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.

e. 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.

f. Erroneous Audit Processes and Standards

The OIG is required, both by law[34/] 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

[34/] 5 U.S.C.A. App. 3, § 2.

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 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.***[35/]

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

1) *Stratifying the Audit Sample*

As discussed above, when CMS conducts RADV audits, it uses stratified proportional sampling with respect to RAF to create the sample.[36/] Stratification ensures that the sample is both random and representative of the population so that the results of an audit sample to be reliably extrapolated to the population. In its Audit, not only did the OIG not follow CMS processes for sample selection, it failed to stratify the sample as discussed in detail above.

2) *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.[37/] PacifiCare's review of the medical records submitted to the OIG in support of the audited HCCs confirms that the medical records also support at least 10 incidental HCCs for certain members.[38/] Under established CMS standards and practices, PacifiCare would receive credit for these HCCs in evaluating the impact of any

---

[35/] 2006 Participant Guide, 8.1.3. (***Emphasis added.***)

[36/] *See* "Sampling Analysis and Payment Error Estimates," slide 102 (Lateefa Hughes, October 23, 2009 slide presentation entitled "Presentation CY 2007 CMS Risk Adjustment Data Validation MA Organization Training").

[37/] *Id.*

[38/] Please see TAB 2 in the spreadsheet attached at Appendix D 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).

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.

3) *Physician Signature Attestations*

The OIG did not follow CMS's audit methodology when it refused to accept physician signature attestations submitted by PacifiCare. The OIG determined that nine 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.[39/] 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.[40/] 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 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.

4) *Individual Payment Adjustments*

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.

5) *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[41/] identified by the IVC are subject to a second, independent medical record review by the Second Validation Contractor (SVC) to

---

[39/] *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).

[40/] 75 Fed. Reg. 19678, 19749 (April 15, 2010).

[41/] 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.

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.[42/] The IVC and SVC are blind to each other's findings.[43/] 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.[44/]

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, the medical review contractor subjected the HCC to another review by staff unaware of the first reviewer's determination. 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 III below.

B. PacifiCare Disagrees with the OIG's Findings that PacifiCare did not have Written Policies and Procedures in Place

The Draft Report asserts that PacifiCare did not have written policies and procedures for obtaining, processing, and submitting diagnoses to CMS. PacifiCare respectfully disagrees with this conclusion. PacifiCare largely uses automated systems for obtaining, processing, and submitting diagnoses to CMS, and had documented system protocols for the processing of data through its systems. The OIG also concludes 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. Again, we respectfully disagree with this conclusion. PacifiCare's chart validation process includes the review of a provider's patient charts to determine whether the charts support certain codes that the provider reported. PacifiCare selects 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

---

[42/] 2006 Participant Guide, Section 8.1.6; 2007 Participant Guide, Section 7.1.6.

[43/] *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).

[44/] 2006 Participant Guide, 8.2.6, 2007 Participant Guide, 7.2.6.

process tests the provider's deviation from that benchmark. Codes found to be inaccurate or incomplete through chart validations are deleted.

In addition, PacifiCare has 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.

C. PacifiCare Strives to Ensure its Practices to Ensure Compliance with the Requirements of the Participant Guide

As stated previously, there has been great flux in the development of risk adjustment data collection policies and regulations over the past few years. PacifiCare keeps current with the guidance set forth by CMS, and is dedicated to ensuring that all requirements are met. As discussed in the section above, PacifiCare maintains operational policies and procedures designed to ensure compliance with CMS requirements, and consistently seeks to improve its practices as requirements change in order to maintain its compliance.

III. 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 six of the OIG's invalidated HCCs were, in fact, supported by the "one best medical record" submitted to the OIG.[45/] 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. Our analysis of the alleged overpayment amount – using the calculation methodology used by the OIG – is reduced from $266,880 to $201,823[46/] 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.

[45/] Please see TAB 3 in the spreadsheet attached as Appendix D 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).

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

Additionally, we not only reviewed the one best medical records that were submitted to the OIG for each of the 50 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. Through our review, for example, we found nine 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.[47/] 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 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 36, Major Depressive Disorder, Single Episode, Moderate

PacifiCare submitted the medical record for an encounter dated May 16, 2006 to support the ICD-9 diagnosis code 296.22 (Major depressive disorder, singe episode, moderate). The provider documented the condition as "depression" with no further descriptive detail noted, and the OIG determined that the submitted medical record did not support the diagnosis.

PacifiCare disagrees with the OIG's conclusion. The patient is noted to have been widowed since February 2006. During the visit, the physician also notes that the patient is "not coping," is "tearful," and "not sleeping." During the May 16, 2006, visit, the patient was started on an antidepressant (Zoloft). In a later encounter on June 20, 2006, the patient is noted to be "still with depression," and her prescription for Zoloft was adjusted. Based on this information, the patient's clinical symptoms and treatment course are clinically consistent with Major Depression.

(2) OIG Patient 64, Congestive Heart Failure

[47/] Please see TAB 4 in the spreadsheet attached as Appendix D 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).

PacifiCare submitted the medical record for an encounter dated December 8, 2006 to support the diagnosis codes 425.4 (Other primary cardiomyopathies), 428.0 (Congestive heart failure, unspecified), and 404.13 (Hypertensive heart and kidney disease, Benign, with heart failure and chronic kidney disease). The OIG determined that the medical record did not support evidence of an evaluation, clinical findings and/or treatment related to the ICD-9 codes. The documentation does support 401.9 Hypertension, NOS which has no HCC.

Progress notes dated October 5th and December 8th of 2006 show that the physician recorded Congestive Heart Failure as one of the member's diagnoses. The member's medical history includes shortness of breath and examinations that included heart, lungs, and extremities, and the member is noted with edema at both visits. The member is also noted to be on a diuretic (lasix) during these visits, which is consistent with the diagnosis. The member is clinically being treated for Congestive Heart Failure on an ongoing basis with both the physical examinations and medications reflecting this.

IV. 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, the OIG failed to use statistically valid methodologies when conducting the Audit. Not only is the sample of 100 beneficiaries utilized by the OIG not fully representative of PacificCare's 344,000 members – or even the 188,829 members who had a risk score based on at least one HCC, an evaluation of the OIG's sample as compared to the sample frame used by OIG shows that the OIG's random sample is not statistically valid when evaluated for RAF or number of HCCs. Such statistical flaws inherent in the audit methodology suggest that the OIG's results are not reasonably reliable.

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
UnitedHealthcare Medicare & Retirement

cc: Antigone Potamianos

APPENDIX A

Comparison of OIG Audit Sample Versus the Population

A. Beneficiary Risk Scores – Sample vs. Population

Each member's risk adjustment factor (RAF) is computed from the member's individual Hierarchical Condition Categories (HCCs). The average RAF for all members in the OIG's sample is 1.64, whereas the average RAF for PacifiCare's population is 1.46. Using the sample mean, population variance, and standard normal z statistic, the 90% confidence interval for the RAF sample mean (among PacifiCare members in the OIG's sample) is (1.48, 1.80) (see following table). As a result, the RAF sample mean, according to commonly accepted statistical methods, is not statistically equal to the RAF population mean (among PacifiCare members in the population), and the sample is not representative of the population with respect to RAF.

Risk Adjustment Factor - Sample vs. Population

		90% confidence interval for population average	
	Average	Lower	Upper
Sample	1.64	1.48	1.80
Population	1.46		

In addition, PacifiCare computed the likelihood of drawing a sample with a RAF average of 1.64 or greater from the OIG-defined population using simulation methods. The results of the simulation suggest that a sample with this mean would be drawn 3.6% of the time, or 1 out of 28 times, which is not representative of the population with respect to RAF based on commonly accepted statistical methods.

B. Number of HCCs – Sample versus Population

Consistent with the RAF in the OIG's sample population, the average number of HCCs per member in the sample is greater than average number of HCCs per member in the population (see following table).

Average Number of HCCs - Sample vs. Population

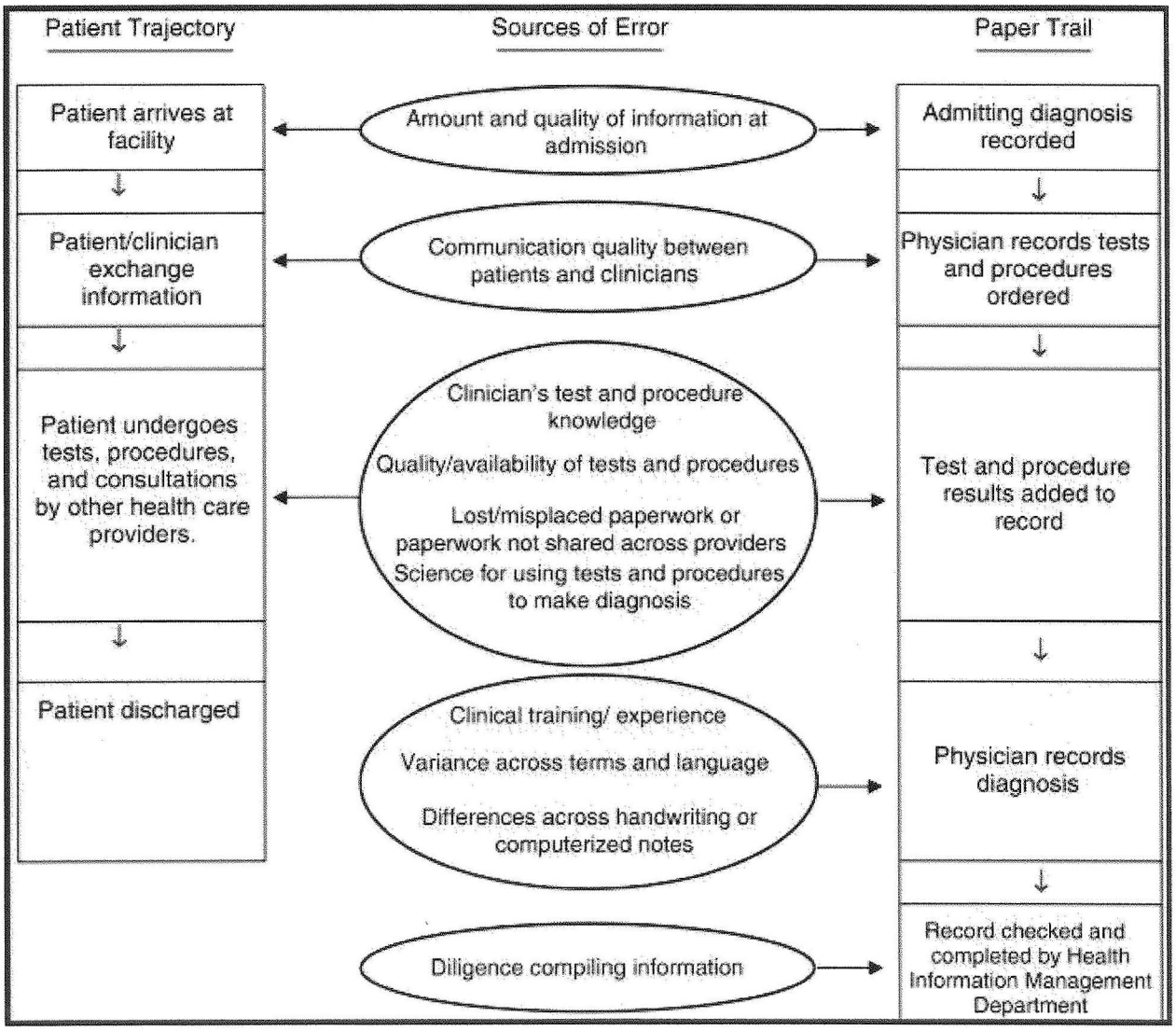
Sample	2.61
Population	2.33

Based on the average number of HCCs per member in the sample, the variance of number of HCCs per member in the population, and the standard normal z-statistic, the 90% confidence interval of the average number of HCCs in the population is (2.31, 2.90). Although the 90% confidence interval includes the population mean at the extreme low end of the interval (the probability of drawing a sample with a mean of 2.61 or greater is 5.8%), the higher number of HCCs per member in the sample is consistent with the high average RAF in the sample versus the population. This evidence suggests that the sample is not representative of the population with respect to RAF and number of HCCs.

APPENDIX B

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. [48/]



[48/] 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.[49/]

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.

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

APPENDIX C

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 50 of the 100 beneficiaries. The remaining 50 beneficiaries have zero overpayment. Using this data, the sample overpayment mean is $2,668.8 and variance is 22,180,609. The lower and upper bounds of the population mean of the overpayment is computed as $2,668.8 ± 1.66*[22,180,609/(100-1)]^0.5, yielding a 90% confidence interval for the population mean of [$1,886.98, $3,450.58]. The overpayment confidence interval for the population is computed by multiplying the confidence interval for the population mean by 188,829 to yield [($356,324,030, $651,571,113].

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.[50/] 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,[51/] 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:

$$D_1 = CP_{claims} - CP_{Medical\ Records}$$

where CP_{claims} is the CMS payment based on claims data, and $CP_{Medical\ Record}$ is the CMS payment based on medical records. 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 model error terms are shown as:

[50/] Pope et al., (2004).
[51/] Pope et al., (2004), p. 131.

$$e_{Medical\ Record} = AE_{Medical\ Record} - CP_{Medical\ Record}$$

$$e_{claims} = AE_{claims} - CP_{claims}$$

where $AE_{Medical\ Record}$ is the actual expenditures for an individual with HCCs found in medical records, and AE_{Claims} is the actual expenditures for an individual with HCCs found in claims data.

The following representation correctly accounts for both sources of uncertainty:

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

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 a sample of 2,675 California members with at least one HCC in 2007 and not in any capitation arrangement with providers. 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 actual 2007 medical expenditures from the forecasted expenditures (risk score times national predicted average annual cost). This approach yielded an estimate of the variance of forecast errors of 386,149,843. Recall that this reflects only members with at least one HCC.

The bootstrap approach consisted of drawing 10,000 samples of 100 observations each. Each of the observations included a random draw of $(CP_{claims} - CP_{Medical\ Record})$ with replacement from the sample of 100 overpayments/ underpayments (including 50 zeros), and an independent separate random draw (with replacement) of each of $e_{Medical\ Record}$ and e_{claims} from the 2,675 proxy errors. In each observation, if a 0 was drawn for $(CP_{claims} - CP_{Medical\ Record})$, (i.e. one of the 50 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.

When assuming the two error terms are independent (i.e., the covariance term is zero), the resulting bootstrap-obtained confidence interval was ($-120,350,276, $1,136,807,540) versus the OIG reported confidence interval of ($356,324,030, $651,571,113). This confidence interval, which includes zero, suggests that the population variance is very high and the population overpayment is not statistically different from zero.

Alternative distributions of $e_{Medical\ Record}$ and e_{claims} could be considered, including cases where $e_{Medical\ Record}$ and e_{claims} are correlated. 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 D, TAB 1
HCCs from OIG's 90 errors that were validated
PacifiCare of California CY 2007

	Sample #	HCC	ICD-9 Code	ICD-9 Code	ICD-9 Code	Validated Submitted HCC?	Review Comments
1	H0543-006	83	412			Y	Per documentation in DOS 7/25/06, the patient presented for a new patient check-up. RRR with occ PVC was documented in the exam notes in the cardiac section. In the A/P the physician states hx of MI (412). The original documentation was not signed by the physician; however, an attetation dated 3/19/09 was provided for this DOS with the physician's signature and credentials.
2	H0543-011	105	440.0			Y	Documentation to support aortic atherosclerosis (440.0) is located in the investigations section of the physician documentation for DOS 9/12/06. Documentation of the patient's prior echo results from September 2005 were documented as AS of 41 mm/Hg. This is significant as the patient is being assessed for cardiac clearance for surgery. Additionally, in the appeal documentation the dictated pre-operative H/P states 3/6 systolic ejection murmur auscultated. The written H/P states CV - AS III/VI. Based on the physician documentation and considering that the patient needed cardiac clearance for surgery, 440.0 is a significant secondary diagnosis.
3	H0543-019	105	451.19	440.1		Y	HCC 105 was validated with an alternate ICD-9-CM in the HCC: 440.0. In the History and Physical provided with the appeal documentation, DOS 12/16/06 - 12/20/06, the physician noted a 2/6 systolic murmur at the left sternal border. The patient had an emergent cath, had stents placed, and was diagnosed with AMI. Additionally, in the discharge summary it is documented that the echocardiogram results revealed aortic sclerosis (440.0) without significant gradient. Therefore, 440.0 is a significant secondary diagnosis.
4	H0543-031	32	579.1	579.0		Y	The physician documents the chronic condition Sprue (579.1) as a diagnosis on DOS 8/25/06. The physician's signature and credentials were not on the medical record documentation; however, the physician provided his signature and credentials on 1/22/09.
5	H0543-031	80	416.8	416.0		Y	DOS 6/30/06 supports pulmonary hypertension (416.8) with increase in edema noted; however, this documentation is not signed by the physician. The appeal documentation, DOS 3/24/06, also supports pulmonary hypertension (416.8). The note states that the patient was on a calcium channel blocker without any symptomatic improvement of his dyspnea; however, the note is not authenticated by the physician. Signatures and credentials were obtained for the two physicians who evaluated this beneficiary on the dates of service mentioned above; therefore, the HCC is validated.

Appendix D, TAB 1
HCCs from OIG's 90 errors that were validated
PacifiCare of California CY 2007

	Sample #	HCC	ICD-9 Code	ICD-9 Code	ICD-9 Code	Validated Submitted HCC?	Review Comments
6	H0543-031	108	496	492.8	491.20	Y	COPD is documented by the physician on 8/25/06, and it is noted that the patient is off oxygen at night. Decreased breath sounds were noted on exam. Therefore, would offer COPD as a diagnosis; however, the documentation is not signed by the physician. A different physician's documentation on 4/26/06 and 5/26/06 also support COPD; however, these notes are not authenticated by the physician. Physician's Impression on 5/26/06 supports moderate COPD with severe dyspnea and O2 dependence secondary to COPD. Signatures and credentials were obtained for the two physicians who evaluated this beneficiary on all dates of service mentioned above; therefore, the HCC is validated.
7	H0543-032	131	585.9			Y	Documentation of chronic renal insufficiency (CRI) noted in DOS 12/5/06 under assessment. Physician states that he discussed the situation of CRI with the patient. The medical record documentation is not signed by the physician; however, an attestation dated 3/13/09 was provided with the physician's signature and credentials for DOS 12/5/06.
8	H0543-034	19	250.00	250.02		Y	ICD-9-CM code 250.00 is supported in DOS 8/29/06 - 9/6/06. The 8/31 Progress Note states elevated blood glucose (255), probably stress related. An Insulin sliding scale was ordered. The Progress Note on 9/1 states hyperglycemia without known diabetes probably due to stress of surgery, better control on Insulin SS, start Lantus. The 9/5 Progress Note states hyperglycemia possibly diabetes, BS reasonably controlled, HgA1C 6.4. Orders were for dietician to advise patient on diabetic diet. The patient was discharged on 1800 cal ADA diet. Per IP guidelines, may code possible diagnoses as if they exist and would offer diabetes (250.00) as a valid diagnosis.
9	H0543-044	74	780.39			Y	Per DOS 1/27/06 (submitted with HCC 52 Appeal), under chief complaint/concern is noted the need for Dilantin as the patient was placed on Dilantin one year ago for seizures (780.39) s/p intracranial bleed. The physician made a decision to discontinue the Dilantin as the patient was without bleed for one year. Based on the documentation, would offer 780.39 as a valid diagnosis that was monitored and treated.

Appendix D, TAB 1
HCCs from OIG's 90 errors that were validated
PacifiCare of California CY 2007

	Sample #	HCC	ICD-9 Code	ICD-9 Code	ICD-9 Code	Validated Submitted HCC?	Review Comments
10	H0543-046	31	560.1			Y	Per documentation on 7/13/06, the patient complained of abdominal pain, N/V, and burning urination while in the ER. A CT of the abdomen read by the radiologist and reviewed by the ER physician showed a mild ileus (560.1) and no other acute pathology. The treatment of mild ileus is often palliative and the patient received IV fluids, IV MSO4, IV Ativan and IV Reglan. Ileus is a valid secondary condition diagnosed by the physician and therefore 560.1 should be coded.
11	H0543-049	108	492.8	496	491.21	Y	Psychotherapy visit (2/21/06) supports that the patient was worried about her COPD. Treatment was aimed towards her expressed feelings of anxiety of which COPD was identified as a stressor. Therefore, would offer COPD (496) as a secondary diagnosis as it was related to the presenting symptoms and treated.
12	H0543-068	105	453.40	443.9	451.83	Y	The entire inpatient hospital record for this beneficiary was reviewed for the stay from 12/29/06 - 1/5/07. Per documentation on 12/31/2006, the physician states questionable right arm thrombus or thromboembolism. Patient was on Heparin IV. Ultrasound of right arm supports thrombus of right brachial vein (451.83). The Discharge Summary also supports the presence of thrombus; therefore, 451.83 is a significant diagnosis and meets IP coding guidelines.
13	H0543-098	131	585.9	585.6		Y	Per documentation in DOS 6/28/06, the patient has a past medical history of chronic renal insufficiency (585.9). Labs (BUN and Creatinine) from 6/6/06 were noted. Therefore, would offer 585.9, as this diagnosis is being monitored and evaluated based on labs performed and reviewed. The Progress Note was not signed by the physician; however, an attest by the providing physician was signed with credentials and dated 2/11/09.

Appendix D, TAB 2
Incidental HCCs validated in sample
PacifiCare of California CY 2007

	Sample #	Incidental HCC Validated	ICD-9 Code Validated	Review Comments
1	H0543-012	71	357.2	Noted documentation of Chronic Kidney Disease (CKD) secondary to diabetes (250.40, 585.9) in the Discharge Summary dated 10/20/06 as well as DM Type 2 with peripheral neuropathy (250.60, 357.2). Patient to resume diabetic diet on discharge and resume meds including Avandia and Glipizide. Would offer as significant manifestation of diabetes as coding guidelines dictate that the manifestation of the DM complication should be coded if known.
2	H0543-015	80	428.0	CHF is listed under the past medical history of note on DOS 6/20/06. A medication documented for this 84 year old patient is Coumadin. CHF (428.0) is a chronic condition and may be linked to the control of the Atrial Fib which is being treated with Coumadin. Therefore, CHF could be offered as a secondary diagnosis.
3	H0543-022	105	440.0	Noted documentation of AS (Aortic Sclerosis) 440.0 in problem list located in DOS 7/12/06. DOS 12/30/06 states aortic sclerosis under problem list with systolic murmur noted on exam. AS is a chronic condition which needs monitoring; therefore, this should be offered as a secondary diagnosis.
4	H0543-026	74	780.39	DOS 2/15/06 documentation supports that the patient takes Dilantin every am and under the problem list it is noted that the patient is with SZ (seizures, ICD-9-CM code 780.39). Therefore, 780.39 is supported as a current diagnosis.
5	H0543-029	176	V44.3	Noted documentation in the H/P (DOS 1/27/06) that the patient has a history of colon cancer with subsequent colectomy. Under exam of the abdomen, it is noted that the patient had a colostomy (V44.3) functioning quite well. Therefore, V44.3 should be coded as a chronic condition and could be significant to the current care of the patient who is suspected of poor po intake.
6	H0543-030	105	443.81	DOS 12/4/06 documentation supports diabetes with peripheral vascular disease (250.70) (443.81). The reason for the patient's visit was to re-check diabetes; her glucose value was documented as 235. Per coding guidelines, when coding diabetes you must code any manifestations present related to diabetes. As the peripheral vascular disease is a manifestation, it should be added as a secondary code.
7	H0543-037	92	427.31	DOS 7/6/06 documentation supports that the patient has a history of A-Fib and is maintaining a regular rhythm with Sotalol. An EKG was performed and demonstrated a regular sinus rhythm. Therefore, 427.31 should be offered as significant secondary diagnosis.
8	H0543-044	108	496	Chronic Obstructive Pulmonary Disease (496) is documented in the listing of the patient's chronic conditions for DOS 11/9/06 and 11/27/06. This chronic condition should be coded as a secondary diagnosis.
9	H0543-053	131	585.2	Noted documentation in DOS 11/14/06 of mild/stable CRI (585.2) and Creatinine of 1.3 with a note to monitor BUN/Cr . Therefore, 585.2 is a significant secondary diagnosis.

Appendix D, TAB 2
Incidental HCCs validated in sample
PacifiCare of California CY 2007

	Sample #	Incidental HCC Validated	ICD-9 Code Validated	Review Comments
10	H0543-092	108	496	Noted documentation of COPD in past medical history in anesthesia notes (DOS 7/25/06) and again in ROS. Due to the fact that this diagnosis is integral to the assessment for administration of anesthesia, it should be coded as it is a significant secondary diagnosis.

Appendix D, TAB 3
HCCs from OIG's 90 errors supported by Clinical Review
PacifiCare of California CY 2007

	Sample #	HCC	ICD-9 Code	ICD-9 Code	ICD-9 Code	Review Comments
1	H0543-022	15	250.40			Type 2 DM and CKD are the first two diagnoses listed under the physician's assessment for DOS 10/30/06. The patient's medications and lab values were evaluated (Creatinine 6.1). Unable to link these diagnoses based on documentation in the record. Clarification of the etiology of CKD obtained on 3/4/09 states patient has Type 2 DM as etiology of CKD with signature of the providing physician. Based on the clarification, 250.40 is a valid diagnosis.
2	H0543-032	83	412			Per DOS 8/18/06 patient has CAD and is on ASA. CAD s/p stent is documented. The clarification note requested clarification of cardiac conditions, and the physician stated old MI (412) prior to PTCA in 2000 and 2003. Based on the clarification, old MI should be coded as a chronic condition pertinent to present pre-op visit.
3	H0543-033	55	296.22			Documentation in DOS 5/16/06 states patient with depression (311) as recently widowed and having a hard time coping. She was started on Zoloft. Clarifying letter as to type of depression dated 2/5/09 for DOS 5/16/06 states major depression. Therefore, based on the physician's clarification, would offer alternate ICD-9-CM code 296.20 which is within HCC 55 to specify the type of depression as Major Depression.
4	H0543-053	10	189.0			DOS 11/14/06 lists the diagnosis codes 189.0 (Malignant neoplasm of kidney and other and unspecified urinary organs, Kidney, except pelvis). The provider noted "left renal cancer - urology follow-up." Full medical record reflects that the patient had undergone a left nephrectomy for renal cell carcinoma in November of 2004. Per current medical literature, the five year survival rate for Stage 3 renal cell carcinoma is 20%. Current standards of practice recommend CT scans 3-4 times a year during this time frame due to the high likelihood of recurrence. Based on clinical judgment, this patient would not be presumed cured of her renal cell carcinoma.
5	H0543-063	80	425.4	428.0	404.13	Per review of the medical records, the primary care physician notes Congestive Heart Failure as one of the patient's diagnoses. The Progress Notes dated 10/5/06 and 12/8/06 note histories with shortness of breath and examinations that included heart, lungs, and extremities. The patient is noted with edema at both visits and is noted to be on a diuretic (Lasix). Both the physical examinations and medications reflect that the patient is clinically being treated for Congestive Heart Failure (428.0) on an ongoing basis.

	Sample #	HCC	ICD-9 Code	ICD-9 Code	ICD-9 Code	Review Comments
6	H0543-068	55	296.20			DOS 12/30/06 lists the diagnosis of depression (311) and supports that the patient was taking Paxil. Clarification of type of depression by the physician noted on 2/23/09 states Major Depression (296.20). Therefore, would offer the specified type of depression based on the physician's clarification.
7	H0543-073	15	250.40			Per documentation, the patient has a diagnosis of DM Type 2. A urine screen for microalbumin was ordered by the physician on 12/14/04, 11/8/05, and 6/26/06 consistent with recommended monitoring for kidney disease in patients with DM. On all of these dates provided, the patient is noted to have higher than normal levels of microalbumin in the urine consistent with DM with renal manifestations. On the 12/4/04 lab sheet, notations indicate consideration was given for an ACEI (Angiotensin Converting Enzyme Inhibitor) to be started which is the recommended treatment for DM with renal manifestations (microalbuminuria). However, an ACEI was not started due to concerns about a high potassium level in this patient. Based on the documentation, there is good clinical evidence of DM with renal manifestations.
8	H0543-082	16	250.60			Per documentation in DOS 8/14/06, the patient has DM. It is noted in the exam that the patient is unable to walk without walker and had decreased sensation bilaterally. A clarification was submitted to the physician to determine if the patient had any complications of DM. On the clarification signed by the physician on 2/10/09, the physician documents "Diabetes with peripheral neuropathy". Therefore, the diagnosis 250.60 is supported by the clarification.
9	H0543-096	55	296.30			Per documentation in DOS 6/8/06, the patient has a history of depression for which he uses Prozac. Assessment states depression under control. The clarification note signed by the physician on 3/4/09, the physician states "Major depression recurrent controlled on meds". Therefore, would offer the specified type of depression based on the physician's clarification.