Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE COMPLIANCE REVIEW OF NORTH CAROLINA BAPTIST HOSPITAL FOR CLAIMS PAID FROM JANUARY 1, 2013, THROUGH AUGUST 31, 2014

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



Brian P. Ritchie Assistant Inspector General for Audit Services

> September 2016 A-04-15-04036

Office of Inspector General

http://oig.hhs.gov

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EXECUTIVE SUMMARY

North Carolina Baptist Hospital did not fully comply with Medicare requirements for billing inpatient services, resulting in estimated overpayments of at least \$1.48 million over 20 months.

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 2014, Medicare paid hospitals \$159 billion, which represents 46 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 this review was to determine whether North Carolina Baptist Hospital (the Hospital) complied with Medicare requirements for billing inpatient 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.

The Hospital is an 885-bed hospital located in Winston Salem, North Carolina. According to CMS's National Claims History data, Medicare paid the Hospital approximately \$280 million for 18,110 inpatient claims between January 1, 2013, and August 31, 2014 (audit period).

Our audit covered \$46,073,853 in Medicare payments to the Hospital for 3,422 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 246 claims with payments totaling \$3,944,218. These 246 inpatient claims were paid by Medicare during our audit period.

Under section 1128J(d) of the Social Security Act and 42 CFR part 401, subpart D, providers are responsible for reporting and returning overpayments within 60 days of identifying an overpayment (the 60-day rule). Providers are required to exercise reasonable diligence to investigate credible information of potential overpayments to determine whether they have received an overpayment and to quantify the amount of the overpayment over the entire 6-year lookback period (42 CFR §§ 401.305(a)(2) and (f) and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016)).

WHAT WE FOUND

The Hospital complied with Medicare billing requirements for 209 of the 246 inpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 37 claims, resulting in net overpayments of \$221,481 for the audit period. These errors occurred primarily because the Hospital 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 the Hospital received overpayments of at least \$1,488,468 for the audit period.

WHAT WE RECOMMEND

We recommend that the Hospital:

- refund to the Medicare contractor \$1,488,468 in estimated overpayments for the audit period for claims that it incorrectly billed;
- strengthen controls to ensure full compliance with Medicare requirements; and
- exercise reasonable diligence to identify and return any additional overpayments received outside of our audit period, in accordance with the 60-day repayment rule.

NORTH CAROLINA BAPTIST HOSPITAL COMMENTS AND OUR RESPONSE

In written comments on our draft report, the Hospital stated that it did not agree with our disallowance determinations on certain claims and indicated that it plans to appeal proposed denials for those claims. The Hospital also contended that the sample results should not be extrapolated because the error rate is less than 5 percent, and the sample precision is low. The Hospital also noted that it had a strong compliance program with training and ongoing third party reviews and that it actively monitored risk areas and conducted internal audits. The Hospital said that it had performed an analysis and had not identified any claims that it needed to report in accordance with the 60-day repayment rule.

After reviewing the Hospital's comments, we continue to maintain that our findings and recommendations are valid. We used an independent medical reviewer to determine whether certain sampled claims were appropriately billed. Additionally, we used valid statistical sampling methodology in our sample selection and in determining the estimated Medicare overpayment. We acknowledge the Hospital's existing compliance program but continue to maintain that, based on our audit results, it still needs to strengthen controls to ensure full compliance with Medicare requirements.

INTRODUCTION
Why We Did This Review1
Objective1
Background 1 The Medicare Program 1 Hospital Inpatient Prospective Payment System 1 Hospital Claims at Risk for Incorrect Billing 1 Medicare Requirements for Hospital Claims and Payments 2 North Carolina Baptist Hospital 2
How We Conducted This Review2
FINDINGS
Billing Errors Associated With Inpatient Claims
OVERALL ESTIMATE OF OVERPAYMENTS
RECOMMENDATIONS
NORTH CAROLINA BAPTIST HOSPITAL COMMENTS
OFFICE OF INSPECTOR GENERAL RESPONSE
APPENDIXES
 A: Audit Scope and Methodology

TABLE OF CONTENTS

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 2014, Medicare paid hospitals \$159 billion, which represents 46 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 North Carolina Baptist Hospital (the Hospital) complied with Medicare requirements for billing inpatient 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

Under the inpatient prospective payment system (IPPS), CMS pays 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.

Hospital Claims at Risk for Incorrect Billing

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

- inpatient manufacturer credits for replaced medical devices,
- inpatient claims billed with high-severity-level DRG codes, and
- inpatient claims paid in excess of charges.

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 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 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), Pub. No. 100-04, chapter 1, section 80.3.2.2, requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly.

Under section 1128J(d) of the Social Security Act and 42 CFR part 401, subpart D, providers are responsible for reporting and returning overpayments within 60 days of identifying an overpayment (the 60-day rule). Providers are required to exercise reasonable diligence to investigate credible information of potential overpayments to determine whether they have received an overpayment and to quantify the amount of the overpayment over the entire 6-year lookback period (42 CFR §§ 401.305(a)(2) and (f) and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016)).

North Carolina Baptist Hospital

The Hospital is an 885-bed hospital located in Winston Salem, North Carolina. According to CMS's National Claims History (NCH) data, Medicare paid the Hospital approximately \$280 million for 18,110 inpatient claims between January 1, 2013, and August 31, 2014 (audit period).

HOW WE CONDUCTED THIS REVIEW

Our audit covered \$46,073,853 in Medicare payments to the Hospital for 3,422 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 246 claims with payments totaling \$3,944,218. These 246 inpatient claims were paid by Medicare during our audit period.

We focused our review on the risk areas identified as a result of prior OIG reviews at other hospitals. We evaluated compliance with selected billing requirements and subjected 83 claims to coding review to determine whether the services were properly coded. This report focuses on selected risk areas and does not represent an overall assessment of all claims submitted by the Hospital 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 of our scope and methodology.

FINDINGS

The Hospital complied with Medicare billing requirements for 209 of the 246 inpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 37 claims, resulting in net overpayments of \$221,481 for the audit period. These errors occurred primarily because the Hospital 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 the Hospital received overpayments of at least \$1,488,468 for the audit period.

See Appendix B for sample design and methodology, Appendix C for sample results and estimates, and Appendix D for results of review by risk area.

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 37 of the 246 inpatient claims that we reviewed. These errors resulted in net overpayments of \$221,481. Three claims contained more than one error.¹

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 34 of the 246 inpatient claims, the Hospital submitted claims to Medicare with incorrect DRG codes. The Hospital did not agree that all 34 claims had errors. However, the Hospital acknowledged that inadvertent human error may have led to some coding mistakes and that professional judgements can vary based on subjective determinations. The Hospital also stated that, to support coding accuracy, it has adopted additional controls and training since our audit period.

As a result of these errors, the Hospital received net overpayments of \$151,473.

¹ For sampled claims that contained more than one type of error, we used the total claim overpayment for error estimation. We did not estimate errors on the same claim twice.

Incorrectly Billed as Inpatient

Medicare payments may not be made for inpatient services unless "a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment ..." (the Act, § 1814(a)(3)).

For 1 of the 246 inpatient claims, the Hospital incorrectly billed Medicare Part A for a beneficiary stay that did not have an inpatient order. The Hospital admitted the patient for observation and treated the patient as an outpatient but incorrectly billed the claim as inpatient. The Hospital stated that this was an inadvertent error due to the implementation of a new electronic medical records system approximately 2 weeks prior to this claim's dates of service.

As a result of this error, the Hospital received overpayments of \$35,141.²

Manufacturer Credits for Replaced Medical Devices Not Reported

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 cost of a device, or (3) the provider receives a credit equal to 50 percent or more of the cost of the device (42 CFR § 412.89). The Manual states that to bill correctly for a replacement device that was provided with a credit, a hospital must code its Medicare claims with a combination of condition code 49 or 50, along with value code "FD" (chapter 3, § 100.8).

For 4 of the 246 inpatient claims, the Hospital received reportable medical device credits from a manufacturer for replaced devices but did not adjust its inpatient claims with the proper condition and value codes to reduce payment as required.

The hospital stated that these errors occurred due to a lack of controls in place and a lack of staff training.

As a result of these errors, the Hospital received overpayments of \$27,500.

Incorrect Discharge Status

Federal regulations state that a discharge of a hospital inpatient is considered to be a transfer when the patient's discharge is assigned to one of the qualifying DRGs and the discharge is to home under a home health agency's written plan of care for home health services that begin within 3 days after the date of discharge (42 CFR § 412.4(c)). A hospital that transfers an inpatient under the above circumstance is paid a graduated per diem rate for each day of the patient's stay in that hospital, not to exceed the full DRG payment that would have been paid if the patient had been discharged to another setting (42 CFR § 412.4(f)).

² The Hospital may be able to bill Medicare Part B for these outpatient services that were incorrectly billed as 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 contractor prior to the issuance of our report.

For 1 of the 246 inpatient claims, the Hospital incorrectly billed Medicare for a patient discharge that should have been billed as a transfer. Specifically, the Hospital coded the discharge status as "to home" instead of "to home health." Thus, the Hospital received the full DRG payment instead of the graduated per diem payment it would have received if it had correctly coded the patient's discharge status. The Hospital stated that this error was due to a late entry to the medical record indicating that a case manager had arranged home health services after discharge.

As a result of this error, the Hospital received overpayments of \$7,367.

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$1,488,468 for the audit period.

RECOMMENDATIONS

We recommend that the Hospital:

- refund to the Medicare contractor \$1,488,468 in estimated overpayments for the audit period for claims that it incorrectly billed;
- strengthen controls to ensure full compliance with Medicare requirements; and
- exercise reasonable diligence to identify and return any additional overpayments received outside of our audit period, in accordance with the 60-day repayment rule.

NORTH CAROLINA BAPTIST HOSPITAL COMMENTS

In written comments on our draft report, the Hospital stated that it did not agree with our disallowance determinations on certain claims, and it contended that the sample results should not be extrapolated. The Hospital also noted that it had a strong compliance program with training and ongoing third party reviews and that it actively monitored risk areas and conducted internal audits. The Hospital said that it had performed an analysis and had not identified any claims that it needed to report in accordance with the 60-day repayment rule.

The Hospital stated that it planned to appeal proposed denials for certain claims that we determined to be billed with the incorrect DRG. It acknowledged that we correctly identified one claim as having been billed incorrectly as inpatient and one claim as having been billed with the incorrect discharge status code. Furthermore, the Hospital did not disagree with the medical device credit errors that we identified but noted that it had already established an aggressive internal review process to identify such errors and had already begun its own audit of all claims for devices replaced under warranty or for credit dating back to 2007. (At our request, the Hospital suspended its review of claims included in our sample.)

The Hospital disagreed with our extrapolation of the sample results to the sample frame. It cited a low error rate and low sample precision as reasons that extrapolation is not justified.

Specifically, the Hospital said, "... we disagree that any extrapolation is appropriate here as there was no finding of sustained errors ..." and, with a precision level "as low as 41-45% in at least one stratum," it is not possible to accurately project an error for that stratum. The Hospital also argued that the single error associated with one claim that it incorrectly billed as inpatient and another error for a claim that it billed with the incorrect discharge status were isolated errors that we should not have included in any extrapolation.

The Hospital's comments are included in their entirety as Appendix E.

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the Hospital's comments, we continue to maintain that our findings and recommendations are valid. We used an independent medical review contractor to determine whether certain sampled claims were appropriately billed. Additionally, we used valid statistical sampling methodology in our sample selection and in determining the estimated Medicare overpayment. We acknowledge the Hospital's existing compliance program but continue to maintain that, based on our audit results, it still needs to strengthen controls to ensure full compliance with Medicare requirements.

As we indicated in Appendix A, during our audit, we used an independent medical review contractor to determine whether 83 claims met coding requirements. The contractor examined all of the medical records documentation submitted for these claims and carefully determined whether the Hospital billed the inpatient claims according to Medicare requirements. The contractor ultimately determined that the Hospital incorrectly billed 34 of these claims. On the basis of the contractor's conclusions, we maintain that the Hospital billed the disputed claims incorrectly. We provided our contractor's conclusions to the Hospital. The Hospital is within its rights to appeal the disputed disallowances through the Medicare appeals process.

The Hospital's assertion that we should not extrapolate because "... there was no finding of sustained errors ..." is not valid. The requirement that a determination of a sustained or high level of payment error or documented failed educational intervention must be made before extrapolation applies only to Medicare contractors.³ None of the criteria cited by the Hospital in support of its argument is applicable to OIG audits.

Regarding the Hospital's contention that our sample precision is too low, the legal standard for the use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.⁴ We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. Because absolute

³ See Social Security Act § 1893(f)(3); CMS Medicare Program Integrity Manual, chapter 8.4.1.4 (effective June 28, 2011).

⁴ See John Balko & Assoc. v. Sebelius, 2012 U.S. Dist. 183052 at *34, 38 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 2016 U.S. Dist. LEXIS 6816 at *31-33, 37-39 (W.D. Tex. 2016); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enter., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

precision is not required, any imprecision in the sample may be remedied by recommending recovery at the lower limit, which was done in this audit.⁵ This approach results in an estimate that is lower than the actual overpayment amount 95 percent of the time, and thus it generally favors the provider.⁶

⁵ See Pruchniewski v. Leavitt, 2006 U.S. Dist. LEXIS 101218 at *46, 51-52 (M.D. Fla. 2006).

⁶ See Puerto Rico Dep't of Health, DAB No. 2385, (2011); Oklahoma Dep't of Human Servs., DAB No. 1436, (1993) (stating that the calculation of the disallowance using the lower limit of the confidence interval gave the State the "benefit of any doubt" raised by use of a smaller sample size).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$46,073,853 in Medicare payments to the Hospital for 3,422 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 246 claims with payments totaling \$3,944,218. These 246 inpatient claims were paid by Medicare during our audit period.

We focused our review on the risk areas identified as a result of prior OIG reviews at other hospitals. We evaluated compliance with selected billing requirements and subjected 83 claims to coding review to determine whether the services were properly coded.

We limited our review of the Hospital's internal controls to those applicable to the inpatient 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 NCH 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 the Hospital for Medicare reimbursement.

Our fieldwork included contacting the Hospital in Winston Salem, North Carolina, from May 2015 through April 2016.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Hospital's inpatient paid claims data from CMS's NCH file for the 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 246 inpatient claims totaling \$3,944,218 for detailed review (Appendix B);
- 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 the Hospital to support the sampled claims;
- requested that the Hospital conduct its own review of the sampled claims to determine whether the services were billed correctly;
- reviewed the Hospital's procedures for assigning DRG and admission status codes for Medicare claims;
- used an independent medical review contractor to determine whether 83 claims met coding requirements;
- discussed the incorrectly billed claims with Hospital 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 overpayment to the Hospital (Appendix C); and
- discussed the results of our review with Hospital 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 contained inpatient claims paid to the Hospital for services provided to Medicare beneficiaries during the audit period.

SAMPLING FRAME

According to CMS's NCH data, Medicare paid the Hospital \$280,189,104 for 18,110 inpatient claims during the audit period.

We obtained a database of claims from the NCH data totaling \$194,743,890 for 11,966 inpatient claims in 15 risk areas. From these 15 areas, we selected 3 consisting of 4,329 claims totaling \$78,615,548 for further review. We then removed the following:

- claims billed with high-severity-level DRG codes with payment amounts less than \$3,000,
- claims under review by the Recovery Audit Contractor (RAC), and
- claims duplicated within individual risk categories.⁷

We assigned each claim that appeared in multiple risk areas to just one area on the basis of the following hierarchy: Inpatient Manufacturer Credits for Replaced Medical Devices, Claims Billed With High-Severity-Level DRG Codes, and Claims Paid in Excess of Charges. This assignment hierarchy resulted in a sample frame of 3,422 unique Medicare claims in 3 risk categories totaling \$46,073,853. We further separated Claims Billed With High-Severity-Level DRG Codes into two categories based on the amount paid.⁸

Table 1: Risk Categories

		Number	Amount of
	Medicare Risk Area	of Claims	Payments
1.	Inpatient Manufacturer Credits for Replaced Medical		
	Devices	6	\$132,533
2.	Inpatient Claims Billed With High-Severity-Level DRG		
	Codes – Low Dollar	1,700	13,696,597
3.	Inpatient Claims Billed With High-Severity-Level DRG		
	Codes – High Dollar	848	17,762,823

⁷ To ensure that our overpayment extrapolation is valid, any sample items that have been reviewed or are currently under review by a RAC will be treated as non-errors. This adjustment results in a valid overpayment estimate regardless of when the RAC claims are identified. As an extra precaution, repayment of claims in the sampling frame reviewed by the RAC will be subtracted from the total overpayments.

⁸ Paid claims less than \$12,961 are in Stratum 2 and paid claims \$12,961 or greater are in Stratum 3.

Medicare Risk Area	Number of Claims	Amount of Payments
4. Inpatient Claims Paid in Excess of Charges	868	14,481,900
Total	3,422	\$46,073,853

SAMPLE UNIT

The sample unit was a Medicare paid claim.

SAMPLE DESIGN

We used a stratified sample. We stratified the sampling frame into four strata on the basis of the Medicare risk area and amount paid. All claims were unduplicated, appearing in only one area and only once in the entire sampling frame.

SAMPLE SIZE

We selected 246 claims for review as follows:

a , ,		Claims in	Claims in
Stratum	Medicare Risk Area	Sample Frame	Sample
1	Inpatient Manufacturer Credits for Replaced Medical Devices	6	6
2	Inpatient Claims Billed With High-Severity- Level DRG Codes – Low Dollar	1,700	80
3	Inpatient Claims Billed With High-Severity- Level DRG Codes – High Dollar	848	80
4	Inpatient Claims Paid in Excess of Charges	868	80
	TOTAL	3,422	246

Table 2: Claims by Stratum

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the claims within strata 2, 3, and 4. After generating the random numbers for strata 2, 3, and 4 we selected the corresponding claims in each stratum. We selected all claims in stratum 1.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to calculate our estimates. We used the lower-limit of the 90-percent confidence interval to estimate the amount of improper Medicare payments in our sampling frame during the audit period.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Stratum	Frame Size (Claims)	Value of Frame	Sample Size	Total Value of Sample	Number of Incorrectly Billed Claims in Sample	Value of Overpayments in Sample
1	6	\$132,533	6	\$132,533	6	\$18,034
2	1,700	13,696,597	80	656,444	16	32,141
3	848	17,762,823	80	1,730,356	7	89,859
4	868	14,481,900	80	1,424,885	8	81,447
Total	3,422	\$46,073,853	246	\$3,944,218	37	\$221,481

Table 3: Sample Results

ESTIMATES

Table 4: Estimates of Overpayments for the Audit Period

Limits Calculated for a 90-Percent Confidence Interval

Point Estimate	\$2,537,232
Lower limit	1,488,468
Upper limit	\$3,585,997

APPENDIX D: RESULTS OF REVIEW BY RISK AREA

Inpatient Risk Area	Selected Claims	Value of Selected Claims	Claims With Underpayments/ Overpayments	Value of Net Overpayments
Manufacturer Credits for Replaced Medical	6	\$132,533	6	\$18,034
Devices				
Claims Billed With High-Severity-Level	80	656,444	16	32,141
DRG Codes – Low Dollar				
Claims Billed With High-Severity-Level	80	1,730,356	7	89,859
DRG Codes – High Dollar				
Claims Paid in Excess of Charges	80	1,424,885	8	81,447
Inpatient Totals	246	\$3,944,218	37	\$221,481

Table 5: Sample Results by Risk Area

Notice: The table above illustrates the results of our review by risk area. In it, we have organized inpatient claims by the risk areas we reviewed. However, we have organized this report's findings by the types of billing errors we found at the Hospital. 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: NORTH CAROLINA BAPTIST HOSPITAL COMMENTS

\mathcal{W} Wake Forest

Baptist Medical Center

John D. McConnell MD Chief Executive Officer

Medical Center Boulevard Winston-Salem, NC 27157 p 336.716.3408

July 29, 2016

Lori S. Pilcher Regional Inspector General for Audit Services Department of Health & Human Services 61 Forsyth Street, SW Suite 3T41 Atlanta, Georgia 30303

Re: North Carolina Baptist Hospital OIG Draft Report Number: A-04-15-04036

Dear Ms. Pilcher:

We appreciate the opportunity to review the U.S. Department of Health and Human Services, Office of Inspector General (OIG) Draft Report entitled *Medicare Compliance Review of the North Carolina Baptist Hospital for Claims Paid from January 1, 2013 Through August 31, 2014* (the "Report") and submit responses to the proposed recommendations. In addition to being dedicated to providing the highest quality of care to our patients and serving our community, we are committed to ensuring that our practices comply with Medicare program standards. We have an active compliance and internal audit department, with professionals working closely with management and all levels of Hospital staff to support our efforts and continually improve our processes.

Overall, based on its findings the OIG recommends that North Carolina Baptist Hospital (the "Hospital or the "Provider") refund our Medicare contractor \$1,488,468 in estimated overpayments for the audit period for claims that were alleged to have been billed incorrectly. In addition, the OIG recommends that the Hospital strengthen its controls to ensure, "full compliance with Medicare requirements." Finally, the OIG recommends that we "exercise reasonable diligence to identify and return any additional overpayments received outside of our audit period, in accordance with the 60-day repayment rule."

As directed, this letter address each of the OIG's proposed findings, explaining our position regarding each. Overall, we disagree that any extrapolation is appropriate here, as there was no finding of sustained errors regarding our Hospital's DRG coding for inpatient admissions as confirmed during our exit conference. Because we disagree with several of the proposed findings and conclusions and intend to appeal adverse determinations, we respectfully disagree that denials of payment for certain sampled claims are accurate. With regard to the billing for medical devices replaced under warranty, *prior* to receiving notice of this audit, our compliance professionals had identified this area as one for focused review and had *already begun* the process of identifying any errors to refund any overpayments. Thus, we believe that our processes and controls demonstrate that our programs are effective.

Although our controls are effective, as part of our diligence in examining the issues raised, we have conducted an analysis of the proposed findings and items related to this Report to ensure that we comply with the "60 day rule" as suggested. At this time, based on our investigation of the issues raised and in

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15

accordance with the applicable legal standards, we did not identify refunds owed outside the audit period for these matters.

For ease of review, we have reproduced the findings identified in the draft Report together with our responses to each.

• OIG Finding: Billing Errors Associated with Inpatient Claims

The OIG auditors asserted that for a total of 37 of 246 inpatient claims, the Hospital made billing errors resulting in a net overpayment of \$221,481. For its draft Report, the OIG sorted these issues into different categories which we identify below.

• OIG Finding: Incorrectly Billed Diagnostic-Related-Group Codes

The Report asserts that for 34 inpatient claims, the Provider incorrectly coded certain diagnostic related groups ("DRGs") for beneficiaries' admissions. The OIG asserts that the alleged errors resulted in net overpayments of \$151,473.

The Hospital's Response:

The OIG stated that the total value of the sampled claims was \$3,944,218. The alleged overpayment divided by total value of the sample results in, *at most*, an error rate of less than 4% for this category of OIG-identified errors.¹ Even assuming *arguendo* that all of the OIG's recommendations are valid regarding the accuracy of our DRG coding, *this low error rate does not support the use of an extrapolated calculation of an alleged overpayment*. Indeed, as CMS own interpretive guidelines specify, Medicare contractors are instructed to *use statistical methods upon finding a "sustained or high level of payment error."* (*See*, Medicare Program Integrity Manual ("PIM") 8.4.1.4 (emphasis added)); echoing the legal standard Congress passed in Section 935 of the 2003 Medicare Prescription Drug Improvement and Modernization Act ("MMA"); (*See also, An Open Letter to Health Care Providers*, HHS OIG (November 20, 2001) (if net financial error rate is less than 5%, no additional sampling and extrapolation is required for providers subject to corporate integrity agreements (CIAs)); HHS Medicare Managed Care Manual, Chapter 7, Section 120.2.5 (CMS requires plans submit "accurate data" to support payment, with error rates *less than 5%*). Here, given the low error rate for all inpatient coding errors allegedly identified, *even assuming all the adverse findings are upheld on appeal*, an extrapolated overpayment estimate is not consistent with CMS or OIG standards.

Importantly, because we do not agree with the OIG conclusions regarding the proper coding for several sampled claims, we intend to appeal proposed denials for sampled claims. Thus, any final error rate will likely be further lowered upon completing the administrative review process.

¹ We acknowledge that the OIG audit process may have created multiple "strata" to separate issues into certain categories that support the proposed extrapolation. Logically, however, the strata and issues identified relate to the overall accuracy of the trained professionals who coded the inpatient records for most issues identified. Thus, measurement of an "error rate" by grouping issues in accordance with the underlying processes is appropriate to support any inferences.

Although our Hospital has appropriate policies, training and systems of controls for our DRG coding practices, we acknowledge that human error may contribute to incorrect code selection in relatively isolated instances. To further strengthen our compliance efforts, we have adopted additional internal reviews and training sessions for our staff. We also have retained third party auditors for ongoing claims reviews, with training support included as part of that program. Ultimately, we believe we have a system of strong controls to prevent incorrect billing of claims.

• OIG Finding: Incorrectly Billed as Inpatient

For one of the 246 inpatient claims reviewed, the OIG identified an error in billing associated with the Hospital's transition to an electronic medical records ("EMR") system. Specifically, in one instance, less than two weeks after the "go live" date for the Hospital's new EMR, one of our treating physicians appropriately documented the beneficiary's medical record to reflect orders and treatment for outpatient observation services for the individual. Inexplicably, however, there was a technical error in transmitting that status order and the order for observation services was recorded as an order for inpatient admission and billed as such by our staff. Due to this error, the Hospital was allegedly overpaid \$35,141.²

The Hospital's Response: Incorrectly Billed As Inpatient

Based on our discussions with the OIG auditors, we understand that in reviewing *each* of the 246 inpatient claims, the auditors verified that the treating physicians appropriately documented orders for inpatient admissions in each patient's record. Importantly, the OIG auditors reviewed 239 charts for the period after our physicians began order entries using the new EMR and did not identify another such error. Rather, *in this one instance*, the physician's documentation supports admission for observation services, but the order entered in the Hospital's EMR was for inpatient admission. As the OIG observed, because this occurred less than two weeks after the EMR "go live" date, it seems that an *isolated* technical issue caused the mistake.

The logical inference that can be made from this finding relates to how our physicians entered admission orders in a patient's record, not how our coders assigned the appropriate DRG to a claim. Accordingly, we separate this finding in calculating the error rate that could be logically inferred, with the result that this finding was made in far less than 1% of the cases reviewed. Although the Hospital will refund any overpayment for this identified claim, we respectfully disagree that there is a basis for including this finding to calculate an extrapolated overpayment for our coding compliance.

• OIG Finding: Manufacturer Credits for Replaced Medical Devices Not Reported

For 4 of the 246 inpatient claims, the OIG found that the Hospital received reportable medical device credits from a manufacturer for replaced devices but did not adjust its inpatient claims with the proper condition and value codes to reduce payment as required. As a result, the OIG states that we were overpaid \$27,500.

 $^{^{2}}$ As stated in the draft Report, this total reflects a complete disallowance of reimbursement, without any payment for the medically necessary services rendered. Because this figure overestimates the amount paid in error, *the Hospital's actual error rate is even lower*.

In its draft Report, the OIG states that the Hospital attributed these errors due to a lack of controls in place and a lack of staff training.

The Hospital's Response: Manufacturer Credits for Replaced Medical Devices Not Reported

Our Hospital had and continues to have policies and certain controls in place to support accurate billing for credited device replacements. Because our staff understood the complexities involved in identifying and reporting such credits, *as part of our controls*, we planned additional audits to monitor our practices. Therefore, our compliance team was already in the process of auditing relevant claims *prior* to the OIG's arrival.

As stated, our compliance staff had already begun a comprehensive internal audit regarding this issue prior to learning of the government's planned review. Indeed, our staff had initiated a review of *all* claims dating back to 2007 for devices replaced under warranty or credit as part of our ongoing monitoring of this issue.

At the entrance conference and as requested by the OIG, our staff excluded the 4 sampled claims from our own review. Our internal auditors completed their comprehensive review, and corrected any errors identified in the remaining claims. We have refunded any overpayments to our Medicare Administrative Contractor. In addition, we adopted processes and controls to coordinate efforts among operating room clinical professionals and administrative staff, vendors, supply chain management, the accounts receivable department as well as our revenue cycle teams to support accurate billing. In addition, we enhanced our policy to include reconciliation with our vendors to ensure credits are recorded and coded properly. We have already re-trained our clinical and administrative staff about the issue and our more enhanced policy.

• OIG Finding: Incorrect Discharge Status

The OIG asserts that for 1 of the 246 inpatient claims reviewed, Hospital staff incorrectly billed one patient's discharge status with a disposition to the beneficiary's home instead of a transfer to a home health agency. As a result, the OIG states that the Hospital was overpaid \$7,367.

The Hospital's Response: Incorrect Discharge Status

As part of the OIG audit process, we understand that *the accuracy of Hospital discharge coding was assessed in all 246 inpatient cases reviewed*. In the sole instance identified, it appears that at the time the inpatient claim was coded and submitted, the medical record did not include any information to suggest that the patient would be discharged with home health services. Instead, it appears that nurses, discharge planners and the attending physician documented a disposition home for the beneficiary, which was coded on the claim. After the claim was submitted, it appears a late entry was made in the patient's chart to suggest that discharge was made with home health services. Unfortunately, due to

timing of the entry and the fact that the CMS common working file (CWF) did not identify this issue, this error occurred.³

Here again, based on our understanding that the OIG auditors assessed the propriety of discharge disposition in all sampled claims, the identified error occurred in far less than 1% of the audited claims and represents an inadvertent, isolated mistake. Accordingly, we respectfully request that the amount of any overpayment related to this issue not be included in calculating any extrapolation.

The Provider Requests That No Extrapolated Overpayment Be Calculated As Proposed In The Draft Report

As explained above, we respectfully disagree with the proposed recommendation to extrapolate findings to assert that the Hospital refund \$1,488,468 in estimated overpayments to Medicare. Even assuming all of the OIG's findings per sampled claims are upheld on appeal, the error rate of less than 5% does not support a conclusion that an extrapolated overpayment is reasonable here. Moreover, as explained to us during the course of the audit and at the exit conference, the OIG auditors did not contend that the errors identified in the draft Report reflect systemic problems across the spectrum of claims that were submitted for the time period reviewed.⁴

The OIG draft Report makes very broad conclusions about the Hospital's compliance efforts by sampling certain claims from so-called, pre-selected "high risk areas." As explained, the sampled claims represent multiple different underlying processes and methods used in coding claims, so that logical inferences must be carefully drawn to ensure that conclusions are based on valid inferences from *representative* samples. Although statistical sampling may support overpayment demands, any sample to support an extrapolation must be *valid* to satisfy due process standards. (*See Chaves County Home Health Services* Inc. v. Sullivan, 931 F.2d 914 (D.C. Cir. 1991) cert. denied, 502 U.S. 1091 (1992); In re Chevron USA, 109 F.3d 1016, 1019-20) (5th Cir. 1997)). The Medicare PIM confirms that statistically *valid* samples be drawn and that statistically *valid methods* be used to project any overpayment. (*See*, PIM, Chapter 8.4.1.1). Fundamentally, any inferences drawn from review of issues must be logical to support the validity of statistical extrapolation. We respectfully disagree with the OIG's finding that an inadvertent or low level of error arising from distinct causes can be accumulated to support an extrapolated overpayment.

For instance, there was *one case* (out of 246 included in the sample), in which a technical error associated with the Hospital's new EMR system resulted in a mistaken order entry. The overwhelming majority of the sampled claims are for the period after the EMR was in place – with no other mistaken physician order entries identified. Because the particular case happened to have been placed into a preconceived (and perhaps biased) stratum that was associated with coding matters, the value of the entire admission

³ Under a limitation of liability theory, based on our staff's knowledge at the time of discharge and coding of the claim, we are investigating whether the Hospital is responsible for the assessed overpayment. (See, CMS Response to May 2014 OIG Report, *Medicare Inappropriately Paid Hospitals' Inpatient Claims Subject To The Postacute Care Transfer Policy* (A-09-13-02036) (based on the OIG findings, CMS made updates to the CWF to resolve "some" of the identified vulnerabilities for transfer billing).

⁴ We understand that the medical device "stratum" was not included in calculations to estimate the alleged overpayment. As explained, we conducted a comprehensive review dating back to 2007 for reported credits and have already corrected any errors identified and refunded any overpayments to CMS.

was "counted" as an error related to the performance of our coding staff. Such a conclusion is not valid. The EMR order entry process has nothing to do with how our coders analyze records and apply standards to select a particular DRG or complication. Ultimately, it is not valid to extrapolate this finding across the population as it does not represent a "category" of errors associated with the sampling method used.

Empirical evidence regarding the lack of precision in each strata that the OIG created further demonstrates that the methods used here are not valid. Specifically, the auditors' calculated precision levels as low as 41- 45% in at least one stratum. When the precision of a sample is less than 50%, it is not possible to predict the actual overpayment in that particular stratum with confidence. Any assertion that the auditors "correct" for such imprecision by applying a "90% confidence interval" is not appropriate: the calculation of a 90% confidence interval is based on assumptions that the data points are distributed with far greater precision.

Ultimately, we respectfully request that no extrapolated overpayment be calculated. The audit findings, even if upheld through the administrative appeals process, do not support concluding that our Hospital had a high error rate such that extrapolation is appropriate.

Conclusion

North Carolina Baptist Hospital has a strong compliance program to which we have committed appropriate resources to support accurate billing and coding. We have policies, training and ongoing third party reviews to enhance Hospital coding and further strengthen our compliance efforts. As noted, we actively monitor risk areas and conduct internal audits as appropriate.

Overall, we respectfully disagree with the Report's conclusions. We do not agree with all reviewer adverse determinations regarding appropriate coding in cases and intend to appeal those cases. Nevertheless, even if all of the OIG coding conclusions are accurate, the Hospital's error rates inferred from the categories reviewed do not support extrapolation.

Thank you for your consideration, and should you have any questions, please do not hesitate to contact me.

Sincerely sto heard

John D. McConnell, M.D. Chief Executive Officer

JDM:YDL:kds

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