

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**RISK ADJUSTMENT DATA VALIDATION
OF PAYMENTS MADE TO EXCELLUS
HEALTH PLAN, INC., FOR
CALENDAR YEAR 2007
(CONTRACT NUMBER H3351)**

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



Daniel R. Levinson
Inspector General

October 2012
A-02-09-01014

Office of Inspector General

<http://oig.hhs.gov>

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

Office of Audit Services

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

Office of Evaluation and Inspections

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

Office of Investigations

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

Office of Counsel to the Inspector General

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

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <http://oig.hhs.gov>

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

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

EXECUTIVE SUMMARY

BACKGROUND

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

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

Excellus Health Plan, Inc. (Excellus), is an MA organization located in Rochester, New York. For calendar year (CY) 2007, Excellus had multiple contracts with CMS, including contract H3351, which we refer to as "the contract." Under the contract, CMS paid Excellus approximately \$488 million to administer health care plans for approximately 48,000 beneficiaries.

OBJECTIVE

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

SUMMARY OF FINDINGS

The diagnoses that Excellus submitted to CMS for use in CMS's risk score calculations did not always comply with Federal requirements. For 53 of the 98 beneficiaries in our sample, the risk scores calculated using the diagnoses that Excellus submitted were valid. The risk scores for the remaining 45 beneficiaries were invalid because the diagnoses were not supported for 1 or more of the following reasons:

- The documentation did not support the associated diagnosis.
- Excellus did not provide any documentation to support the associated diagnosis.
- The diagnosis was unconfirmed.

Although Excellus had written policies and procedures for obtaining, processing, and submitting diagnoses to CMS, its 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* and the *2007 Risk Adjustment Data Training for Medicare Advantage Organizations Participant Guide*. Excellus officials stated that the providers were responsible for the accuracy of the diagnoses that Excellus submitted to CMS.

As a result of these unsupported and unconfirmed diagnoses, Excellus received \$157,777 in overpayments from CMS. Based on our sample results, we estimated that Excellus was overpaid approximately \$41,588,811 in CY 2007.

RECOMMENDATIONS

We recommend the following:

- Excellus should refund to the Federal Government \$157,777 in overpayments identified for the sampled beneficiaries.
- Excellus should work with CMS to determine the correct contract-level adjustment for the projected \$41,588,811 of overpayments. (This amount represents our point estimate. However, it is our policy to recommend recovery of overpayments at the lower limit of the 90-percent confidence interval, which is \$28,875,675. See Appendix B.)
- Excellus should improve its current practices to ensure compliance with the Federal requirements.

EXCELLUS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Excellus disagreed with our recommended financial disallowance and the results of our first and second rounds of medical review for 13 HCCs, and Excellus provided further information regarding the HCCs under separate cover. In addition, Excellus stated that our overpayment finding was inflated and based on flawed data, including the size of our sampling frame. Excellus also stated that an adjustment should be made to account for the documentation shortfalls that were inherent in the calibration of the payment model, which is based on fee-for-service claim data. Excellus added that our audit practices differed significantly from CMS's risk adjustment data validation audit procedures. Finally, regarding our recommendation to improve its current practices to ensure compliance with Federal requirements, Excellus described steps it has taken to improve its processes. Excellus' comments appear in their entirety as Appendix D.

We submitted the additional information provided by Excellus to our medical review contractor for a third medical review and revised our findings accordingly. Also, after verifying that some beneficiaries no longer met our criteria, we removed them from the sampling frame. Based on the results of the medical review and the adjusted sampling frame, we revised our report accordingly.

Although an analysis to determine the potential impact of error rates inherent in fee-for-service 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 Excellus refund only the overpayments identified for the sampled beneficiaries rather than refund the projected overpayments and (2) added a recommendation that Excellus work with CMS to determine the correct contract-level adjustments for the projected overpayments.

TABLE OF CONTENTS

Page

INTRODUCTION..... 1

BACKGROUND 1

 Medicare Advantage Program 1

 Risk-Adjusted Payments 1

 Federal Requirements 1

 Excellus Health Plan, Inc. 2

OBJECTIVE, SCOPE, AND METHODOLOGY 2

 Objective 2

 Scope 2

 Methodology 3

FINDINGS AND RECOMMENDATIONS 4

FEDERAL REQUIREMENTS..... 5

UNSUPPORTED HIERARCHICAL CONDITION CATEGORIES 6

 Unsupported Diagnosis Coding 6

 No Documentation Provided..... 7

 Unconfirmed Diagnosis 7

CAUSES OF OVERPAYMENTS..... 7

ESTIMATED OVERPAYMENTS 7

RECOMMENDATIONS 8

EXCELLUS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE 8

 Statistical Issues Related to the Office of Inspector General’s

 Extrapolation Methodology 9

 Fee-for-Service Error Rate Adjustment 9

 Missing Provider Signature and/or Credentials 10

 Additional Codes and Underpayment Calculations 10

 Diagnosis Coding Issues 11

 Sample Enrollment Discrepancies 12

 Sample Frame Enrollment Discrepancies 12

 Inclusion of Beneficiaries With End-Stage Renal Disease 12

 Due Process/Opportunity To Be Heard 13

APPENDIXES

A: SAMPLE DESIGN AND METHODOLOGY

B: SAMPLE RESULTS AND ESTIMATES

C: DOCUMENTATION ERRORS IN SAMPLE

D: EXCELLUS COMMENTS

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.

Excellus Health Plan, Inc.

Excellus Health Plan, Inc. (Excellus), is an MA organization located in Rochester, New York. For CY 2007, Excellus had multiple contracts with CMS, including contract H3351, which we refer to as “the contract.” Under the contract, CMS paid Excellus approximately \$488 million to administer health care plans for approximately 48,000 beneficiaries.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

Scope

Our review covered approximately \$261 million of the CY 2007 MA organization payments that CMS made to Excellus on behalf of 25,832 beneficiaries. These payments were based on risk adjustment data that Excellus 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 2007³ and (2) had a CY 2007 risk score that was based on at least one HCC. We limited our review of Excellus’ internal control structure to controls over the collection, processing, and submission of risk adjustment data.

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

We performed our fieldwork at Excellus’ corporate office in Rochester, New York, and at CMS in Baltimore, Maryland, from December 2008 to January 2010.

³ We limited our sampling frame to continuously enrolled beneficiaries to ensure that Excellus 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 Excellus submitted supported the HCCs associated with the beneficiaries in our sample.
- We interviewed Excellus officials to gain an understanding of Excellus' 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 25,832 beneficiaries⁴ 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 98 beneficiaries⁵ with 215 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 Excellus submitted to CMS associated with the beneficiary's HCC(s);
 - requested that Excellus provide us with the one medical record that, in Excellus' judgment, best supported the HCC(s) that CMS used to calculate the beneficiary's risk score;

⁴ After we issued our draft report, Excellus performed a membership analysis and resolved a vendor Risk Adjustment Processing System software issue. As a result, we removed 38 beneficiaries who no longer met our sample criteria from our original sampling frame of 25,870.

⁵ We removed 2 beneficiaries included in our original sample size of 100. These 2 were included in the 38 described in footnote 4.

- obtained Excellus’ certification that the documentation provided represented “the one best medical record to support the HCC”;⁶ and
 - submitted Excellus’ documentation and HCCs for each beneficiary to our medical review contractor for a first round of review and requested additional documentation from Excellus for a second round of review if the contractor found that documentation submitted during the first round did not support the HCCs.
- For HCCs we questioned in our draft report with which Excellus disagreed,⁷ Excellus provided additional information. We then submitted this information to our medical review contractor for a third round of 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 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 Excellus submitted to CMS for use in CMS’s risk score calculations did not always comply with Federal requirements. For 53 of the 98 beneficiaries in our sample, the risk scores calculated using the diagnoses that Excellus submitted were valid. The risk scores for the remaining 45 beneficiaries were invalid because the diagnoses were not supported for 1 or more of the following reasons:

- The documentation did not support the associated diagnosis.
- Excellus did not provide any documentation to support the associated diagnosis.

⁶ 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, require plans to select the “one best medical record” to support each HCC and indicate that the best medical record could 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).

⁷ Excellus disagreed with 13 of 80 HCCs questioned in our draft report.

- The diagnosis was unconfirmed.⁸

Although Excellus had written policies and procedures for obtaining, processing, and submitting diagnoses to CMS, its practices were not effective in ensuring that the diagnoses it submitted to CMS complied with the requirements of the 2006 and 2007 Participant Guides. Excellus officials stated that providers were responsible for the accuracy of the diagnoses that Excellus submitted to CMS.

As a result of these unsupported and unconfirmed diagnoses, Excellus received \$157,777 in overpayments from CMS. Based on our sample results, we estimated that Excellus was overpaid approximately \$41,588,811 in CY 2007.

FEDERAL REQUIREMENTS

Regulations (42 CFR § 422.310(b)) state: “Each MA organization must submit to CMS (in accordance with CMS instructions) the data necessary to characterize the context and purposes of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data necessary to characterize the functional limitations of enrollees of each MA organization.” The 2007 Participant Guide, section 8.7.3, and the 2006 Participant Guide, section 7.7.3, state that “MA organizations are responsible for the accuracy of the data submitted to CMS.”

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

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

⁸ The 2006 and 2007 Participant Guides state that physicians and hospital outpatient departments may not code diagnoses documented as “probable,” “suspected,” “questionable,” “rule out,” or “working.” The Participant Guides consider these diagnoses as unconfirmed. (See section 5.4.2 of the 2006 Participant Guide and section 6.4.2 of the 2007 Participant Guide.)

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, Excellus 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 Excellus submitted to CMS were not supported, confirmed, or both. These diagnoses were associated with 60 HCCs. Appendix C shows the documentation error or errors found for each of the 60 HCCs. These errors were for unsupported diagnosis coding, no documentation provided, and an unconfirmed diagnosis.

Unsupported Diagnosis Coding

The documentation that Excellus submitted to us for medical review did not support the diagnoses associated with 59 HCCs. The following are examples of HCCs that were not supported by Excellus' documentation.

- For one beneficiary, Excellus submitted the diagnosis code for “intermediate coronary syndrome.” CMS used the HCC associated with this diagnosis in calculating the beneficiary's risk score. However, the documentation that Excellus provided noted the diagnosis as coronary artery disease, which does not have an associated HCC.
- For a second beneficiary, Excellus submitted the diagnosis code for “diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled.” CMS used the HCC associated with this diagnosis in calculating the beneficiary's risk score. However, the documentation that Excellus provided indicated that the patient was treated for left leg cellulitis with rigors, coronary artery disease, hypertension, hyperlipidemia, and “new right bundle branch block.”⁹ The documentation did not mention diabetes or indicate that diabetes had affected the care, treatment, or management provided during the encounter.
- For a third beneficiary, Excellus submitted the diagnosis code for “chronic glomerulonephritis with unspecified pathological lesion in kidney.”¹⁰ CMS used the HCC associated with this diagnosis in calculating the beneficiary's risk score. However, the documentation that Excellus provided referenced an outpatient colonoscopy. The documentation did not mention glomerulonephritis or indicate that glomerulonephritis had affected the care, treatment, or management provided during the encounter.

⁹ Cellulitis is a bacterial infection of the skin, coronary artery disease and bundle branch blocks are related to the heart, hypertension relates to high blood pressure, and hyperlipidemia relates to high blood cholesterol levels.

¹⁰ Glomerulonephritis is a type of kidney disease in which the part of the kidneys that helps filter waste and fluids from the blood is damaged.

No Documentation Provided

One HCC was unsupported because Excellus did not provide any documentation.

Excellus submitted the diagnosis code for “diabetes with renal or peripheral circulatory manifestation.” CMS used the HCC associated with this diagnosis in calculating the beneficiary’s risk score. However, Excellus officials indicated that they could not obtain any medical records to support the HCC.

Unconfirmed Diagnosis

One HCC was unsupported because the diagnosis submitted to CMS was unconfirmed.

Excellus submitted the diagnosis code for “peripheral vascular disease, unspecified.” CMS used the HCC associated with this diagnosis in calculating the beneficiary’s risk score. The documentation that Excellus submitted noted the diagnosis as “? peripheral vascular disease.” Diagnoses that are “probable,” “suspected,” “questionable,” or “working” should not be coded.

CAUSES OF OVERPAYMENTS

During our audit period, Excellus had written policies and procedures for obtaining, processing, and submitting risk adjustment data to CMS. According to these policies and procedures, Excellus used chart validation to ensure the accuracy of the diagnoses that it submitted to CMS. Excellus officials told us that they used provider outreach for the same purpose.

- Chart validation is a review of documentation to ensure that the diagnoses submitted to CMS are correctly coded. Excellus officials stated that Excellus currently validates approximately 25 percent of charts; however, the officials stated that Excellus reviewed fewer charts during our audit period.
- Excellus conducts provider outreach through its Web site and monthly newsletters, which include tips for accurate risk adjustment coding.

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

ESTIMATED OVERPAYMENTS

As a result of the unsupported and unconfirmed diagnoses in our sample, Excellus received \$157,777 in overpayments from CMS. Based on our sample results, we estimated that Excellus was overpaid approximately \$41,588,811 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 the potential impact of error rates inherent in FFS data on MA payments to MA organizations.¹¹

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

RECOMMENDATIONS

We recommend the following:

- Excellus should refund to the Federal Government \$157,777 in overpayments identified for the sampled beneficiaries.
- Excellus should work with CMS to determine the correct contract-level adjustment for the projected \$41,588,811 of overpayments¹².
- Excellus should improve its current practices to ensure compliance with the Federal requirements.

EXCELLUS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Excellus disagreed with our recommended financial disallowance and the results of our first and second rounds of medical review for 13 HCCs, and Excellus provided further information regarding the HCCs under separate cover. In addition, Excellus stated that our overpayment finding was inflated and based on flawed data, including the size of our sampling frame. Excellus also stated that an adjustment should be made to account for the documentation shortfalls that were inherent in the calibration of the payment model, which is based on FFS claim data. Excellus added that our audit practices differed significantly from CMS's risk adjustment data validation (RADV) audit procedures. Finally, regarding our recommendation to improve its current practice to ensure compliance with Federal requirements, Excellus described steps it has taken to improve its processes. Excellus' comments appear in their entirety as Appendix D.

We submitted the additional information provided by Excellus to our medical review contractor for a third medical review and revised our findings accordingly. Also, after verifying that some beneficiaries no longer met our criteria, we removed them from the sampling frame. Based on the results of the medical review and the adjusted sampling frame, we revised our report accordingly.

¹¹ 75 Fed. Reg. 19749 (April 15, 2010).

¹² This amount represents our point estimate. However, it is our policy to recommend recovery of overpayments at the lower limit of the 90-percent confidence interval, which is \$28,875,675. See Appendix B.

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.¹³ Therefore, because of the potential impact these error rates could have on the CMS model that we used to recalculate MA payments for the beneficiaries in our sample, we (1) modified one recommendation to have Excellus refund only the overpayments identified for the sampled beneficiaries rather than refund the projected overpayments and (2) added a recommendation that Excellus work with CMS to determine the correct contract-level adjustments for the projected overpayments.

Statistical Issues Related to the Office of Inspector General’s Extrapolation Methodology

Excellus Comments

Excellus stated that our sample of 100 beneficiaries was too small to meet acceptable confidence and precision levels and should not be used to measure a potential overpayment. Further, Excellus stated that the sample was not representative of the population, as Excellus underwent a CMS RADV audit for the same contract for the prior payment year with significantly different results. In addition, Excellus stated that it believes that the Office of Inspector General (OIG) should use a 99-percent rather than a 90-percent confidence interval, given the recommended payment retraction amount.

Office of Inspector General Response

Our sample size of 100 beneficiaries provided a fair and unbiased representation of the beneficiaries in our sampling frame (population). A sample of 100 beneficiaries is both consistent with our established policy and sufficient to ensure valid sample results. We acknowledge that the error rate for the CMS RADV audit was different; however, we note that the population reviewed as part of that audit was different from the population reviewed as part of this audit. In addition, when specifying a recovery amount, it is OIG policy to use the lower limit of the 90-percent confidence interval, as we have 95-percent confidence that the actual amount overpaid is greater than the recommended recovery amount.

Fee-for-Service Error Rate Adjustment

Excellus Comments

Excellus stated that an adjustment should be made to the error rate to account for documentation shortfalls that were inherent in the calibration of the risk-adjusted payment model. Excellus also stated that the MA risk-adjusted payment methodology was developed and calibrated based on claim data; however, CMS determined that the underlying medical record is the ultimate source of diagnosis information. Excellus stated that an adjustment to the error rate would address this inconsistency.

¹³ 75 Fed. Reg. 19749 (April 15, 2010).

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 Excellus’ 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.¹⁴ 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 Excellus work with CMS to determine the correct contract-level adjustments for the projected overpayments.

Missing Provider Signature and/or Credentials

Excellus Comments

Excellus stated that we should have allowed provider signature attestations at the outset of the audit to be consistent with CMS’s RADV audit methodology and indicated that OIG recently changed its stance on the subject.

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 signature attestations and revised our findings accordingly.

Additional Codes and Underpayment Calculations

Excellus Comments

Excellus stated that we did not accept additional HCCs identified within the medical records submitted for review that could have affected an audit member’s risk score. Excellus stated that CMS’s Final Rule indicates CMS’s willingness to accept additional diagnosis codes and relative HCCs found with the medical record submitted for audit purposes. Excellus stated that our failure to allow consideration of these additional codes denied Excellus its right to have the codes considered under CMS’s procedures.

¹⁴ 75 Fed. Reg. 19749 (April 15, 2010).

Office of Inspector General Response

Our objective was to determine whether the diagnoses that Excellus 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. Therefore, we did not consider additional diagnoses.

Diagnosis Coding Issues

Excellus Comments

Excellus stated that it did not agree with the findings for 13 HCCs¹⁵ for which our medical review contractor did not find support during the first and second medical reviews. Under separate cover, Excellus provided additional information related to these HCCs that was not presented during the first two medical reviews.¹⁶

Excellus also stated that for four of the five HCCs for which no documentation was provided, an error in its vendor's software had incorrectly submitted diagnosis clusters under the wrong Medicare health insurance claim number. Excellus stated that, after discovering the error, it performed an analysis on all contracts and submitted a deletion file to CMS of over 600 diagnosis clusters and completed a payment retraction in August 2010. Excellus stated that the four HCCs should be excluded from the audit because any risk-adjusted payments based on them were reconciled with CMS.

Office of Inspector General Response

We submitted the additional information provided by Excellus for the 13 HCCs to our medical review contractor for a third medical review. For the 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 4 of the 13 HCCs. Therefore, we revised our findings accordingly.

Regarding the four HCCs for which no documentation was provided, we verified that the payments were retracted and removed the HCCs from our audit. This resulted in removing one of the beneficiaries from our sample, as the beneficiary no longer had any related HCCs during our audit period. We revised our report accordingly.

¹⁵ In its comments on our draft report, Excellus contested the decision of our medical reviewers for eight HCCs. Under separate cover, Excellus contested an additional five HCCs.

¹⁶ Specifically, Excellus stated that five of the HCCs were determined to be invalid because they were contained within a diagnostic report that OIG's reviewers commented was an inappropriate documentation source; however, providers of the referenced services are either the ordering provider or a member of the practice, and the findings are considered a final diagnosis. In addition, Excellus maintained that OIG's reviewers did not validate eight other HCCs because the reviewers incorrectly applied CMS or ICD-9 coding guidelines. Excellus requested that the records be reviewed by another coder.

Sample Enrollment Discrepancies

Excellus Comments

Excellus stated that enrollment and payment discrepancies related to our sample must be corrected based on current monthly membership report information. Excellus also stated that one beneficiary was retroactively disenrolled for all of payment year 2007 and that another beneficiary, assumed to be enrolled for the full calendar year 2007, was only enrolled during the first 8 months of the year. Therefore, Excellus requested that we adjust our calculations.

Office of Inspector General Response

We confirmed that one beneficiary was retroactively disenrolled for all of payment year 2007 and that payments related to the beneficiary were retracted. We removed the beneficiary from our sample and revised our report accordingly. Regarding the beneficiary enrolled only during the first 8 months of the year, we determined—and confirmed with Excellus—that the beneficiary was enrolled under the contract during the rest of the year under a different health insurance claim number.

Sample Frame Enrollment Discrepancies

Excellus Comments

Excellus stated that it found more than 1,200 beneficiaries included in the sampling frame who no longer met the criteria of having been continuously enrolled with Excellus for the 13-month period from January 2006 through January 2007 and having at least 1 HCC for payment year 2007. Excellus stated that the beneficiaries either did not have an HCC or did not meet the enrollment criteria and, therefore, should be excluded from the extrapolation calculation.

Office of Inspector General Response

Under separate cover, Excellus provided a listing of the 1,218 beneficiaries whom it wanted excluded from the sampling frame. After selecting a sample for review and providing additional demographic information, Excellus determined that only 231 of the 1,218 beneficiaries should be excluded from the sampling frame. However, Excellus provided documentation to support only 38 of these cases, which we accepted. Therefore, we revised our report accordingly.

Inclusion of Beneficiaries With End-Stage Renal Disease

Excellus Comments

Excellus stated that our sample included two beneficiaries with end-stage renal disease (ESRD), a number that it believed was not proportionate to the number of beneficiaries in the population. Excellus stated that it believes that CMS excludes beneficiaries with ESRD from its RADV audits because a single unsubstantiated HCC for a member with ESRD can lead to a

disproportionately large payment error. Therefore, Excellus requested that we remove these beneficiaries from our sample.

Office of Inspector General Response

We included all beneficiaries that met the criteria in our population, regardless of whether they had ESRD. Our sample was randomly selected and, by definition, was representative of the population. In addition, although there were several outliers (large values) in our sample, which utilizes the Central Limit Theorem, the presence of some outliers is of no consequence.¹⁷

Due Process/Opportunity To Be Heard

Excellus Comments

Excellus stated that it should be provided an administrative appeal process more extensive than the right to submit a response to our findings. Further, Excellus stated that CMS has an appeals process for its RADV audits that provides a safeguard against erroneous audit results and that audits conducted on behalf of CMS should be at least as accurate and fair as audits conducted by CMS itself.

Office of Inspector General Response

Pursuant to the Inspector General Act of 1978, 5 U.S.C. App., our audits are intended to provide an independent assessment of U.S. Department of Health and Human Services programs and operations. We did not conduct our audit on behalf of CMS. 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 Excellus submitted to CMS for use in CMS's risk score calculations complied with Federal requirements. Moreover, our audit makes recommendations which are not final actions from which due process rights may arise.

¹⁷ The theorem states that the distribution of the sample mean is approximately normal for large samples regardless of the shape and nature of the population.

APPENDIXES

APPENDIX A: SAMPLE DESIGN AND METHODOLOGY

SAMPLING FRAME

The sampling frame consisted of 25,832 beneficiaries on whose behalf the Centers for Medicare & Medicaid Services paid Excellus Health Plan, Inc. (Excellus), approximately \$261 million in calendar year (CY) 2007. These beneficiaries (1) were continuously enrolled under contract H3351 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 98 beneficiaries.

SOURCE OF THE RANDOM NUMBERS

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

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the sample units in the sampling frame. After generating the random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used RAT-STATS 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
25,832	98	\$1,028,811	45	\$157,777

Estimated Value of Overpayments

(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	\$41,588,811
Lower limit	28,875,675
Upper limit	54,301,947

APPENDIX C: DOCUMENTATION ERRORS IN SAMPLE

A	Unsupported diagnosis coding
B	No documentation provided
C	Unconfirmed diagnosis

	Hierarchical Condition Category	A	B	C	Total Errors
1	Metastatic cancer and acute leukemia	X			1
2	Diabetes with renal or peripheral circulatory manifestation	X			1
3	Nephritis	X			1
4	Vascular disease	X			1
5	Lymphatic, head and neck, brain, and other major cancers	X			1
6	Diabetes with renal or peripheral circulatory manifestation	X			1
7	Seizure disorders and convulsions	X			1
8	Angina pectoris/old myocardial infarction	X			1
9	Vascular disease	X			1
10	Vascular disease	X			1
11	Schizophrenia	X			1
12	Major depressive, bipolar, and paranoid disorders	X			1
13	Congestive heart failure	X			1
14	Diabetes with renal or peripheral circulatory manifestation	X			1
15	Congestive heart failure	X			1
16	Hip fracture/dislocation	X			1
17	Chronic obstructive pulmonary disease	X			1
18	Congestive heart failure	X			1
19	Breast, prostate, colorectal, and other cancers and tumors	X			1
20	Vascular disease	X		X	2
21	Rheumatoid arthritis and inflammatory connective tissue disease	X			1
22	Lung, upper digestive tract, and other severe cancers	X			1
23	Hip fracture/dislocation	X			1
24	Decubitus ulcer of skin	X			1
25	Diabetes with ophthalmologic or unspecified manifestation	X			1
26	Unstable angina and other acute ischemic heart disease	X			1
27	Diabetes with renal or peripheral circulatory manifestation	X			1
28	Diabetes with ophthalmologic or unspecified manifestation	X			1
29	Diabetes with renal or peripheral circulatory manifestation	X			1
30	Unstable angina and other acute ischemic heart disease	X			1
31	Vascular disease	X			1
32	Angina pectoris/old myocardial infarction	X			1
33	Rheumatoid arthritis and inflammatory connective tissue disease	X			1
34	Vascular disease	X			1
35	Angina pectoris/old myocardial infarction	X			1
36	Major complications of medical care and trauma	X			1
37	Diabetes with renal or peripheral circulatory manifestation	X			1
38	Breast, prostate, colorectal, and other cancers and tumors	X			1
39	Metastatic cancer and acute leukemia	X			1

	Hierarchical Condition Category	A	B	C	Total Errors
40	Lung, upper digestive tract, and other severe cancers	X			1
41	Vascular disease with complications	X			1
42	Breast, prostate, colorectal, and other cancers and tumors	X			1
43	Breast, prostate, colorectal, and other cancers and tumors	X			1
44	Diabetes with renal or peripheral circulatory manifestation		X		1
45	Ischemic or unspecified stroke	X			1
46	Unstable angina and other acute ischemic heart disease	X			1
47	Diabetes without complication	X			1
48	Vascular disease	X			1
49	Hip fracture/dislocation	X			1
50	Breast, prostate, colorectal, and other cancers and tumors	X			1
51	Unstable angina and other acute ischemic heart disease	X			1
52	Ischemic or unspecified stroke	X			1
53	Diabetes without complication	X			1
54	Ischemic or unspecified stroke	X			1
55	Breast, prostate, colorectal, and other cancers and tumors	X			1
56	Vascular disease	X			1
57	Breast, prostate, colorectal, and other cancers and tumors	X			1
58	Vascular disease	X			1
59	Angina pectoris/old myocardial infarction	X			1
60	Ischemic or unspecified stroke	X			1
	Total	59	1	1	61

APPENDIX D: EXCELLUS COMMENTS



December 23, 2010

Mr. James P. Edert
Regional Inspector General for Audit Services
Region II
Office of Inspector General
U.S. Department of Health & Human Services
Jacob Javits Federal Building
26 Federal Plaza, Room 3900
New York, NY 10278

Re: U.S. Department of Health & Human Services,
Office of Inspector General (OIG)
Risk Adjustment Data Validation of Payments Made to
Excellus Health Plan, Inc. for Calendar Year 2007
(Contract H3351) Draft Report
Report Number: A-02-09-01014

Dear Mr. Edert:

Excellus Health Plan, Inc. hereby submits this letter and the enclosed comments in response to the draft audit report of the Office of Inspector General titled *Risk Adjustment Data Validation of Payments Made to Excellus Health Plan, Inc. for Calendar Year 2007 (Contract H3351)*.

Excellus Health Plan, Inc. ("Excellus" or "The Plan") is a regional, non-profit health plan committed to the health and well-being of its members and the communities it serves. While its roots can be traced to the 1935 founding of Rochester Hospital Service Corporation, today's Excellus was created through the 1998 merger of BlueCross BlueShield of the Rochester Area, BlueCross BlueShield of Central New York, and BlueCross BlueShield of Utica-Watertown into a single entity. Univera Healthcare merged into Excellus Health Plan as of October 1, 2001. Excellus offers group and individual commercial health care coverage, Medicaid Managed Care coverage, Medicare Advantage Plans, and Medicare Prescription Drug Plans, among other types of health care coverage. Today, we provide coverage to over 1.7 million members across upstate New York. The Medicare Advantage Plans, Medicare Prescription Drug Plans, and Medicare Supplemental Plans we offer provide the foundation of our ongoing commitment to provide seniors with affordable and dignified access to needed and effective health care coverage. We work diligently to ensure that we have a broad array of coverage options to meet seniors' health care coverage needs. One of our predecessor plans, Univera Health Plans, offered a Medicare risk contract at the beginning of the Medicare risk program in 1985.

In keeping with this commitment, we strive to prevent and detect fraud, waste and abuse. We have a comprehensive fraud, waste and abuse prevention and detection program. We

Mr. James P. Edert
December 23, 2010
Page 2

have a Special Investigation Unit with eleven full-time employees whose main function is to investigate allegations of fraud and abusive billing practices. The Special Investigations Unit is a member of the National Health Care Anti-Fraud Association, which provides current information on legislation and continuing education for all staff members. This program and others give us the ability to deliver high quality health care coverage in a cost effective way.

The OIG made two findings in its audit report: 1) the Plan was overpaid in 2007 because the diagnoses submitted by Excellus for use in risk score calculations were not supported, and 2) the Plan needs to improve upon its current practices in order to ensure compliance with the requirements of the Participant Guide. The Health Plan disputes the OIG findings. The overpayment finding is inflated and based on flawed data. For the reasons stated in this letter and the enclosed comments, Excellus does not concur with the finding regarding overpayment and requests that: 1) the audit results be corrected and 2) the results not be used to extrapolate across the entire population. Our detailed response is attached and a brief summary follows.

Comments Regarding Payment Accuracy

Excellus has serious questions regarding the ability of the OIG to extrapolate its findings, as well as the accuracy of the findings, for the following reasons:

Statistical Issues:

Inadequate sample size. An overpayment should not be extrapolated from the audit findings to the entire population because the audit was conducted upon only 100 enrollees. This sample size is too small to meet the acceptable levels of confidence and precision. The sample size used by the OIG is inconsistent not only with the OIG's own protocols, but also with the standards set by the statistical community and those applied by CMS in evaluating overpayments under the Improper Payments Information Act of 2002 (P. L. No. 107-300), as amended by the Improper Payments Elimination and Recovery Act of 2010 (P. L. No. 111-204). Moreover, the OIG's sample size is one-half the sample size used by CMS in its RADV audits, resulting in a significant diminishment (29%) of the level of precision as compared to the level obtained by CMS in its audits.

Unrepresentative Sample. Excellus underwent a CMS RADV audit for the same contract for the prior payment year with a similar sample size. The results of those audits were significantly different. The probability of drawing two representative samples from the same population with such disparate error rates was 0.000509, or extremely unlikely. This demonstrates that a sample of 100 is too small to get a representative sample. Knowing whether or not a sample is representative is extremely difficult because critical factors such as provider documentation practices and coding staff ability and accuracy vary widely and cannot be easily measured to ensure sample representativeness.

Mr. James P. Edert
December 23, 2010
Page 3

99% Confidence Interval. We believe that, if a federal governmental agency is going to retract tens of millions of dollars in payment, it must be certain that its calculation of the amount to be retracted is accurate. Therefore, a 99% confidence interval should be used rather than the 90% used by the OIG. This request is consistent with the proposed RADV sampling and extrapolation methodology in CMS's recent memo dated December 20, 2010 titled "*Medicare Advantage Risk Adjustment Data Validation (RADV) Notice of Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits*". However, we emphasize that use of a 99% confidence interval does not correct for the cited deficiencies in sample size and lack of representativeness.

No Fee-For-Service Error Adjustment.

CMS calibrated the Medicare Advantage payment model using traditional Medicare Fee-For-Service ("FFS") claims data and assumed that that data was 100% accurate. However, there is a disconnect in provider documentation contained in claims submitted for reimbursement and underlying medical records. Medicare Advantage plans' enrollees use the same providers as traditional Medicare FFS beneficiaries, and there is no reason to believe that providers document differently for Medicare Advantage than they do for FFS Medicare patients. Therefore, an adjustment should be made to account for the documentation shortfalls that were inherent in the calibration of the payment model. To do otherwise, would result in the government underpaying the health plans being audited.

Other Methodological Challenges.

The sample overpayment finding of \$213,166 is inflated and should be reduced to account for the following factors:

Provider Signature/Credential Attestations. Considerations of attestations to correct omitted physician signatures and credentials (this would be consistent with CMS's RADV audit methodology). We believe this is a point on which there is agreement as the OIG recently requested attestations from the plan;

Additional Diagnoses. The OIG audit only considered over payments, there was no consideration of diagnoses contained within the medical records but for which the Plan was not paid. If the purpose of the audit is to ensure appropriate payment based on the medical record documented diagnoses, there must be an allowance for additional codes found during the audit;

Mr. James P. Edert
December 23, 2010
Page 4

Expansion of Excluded CPT Code Ranges. The OIG's auditors inappropriately expanded the range of impermissible diagnostic radiology codes beyond the CPT ranges specified in CMS's manuals. We request a review of those records;

Medical Coding Discrepancies. We disagree with several coding determinations of the OIG's auditors. We request a review of the medical records in question;

Membership Discrepancies. There are membership discrepancies in both the sample and the sample frame which illustrate that the OIG failed to follow correctly its own study design; at a minimum, these errors need to be corrected; and

Inclusion of ESRD Members. Consistent with CMS RADV audit methodology, the OIG should remove enrollees with ESRD from our sample population and extrapolation calculation.

Due Process.

The OIG RADV audit practices differed significantly from the CMS RADV audit procedures. As a matter of fairness, health plans should be held to the same audit standards by the Department of Health and Human Services. OIG used a sample size of 100, about half of that used by CMS. CMS uses a stratified sample. The OIG did not. CMS has provided an appeals process for its RADV audits, but it is unclear how the OIG RADV audits fall into that scheme.

Comments Regarding the Improvement of Current Practices to Ensure Compliance with the Participant Guide

With regard to the OIG's second recommendation, Excellus is always looking to improve its processes. Recent steps include:

- Significantly increased number of medical record reviews.
- RFI to replace our RAPS vendor.
- Implementation of prospective programs such as our frail elderly program which strives to identify those members that require high-touch in-home care management interventions and coordination of care. These activities conducted by a qualified practitioner will allow the Plan to accurately document diagnosis submitted to CMS.
- Implementation of better quality assurance processes of chart reviews.

Excellus recognizes the importance of continual process improvements. However, the physicians with whom the Plan contracts treat far more patients covered under Original Medicare than any one Medicare Advantage plan. Excellus believes the issues that were identified as part of this audit arise equally in the medical records of patients covered

Mr. James P. Edert
December 23, 2010
Page 5

under Original Medicare. Excellus believes that unless and until CMS takes a significant leadership role in directing physicians to correctly reflect the diagnoses in the medical record and claims submitted for reimbursement, it is unreasonable to expect that any single health plan acting alone will be able assure complete documentation compliance by physicians treating its Medicare Advantage enrollees, as directed by the OIG. Excellus urges the OIG to adopt this point as one of its recommendations in its final report.

We thank the OIG for this opportunity to comment on your draft report and look forward to working with you to improve the Medicare Advantage program.

Sincerely,

A handwritten signature in black ink that reads "Tove Stigum". The signature is written in a cursive style with a long horizontal stroke at the end.

Tove Stigum
Vice President, Medicare Finance

Enclosure

Comments to Department of Health and Human Services Office of Inspector
General Regarding:
Risk Adjustment Data Validation of Payments Made to Excellus Health Plan, Inc.
for Calendar Year 2007 (Contract H3351) June 2010

Table of Contents

I. Statistical Issues Related to the OIG’s Extrapolation Methodology	8
A. Background	8
B. Evaluation of Sample Size Adequacy	9
C. Evaluation of Sample Representativeness and Other Considerations.....	12
D. Conclusion	13
II. Methodology Issues.....	14
A. Need for Fee-for-Service Adjustment.....	14
B. Missing Provider Signature and/or Credentials	16
C. Additional Codes and Underpayment Calculations.....	17
D. Diagnosis Coding Issues	17
i. Definition of Diagnostic Radiology.....	17
ii. Coding Guideline Interpretation Differences	19
iii. No Documentation Provided	19
E. Sample Enrollment Discrepancies	20
F. Sample Frame Enrollment Discrepancies.....	20
G. Inclusion of ESRD Members	20
III. Process Improvement.....	21
IV. Due Process/Opportunity to Be Heard.....	22
V. Technical Notes	24

Excellus Health Plan, Inc. (“Excellus”) submits the following comments to the “Risk Adjustment Data Validation of Payments Made to Excellus Health Plan, Inc. for Calendar Year 2007 (Contract H3351)” Draft Report, dated June 29, 2010 (“Draft Report”). Our primary concerns regarding the Draft Report turn on the following issues: (1) statistical issues with the extrapolation; (2) methodological issues; (3) coding disputes; and (4) due process.

I. Statistical Issues Related to the OIG’s Extrapolation Methodology

A. Background

In order to evaluate the potential overpayment to Excellus Health Plan, Inc. (Excellus), the Office of Inspector General (OIG), Office of Audit Services randomly sampled 100 beneficiaries of 25,870 eligible beneficiaries. According to the OIG’s study design, eligible beneficiaries consisted of those who:

- Were continuously enrolled under contract H3351 during all of CY2006 and January of CY2007 and
- Had a CY2007 risk score that was based on at least one Hierarchical Condition Category (HCC)

The audit of the 100 beneficiary sample resulted in a finding that a risk adjusted payment for 54 beneficiaries was paid in error with a total overpayment of \$213,166 out of a total of \$1,041,179 sampled. In this audit, only overpayments were considered errors and were not offset by underpayments. These results were then extrapolated over the entire population of 25,870 beneficiaries. The total dollar error was estimated to be \$55,146,067, or approximately over 20% of all dollars paid to Excellus, with 90% confidence limits of \$40,397,674 to \$69,894,461. (See V. Technical Notes, (1), page 20)

Below we have summarized our analysis to show that:

- The sample size of 100 is too small to obtain an extrapolation of error that fits into the norms of statistical inference.
- The sample results are not representative of the population from which they were drawn.

Calculations used in this report are summarized in V. Technical Notes below.

B. Evaluation of Sample Size Adequacy

When making an estimate about a numerical value associated with a population, such as the average payment error rate in the RADV audit, it is often impractical or impossible to measure every single member of the population. When this is the case, a sample is used to estimate the numerical value. Any sample that is smaller than the population will not be a perfect representation of the population, so there will be an error between the true numerical value for the population and the numerical value found in the sample. For this reason, a range around the numerical value found in the sample is used. This range is called a confidence interval. With a given confidence interval, there is a probability that the true numerical value falls within that range. This probability is called the level of confidence.

In order for a confidence interval to be usable or credible, a sample of sufficient size must be taken from the population. If the sample is sufficiently large, the sample will be representative of the population, and the difference between the numerical measurement associated with the population will not be very different from the numerical value associated with the sample with a high level of confidence. If the sample is not representative, extrapolating the sampled confidence interval would not be meaningful.

Typical levels of confidence are 90%, 95%, or 99%. A 99% level of confidence can be interpreted with the understanding that if the sampling is repeated 100 times and a confidence interval is created every time, 99 out of those 100 intervals will contain the true population parameter. We believe that given the payment retraction amount recommended in the Draft Report, the OIG should be aiming for a higher level of confidence such as 99%.

The size or width of the confidence interval depends on the variance of the underlying population and the level of confidence. A larger variance indicates more uncertainty and will increase the size of the confidence interval. Similarly, a higher level of confidence will also lead to a wider range. Everything else being equal, an interval that has 99% likelihood to contain the mean will be larger than an interval that is 90% likely to contain the mean.

In order to create a credible confidence interval, an adequate sample size is necessary. The sample size (n) for a simple random sample is usually based on the following formula

$$n_0 = \left[\frac{z \times s}{d} \right]^2$$

$$n = \frac{n_0 \times N}{n_0 + N - 1}$$

where,

n_0 = interim sample size

z = normal distribution value associated with the level of confidence that the actual mean will fall within the confidence interval (typically levels of 90%, 95%, 99% are used)

s = estimate of population standard deviation

d = desired precision (typically between $\pm 5\%$ or $\pm 10\%$ of the population mean). This represents the desired size or width of the resulting confidence interval.

n = final sample size

N = population size

These formulas are consistent with the sample size calculation that appears in the OIG's RAT-STATS Software (See Section 5 of Users Manual and V. Technical Notes, (2), page 21). In the case of the Excellus OIG audit, this formula was not applied, but rather a random sample of 100 (n) was used. If these formulas had been applied, a pilot or probe sample of 30 to 50 beneficiaries would probably have been used to estimate the population standard deviation. (This is what is typically done when the population standard deviation is unknown.) The RAT-STATS manual explains this in section 5-3.

However, the information included with the sample audit provides enough information that the standard deviation can be calculated using the formulas above. Given that the payment rates for 100 beneficiaries were sampled and the total value of the overpayment is \$213,166, the average overpayment per beneficiary is \$2,131.66. (See V. Technical Notes, (3), page 23.) Using the derived confidence interval, we can determine that the standard deviation used to calculate the sample is \$3,465.63 per beneficiary. (See V. Technical Notes, (4), page 23). To estimate the sample size necessary to be 90% confident the overpayment estimate was within $\pm 10\%$ of the population mean, the sample size would need to be 697 as shown below.

$$n_0 = \left[\frac{z \times s}{d} \right]^2 = \left[\frac{1.645 \times \$3,465.63}{\$213.17} \right]^2 = 716$$

$$n = \frac{n_0 \times N}{n_0 + N - 1} = \frac{716 \times 25,870}{716 + 25,870 - 1} = 697$$

This sample size would be at the low end of a sample size that may produce a meaningful extrapolation and is almost seven times larger than the audit sample size. A more rigorous estimate which is more frequently used in the statistical field would be to use 95% confidence within $\pm 5\%$ precision. The sample size necessary to produce this level of confidence and precision is 3,511 (See V. Technical Notes, (5), page 23), more than 35 times the size of the audit.

Another way to evaluate the adequacy of the sample size would be to look at the implied level of precision given the OIG audit's sample size of 100. From above, the sample size is based on the desired level of confidence, the estimated standard deviation and the desired level of precision, or size of the confidence interval. The table below shows the implied levels of precision given fixed levels of confidence and sample size of 100. The first line in the table can be interpreted as meaning we are 90% certain that the actual mean of the population has been measured to within $\pm 27\%$ by a sample of size 100. (Also see the illustration in V. Technical Notes, (9), page 24).

Level of Confidence Fixed at:	Resulting Implied Level of Precision:
90% (Level found in the OIG audit)	$\pm 27\%$ (See Technical Note (6))
95%	$\pm 32\%$ (See Technical Note (7))
99%	$\pm 42\%$ (See Technical Note (8))

Still another way to evaluate the sample size would be to fix the level of precision at an acceptable level and look at the implied level of confidence. The interpretation of the first line below is that we can be only 46% certain that the actual mean of the population has been measured to within $\pm 10\%$ by a sample of size 100.

Level of Precision Fixed at:	Resulting Implied Level of Confidence:
$\pm 10\%$	46% (See Technical Note (10))
$\pm 5\%$	24% (See Technical Note (11))

From this analysis, it can be concluded that the sample size is not adequate to measure the mean or confidence limits to provide any statistically meaningful results. Depending on the desired confidence level and level of precision, the sample is about 7 to 35 times smaller than

what is needed. To have a statistically acceptable level of confidence, the degree of precision is about three times or more (27% to 32%) outside of the norms of what are usually considered statistically acceptable results. To estimate the actual mean with any level of acceptable precision, there is no statistically acceptable degree of confidence, given a sample size of 100. A sample size of one hundred might be more appropriate for a compliance audit than for an audit with extrapolated results of this magnitude.

C. Evaluation of Sample Representativeness and Other Considerations

Excellus had a prior CMS RADV audit for payment year 2006 that is materially inconsistent with the current OIG audit. The CMS RADV audit revealed an error rate of 30.3% (33 beneficiaries out of 109). This error rate was calculated based on only overpayments, so the error rate is comparable to the OIG error rate determination. The OIG audit produced an error rate of 54 out of 100 beneficiaries, or 54%. The probability of drawing two representative samples from the same population with error rates of 33 out of 109 and 54 out of 100 is 0.000509. (See V. Technical Notes, (12), page 24) It is quite unlikely that this difference could have come from changes to policies and procedures within Excellus over a one year period. It is quite likely that the difference in error rates is caused by a sample that is not representative and the CMS and OIG processes for measuring errors are significantly different.

A report issued by the American Health Lawyers Association titled *Statistical Sampling in the Medicare Program: Challenging Its Use* states that the sample coefficient of variation ((standard deviation/mean) – 1) stated as a percentage should not exceed twelve percent. (Id., page 18) The coefficient of variation (also known as the estimated relative error) for this sample is 63% (See V. Technical Notes, (13), page 25) which implies that given the size of the sample, the variation within the sample is probably too large to allow the sample to be representative of the overall population. This is usually caused by unrepresentative large outliers that can appear in a small sample. This can lead to a bias that can make the estimate of the overpayment overstated, an unrepresentative sample and an invalid extrapolation.

This is further supported by information published by the Wisconsin Department of Health Services', Wisconsin Interactive Statistics on Health¹⁸. This states that for a confidence interval of 8% to 9% of the sampled mean or larger, the reliability of the estimate becomes suspect. In addition, the coefficient of variation should not exceed 30%. In Excellus' case, the

¹⁸ See www.dhs.wisconsin.gov/wish/main/BRFS/rse.htm

confidence limit is $\pm 27\%$ with 90% confidence and a coefficient of variation of 63%, which is much higher than 30%. Even with these more liberal standards, the OIG audit has produced results which bring into question the overall conclusions drawn in OIG's report.

D. Conclusion

Sampling is not a "one size fits all" process. Using standard statistical formulas and methodology for calculating audit sample size, it is clear that a sample size of 100 is not close to being adequate to measure a potential overpayment to Excellus. The sample size is anywhere from 7 to over 35 times too small to make conclusive extrapolations. If standard statistical confidence levels ($\geq 90\%$) are met, the desired precision is not. If the desired level of precision ($\leq \pm 10\%$) is met, the confidence levels are too low.

The coefficient of variation of 63% far exceeds the level of two sources (the American Health Lawyers Association and the Wisconsin Department of Health Services) for accepting a sample as being representative of the population from which it was selected.

If attestation errors and a few other differences are allowed to be corrected in the OIG audit, a significant drop in the lower bound of the confidence level (roughly 51% for a 99% confidence level) is obtained. These issues need to be explored further before any final conclusions are drawn.

The significant difference in the error rate between the CMS RADV audit error rate from 2006 and the OIG error rate from 2007 counted on a consistent basis (overpayments only) raises serious concerns about the representativeness of the sample and differences in how CMS RADV and OIG audits are performed. This is supported by the fact that the difference in the error rate between the two audits is highly significant ($p = 0.000509$). Another way of saying this is that the probability of drawing two representative samples that have means so far apart using the same methodology from the same population is 0.000509.

For these reasons, the results of this 100 sample audit should not be used for extrapolation of an error rate across the entire population. The sample size was too small to meet the acceptable levels of confidence and precision. The sample size was inconsistent with the OIG's own protocols, those applied by CMS in its RADV audits and the standards set by the statistical community. Further, the sample was unrepresentative of the population as demonstrated by the fact that Excellus underwent a CMS RADV audit for the same contract for the prior payment year with significantly different results. The sample size used together with

the confidence and precision levels applied do not lead to a reliable estimate of any alleged overpayment. The results should be corrected for the reasons outlined below and any overpayments should be limited to the specific records audited.

II. Methodology Issues

A. Need for A Fee-for-Service Error Rate Adjustment

The current Medicare Advantage risk-adjusted payment methodology was developed and calibrated based on Medicare Fee-For-Service (“FFS”) data, and more specifically claims data. At the time, CMS determined that the underlying medical record would be the ultimate source of diagnosis information. However, the model was calibrated using claims data, not medical records. As the RADV audits have demonstrated, there is a material gap in documentation between claims data and medical record data. The OIG’s RADV audit needs to adjust for this inconsistency. This adjustment is consistent with CMS’s frequently asserted position that an adjustment to the CMS-HCC model needs to be done to account for coding differences between MA plans and Original Medicare.

An alternative way of illustrating this inconsistency is to consider the average risk score of the entire Medicare FFS population. CMS calibrates the HCC risk model so that the average risk factor of the FFS population is 1.00, using only claims record data to determine the probability of having a certain HCC. If CMS had audited the FFS data that was used to normalize the risk-adjustment model to a risk score of 1.0, the average risk score of that population would drop significantly to reflect a similar disconnect between claims data and medical record data experienced in this audit. In short the payment model is calibrated to arrive at an average risk score of 1.0, but the average risk score under RADV audit methodologies will naturally fall significantly below 1.0. This means that a correction for the FFS error rate (not the published error rate, but a similar RADV type error rate) must be made, or plans undergoing RADV audits will be underpaid relative to what was intended and publicized at the time the bids were developed. In short, by basing HCC verification on a medical record standard rather than a claims data standard, the probabilities of having a certain HCC will be materially reduced and an adjustment must be made for this.

For example, at a recent industry conference, a speaker noted that providers often code an active cancer diagnosis rather than a history of cancer, for follow-up appointments. If this is

true, then cancer diagnoses are over represented in claims data, and the payment factor applied to cancer diagnoses is too low relative to the true incidence of cancer. For purposes of illustration, we provide a highly simplified example of this principle. Assume that based upon claims information only, the risk-adjusted payment calibration data showed 10,000 members with a diagnosis of active breast cancer, and the costs of their health care totaled approximately \$250,000,000; this would indicate an average cost of care of approximately \$25,000 per member diagnosed with an active breast cancer diagnosis. The calibration for breast cancer would then be a factor that arrived at an average payment of \$25,000 per member. However, if the medical record data for those members was examined and an error rate of 50 percent was found, then the adjustment factor really should have been such that the average payment was \$50,000, which would be more in line with the true cost of care.

If payments to health plans are based upon a model that is calibrated on claims data, but audits of those payments are based upon medical records rather than claims data, a disconnect arises. For every enrollee, who we thought had cancer based on claims data submitted by her provider, there are thousands of Medicare beneficiaries in the FFS data used to calibrate the model where the diagnosis in the claims data does not match the underlying medical record. In effect, the audit would reset payment levels to a level that is lower than originally intended, because of discrepancies between the provider's claims data and the medical record. CMS's model calibration assumed claims data to be accurate, but the results from the RADV audits illustrate that this is not the case. The audits will inherently set payment levels below what was assumed during payment model calibration.

Furthermore, for the month of November, Excellus averaged almost 8,500 medical claims per day for our Medicare Advantage members, of which a large percentage are claims RAPS eligible. The RADV audit standard implies that health plans would need to collect and review every single medical record that supports the RAPS eligible claims. This would create an undue and costly administrative burden on providers and the health plans. One must ask if diverting such significant dollars away from patient care and into administrative tasks is the best value for Medicare Advantage beneficiaries. We recognize that HHS has a fiduciary interest in ensuring accurate payments to health plans and in reducing fraud, waste and abuse; however it is not clear that holding health plans to a costly audit standard that is unrelated to the payment model calibration is the appropriate audit protocol.

Therefore, an adjustment should be made to account for the documentation shortfalls that were inherent in the calibration of the risk adjusted payment model. To do otherwise, would result in a significant underpayment to the Plan.

B. Missing Provider Signature and/or Credentials

Current CMS RADV audit practice allows for signature attestations (except for inpatient hospital records), on a CMS-provided, audit specific form. In the final rule revising the regulations that govern the Medicare Advantage program, published in the Federal Register on April 15, 2010 (the “Final Rule”), CMS states:

We noted that analysis of data originating from medical records submitted by MA organizations that have undergone RADV audit indicates that a substantial percentage of medical record-related payment error determinations are due to missing signatures or credentials on medical records . . . RADV audit procedures require that, in addition to finding diagnosis information that would support the HCCs submitted by the MA organization for risk adjustment purposes, physician signatures, and appropriate credentials must be present on medical records . . . the presence of a signature or credential attestation to accompany these medical records would in our opinion, provide justification for preventing both contract-level and national-level RADV payment errors that would otherwise originate from medical record signature, or credential-related discrepancies¹⁹

In its draft report, the OIG emphasized that in conducting its audits, it applied the 2007 Risk Adjustment Data Training for Medicare Advantage Organizations and that it reviewed federal laws, regulations and guidance regarding payment to MA organizations. However, unlike CMS, the OIG did not allow for signature attestations at the outset of the RADV audit two years ago, and the OIG’s draft report reflects this stance.

It must be noted that the OIG has recently changed its stance on the provider attestations; however, almost two additional years have passed since the audit started and the plan was asked to provide attestations with specific language included. This means that the plan may not be able to collect all the signature attestations that are required as providers have since moved, retired or

¹⁹ 72 Fed. Reg. 19678, 19742 – 43 (April 15, 2010).

passed away. To the extent that this is the case, Excellus requests that the OIG accept the original attestations provided.

C. Additional Codes and Underpayment Calculations

Amongst the best medical records submitted to the OIG, additional codes were identified in support of HCCs that could affect an audit member's risk score. Twelve additional medical diagnosis codes and relative HCCs were supported by documentation found within submitted best medical records of audit codes. The OIG refused to acknowledge, review, and accept for risk score calculation any of these additional codes identified by Excellus.

Further, Excellus identified, within medical records reviewed, 22 other additional codes, in support of HCCs that could affect an audit member's risk score. The OIG would not accept for risk score calculation any of these additional codes identified by Excellus. In the Final Rule, CMS indicated its willingness to accept additional diagnosis codes and relative HCCs found within the best medical record submitted for RADV audit purposes. CMS noted that accepting these codes would aid in fully representing a member's status and decreasing a member plan's overall payment error calculation.

Excellus requests that the OIG recognize the additional codes, located within a best medical record submitted to support audit HCCs, in calculating the patients' risk scores and the overall financial impact to the plan. The OIG's failure to allow these additional codes that are part of the best medical record denies Excellus its right under CMS procedures to have those codes considered. Accordingly, these codes should be included in the audit findings and used to recalculate the payment error.

Finally, although not part of CMS's current methodology, Excellus believes that the standard for documenting diagnoses should be expanded to allow for other credible sources. At a minimum, if OIG considers additional codes in the "best medical record", Excellus requests the ability to substitute the "best medical records" to support those additional codes.

D. Diagnosis Coding Issues

i. Definition of Diagnostic Radiology

In its 2006 and 2007 Risk Adjustment Data Training Manuals ("2006 Manual" and "2007 Manual"), CMS has outlined its data collection/submission and RADV audit procedures for the 2007 payment year. The 2006 and 2007 Manuals provide guidance on approved provider types

and services from which to collect and submit data for risk-adjustment, as well as appropriate sources of documentation to use as the best medical record for data validation. The 2006 Manual specified the CPT range²⁰ of diagnostic services, all being within the radiology services, from which data should not be collected and submitted for risk-adjustment. Further, both Manuals clearly outline CMS's reasons for objecting to the use of diagnostic radiology as the best medical record to validate HCCs. Extending the exclusion of diagnostic reports beyond the specified CPT ranges contradicts the instructions provided by CMS and unfairly penalizes the plan. In essence, the rules set by CMS specify the CPT ranges to be excluded. The OIG cannot broaden the exclusion list years later.

Based on the 2006 and 2007 Manuals, Excellus does not agree that the five HCCs listed below were not substantiated.

HCC Audit #	HCC	CPT code	Outside Omitted Range	Provider Type	Allowed Provider Type
H3351-001 HCC 10	HCC7	9921325	Y	Physician	Y
H3351-050 HCC83	HCC83	93000	Y	Hospital Outpatient	Y
H3351-049 HCC105	HCC105	93925, 93923	Y	Physician	Y
H3351-067 HCC105	HCC105	99213	Y	Physician	Y
H3351-009 HCC105	HCC105	93320, 93015, 93325, 39950	Y	Physician	Y

These five HCCs failed because they were contained within a diagnostic report that the OIG's reviewers specifically commented was an inappropriate documentation source. None of these diagnostic studies fell within the excluded diagnostic radiology code range specified by CMS. Further, all of the service providers were approved by CMS as appropriate sources of risk-adjustment data. Finally, unlike a diagnostic radiologist, providers of the referenced services are either the ordering provider or a member of that provider's practice. As such, the

²⁰ In relevant part, section 4-11 of the 2006 Manual states: "For those plans that use CPT codes to screen diagnosis codes submitted to CMS, please note that the CPT range for radiology is 7000 through 79999. The following CPT codes indicate diagnostic radiology and diagnoses on claims should not be submitted to CMS in risk-adjustment data: 70010 through 76999 and 78000 through 78999". The same quote can be found in section 4-11 of the 2007 Manual.

findings can also be considered final diagnosis. Excellus requests that these records be reconsidered.

ii. Coding Guideline Interpretation Differences

As mentioned previously, when Excellus initiated record recovery and review of medical records for data validation for the audit, it was instructed to utilize those rules set forth in the CMS training manual for RADV audits. Excellus utilized the coding guidelines published in the 2006 ICD-9 coding book, the 2006 Manual and the 2007 Manual when identifying records that best supported the indicated diagnoses.

The OIG validation contractors appear to have excluded three medical records substantiating the indicated diagnoses and relative HCCs, based on an incorrect application of CMS or ICD-9 coding guidelines. Excellus maintains that the date of service on one record was misread and, therefore, thought to be outside the year of service requested. A second was found to be supportive of a diabetic manifestation code, but deemed not to be supportive of the underlying diabetes, which is counterintuitive to the coding guidelines. The third was found to be unresponsive of angina while the member had a stated diagnosis of and was receiving treatment for angina. Excellus requests that these records be reviewed by another coder.

iii. No Documentation Provided

As mentioned in the Draft Report, five HCCs were found to be unsupported by the medical record. During the course of the OIG RADV, Excellus discovered that an error within its vendor's RAPS Management software that affected four HCCs. Within the logic used to create the Excellus RAPS files, there was a wrapping issue that incorrectly submitted diagnosis clusters under the wrong HICN. The four HCCs were triggered solely by the errant submission. Because the issue affected more than one contract and more than one payment year, Excellus felt that a global fix with CMS was needed and the issue was immediately addressed with CMS. An analysis was performed on all Excellus contracts, resulting in the deletion of over 600 diagnosis clusters with 2006 - 2009 dates of service. A RAPS deletion file was submitted and accepted. The payment retraction for those errors was recently completed in the August payment and the HCCs were removed from the members' history. Thus, the OIG audit should exclude those four HCCs as any risk-adjusted payments based on those were already reconciled with CMS.

With respect to the fifth HCC that the OIG classified as unsupported, Excellus agrees with this classification. The HCC originally resulted from human error in a chart review audit. As discussed in greater detail below, Excellus has significantly improved quality assurance

("QA") procedures to ensure that this type of error is minimized going forward. An outside vendor has been engaged and is conducting the vast majority of the Excellus chart audits. A key factor in the vendor selection was that the vendor has rigorous coder training and QA procedures to minimize the impacts of coder error.

E. Sample Enrollment Discrepancies

Member enrollment and payment discrepancies related to the 100 beneficiary sample must be corrected based on current MMR information. Beneficiary #042 was retroactively disenrolled as of the January 2010 MMR for all of payment year 2007. That member and the \$1,789.15 payment discrepancy attributed to him/her should be removed from the sample statistics. Additionally, beneficiary #089 was assumed to have been enrolled for the full calendar year of 2007. However, MMRs indicate that he/she was only enrolled the first eight months of the year. That would reduce the calculated overpayment for that beneficiary from \$2,225.58 to \$1,483.72. We request that the OIG adjust their calculations to reflect these two enrollment discrepancies in the sample.

F. Sample Frame Enrollment Discrepancies

The OIG started with a sample frame of 25,870 members who met the criteria of having been continuously enrolled with Excellus for the 13 month period from January 2006 through January 2007 and the members must have at least one HCC for payment year 2007. The sample frame is the universe from which the member sample was selected as well as the membership against which the extrapolation was calculated. The OIG provided Excellus with the sample frame membership so that we might be able to verify the accuracy of that membership. As the sample frame membership is a key component of the extrapolation calculation, it is critical that the membership count is accurate. We have found that a little over 1,200 members included in the sample frame do not meet the criteria based on current data. These members either do not have an HCC or they did not meet the enrollment criteria. Therefore, they should be excluded from any extrapolation calculation.

G. Inclusion of ESRD Members

The OIG selected two members with ESRD in their sample. The proportion of members with ESRD in the sample was six times the incidence in our member population. It is our understanding that CMS excludes members with ESRD from their RADV audits, in part because

a single unsubstantiated HCC for a member with ESRD can lead to a disproportionately large payment error, thus potentially skewing results. Excellus requests that the members with ESRD be removed from the sample in order to ensure more consistency between audit protocols at HHS.

III. Process Improvement

Excellus is continually striving to improve its processes. Recent initiatives to improve coding accuracy are discussed below.

Excellus has significantly expanded the number of provider charts reviewed. Increased quality assurance processes around those chart reviews including: checks and balances to assure that more than one coder is in agreement that the codes are clearly documented in the medical record. Excellus performed blind reviews in order not to bias the coder with information about previously submitted codes by providers.

Excellus has selected a new vendor for reporting information to CMS. In 2009, the Plan completed a Request for Information (“RFI”) process to evaluate vendors’ capabilities in the area of HCC management and reporting. A goal of this vendor change has been to implement additional quality controls around the claims data feeds that form the basis of the Excellus’s RAPS submissions to CMS.

The new RAPS vendor’s application provides capabilities for provider reporting around coding and documentation accuracy as seen through the chart review process. This reporting will allow Excellus to do more specific outreach to provider offices based on each provider or provider group’s data. We have started the implementation of this application and anticipate that it will be in operation in 2011.

Excellus has approved the addition of 2 full-time employees to provide auditing and quality oversight to the coding staff as well as to perform provider outreach. The provider outreach is intended to educate providers on proper coding and maintenance of medical record documentation standards. In addition, in an effort to improve communication surrounding coding and documentation practices and frequently observed coding discrepancies, Excellus has increased the number of provider newsletter articles.

Excellus has expanded its Care Management Program. Excellus has implemented a frail elderly program and a home evaluation program to better identify those members with a significant burden of illness that require in-home care management interventions and

coordination of care. These activities conducted by a qualified practitioner will allow the health plan to accurately document diagnosis submitted to CMS.

IV. Due Process/Opportunity to Be Heard

The OIG should provide Excellus with an administrative appeal process more extensive than the right to submit a response to the OIG's findings. Excellus believes that, at a minimum, the same rights and appeals mechanisms that CMS gives to MA organizations that undergo CMS RADV audits should be available in connection with an OIG audit; Excellus is assuming that, should it opt to appeal the OIG's findings, in whole or in part, the appeal would be handled through CMS.

Under the CMS process, audited plans have a right to appeal the medical record review results. An independent validation contractor reviews the results of the Initial Validation Contractor ("IVC"). Under the CMS process, audited plans also have access to the document dispute process, so that they can ensure that CMS and its contractors correctly collect all documents submitted by the plans. In addition, and as mentioned above, under the CMS process, an audited plan may submit signature and credentialing attestations.

In the October 22, 2009 Notice of Proposed Rulemaking ("NPRM") and reiterated in its April 15, 2010, final rule, CMS asserts that the "methodology that [CMS] employ[s] to calculate RADV payment errors is methodologically sound and academically defensible." In contrast, as discussed in detail, the methodology employed by the OIG is not methodologically and academically defensible, yet there does not appear to be an administrative appeal mechanism to challenge the methodology used by the OIG, which differs significantly from that used by CMS. Fundamental fairness dictates that access be provided an appeals mechanism designed to ensure that the methodology of RADV audits conducted on behalf of CMS would be at least as accurate and fair as the audits conducted by CMS, itself.

As a matter of fairness, Excellus should not be held to inconsistent audit standards by two agencies within the Department of Health and Human Services. OIG used a sample size of 100, about half of that used by CMS. CMS uses a stratified sample. The OIG did not. CMS has an appeals process for its RADV audits which provides a safeguard against erroneous audit results. Those same standard and rights provided by CMS should be applied in this matter.

CONCLUSION

Excellus does not concur with the OIG's findings regarding overpayments. As demonstrated above: 1) the sample size of 100 is too small to obtain an extrapolation of error that

fits into the norms of statistical inference, 2) the sample results are not representative of the population from which they were drawn, and 3) there is an inherent documentation error rate in the calibration of the payment model itself. For these reasons, no extrapolation should be made from the audit findings. Further, there are a number of discrepancies in the sample frame used, the sample drawn and certain coding determinations. Also, Excellus should be afforded the same rights for: 1) submission of provider signature and credential attestations, 2) consideration of additional diagnosis codes and 3) record review by another coder, all of which are provided by CMS under its RADV Audit procedures. For these reasons, the audit findings should be corrected to determine an accurate overpayment amount based on only those records audited.

V. Technical Notes

For formulae below, the following definitions apply:

\bar{x} = point estimate of extrapolated sample (mean)

x_U = upper end of 90% confidence limit for extrapolated sample

n_0 = interim sample size

z = normal distribution value associated with the level of confidence that the actual mean will fall within the confidence interval (typically levels of 90%, 95%, 99% are used)

s = estimate of population standard deviation

d = desired precision of the sample (typically between $\pm 5\%$ or $\pm 10\%$ of the population mean)

n = final sample size

N = population size

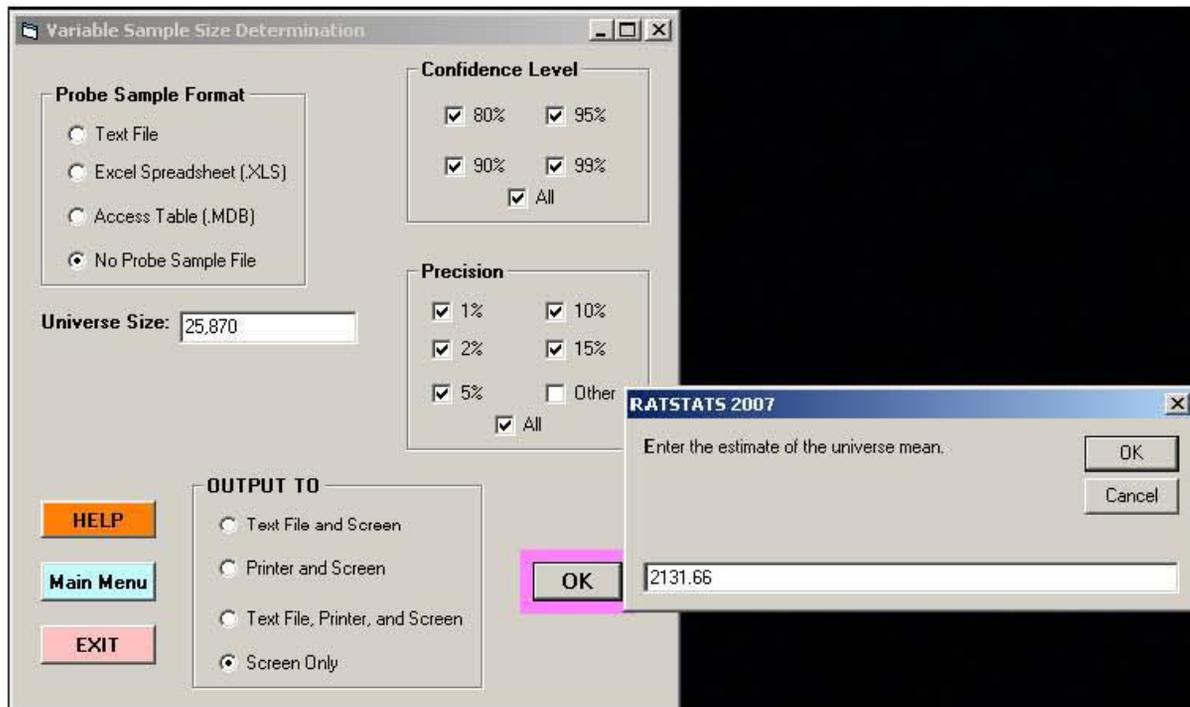
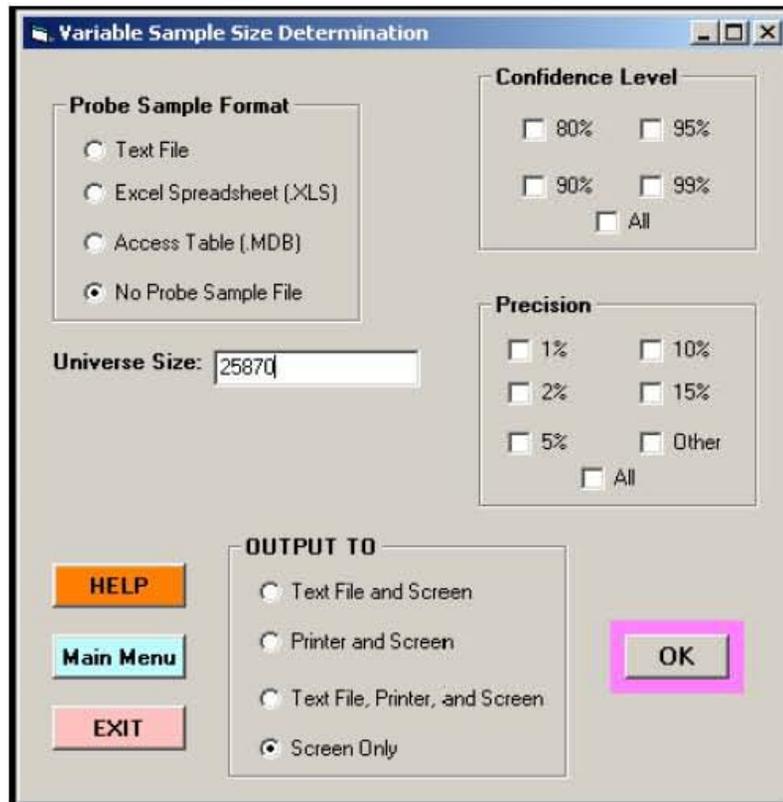
- (1) Alternative confidence ranges for 95% and 99% confidence are calculated using the following formula:

$$\bar{x} \pm z \frac{s}{\sqrt{n}}$$

for 95% confidence, the range is \$37,573,521 - \$72,718,613

for 99% confidence, the range is \$32,014,865 - \$78,277,278

(2) Sample Size calculation from RAT-STATS Software:



Variable Sample Size Determination

Probe Sample Format

- Text File
- Excel Spreadsheet (.XLS)
- Access Table (.MDB)
- No Probe Sample File

Confidence Level

- 80% 95%
- 90% 99%
- All

Precision

- 1% 10%
- 2% 15%
- 5% Other
- All

Universe Size:

OUTPUT TO

- Text File and Screen
- Printer and Screen
- Text File, Printer, and Screen
- Screen Only

HELP **Main Menu** **EXIT**

RATSTATS 2007

Enter the estimate of the universe standard deviation.
NOTE: This value must be positive.

OK **Cancel**

Variable Sample Size Output

Confidence Level

	80%	90%	95%	99%
1%	16210	18998	20617	22544
2%	7645	10572	12812	16270
5%	1627	2576	3510	5519
10%	427	696	977	1642
15%	192	314	444	757

Sample Precision

Universe Size

Parameter Estimates

Mean

Std. Deviation

HELP **EXIT** **Previous Screen** **Main Menu**

(3) Total Sample Dollars in Error ÷ n

$$\$213,166 \div 100 = \$2,131.66$$

(4) Standard Deviation

$$s = \frac{(\alpha_U - \bar{x}) \times \sqrt{n}}{z \times N}$$

$$s = \frac{(69,894,461 - 55,146,067) \times \sqrt{100}}{1.645 \times 25,870} = \$3,465.63$$

(5) Sample Size Calculation

$$n_0 = \left[\frac{z \times s}{d} \right]^2 = \left[\frac{1.96 \times \$3465.63}{\$106.58} \right]^2 = 4,062$$

$$n = \frac{n_0 \times N}{n_0 + N - 1} = \frac{4,062 \times 25,870}{4,062 + 25,870 - 1} = 3,511$$

(6) Level of Precision with 90% Level of Confidence and Sample Size of 100

$$d = \frac{z \times s}{\sqrt{n}} = \frac{1.645 \times \$3,465.63}{\sqrt{100}} = \$570.10$$

$$\$570.10 \div \$2,131.66 = \pm 27\%$$

(7) Level of Precision with 95% Level of Confidence and Sample Size of 100

$$d = \frac{z \times s}{\sqrt{n}} = \frac{1.96 \times \$3465.63}{\sqrt{100}} = \$679.26$$

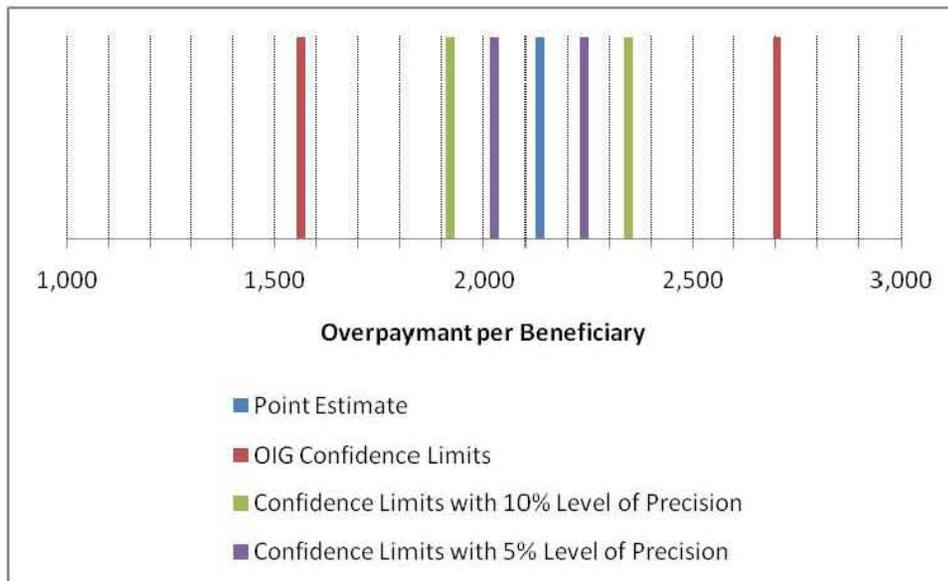
$$\$679.26 \div \$2,131.66 = \pm 32\%$$

(8) Level of Precision with 99% Level of Confidence and Sample Size of 100

$$d = \frac{z \times s}{\sqrt{n}} = \frac{2.576 \times \$3465.63}{\sqrt{100}} = \$892.69$$

$$\$892.69 \div \$2,131.66 = \pm 42\%$$

(9) Illustration of levels of precision.



(10) Level of Confidence with 10% Level of Precision and Sample Size of 100

$$z = \frac{d \times \sqrt{n}}{s} = \frac{\$213.17 \times \sqrt{100}}{\$3,465.63} = .62$$

$$z = .62 \rightarrow 46\% \text{ Confidence}$$

(11) Level of Confidence with 5% Level of Precision and Sample Size of 100

$$z = \frac{d \times \sqrt{n}}{s} = \frac{\$106.58 \times \sqrt{100}}{\$3,465.63} = .31$$

$$z = .31 \rightarrow 24\% \text{ Confidence}$$

(12) Based on the Binomial Distribution hypothesis test:

$$H_0: \pi_1 = \pi_2$$

$$H_1: \pi_1 \neq \pi_2$$

$$p_1 = \frac{54}{100}, \quad p_2 = \frac{33}{109}, \quad p_c = \frac{54 + 33}{100 + 109} = \frac{87}{209}$$

p_1 and p_2 from OIG audit, CMS audit, respectively. p_c represents the average proportion among both samples.

$$z = \frac{p_1 - p_2}{\sqrt{\frac{p_c(1-p_c)}{n_1} + \frac{p_c(1-p_c)}{n_2}}} = \frac{\frac{54}{100} - \frac{33}{109}}{\sqrt{\frac{87}{209} \left(\frac{122}{209}\right) + \frac{87}{209} \left(\frac{122}{209}\right)}} = 3.4758$$

$$p\text{-value} = 0.000509$$

(13)

$$\text{Coefficient of Variation} = \left(\frac{\text{Sample Standard Deviation}}{\text{Sample Mean}} \right) - 1 = \left(\frac{\$3,465.63}{\$2,131.66} \right) - 1 = 63\%$$