

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE COMPLIANCE REVIEW
OF PRINCETON BAPTIST
MEDICAL CENTER FOR
CALENDAR YEARS 2010 AND 2011**

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April 2014
A-04-12-00084

Office of Inspector General

<https://oig.hhs.gov>

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EXECUTIVE SUMMARY

Princeton Baptist Medical Center did not fully comply with Medicare requirements for billing inpatient and outpatient services, resulting in estimated overpayments of approximately \$472,000 over 2 years.

WHY WE DID THIS REVIEW

This review is part of a series of hospital compliance reviews. Using computer matching, data mining, and other data analysis techniques, we identified hospital claims that were at risk for noncompliance with Medicare billing requirements. For calendar year (CY) 2011, Medicare paid hospitals \$151 billion, which represents 45 percent of all fee-for-service payments; therefore, the Office of Inspector General must provide continual and adequate oversight of Medicare payments to hospitals.

The objective of our review was to determine whether Princeton Baptist Medical Center (Princeton) complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) pays inpatient hospital costs at predetermined rates for patient discharges. The rates vary according to the diagnosis-related group (DRG) to which a beneficiary's stay is assigned and the severity level of the patient's diagnosis. The DRG payment is, with certain exceptions, intended to be payment in full to the hospital for all inpatient costs associated with the beneficiary's stay. CMS pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification.

Princeton is a 499-bed acute care facility located in Birmingham, Alabama. Medicare paid Princeton approximately \$124 million for 12,757 inpatient and 39,584 outpatient claims for services provided to beneficiaries during CYs 2010 and 2011 based on CMS's National Claims History data.

Our audit covered \$9,384,096 in Medicare payments to Princeton for 1,191 claims that were potentially at risk for billing errors. We selected a stratified random sample of 139 claims with payments totaling \$1,399,833 for review. These 139 claims had dates of service in CYs 2010 or 2011 and consisted of 127 inpatient claims and 12 outpatient claims.

WHAT WE FOUND

Princeton complied with Medicare billing requirements for 117 of the 139 inpatient and outpatient claims we reviewed. However, Princeton did not fully comply with Medicare billing requirements for the remaining 22 claims, resulting in overpayments of \$114,019 for CYs 2010 and 2011 (audit period). Specifically, 20 inpatient claims had billing errors, resulting in overpayments of \$112,319, and 2 outpatient claims had billing errors, resulting in overpayments

of \$1,700. These errors occurred primarily because Princeton did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

On the basis of our sample results, we estimated that Princeton received overpayments of at least \$471,654 for the audit period.

WHAT WE RECOMMEND

We recommend that Princeton:

- refund to the Medicare program \$471,654 in estimated overpayments for claims that it incorrectly billed for the audit period and
- strengthen controls to ensure full compliance with Medicare requirements.

PRINCETON BAPTIST MEDICAL CENTER COMMENTS

In written comments on our draft report, Princeton disagreed with our recommendations. It requested that we amend our first recommendation to remove extrapolation completely and to decrease \$471,654 in estimated overpayments to \$45,144 in estimated overpayments net of estimated Part B offsets. In regard to our second recommendation, Princeton asserted that it was substantially in compliance with Medicare billing guidelines.

Princeton objected to our use of nonphysician CMS Medicare Administrative Contractor (MAC) medical review staff and to our inability to reduce overpayments by potential Part B reimbursements. Furthermore, Princeton specifically disputed findings related to nine claims incorrectly billed as inpatient and two claims having incorrectly billed DRG codes. It commented that its independent, third-party physicians and certified coders reviewed and agreed with the original coding on these claims. Princeton also stated that we did not report specific actionable items, that we did not identify clear criteria used, and that we had no basis, other than a difference of opinion, for denial of the disputed claims.

Additionally, Princeton objected to our use of extrapolation of the sample results to the sampling frame and consequent recommendation of a \$471,654 refund in estimated overpayments for CYs 2010 and 2011 as unjust and fundamentally unfair. Princeton also stated that it did not “have enough information to agree or disagree with our assertion that extrapolation is statistically valid” and that “extrapolation potentially violates [its] due process rights because extrapolation ... precludes [its] rights to appeal denied claims.”

OUR RESPONSE

We stand by the MAC medical review staff’s determinations and the auditors’ professional judgments that Princeton did not fully comply with Medicare billing requirements for 22 claims. As stated in the report, we were unable to determine the effect that billing Medicare Part B would have on the overpayment amount because Princeton had not billed and the MAC had not

adjudicated these services prior to the issuance of our report. We also maintain that the claims that we identified as errors did not comply with the criteria cited and did not merely represent a difference of opinion. Rather, they represented specific actionable items that warranted our recommendations.

As the hospital compliance review initiative has matured, we have refined our audit methodologies. Some reviews use statistical sampling and estimation techniques to draw conclusions about a larger portion of a hospital's claims while other reviews use judgmental sampling. Each hospital review is unique, and the sampling method used in each of these reviews will vary. For this reason, we review different risk areas at different hospitals and use both statistical and nonstatistical methods for selecting our samples.

In response to Princeton's objections to our statistical sampling and estimation, Federal courts have established the use of statistical sampling and estimation as a viable audit technique. Questioning whether the sample could have been more precise or optimal does not indicate that our methodology was invalid. We properly executed our statistical sampling methodology in that we have defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and applied the correct formulas for the estimation.

With respect to sample size, we point to the Medicare Program Integrity Manual, which indicates that it is neither possible nor desirable to specify a minimum sample size that applies to all situations. A challenge to the validity of the sample that is sometimes made is that the particular sample size is too small to yield meaningful results. Such a challenge is without merit as it fails to take into account all of the other factors that are involved in the sample design. As sample sizes decrease so does the estimated overpayment amount at the lower limit of the confidence interval; thus giving the benefit of a smaller sample to the Medicare provider.

During the course of our audit, we discussed with Princeton officials our plans to use statistical sampling, and we recently provided them with our sampling plan, sampling frame, sample, random numbers, seed number, input to RAT-STATS for appraisal, and output from RAT-STATS.

Furthermore, our use of statistical sampling by no means removes Princeton's right to appeal the individual determinations on which the estimation is based through the normal appeals process.

Therefore, we continue to recommend that Princeton refund to the Medicare program \$471,654 in estimated overpayments for CYs 2010 and 2011 and that it strengthen controls to ensure full compliance with Medicare requirements.

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INTRODUCTION

WHY WE DID THIS REVIEW

This review is part of a series of hospital compliance reviews. Using computer matching, data mining, and other data analysis techniques, we identified hospital claims that were at risk for noncompliance with Medicare billing requirements. For calendar year (CY) 2011, Medicare paid hospitals \$151 billion, which represents 45 percent of all fee-for-service payments; therefore, the Office of Inspector General (OIG) must provide continual and adequate oversight of Medicare payments to hospitals.

OBJECTIVE

Our objective was to determine whether Princeton Baptist Medical Center (Princeton) complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims.

BACKGROUND

The Medicare Program

Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge, and Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

CMS contracts with Medicare contractors to, among other things, process and pay claims submitted by hospitals.

Hospital Inpatient Prospective Payment System

CMS pays hospital costs at predetermined rates for patient discharges under the inpatient prospective payment system (IPPS). The rates vary according to the diagnosis-related group (DRG) to which a beneficiary's stay is assigned and the severity level of the patient's diagnosis. The DRG payment is, with certain exceptions, intended to be payment in full to the hospital for all inpatient costs associated with the beneficiary's stay.

Hospital Outpatient Prospective Payment System

CMS implemented an outpatient prospective payment system (OPPS), which is effective for services furnished on or after August 1, 2000, for hospital outpatient services. Under the OPPS, Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification (APC). CMS uses Healthcare Common Procedure Coding System (HCPCS) codes and descriptors to identify and group the services

within each APC group.¹ All services and items within an APC group are comparable clinically and require comparable resources.

Hospital Claims at Risk for Incorrect Billing

Our previous work at other hospitals identified these types of claims at risk for noncompliance:

- inpatient short stays,
- inpatient and outpatient manufacturer credits for replaced medical devices, and
- inpatient claims billed with high-severity-level DRG codes.

For the purposes of this report, we refer to these areas at risk for incorrect billing as “risk areas.” We reviewed these risk areas as part of this review.

Medicare Requirements for Hospital Claims and Payments

Medicare payments may not be made for items and services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Social Security Act (the Act), § 1862(a)(1)(A)). In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§ 1833(e)).

Federal regulations state that the provider must furnish to the Medicare contractor sufficient information to determine whether payment is due and the amount of the payment (42 CFR § 424.5(a)(6)).

The *Medicare Claims Processing Manual* (the Manual) requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly (Pub. No. 100-04, chapter 1, § 80.3.2.2). In addition, the Manual states that providers must use HCPCS codes for most outpatient services (chapter 23, § 20.3).

Princeton Baptist Medical Center

Princeton 499-bed acute care facility located in Birmingham, Alabama. According to CMS’s National Claims History files, Princeton approximately \$124 million for 12,757 inpatient and 39,584 outpatient claims for services provided to beneficiaries during CYs 2010 and 2011.

¹ HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

HOW WE CONDUCTED THIS REVIEW

Our audit covered \$9,384,096 in Medicare payments to Princeton for 1,191 claims that were potentially at risk for billing errors. We selected a stratified random sample of 139 claims with payments totaling \$1,399,833 for review. These 139 claims had dates of service in CYs 2010 or 2011 and consisted of 127 inpatient claims and 12 outpatient claims. We focused our review on the risk areas that we identified as a result of prior OIG reviews at other hospitals. We evaluated compliance with selected billing requirements and subjected 11 claims to medical review to determine whether the services were medically necessary. This report focuses on selected risk areas and does not represent an overall assessment of all claims submitted by Princeton for Medicare reimbursement.

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

See Appendix A for the details on our scope and methodology.

FINDINGS

Princeton complied with Medicare billing requirements for 117 of the 139 inpatient and outpatient claims we reviewed. However, Princeton did not fully comply with Medicare billing requirements for the remaining 22 claims, resulting in overpayments of \$114,019 for CYs 2010 and 2011 (audit period). Specifically, 20 inpatient claims had billing errors, resulting in overpayments of \$112,319, and 2 outpatient claims had billing errors, resulting in overpayments of \$1,700. These errors occurred primarily because Princeton did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

Based on our sample results, we estimated that Princeton received overpayments of at least \$471,654 for the audit period. See Appendix B for details on our sample design and methodology, Appendix C for details on our sample results and estimates, and Appendix D for the results of our review by risk area.

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

Princeton incorrectly billed Medicare for 20 of 127 sampled inpatient claims, which resulted in overpayments of \$112,319.

Incorrectly Billed as Inpatient

Medicare payments may not be made for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Act, § 1862(a)(1)(A)).

For 11 of the 127 sampled claims, Princeton incorrectly billed Medicare Part A for beneficiary stays that it should have billed as outpatient or outpatient with observation services. Princeton officials stated that the hospital followed a clinical evaluation process, following Medicare guidance and physician documentation when determining patient status. As a result of these errors, Princeton received overpayments of \$71,613.²

Incorrectly Billed Diagnosis-Related Group Codes

Medicare payments may not be made for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Act, § 1862(a)(1)(A)). In addition, the Manual states: “In order to be processed correctly and promptly, a bill must be completed accurately” (chapter 1, § 80.3.2.2).

For 7 of the 127 sampled claims, Princeton billed Medicare for incorrect DRG codes. For example, Princeton coded hypertensive heart and chronic kidney disease as the principle diagnosis for one sample item; however, Princeton staff members were unable to locate supporting documentation for chronic kidney disease. As a result, the principle diagnosis changed, which caused the DRG code to change as well. Princeton officials indicated that these errors occurred because of the technical requirements of coding and the interpretations of complicated medical records. As a result of these errors, Princeton received overpayments of \$32,332.

Manufacturer Credit for a Replaced Medical Device Not Obtained

Federal regulations require reductions in the IPPS payments for the replacement of an implanted device if (1) the device is replaced without cost to the provider, (2) the provider receives full credit for the device cost, or (3) the provider receives a credit equal to 50 percent or more of the device cost (42 CFR § 412.89). The Manual states that to bill correctly for a replacement device that was provided with a credit, hospitals must code Medicare claims with a combination of condition code 49 or 50, along with value code “FD” (chapter 3, § 100.8). In addition, Federal regulations state, “All payments to providers of services must be based on the reasonable cost of

² Princeton may be able to bill Medicare Part B for all services (except for services that specifically require an outpatient status) that would have been reasonable and necessary had the beneficiary been treated as a hospital outpatient rather than admitted as an inpatient. We were unable to determine the effect that billing Medicare Part B would have on the overpayment amount because these services had not been billed and adjudicated by the Medicare administrative contractor prior to the issuance of our report.

services...” (42 CFR § 413.9). The CMS *Provider Reimbursement Manual* (PRM) reinforces these requirements in additional detail (Pub. No. 15-1).³

For 1 of the 127 sampled claims, Princeton did not obtain a credit for a replaced medical device for which a credit was available under the terms of the manufacturer’s warranty. Princeton officials stated that the error occurred because of an oversight. Both the device and lead were removed; the device was an upgrade and not eligible for a credit. Only the lead was potentially eligible for a credit. However, Princeton staff did not return the lead to the manufacturer and request the credit. As a result of this error, Princeton received an overpayment of \$5,203.

Incorrectly Billed as a Separate Inpatient Stay

The Manual, chapter 3, section 40.2.5, states:

When a patient is discharged/transferred from an acute care Prospective Payment System (PPS) hospital, and is readmitted to the same acute care PPS hospital on the same day for symptoms related to, or for evaluation and management of, the prior stay’s medical condition, hospitals shall adjust the original claim generated by the original stay by combining the original and subsequent stay onto a single claim.

For 1 of the 127 sampled claims, Princeton billed Medicare separately for a related discharge and readmission within the same day. Princeton officials stated that the error occurred because of human error in reviewing the billing information. As a result of this error, Princeton received an overpayment of \$3,171.

BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS

Princeton incorrectly billed Medicare for 2 of 12 sampled outpatient claims, which resulted in overpayments of \$1,700.

Incorrectly Billed Healthcare Common Procedure Coding System Codes

The Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§ 1833(e)). The Manual states: “In order to be processed correctly and promptly, a bill must be completed accurately” (chapter 1, § 80.3.2.2).

³ The PRM states: “Implicit in the intention that actual costs be paid to the extent they are reasonable is the expectation that the provider seeks to minimize its costs and that its actual costs do not exceed what a prudent and cost conscious buyer pays for a given item or service” (part I, § 2102.1). Section 2103 further defines prudent buyer principles and states that Medicare providers are expected to pursue free replacements or reduced charges under warranties. Section 2103(C)(4) provides the following example: “Provider B purchases cardiac pacemakers or their components for use in replacing malfunctioning or obsolete equipment, without asking the supplier/manufacturer for full or partial credits available under the terms of the warranty covering the replaced equipment. The credits or payments that could have been obtained must be reflected as a reduction of the cost of the equipment.”

For 2 of the 12 sampled claims, Princeton submitted the claims to Medicare with incorrect HCPCS codes. Princeton officials attributed the duplicate codes to human error. As a result of these errors, Princeton received overpayments of \$1,700.

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that Princeton received overpayments of at least \$471,654 for the audit period.

RECOMMENDATIONS

We recommend that Princeton:

- refund to the Medicare program \$471,654 in estimated overpayments for claims that it incorrectly billed for the audit period and
- strengthen controls to ensure full compliance with Medicare requirements.

PRINCETON BAPTIST MEDICAL CENTER COMMENTS

In written comments on our draft report, Princeton disagreed with our recommendations. It requested that we amend our first recommendation to remove extrapolation completely and to decrease \$471,654 in estimated overpayments to \$45,144 in estimated overpayments net of estimated Part B offsets. In regard to our second recommendation, Princeton asserted that it was substantially in compliance with Medicare billing guidelines.

Princeton objected to our use of nonphysician CMS Medicare Administrative Contractor (MAC) medical review staff and to our inability to reduce overpayments by potential Part B reimbursements. Furthermore, Princeton specifically disputed findings related to nine claims incorrectly billed as inpatient and two claims having incorrectly billed DRG codes. It commented that its independent, third-party physicians and certified coders reviewed and agreed with the original coding on these claims. Princeton also stated that we did not report specific actionable items, that we did not identify clear criteria used, and that we had no basis, other than a difference of opinion, for denial of the disputed claims.

Additionally, Princeton objected to our use of extrapolation of the sample results to the sampling frame and consequent recommendation of a \$471,654 refund in estimated overpayments for CYs 2010 and 2011 as unjust and fundamentally unfair. Princeton also stated that it did not “have enough information to agree or disagree with our assertion that extrapolation is statistically valid” and that “extrapolation potentially violates [its] due process rights because extrapolation ... precludes [its] rights to appeal denied claims.” With the exception of medical record information, which we redacted, Princeton’s comments are included in their entirety as Appendix E.

OFFICE OF INSPECTOR GENERAL RESPONSE

We stand by the MAC medical review staff's determinations and the auditors' professional judgments that Princeton did not fully comply with Medicare billing requirements for 22 claims. As stated in the report, we were unable to determine the effect that billing Medicare Part B would have on the overpayment amount because Princeton had not billed and the MAC had not adjudicated these services prior to the issuance of our report. We also maintain that the claims that we identified as errors did not comply with the criteria cited and did not merely represent a difference of opinion. Rather, they represented specific actionable items that warranted our recommendations.

As the hospital compliance review initiative has matured, we have refined our audit methodologies. Some reviews use statistical sampling and estimation techniques to draw conclusions about a larger portion of a hospital's claims while other reviews use judgmental sampling. Each hospital review is unique, and the sampling method used in each of these reviews will vary. For this reason, we review different risk areas at different hospitals and use both statistical and nonstatistical methods for selecting our samples.

In response to Princeton's objections to our statistical sampling and estimation, Federal courts have established the use of statistical sampling and estimation as a viable audit technique.⁴ Questioning whether the sample could have been more precise or optimal does not indicate that our methodology was invalid.⁵ We properly executed our statistical sampling methodology in that we have defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and applied the correct formulas for the estimation.

With respect to sample size, we point to the Medicare Program Integrity Manual, which indicates that it is neither possible nor desirable to specify a minimum sample size that applies to all situations. A challenge to the validity of the sample that is sometimes made is that the particular sample size is too small to yield meaningful results. Such a challenge is without merit as it fails to take into account all of the other factors that are involved in the sample design. As sample sizes decrease so does the estimated overpayment amount at the lower limit of the confidence interval, thus giving the benefit of a smaller sample to the Medicare provider.⁶

During the course of our audit, we discussed with Princeton officials our plans to use statistical sampling, and we recently provided them with our sampling plan, sampling frame, sample, random numbers, seed number, input to RAT-STATS for appraisal, and output from RAT-STATS.

⁴ Chaves County Home Health Service, Inc. v. Sullivan, 931 F.2d 914 (D.C. Cir. 1991).

⁵ Miniet v Sebelius, No. 10-24127-CIV (S.D. Fla. 2012).

⁶ Schuldt Chiropractic Wellness Center v Sebelius, No. 8:13CV4 (D. Neb. 2014).

Furthermore, our use of statistical sampling by no means removes Princeton's right to appeal the individual determinations on which the estimation is based through the normal appeals process.⁷ Therefore, we continue to recommend that Princeton refund to the Medicare program \$471,654 in estimated overpayments for CYs 2010 and 2011 and that it strengthen controls to ensure full compliance with Medicare requirements.

⁷ Pruchniewski v. Leavitt, No. 08:04-CV-2200-T-23TBM (M.D. Fla 2006).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$9,384,096 in Medicare payments to Princeton for 1,191 claims that were potentially at risk for billing errors. We selected a stratified random sample of 139 claims with payments totaling \$1,399,833 for review. These 139 claims had dates of service in CYs 2010 or 2011 and consisted of 127 inpatient claims and 12 outpatient claims.

We focused our review on the risk areas that we identified as a result of prior OIG reviews at other hospitals. We evaluated compliance with selected billing requirements and subjected 11 claims to medical review to determine whether the services were medically necessary.

We limited our review of Princeton's internal controls to those applicable to the inpatient and outpatient areas of review because our objective did not require an understanding of all internal controls over the submission and processing of claims. We established reasonable assurance of the authenticity and accuracy of the data obtained from the National Claims History file, but we did not assess the completeness of the file.

This report focuses on selected risk areas and does not represent an overall assessment of all claims submitted by Princeton for Medicare reimbursement.

We conducted our fieldwork in Birmingham, Alabama, from November 2012 through May 2013.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted Princeton's inpatient and outpatient paid claim data from CMS's National Claims History file for CYs 2010 and 2011 (audit period);
- obtained information on known credits for replaced cardiac medical devices from the device manufacturers for the audit period;
- used computer matching, data mining, and analysis techniques to identify claims potentially at risk for noncompliance with selected Medicare billing requirements;
- selected a stratified random sample of 139 claims (127 inpatient and 12 outpatient) for detailed review;
- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been cancelled or adjusted;

- reviewed the itemized bills and medical record documentation provided by Princeton to support the sampled claims;
- requested that Princeton conduct its own review of the sampled claims to determine whether the services were billed correctly;
- reviewed Princeton's procedures for submitting Medicare claims;
- used CMS's Medicare contractor medical review staff to determine whether 11 sampled claims met medical necessity requirements;
- discussed the incorrectly billed claims with Princeton personnel to determine the underlying causes of noncompliance with Medicare requirements;
- calculated the correct payments for those claims requiring adjustments;
- used the results of the sample review to calculate the estimated Medicare overpayments to Princeton (Appendix C); and
- discussed the results of our review with Princeton officials.

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

APPENDIX B: SAMPLE DESIGN AND METHODOLOGY

POPULATION

The population was inpatient and outpatient claims paid to Princeton for services provided to Medicare beneficiaries during the audit period.

SAMPLING FRAME

\$124,159,879 for 12,757 inpatient and 39,584 outpatient claims for services provided to beneficiaries during the audit period.

We obtained a database of claims for the audit period from the NCH data totaling \$63,248,571 for 4,893 inpatient and 28,804 outpatient claims in 30 risk areas.

From this initial sampling frame, we selected claims from three risk areas consisting of 3,899 claims totaling \$38,930,609 for further refinement. The risk areas were:

1. Inpatient Short Stays,
2. Inpatient and Outpatient Manufacturer Credits for Replaced Medical Devices, and
3. Inpatient Claims Billed With High-Severity-Level DRG Codes.

We then removed claims as follows:

- all \$0 paid claims,
- all claims under review by the Recovery Audit Contractor, and
- all duplicate claims within individual risk areas.

We assigned each claim that appeared in multiple risk areas to just one risk area based on the following hierarchy: Inpatient and Outpatient Manufacturer Credits for Replaced Medical Devices, then Inpatient Short Stays, and then Inpatient Claims Billed With High-Severity-Level DRG Codes. This resulted in a sampling frame of 1,191 unique Medicare claims in three risk areas totaling \$9,384,096.

Risk Areas Sampled

Risk Area	Number of Claims	Amount of Payments
Inpatient Short Stays	839	\$6,457,120
Inpatient and Outpatient Manufacturer Credits for Replaced Medical Devices	32	574,947
Inpatient Claims Billed With High-Severity-Level DRG Codes	320	2,352,029
Total	1,191	\$9,384,096

SAMPLE UNIT

The sample unit was a Medicare paid claim.

SAMPLE DESIGN

We used a stratified random sample. We divided the sampling frame into three strata based on the risk area.

SAMPLE SIZE

We randomly selected 139 claims as follows:

Sampled Claims by Stratum

Stratum	Risk Area	Sample Size
1	Inpatient Short Stays	60
2	Inpatient and Outpatient Manufacturer Credits for Replaced Medical Devices	32
3	Inpatient Claims Billed With High-Severity-Level DRG Codes	47
	Total Sampled Claims	139

SOURCE OF RANDOM NUMBERS

We generated the random numbers using the Office of Inspector General, Office of Audit Services (OIG/OAS) statistical software.

METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the claims within strata one and three. After generating the random numbers for these strata, we selected the corresponding frame items. We selected all claims in stratum two.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the amount of improper Medicare payments in our sampling frame for Princeton for the audit period.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

SAMPLE RESULTS

Stratum	Frame Size (Claims)	Value of Frame	Sample Size	Total Value of Sample	Number of Improperly Billed Claims in Sample	Value of Overpayments in Sample
1	839	\$6,457,120	60	\$466,370	12	\$74,783
2	32	574,947	32	574,948	4	20,988
3	320	2,352,029	47	358,515	6	18,248
Total	1,191	\$9,384,096	139	\$1,399,833	22	\$114,019

ESTIMATES

Estimated Value of Overpayments for the Audit Period
Limits Calculated for a 90-Percent Confidence Interval

Point Estimate	\$1,190,954
Lower limit	\$ 471,654
Upper limit	\$1,910,254

APPENDIX D: RESULTS OF REVIEW BY RISK AREA

Risk Area	Selected Claims	Value of Selected Claims	Claims With Over-payments	Value of Over-payments
Inpatient				
Short Stays	60	\$466,370	12	\$74,783
Manufacturer Credits for Replaced Medical Devices	20	445,449	2	19,288
Claims Billed With High-Severity-Level Diagnosis-Related Group Codes	47	358,515	6	18,248
Inpatient Totals	127	\$1,270,334	20	\$112,319
Outpatient				
Manufacturer Credits for Replaced Medical Devices	12	\$129,499	2	\$1,700
Outpatient Totals	12	\$129,499	2	\$1,700
Inpatient and Outpatient Totals	139	\$1,399,833	22	\$114,019

Notice: The table above illustrates the results of our review by risk area. In it, we have organized inpatient and outpatient claims by the risk areas we reviewed. However, we have organized this report’s findings by the types of billing errors we found at Princeton. Because we have organized the information differently, the information in the individual risk areas in this table does not match precisely with this report’s findings.

APPENDIX E: PRINCETON BAPTIST MEDICAL CENTER RESPONSE



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As a Witness
to the love of God,
revealed through
Jesus Christ,
Baptist Health
System is committed
to ministries that
enhance the health,
dignity and
wholeness
of those we serve
through Integrity,
Compassion,
Advocacy,
Resourcefulness and
Excellence.

December 20, 2013

Ms. Lori S. Pilcher
Regional Inspector General for Audit Services
Office of Audit Services, Region IV
61 Forsyth Street SW, Suite 3T41
Atlanta, GA 30303

RE: *OIG draft report (A-04-12-00084): Medicare Compliance Review of Princeton Baptist Medical Center for Calendar Years 2010 and 2011*

Dear Ms. Pilcher:

I am writing on behalf of Princeton Baptist Medical Center (Princeton), which is in receipt of the above-referenced draft audit report. Princeton appreciates the opportunity to comment on the Office of Inspector General (OIG) draft report. Princeton is committed to complying with all regulations and standards governing federal health care programs, and therefore embraces opportunities to improve our educational, audit, and compliance programs. This includes the implementation of operational procedures and controls to minimize the risk of billing errors and a strong compliance monitoring program. Because of the complexity and ambiguity of the Medicare regulations, the systems required to process thousands of transactions, and the necessary human component that can result in unintentional errors, Princeton has established an effective compliance program to ensure, to the extent reasonably possible, that the claims billed to Medicare comply with the laws and regulations. Princeton has reviewed the draft report in detail and asserts that Princeton is substantially in compliance with Medicare billing guidelines. Princeton has reviewed the findings and recommendations in the draft report and specifically responds as follows:

I. BACKGROUND

The OIG did not audit Princeton due to any allegation of improper billing or compliance practices. Rather, this audit was conducted as part of an ongoing national auditing initiative focused on “known areas of noncompliance identified during past Office of Inspector General (OIG) reviews of hospitals,¹” i.e., OIG targeted risk areas for hospitals across the country.

In this case, the OIG audit consisted of three risk areas identified in the opening letter: (1) inpatient claims indicating short stays, (2) inpatient and outpatient medical devices (manufacturer credits for replaced medical devices), and (3) inpatient claims with complications and comorbidities (billed with high severity level DRG codes). From the \$124,159,879 of Medicare payments during the years 2010 and 2011, the OIG selected \$63,248,571 of inpatient and outpatient claims from over 30 OIG identified high risk areas. Only three of the risk areas were ultimately selected for audit at Princeton. To date, the

¹ OIG Audit Introduction letter dated 10/25/2012.

OIG has provided no specific information as to how Princeton was selected as a provider, nor as to how the three risk areas for audit were chosen.

From an original sampling frame of 3899 claims found in the risk areas, the OIG stated that it removed claims that were: (1) zero dollar (\$0) claims, (2) claims under review by the RAC, and (3) duplicate claims. A final sampling frame of 1191 claims totaling \$9,384,096 was created from which 139 claims were drawn for audit. The OIG used a sample design as follows: "We used a stratified random sample. We divided the sampling frame into three strata based on the risk area."² The reported sample claims by strata are as follows:

Table 1

STRATUM	CLAIM TYPE/RISK AREA	CLAIMS SAMPLED	STRATUM POPULATION (Frame Size)	SAMPLE % OF POPULATION
1	Inpatient Short Stays	60	839	7.15%
2	Inpatient and Outpatient Manufacturer Credits for Replaced Medical Devices	32	32	100%
3	Inpatient Claims Billed with High Severity Level DRG Codes	47	320	14.7%
TOTAL		139	1191	11.7%

Both the draft report and the pre-audit workbook³ indicate that the strata were defined pre-audit. However, the OIG disclosed, for the first time, in Appendix B, page 10 of the draft report that it used a "hierarchy" to determine which claims would be assigned to which stratum when the claim appeared in multiple risk areas. The hierarchy is as follows: Inpatient and Outpatient Manufacturer Credits for Replaced Medical Devices, then Inpatient Short Stays, and then Inpatient Claims Billed with High Severity Level DRG Codes. There is no explanation as to how the hierarchy was developed, nor why claims with attributes of multiple strata were not excluded from the sampling frame. Though Princeton has requested a listing of the 1191 patients in the sample frame population, the OIG has not provided it. Without access to the population, Princeton does not have the ability to analyze the impact of the hierarchy on the stratified random sampling.

² OIG Draft Report (A-04-12-00084): *Medicare Compliance Review of Princeton Baptist Medical Center for Calendar Years 2010 and 2011*, pg. 10.

³ Pre Audit Spreadsheet (filename: A04120008420 Pre-Audit Workbook 20102412) submitted to Princeton 10/25/2012 with patient and defined areas of "vulnerabilities by issue."

II. OIG FINDINGS

The OIG concluded that 22 of the 139 claims did not fully comply with Medicare billing requirements resulting in alleged overpayments of \$114,019. Specifically, the OIG alleged that 20 inpatient claims had billing errors resulting in overpayments of \$112,319 and two (2) outpatient claims had billing errors resulting in overpayments of \$1700. Based on the OIG's findings, there is an alleged 8.15% error rate by dollars and an alleged 15.83% error rate by claims.

The OIG recommended not only the repayment of the \$114,019 based on their audit findings, but through the use of extrapolation, further recommends an additional \$357,635 in "estimated" overages resulting in a total demand of \$471,654. Princeton takes strong exception to these recommendations.

As with all of the OIG audits conducted as part of this national initiative, the OIG alleged that the hospital did not have adequate controls. The OIG's recommendation to Princeton (and other hospitals that have been audited) is to "strengthen controls to ensure full compliance with Medicare requirements." No specific actionable items were included in the draft report. The OIG did not identify a clear criteria used, nor a basis for denial of the disputed claims other than a difference of opinion. This is important to note because 50% of the alleged overpayments are related to claims where the billing status (inpatient versus outpatient) is at issue. Nationally, this has been the subject of great debate. CMS has acknowledged in recent rulemaking that the determination of inpatient versus outpatient status is fraught with error due to a lack of clarity in the standards rather than a lack of good controls by providers.

"So the heart [of the issue] being an urge by both the hospital communities and by the beneficiary communities that we'll need a greater clarity on which cases are outpatient stays versus inpatient stays."⁴

In essence, the OIG proposes denial of these disputed claims based a difference of opinion between the physician caring for the patient in real time and a nurse's retrospective review of the medical record.

III. CLAIMS ALLEGEDLY INCORRECTLY BILLED AS INPATIENT VERSUS OUTPATIENT

A. Princeton respectfully disagrees with substantive findings in the OIG draft report

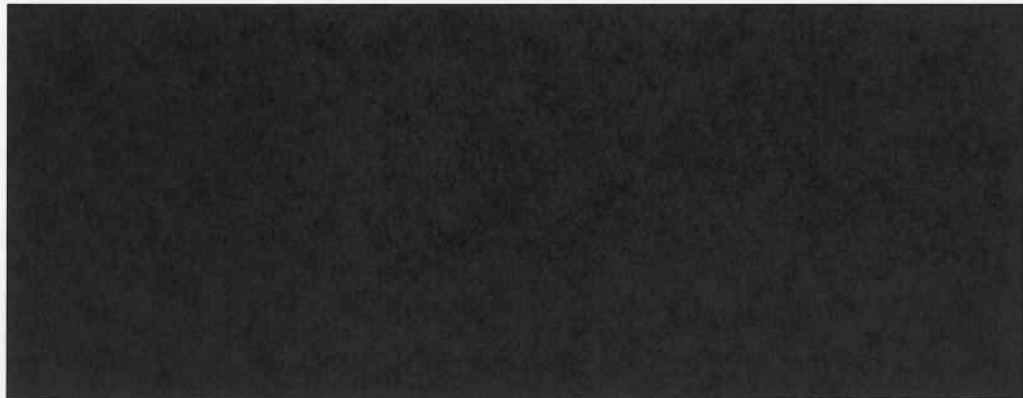
The OIG alleges that Princeton incorrectly billed Medicare Part A for beneficiary stays that should have been billed as outpatient or outpatient with observation services in 11 of the 127 sampled inpatient claims. Princeton concurs with the OIG on two claims. However, Princeton respectfully disagrees with the findings of the OIG regarding nine of the sampled claims and intends to fully appeal these claims. The prevailing reason for the disagreement is Princeton's belief that the denials, which were made by non-physician reviewers retrospectively reviewing complex medical decisions made by the treating physician at the time of care, are prejudiced by outcome bias and are

⁴ CMS Special Open Door Forum, Thursday, September 26, 2013.

therefore subjective and flawed. Moreover, Princeton had all claims selected in this stratum re-reviewed by independent third-party **physician reviewers** who are experts in Medicare rules and regulations as well as patient care. These independent physician experts concluded, on the merits, that Princeton correctly billed as inpatient all but two of the 60 cases that were included in the stratum. Thus, Princeton asserts that it had only a 3.33% margin of billing error related to inpatient status.

On April 3, 2013, after the independent physician reviews were completed at Princeton's expense and per the OIG audit protocol, Princeton officials and the physicians who conducted the reviews met with OIG auditors to provide the detailed clinical information below supporting Princeton's correct billing of patient status. After additional information was provided, the OIG declined the hospital's request to have the disputed cases re-reviewed by physicians. However, the draft report states on pages 3 and 7, that it "subjected 11 claims to medical review." Similarly, page 8 of the draft report states that it "used CMS's Medicare Contractor medical review staff to determine whether 11 sampled claims met medical necessity requirements." It is unclear if there was a separate undisclosed review or if this is merely an error whereby the disputed case number was inserted rather than the total number of claims reviewed.

For example, please find below a de-identified clinical summary of a disputed claim:
(Summaries of all nine disputed cases can be found at the end of this document Appendix A.)



The information offered above and in Appendix A is presented in an effort to demonstrate that the patients treated at Princeton were clearly ill and in need of inpatient services. Princeton respectfully asks the OIG to again consider the complexity of the medical decision making involved, the need for physician level review to fairly evaluate physician decision making and an acknowledgement that the CMS billing guidelines in place at the time did not provide clear delineation between inpatient and outpatient status. Because of the subjective, multifactorial nature of determining patient status, these types of cases are difficult to audit, despite the best efforts of the professional auditors who completed the field work. As evidenced in OIG's recent audit report, "Medicare Compliance Review of St. Vincent's Medical Center for Calendar Years 2009-2010," the OIG obtained independent medical reviews of claims which the hospital disputed in the draft report.

After the review, the OIG reduced the number of claims in error from 56 to 47, which reduced the reported errors by 16%⁵. The report does not provide information as to the identity of the first and second set of reviewers, nor of their credentials; however, it does demonstrate that even among reviewers contracted by the OIG to assist with the audits, there is error.

In summary, Princeton and its independent physician reviewers believe that the nine disputed cases were properly billed as inpatients. A redetermination finding that these cases were properly placed in inpatient status would reduce the number of incorrect claims from 11 to two, reduce the overpayment amount from \$71,612.34 to \$32,475.33 (exclusive of an additional Part B offset, see below for explanation), and would eliminate any extrapolation derived therefrom.

B. The OIG should reduce the alleged overpayment amount by the Part B Offset

Without conceding any of the above disputed claims as inpatient, the OIG should reduce the alleged overpayment amount by the amount due to the hospital under the Medicare Part B payment system. There is no dispute as to the medical necessity of hospital services. The only question is whether or not the hospital billed under the correct patient status. Princeton repeatedly requested that the OIG offset any alleged overpayments by the Part B amount. OIG indicated that it did not have the ability to calculate the Part B reimbursements. Princeton provided the OIG auditing staff with the estimated Part B reimbursement so that the alleged overpayment, and the resulting extrapolation, could be reasonably reduced. (See Table 2 below.)

⁵ Medicare Compliance Review of St. Vincent's Medical Center for Calendar Years 2009-2010, page 10, OIG Audit #A-04-12-08013, December 2013.

Table 2⁶

SAMPLE ITEM #	ALLEGED OVERPAYMENT AMOUNT	ESTIMATED PART B REIMBURSEMENT	NET ALLEGED OVERPAYMENT
9	\$ 4,956.87	\$ 3,738.78	\$ 1,218.09
11	\$ 5,440.16	\$ 1,854.56	\$ 3,585.60
15	\$ 2,142.96	\$ 1,039.60	\$ 1,103.36
16	\$ 3,176.32	\$ 473.45	\$ 2,702.87
23	\$ 10,121.17	\$ 7,121.07	\$ 3,000.10
35	\$ 2,601.02	\$ 424.41	\$ 2,176.61
36	\$ 2,279.82	\$ 1,347.66	\$ 932.16
40	\$ 6,056.87	\$ 1,509.85	\$ 4,547.02
48	\$ 2,361.82	\$ 761.00	\$ 1,600.82
Subtotal Claims in Dispute	\$ 39,137.01	\$ 18,270.38	\$ 20,866.63
37	\$ 2,946.84	\$ 426.94	\$ 2,519.90
38	\$ 29,528.49	\$ 24,212.51	\$ 5,315.98
Subtotal Claims in Agreement	\$ 32,475.33	\$ 24,639.45	\$ 7,835.88
TOTAL ALLEGED OVERPAYMENTS	\$ 71,612.34	TOTAL ALLEGED OVERPAYMENTS NET OF OFFSETS	\$ 28,702.51

⁶ Note: The calculation of the outpatient charges in Table 2 in no way indicates that Princeton concurs with the OIG's assertion that all of the claims on Table 2 should be billed as outpatient. Rather, the figures are provided only to demonstrate the minimum offset amount.

The OIG declined to use the information in preparation of the draft report. Footnote 2, page 4 of the OIG draft report states that “the hospital may be able to rebill Medicare Part B for some services that would have been reasonable and necessary had the beneficiary been treated as a hospital outpatient rather than admitted as an inpatient. We were unable to determine the effect the billing Medicare Part B would have on the overpayment amount because these services have not been billed and adjudicated by the Medicare Administrative Contractor (MAC) prior to the issuance of our draft report.” The statement that the cases have not been adjudicated is contrary to the OIG’s argument. The non-physician reviewer at the MAC opened each review in the disputed cases with the statement, “Observation is appropriate.”

Further, Princeton cannot rebill because it disputes the accuracy of the nurse reviewers’ findings. Thus, if Princeton rebills, it would forfeit the right to appeal. Additionally, all of the cases reviewed by the OIG are outside of the 12-month timely filing window. Therefore, the claims are not eligible for rebill. Because the OIG had access to the Part B billing amounts and a statement of “adjudication” from the MAC that observation services were appropriate, it should have reduced the recommended demand amount.

C. Summary

After detailed clinical review of the claims completed by independent physician reviewers, Princeton concurs with the OIG on two claims totaling \$32,475. After reducing those claims by the Part B allowable payment, Princeton asserts that the overpayment amount is approximately \$7836.⁷

IV. CLAIMS ALLEGEDLY USING INCORRECT DIAGNOSIS RELATED GROUP CODES

With regard to the diagnosis related group (DRG) coding issues, the OIG alleges in its draft report that Princeton had seven errors. However, in the last spreadsheet provided by the OIG auditors in August 2013, prior to the issuance of this draft, only six claims had been identified as incorrect. Of the six claims (Stratum 3, Samples: 6, 10, 12, 31, 40, 46), Princeton concurs with the OIG on four claims. However, Princeton strongly disagrees with the OIG findings on Stratum 3, Samples 40 and 46. Princeton provided additional coding information to the OIG and asked for reconsideration of the disputed claims after no less than three certified coders reviewed and agreed with the original Princeton coding. Below is a summary of the information which was submitted:



⁷ (Sample #37 + Sample #38) – Part B offsets = \$7836.

To verify the use of this code without the e code, we have the following resources:

- Coding guidance from the Precyse Solutions, LLC , Medical Management Plus Incorporated, and University of Alabama Birmingham indicate that it is not appropriate to add an E code since the encephalopathy is not due to a drug. The term “toxic” and “due to drugs” index to the same code leading to an instructional note to add the E code when due to a drug. In these cases, the E code is not applicable because the encephalopathy though toxic was NOT drug induced, but metabolic in nature.
- The National Center for Biotechnology Information (<http://www.ncbi.nlm.nih.gov/books/NBK7405/>): Gives sepsis as an example of a cause of toxic metabolic encephalopathy. The patient may present with toxic effects of the infection.
- An article from E Medicine Health (http://www.emedicinehealth.com/encephalopathy/page3_em.htm): Lists causes of metabolic encephalopathy. Lists toxic metabolic encephalopathy in parenthesis. These include electrolyte abnormalities. Also lists drug side effects as a cause but it is not the only cause listed.

Toxic metabolic encephalopathy is a type of encephalopathy that is used as a catch-all phrase for brain dysfunction caused by infection, organ failure, or intoxication. Therefore, based on the fact that the term “toxic metabolic encephalopathy” is documented by physicians in the medical record, and since the term “toxic metabolic encephalopathy” is listed in the Index of ICD-9-CM codes as 349.82, it is appropriate to add this code without an e code when it is not related to a toxic drug induced cause, but rather a toxic metabolic cause. Thus, we do not agree with the removal of ICD-9-CM code 349.82 from the claims.

In a spreadsheet submitted to Princeton by the OIG on August 2, 2013 copied below in Table 3 (formatting added), the net potential overpayments alleged was \$18,248*.

Table 3

STRATUM	SAMPLE SIZE	TOTAL VALUE OF SAMPLE	NUMBER OF IMPROPERLY BILLED CLAIMS IN SAMPLE ⁸	VALUE OF OVERPAYMENTS IN SAMPLE
Short Stays	60	\$466,370	12	\$74,783
Medical Devices	32	\$574,947	4	\$20,988
MCC/CC	47	\$358,516	6	\$18,248*
TOTAL	139	\$1,399,833	22	\$114,019

In Stratum 3 (referred to as “MCC/CC” in the chart above) Princeton disagrees with two cases valued at \$5099 and concurs with OIG findings regarding the other four cases. Therefore, Princeton concurs with an overpayment of \$13,149.

⁸ This heading title was authored by the OIG and is reflective of OIG’s findings. By reproducing this data, Princeton in no way adopts the findings therein.

The 7th claim referenced in the OIG draft report section entitled, "Incorrectly Billed Diagnosis-Related Group Codes" comes from Inpatient and Outpatient Manufacturer Credits for Replaced Medical Devices, Stratum 2, Sample #24, and therefore is not included in the stratified random sample of 47 claims from Stratum 3. Princeton agrees that the DRG is incorrect, which resulted in an overpayment of \$14,085. This is significant because the OIG stated that it would apply extrapolation if the alleged errors exceeded six cases.

Therefore, Princeton agrees that there are five cases from Stratum 2 and Stratum 3 which relate to DRG changes resulting in a combined overpayment of \$27,234. These errors are attributable to human error which can occur when interpreting complex medical records in order to translate the documentation into the technical coding requirements. Princeton provides ongoing education and evaluation of coders as part of the hospital's compliance program.

V. INCORRECTLY BILLED AS SAME DAY DISCHARGE AND READMISSION

The OIG identified one case, Sample #33, from Stratum 1 where the patient was discharged and readmitted on the same day. Princeton concurs with the OIG's findings and agrees that the charges should have been bundled. Due to human error, the charges were not bundled resulting in a net overpayment of \$3171. Princeton will continue to provide ongoing education to the billing staff regarding the bundling of charges that is required in these rare cases.

However, the issue is whether or not Stratum 1, Sample #33 should be included in Stratum 1 at all, when Stratum 1 consists of 60 samples categorized as "inpatient short stays." It is Princeton's understanding that inpatient short stays are cases where the patient was either: (1) admitted and discharged on the same day, or (2) admitted and discharged the day after admission. When Princeton questioned the inclusion of this type of error being combined with the 11 claims related to inpatient versus outpatient status, the OIG responded in an email as follows: "I discussed this situation with our stats staff, and they explained that the strata were determined by the type of claim and not the type of error. Therefore since Sample #33 was correctly classified as a short stay claim, it is statistically valid to include Sample #33 in our results."⁹ However, using the patient control number supplied by the OIG in its original documents, Sample #33 was found to have had a length of stay of five days. Therefore, Stratum 1, Sample #33 is not a short stay.

Though Princeton agrees with the OIG with respect to the overpayment of \$3171, it disagrees with its inclusion in Stratum #1 because it does not meet the stratum criteria.

VI. MANUFACTURER CREDIT FOR A REPLACED MEDICAL DEVICE NOT OBTAINED

Princeton agrees with the OIG findings of one (1) case of a missed device credit from the 32 cases in the sample, resulting in a potential overpayment of \$5203. Please note that Princeton did not receive a credit from the manufacturer; nevertheless, it acknowledges the duty to apply for any potential credits .

⁹ OIG email to BHS Director, Fiscal Integrity, 08/02/2013, subject: "A-04-12-00084."

The interdepartmental communication which supported coding the claim with the correct codes and modifiers was not optimal, and thus staff did not always know when a device credit was possible. Princeton has developed an interdisciplinary team to refine and strengthen the existing process to communicate when a device has been replaced to all appropriate parties including the party sourcing the device, persons returning the device for manufacturing instructions, and communicating the percentage and amount of any credits received to billing. With respect to corrective actions, the hospital will continue to request manufacturer credits when appropriate.

VII. INCORRECTLY BILLED HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) CODES

The OIG auditors identified two (2) cases that contained incorrect HCPCS codes when reviewing the 32 inpatient and outpatient medical device cases from Stratum 2. Princeton agrees with the OIG findings which resulted in a \$1700 overpayment. Princeton will continue to provide ongoing education and audits to minimize human error in the billing process.

VIII. PRINCETON OBJECTS TO THE APPLICATION OF EXTRAPOLATION

A. Princeton does not have adequate information to fully respond to the OIG draft report.

Princeton does not have adequate information to respond fully to the OIG draft report because it is missing information related to the population, the stratification design, the application of sampling to the strata, the extrapolation calculations, and the credentials of the statistician who designed the model. During the closing conference in May 2013, OIG officials stated that the details of the statistical methodology would be disclosed as part of the draft report. Princeton respectfully requests that the OIG provide: (1) a detailed narrative explanation of the sampling process and extrapolation estimates, (2) calculations used to create the stratification model, the hierarchy, and the underlying theory in support thereof, (3) the calculations used to determine the extrapolated estimated overpayment by stratum including, but not limited to, the dollar amounts applied, the error rates used, and precision points, (4) list of the patients included in each stratum population (sampling frame), and (5) the credentials of the statistician who designed the model. Because the application and calculation of extrapolation estimates is not an investigatory practice, there is no need to preserve the technique for future audits.

1. No detail is provided related to the statistical design methodology of the stratum hierarchy and sample integrity.

When using a stratified random sample to extrapolate an estimated (predicted) result to a population, the stratified sample must be homogenous within the stratum and heterogeneous among the strata in order for extrapolation to be reliable. As explained in The Essentials of Survey Sampling: “The principle of stratification which is as follows: The Stratification should be so implemented that (i) variate-values should be

as *alike* as possible among themselves within each stratum while (ii) the strata themselves should be as *unlike* as possible relative to each other...”¹⁰

It is clear that several Princeton sample cases met the criteria of more than one of the strata. The OIG used a hierarchy to assign claims to a particular stratum when the claim met more than one criteria. There is no information provided in the draft report to describe the methodology used to develop the hierarchy, nor any explanation of how the hierarchy is incorporated into the sampling frame and stratification model or the applicable theorem to support it. Without more quantitative detail, the strata do not appear sufficiently discrete to reduce variability and increase outcome reliability.

Further, as outlined in Section V., there is a claim with a five day length of stay that is included in Stratum 1 which is categorized as a claim type “Short Stay.” The inclusion of this claim calls into question the homogeneity of the sample when the sampled claim exceeds the one day length of stay that defines the stratum. If the stratum is not sufficiently homogenous or there was an error in picking the population and/or samples, then the integrity of the extrapolation is degraded.

2. Stratification must be designed and sampled appropriately to be reliable.

It is unclear why stratification was used when the strata means are so similar. Stratification is used by statisticians to reduce variability and increase the reliability of results. Stratification is employed to improve efficiency in the estimation, which is achieved by producing groups that have different means in order to obtain distinct, stratum-based estimates of the variance/precision. In this audit, the first and third strata have similar mean payment amounts, which calls into question the reason why stratification was used. Princeton needs additional information regarding the stratification process, including a listing of the universe, and the means and the standard deviations of the strata in order to fully respond to the draft report.

Further, it is unclear when and how the sampling was done. The only information regarding how the samples were drawn from the strata is found in the draft report, page 11: “We consecutively numbered the claims within strata one and three. After generating the random numbers for these strata, we selected the corresponding frame items. We selected all claims in stratum two.” It is unclear if Stratum 1 and Stratum 3 were consecutively numbered or if there were two sets of consecutive numbers, one for each stratum. Further, at least one case was moved between Stratum 2 and Stratum 3 as discussed in Section IV. It is unknown if this case was used in determining the extrapolation calculation error rate and the calculation of dollars for Stratum 3 because the charts in the appendices do not match the text of the report.

Moreover, there is no information provided in the draft report related to the derivation of the 139 sample size, nor when or how the number of samples were allocated to

¹⁰ Chaudhuri, Arijit, Essentials of Survey Sampling, Kindle Loc. 842, PHI Private Learning Limited, New Dehli, 2010.

Stratum 1 and Stratum 3. Though it is apparent that neither equal nor proportionate sampling were used, the draft report does not state whether optimum allocation sampling or some other statistical theory was used. Therefore, Princeton requests that the OIG provide detailed information related to sampling methodology and allocation of the samples.

3. Princeton is unaware of the legal authority or quantitative justification for the imposition of extrapolation when a threshold of six errors is reached within a stratum.

As noted in Section IV, the OIG stated that it would apply extrapolation if errors were found in six or more cases. Princeton is unaware of the legal authority or quantitative justification for the imposition of extrapolation when a threshold of six errors is reached within a stratum. Princeton requests that the OIG provide an explanation as to the use of this threshold.

Princeton does not have enough information to agree or disagree with the OIG's assertion that extrapolation is statistically valid. Therefore, Princeton requests all work papers including but not limited to the information requested above, documents, emails, spreadsheets, seed numbers and reference materials that were used in creating or related to: population selection and the narrowing thereof, the sampling frame, sample selection, standard deviations, precision points, and extrapolation calculations as well as the information requested above (VIII.) so that Princeton can more properly respond to the draft report. Princeton respectfully requests the right to amend its response to the draft after the requested information is provided.

B. Extrapolation potentially violates Princeton's due process rights.

Extrapolation potentially violates Princeton's due process rights because extrapolation exposes Princeton to duplicate payments and precludes Princeton's right to appeal denied cases. Extrapolation subjects Princeton to duplicate overpayments because: (1) to date, Princeton has not received a list of the patients in the population to verify that other government auditors have not reviewed the same claims, and (2) because without the list of all patients in the population, Princeton is denied the equitable defense of Res Judicata should government auditors seek to re-review the same claims in the future. As part of building the audit sampling frame, the OIG excluded claims that were under RAC review at the time the sampling frame was built. (The draft report does not indicate the date that the sampling frame was created.) However, RAC or other government auditors could have requested records that were included in this audit. In another audit report, the OIG responded to a hospital with similar concerns by suggesting that the hospital send a list of all the claims that are under RAC review from the time frame of the audit to the OIG. However, hospitals now face scrutiny of the same records from the OIG, RAC, MAC, ZPICs and possibly others. Even if Princeton compiled a list of claims audited by all government and contract government auditors for 2010 and 2011, the list would be out of date as soon as it was submitted. The hospital would have to send almost daily updates to the OIG to cross reference against the population list.

Because submitting ongoing reports to the OIG regarding the activities of other auditors is burdensome and wasteful, Princeton requests that the OIG provide a list of the 1191 patients in the population.

Further, extrapolation denies Princeton the opportunity to appeal denied claims. It is important to note that the eleven claims that are disputed in this audit were evaluated by non-physician reviewers at the MAC and thus are currently denials. Because the audit is not complete until a binding determination of error is made on a case by case basis, these claims are not actual errors until fully adjudicated through an appeals process. However, the imposition of extrapolation would deny the hospital procedural due process rights to appeal cases based on the merits because by its nature, extrapolation estimates an error to a population rather than to identify specific cases.

C. Princeton objects to the use of extrapolation as unjust and fundamentally unfair.

The Medicare Prescription Drug Improvement and Modernization Act of 2003 (42 USC § 1395 ddd (f)(3)) provides very limited circumstances under which CMS or its contractors may extrapolate results for overpayment purposes. As is set forth below, none of the circumstances are at issue in this audit.

Further, the CMS Program Integrity Manual instructs that before using extrapolation to determine overpayment amounts, there must be a determination of sustained high level of payment error or documentation that educational intervention has failed to correct the payment error. There has been no such finding in this case. Even if one uses Princeton's alleged error rate of 15.83%, the OIG has published numerous reports this year where hospitals included in this same audit initiative were found to have had alleged error rates in excess of 50%, and, in at least two audits, where the alleged error rate exceeded 70%. Nonetheless, the OIG chose not to extrapolate in those cases. Thus, the OIG should, at the very least, remain consistent in its application of the high error rate criteria before imposing the punitive measure of extrapolation. Due process and fair treatment under the law is called into question when providers who had quadruple the error rate alleged in this report are not found to have a "high error rate," or were not for some other undocumented reason subject to extrapolation.

The OIG has noted in other recently issued audit reports that extrapolation has been applied in some cases and not others because the audit methods have improved. However, that explanation does not explain the seemingly disparate treatment of hospitals in different regions. During previous OIG audits conducted during this initiative, the OIG identified multiple risk areas by **error type** to use during the audit. By using claim types, rather than error type as strata, the OIG has created larger strata and therefore a higher probability of exceeding the six-error threshold as set by the OIG in our audit. Princeton asserts that the OIG should have identified all of the risk areas that were audited at Princeton separately as it has in previous audits (patient status, readmissions, medical device credits, HCPCS, and DRG coding). This would have resulted in lower error rates per area. Instead, it appears that the cases were artificially bundled into three risk categories containing multiple error types in order to meet extrapolation minimum thresholds. An example of this occurred when the single discharge and readmission during the same day claim was

added to the inpatient versus outpatient status errors. Different types of alleged errors should not be added to together to make a larger stratum. This is fundamentally unfair and logically flawed.

Because Princeton's error rate, as calculated by the OIG, is one of the lowest published rates found during this audit initiative, Princeton strongly objects to the imposition of extrapolation and respectfully requests that the OIG remove all extrapolated overpayment recommendations from its final report.

IX. SUMMARY

Princeton concurs in part and objects in part to the OIG findings. Princeton asserts that the total errors by category are as follows:

Table 4

ERROR TYPE	ERRORS	OVERPAYMENTS NET OF PART B OFFSETS
Inpatient Short Stays	2	\$7836
DRG Coding from Stratum 3	4	\$13,149
DRG Coding from Stratum 2	1	\$14,085
Same day discharge readmission	1	\$3171
Medical device credits	1	\$5203
HCPCS Coding	2	\$1700
Estimated Total Overpayments	<u>11</u>	<u>\$45,144</u>

Because of: (1) CMS' acknowledgment of lack of clarity in the inpatient versus outpatient status rules; (2) the serious clinical disagreements between the OIG and Princeton as to medical necessity of inpatient services; (3) the lack of application of Part B offsets to denied Part A claims; (4) the failure to re-review the supporting coding clinic guidelines; (5) the information still not provided related to the statistical methodology and calculations; and (6) the huge variation in the imposition of extrapolation among facilities, Princeton Baptist Medical Center respectfully requests that the OIG amend the draft report recommendations to remove extrapolation completely and decrease the overpayment amounts to the \$45,144 noted above.

Thank you in advance for your consideration of our response.



Keith Parrott
 President and CEO
 Baptist Health System, Inc.

