MEDICARE COMPLIANCE
REVIEW OF UNIVERSITY OF
NORTH CAROLINA HOSPITALS
FOR THE PERIOD JANUARY 1, 2011,
THROUGH SEPTEMBER 30, 2012

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

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EXECUTIVE SUMMARY

*University of North Carolina Hospitals did not fully comply with Medicare requirements for billing inpatient and outpatient services, resulting in estimated overpayments of at least $2.4 million over nearly 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 2012, Medicare paid hospitals $148 billion, which represents 43 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 University of North Carolina Hospitals (the Hospital) 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.

The Hospital is an 830-bed acute care facility located in Chapel Hill, North Carolina. According to CMS’s National Claims History data, Medicare paid the Hospital approximately $371 million for 16,145 inpatient and 248,812 outpatient claims for services provided to beneficiaries during January 1, 2011, through September 30, 2012 (audit period).

Our audit covered $33,135,058 in Medicare payments to the Hospital for 2,462 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 251 claims with payments totaling $3,539,265. These 251 claims had dates of service in our audit period and consisted of 244 inpatient and 7 outpatient claims.

WHAT WE FOUND

The Hospital complied with Medicare billing requirements for 192 of the 251 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 59 claims, resulting in net overpayments of $451,995 for the audit period. Specifically, 58 inpatient claims had billing errors resulting in net overpayments of $451,412 and 1 outpatient claim had a billing error resulting in an overpayment.
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 $2,492,687 for the audit period.

WHAT WE RECOMMEND

We recommend that the Hospital:

• refund to the Medicare contractor $2,492,687 in estimated overpayments for the audit period for claims that it incorrectly billed and

• strengthen controls to ensure full compliance with Medicare requirements.

UNIVERSITY OF NORTH CAROLINA HOSPITALS COMMENTS AND OUR RESPONSE

University of North Carolina Hospitals Comments

In written comments on our draft report, the Hospital agreed that 3 of the 59 claims were billed incorrectly and described the actions it had taken or planned to take to address them. The Hospital generally disagreed with our determinations on the remaining 56 claims and provided reasons why it disagreed.

The Hospital disagreed with our determinations related to all 37 claims that we identified as incorrectly billed as inpatient and stated that it intends to appeal the denial of those claims. The Hospital did acknowledge incorrect coding in “limited instances” for the 19 claims we identified with incorrect DRG codes. For one of those 19 claims, which also contained the incorrect discharge status code, the Hospital stated that it coded the discharge status code as documented in the patient’s chart and requested that the finding be removed from the report.

The Hospital further stated that our sample selection violated legal due process standards and valid statistical methods. The Hospital requested that no extrapolation be performed, but if performed, requested that any calculated overpayments be modified to compensate the Hospital for medically necessary care.

Our Response

During our audit, we used an independent medical review contractor to determine whether certain claims in our sample, including the claims in question, met medical necessity requirements and were properly coded. The contractor examined all of the medical records and documentation submitted for these claims and determined that the Hospital incorrectly billed Medicare Part A for these claims. On the basis of the contractor’s conclusions, we maintain that the Hospital billed the disputed claims incorrectly. Additionally, the Hospital’s not being at fault
for the incorrect discharge status code on one claim does not change our determination that the claim was billed in error and the related overpayment should be included in our sample results.

Regarding the Hospital’s objections to our statistical sampling and extrapolation, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare. The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology. The use of statistical sampling and extrapolation to determine overpayment amounts in Medicare does not violate due process because the auditee is given the opportunity to appeal the audit results through the Medicare appeals process.
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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 2012, Medicare paid hospitals $148 billion, which represents 43 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 University of North Carolina Hospitals (the Hospital) 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

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

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. Chapter 23, section 20.3, of the Manual states that providers must use HCPCS codes for most outpatient services.

**University of North Carolina Hospitals**

The Hospital is an 830-bed acute care facility located in Chapel Hill, North Carolina. According to CMS’s National Claims History (NCH) data, Medicare paid the Hospital approximately $371 million for 16,145 inpatient and 248,812 outpatient claims for services provided to beneficiaries during January 1, 2011, through September 30, 2012 (audit period).

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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 $33,135,058 in Medicare payments to the Hospital for 2,462 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 251 claims with payments totaling $3,539,265. These 251 claims had dates of service in our audit period and consisted of 244 inpatient and 7 outpatient claims.

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 93 claims to medical review and coding review to determine whether the services were medically necessary and 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 192 of the 251 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 59 claims, resulting in net overpayments of $451,995 for the audit period. Specifically, 58 inpatient claims had billing errors resulting in net overpayments of $451,412, and 1 outpatient claim had a billing error resulting in an overpayment of $583. 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 $2,492,687 for the audit period.

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

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 58 of the 244 inpatient claims that we reviewed. These errors resulted in net overpayments of $451,412. One claim contained more than one type of error.²

² For randomly 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 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 37 of the 244 inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that should have been billed as outpatient or outpatient with observation services. The Hospital did not offer a cause for these errors because it did not believe the claims were billed in error.

As a result of these errors, the Hospital received overpayments of $293,230.3

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 19 of the 244 inpatient claims, the Hospital submitted claims to Medicare with incorrect DRG codes. For two claims, the Hospital stated that at least part of the miscoding was due to human error.4 For these two claims, a Hospital coder entered information describing a procedure code incorrectly into the Hospital’s coding software. The Hospital did not offer a cause for the remaining errors because it did not believe the claims were billed in error.

As a result of these errors, the Hospital received net overpayments of $144,958.

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).

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3 The Hospital 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 contractor prior to the issuance of our draft report.

4 For one of these two claims, we identified two errors with the coding of the claim. The Hospital agreed with one error we identified, but disagreed with the other.
For 2 of the 244 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 because of a lack of coordination between Hospital staff in various departments and representatives for the device manufacturer.

As a result of these errors, the Hospital received overpayments of $11,600.

**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)).

For 1 of the 244 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 said that this error occurred because the patient arranged for home health care after discharge and the Hospital was not aware of the home health services.

As a result of this error, the Hospital received overpayments of $1,624.

**BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS**

The Hospital incorrectly billed Medicare for 1 of the 7 outpatient claims that we reviewed. This error resulted in overpayments of $583.

**Manufacturer Credits for Replaced Medical Devices Not Reported or Obtained**

Federal regulations require a reduction in the OPPS payment for the replacement of an implanted device if (1) the device is replaced without cost to the provider or the beneficiary, (2) the provider receives full credit for the cost of the replaced device, or (3) the provider receives partial credit equal to or greater than 50 percent of the cost of the replacement device (42 CFR § 419.45). The CMS *Provider Reimbursement Manual* (PRM) reinforces these requirements in additional detail (Pub. No. 15-1).

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.”

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5 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.”
CMS guidance in Transmittal 1103, dated November 3, 2006, and the Manual, chapter 4, section 61.3, explain how a provider should report no-cost and reduced-cost devices under the OPPS. For services furnished on or after January 1, 2007, CMS requires the provider to report the modifier “FB” and reduced charges on a claim that includes a procedure code for the insertion of a replacement device if the provider incurs no cost or receives full credit for the replaced device. If the provider receives a replacement device without cost from the manufacturer, the provider must report a charge of no more than $1 for the device.

For 1 of the 7 outpatient claims, the Hospital incorrectly billed Medicare for medical devices that were under warranty. The Hospital received a full credit for a replaced medical device but did not report the “FB” modifier and reduced charges on its claim. The Hospital said that this error occurred due to a lack of coordination between Hospital staff in various departments and representatives for the device manufacturer.

As a result of this error, the Hospital received overpayments of $583.

OVERALL ESTIMATE OF OVERPAYMENTS

Based on our sample results, we estimated that the Hospital received overpayments of at least $2,492,687 for the audit period.

RECOMMENDATIONS

We recommend that the Hospital:

- refund to the Medicare contractor $2,492,687 in estimated overpayments for the audit period for claims that it incorrectly billed and
- strengthen controls to ensure full compliance with Medicare requirements.

UNIVERSITY OF NORTH CAROLINA HOSPITALS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

University of North Carolina Hospitals Comments

In written comments on our draft report, the Hospital agreed that 3 of the 59 claims were billed incorrectly and described the actions it had taken or planned to take to address them. The Hospital generally disagreed with our determinations on the remaining 56 claims and provided reasons why it disagreed.

The Hospital disagreed with our determinations related to all 37 claims that we identified as incorrectly billed as inpatient and stated that it intends to appeal the denial of those claims. The Hospital did acknowledge incorrect coding in “limited instances” for the 19 claims we identified with incorrect DRG codes. For one of those 19 claims, which also contained the incorrect
discharge status code, the Hospital stated that it coded the discharge status code as documented in the patient’s chart and requested that the finding be removed from the report.

The Hospital further stated that our sample selection violated legal due process standards and valid statistical methods. The Hospital requested that no extrapolation be performed, but if performed, requested that any calculated overpayments be modified to compensate the Hospital for medically necessary care.

**Office of Inspector General Response**

As we indicated in Appendix A, during our audit, we used an independent medical review contractor to determine whether certain claims in our sample, including the claims in question, met medical necessity requirements and were properly coded. The contractor examined all of the medical records and documentation submitted for these claims and determined that the Hospital incorrectly billed Medicare Part A for 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. Additionally, the Hospital’s not being at fault for the incorrect discharge status code on one claim does not change our determination that the claim was billed in error and the related overpayment should be included in our sample results.

Regarding the Hospital’s objections to our statistical sampling and extrapolation, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare. *See Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010). Use of sampling and extrapolation has also been upheld in the context of extrapolating an overpayment for a larger population based on determinations of lack of medical necessity within a smaller sample. *See United States ex rel. Martin v. Life Care Centers of America, Inc.*, 2014 LEXIS 142660 at 48-50, in which the court concluded the following: “The fact that these factors [differing among patients] exist and are likely unique to each patient does not necessarily preclude the use of statistical sampling,” and “If all of the claims were exactly the same in every respect, there would be no need for statistical sampling and extrapolation in litigation because each individual unit would be identical, and it would be relatively simple to formulate a mathematical calculation for a large number of claims.” The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology. *See 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). 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.

The use of statistical sampling and extrapolation to determine overpayment amounts in Medicare does not violate due process because the auditee is given the opportunity to appeal the audit results through the Medicare appeals process. *See Transyd Enter., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *34 (S.D. Tex. 2012).
We acknowledge the Hospital’s efforts to strengthen its compliance with Medicare requirements.

The Hospital’s comments are included in their entirety as Appendix E.
APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $33,135,058 in Medicare payments to the Hospital for 2,462 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 251 claims with payments totaling $3,539,265. These 251 claims consisted of 244 inpatient and 7 outpatient claims and had dates of service from January 1, 2011, through September 30, 2012.

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 93 claims to medical review and coding review to determine whether the services were medically necessary and properly coded.

We limited our review of the Hospital’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 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.

We conducted our fieldwork at the Hospital from October 2013 through August 2014.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Hospital’s inpatient and outpatient 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 251 claims (244 inpatient and 7 outpatient) totaling $3,539,265 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 93 claims met medical necessity and 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 and outpatient 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 $370,986,381 for 16,145 inpatient and 248,812 outpatient claims for services provided to beneficiaries during the audit period.

We obtained a database of claims from the NCH data totaling $260,420,768 for 9,097 inpatient and 81,956 outpatient claims in 27 risk areas. From these 27 areas, we selected 5 consisting of 7,708 claims totaling $118,675,688 for further review.

We then removed the following:

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

We assigned each claim that appeared in multiple risk areas to just one area based on the following hierarchy: Manufacturer Credits for Replaced Medical Devices, Claims Billed With High-Severity-Level DRG Codes, Claims Paid in Excess of Charges, and Short Stays. This resulted in a sample frame of 2,462 unique Medicare claims in 5 risk categories totaling $33,135,058.

<table>
<thead>
<tr>
<th>Medicare Risk Area</th>
<th>Number of Claims</th>
<th>Amount of Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Inpatient Manufacturer Credits for Replaced Medical Devices</td>
<td>4</td>
<td>$111,017</td>
</tr>
<tr>
<td>2. Inpatient Claims Billed With High-Severity-Level DRG Codes</td>
<td>1,515</td>
<td>20,520,595</td>
</tr>
<tr>
<td>3. Inpatient Claims Paid in Excess of Charges</td>
<td>346</td>
<td>7,500,363</td>
</tr>
<tr>
<td>4. Inpatient Short Stays</td>
<td>590</td>
<td>4,899,922</td>
</tr>
<tr>
<td>5. Outpatient Manufacturer Credits for Replaced Medical Devices</td>
<td>7</td>
<td>103,161</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2,462</strong></td>
<td><strong>$33,135,058</strong></td>
</tr>
</tbody>
</table>
SAMPLE UNIT

The sample unit was a Medicare paid claim.

SAMPLE DESIGN

We used a stratified sample. We stratified the sampling frame into five strata based on the Medicare risk area. All claims were unduplicated, appearing in only one area and only once in the entire sampling frame.

SAMPLE SIZE

We selected 251 claims for review as follows:

<table>
<thead>
<tr>
<th>Stratum</th>
<th>Medicare Risk Area</th>
<th>Claims in Sample Frame</th>
<th>Claims in Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Inpatient Manufacturer Credits for Replaced Medical Devices</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>Inpatient Claims Billed With High-Severitv-Level DRG Codes</td>
<td>1,515</td>
<td>100</td>
</tr>
<tr>
<td>3</td>
<td>Inpatient Claims Paid in Excess of Charges</td>
<td>346</td>
<td>70</td>
</tr>
<tr>
<td>4</td>
<td>Inpatient Short Stays</td>
<td>590</td>
<td>70</td>
</tr>
<tr>
<td>5</td>
<td>Outpatient Manufacturer Credits for Replaced Medical Devices</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td>2,462</td>
<td>251</td>
</tr>
</tbody>
</table>

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 strata 1 and 5.

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

### SAMPLE RESULTS

<table>
<thead>
<tr>
<th>Stratum</th>
<th>Frame Size (Claims)</th>
<th>Value of Frame</th>
<th>Sample Size</th>
<th>Total Value of Sample</th>
<th>Number of Incorrectly Billed Claims in Sample</th>
<th>Value of Overpayments in Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
<td>$111,017</td>
<td>4</td>
<td>$111,017</td>
<td>2</td>
<td>$11,600</td>
</tr>
<tr>
<td>2</td>
<td>1,515</td>
<td>20,520,595</td>
<td>100</td>
<td>1,368,697</td>
<td>9</td>
<td>69,673</td>
</tr>
<tr>
<td>3</td>
<td>346</td>
<td>7,500,363</td>
<td>70</td>
<td>1,461,315</td>
<td>13</td>
<td>178,153</td>
</tr>
<tr>
<td>4</td>
<td>590</td>
<td>4,899,922</td>
<td>70</td>
<td>495,075</td>
<td>34</td>
<td>191,986</td>
</tr>
<tr>
<td>5</td>
<td>7</td>
<td>103,161</td>
<td>7</td>
<td>103,161</td>
<td>1</td>
<td>583</td>
</tr>
<tr>
<td>Total</td>
<td>2,462</td>
<td>$33,135,058</td>
<td>251</td>
<td>$3,539,265</td>
<td>59</td>
<td>$451,995</td>
</tr>
</tbody>
</table>

### ESTIMATES

Estimates of Overpayments for the Audit Period

* Limits Calculated for a 90-Percent Confidence Interval

- Point Estimate: $3,566,481
- Lower limit: $2,492,687
- Upper limit: $4,640,276
APPENDIX D: RESULTS OF REVIEW BY RISK AREA

<table>
<thead>
<tr>
<th>Risk Area</th>
<th>Selected Claims</th>
<th>Value of Selected Claims</th>
<th>Claims With Underpayments/Overpayments</th>
<th>Value of Net Overpayments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short Stays</td>
<td>70</td>
<td>495,075</td>
<td>34</td>
<td>$191,986</td>
</tr>
<tr>
<td>Claims Paid in Excess of Charges</td>
<td>70</td>
<td>1,461,315</td>
<td>13</td>
<td>178,153</td>
</tr>
<tr>
<td>Claims Billed With High-Severity-Level DRG Codes</td>
<td>100</td>
<td>1,368,697</td>
<td>9</td>
<td>69,673</td>
</tr>
<tr>
<td>Manufacturer Credits for Replaced Medical Devices</td>
<td>4</td>
<td>$111,017</td>
<td>2</td>
<td>11,600</td>
</tr>
<tr>
<td>Inpatient Totals</td>
<td>244</td>
<td>$3,436,104</td>
<td>58</td>
<td>$451,412</td>
</tr>
<tr>
<td>Outpatient</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturer Credits for Replaced Medical Devices</td>
<td>7</td>
<td>$103,161</td>
<td>1</td>
<td>$583</td>
</tr>
<tr>
<td>Outpatient Totals</td>
<td>7</td>
<td>$103,161</td>
<td>1</td>
<td>$583</td>
</tr>
<tr>
<td>Inpatient and Outpatient Totals</td>
<td>251</td>
<td>$3,539,265</td>
<td>59</td>
<td>$451,995</td>
</tr>
</tbody>
</table>

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

Re: University of North Carolina Hospitals (UNC Hospitals)  
OIG Draft Report Number: A-04-13-04018

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 University of North Carolina Hospitals for the Period January 1, 2011, Through September 30, 2012 (the "Report") and submit responses to each of the proposed findings.

Overall, based on its findings OIG recommends that the Hospital refund its Medicare contractor $2,492,687 in estimated overpayments for the audit period for claims that were alleged to have been billed incorrectly. In addition, OIG recommends that UNC Hospitals (the "UNC Hospitals or the "Provider") strengthen its controls to ensure compliance with Medicare requirements.

UNC Hospitals takes compliance with program requirements seriously and has devoted extensive resources and adopted comprehensive measures to support its billing programs. Although we acknowledge that in limited instances, human error did lead to inaccurate billing, the Provider takes exception to several of the proposed findings regarding the overall accuracy of its admissions and coding programs as well as the assertion that UNC Hospitals does not have adequate internal controls to prevent billing errors. With regard to medical devices for which
credits were processed, we have developed more comprehensive measures to ensure that bills are coded correctly, incorporating both internal and external controls to ensure ongoing compliance.

UNC Hospitals respectfully requests that the OIG reconsider its findings as identified in the draft Report based on information and documentation supplied in the course of the review as well as information submitted with the August 2014 exit conference. In particular, because we understand that OIG contracted with [redacted] medical and coding professionals to review certain sampled claims, our physician advisor, case management and coding staff were not able to participate in discussions with [redacted] to correct any misunderstandings before the draft Report was prepared. As highlighted herein, because we believe that the coding and admissions denials issued by [redacted] contradict well understood standards that CMS has adopted, the inability to have any peer-to-peer discussions left UNC Hospitals without guidance as to why admissions or processes were viewed as “non-compliant” in certain instances. 6

Moreover, as OIG noted in the draft, since the [redacted] medical reviewers do not dispute that medically necessary care was provided in the cases reviewed, we request that the calculated overpayments, at a minimum, be modified to compensate the Provider for appropriate care as explained further below. In addition, because we believe that the sampling method and calculations have not been adjusted to account for the inherent bias that occurs when sampling patient admissions with widely variable payments, we respectfully request that no extrapolated calculation be performed to assess an overpayment. At a minimum, we request that in the final report, OIG recommend that revised payment estimates be calculated in each of the sampled cases to account for appropriate reimbursement in each before an extrapolation is performed.

For ease of review, we have reproduced the Report findings together with our responses below.

6Office of Inspector General Note — We redacted the name of the medical review contractor from the Hospital’s comments.
Billing Errors Associated with Inpatient Claims

OIG Finding: Incorrectly Billed as Inpatient

The Report asserts that for 37 of the 244 inpatient claims, UNC Hospitals incorrectly billed Medicare Part A for “short stays” or certain admissions that should have been billed as outpatient services or outpatient with observation services. For these claims, the Report states that the Provider was overpaid $293,230.

UNC Hospitals Response: The Claims For Admissions For Each Patient In the Sample Were Correctly Billed Under Part A For Medically Necessary Inpatient Care.

UNC Hospitals disputes the findings denying coverage for the selected inpatient admissions and intends to appeal any adverse determinations.

At the outset, the Report states that OIG sampled “short stay” claims in its review for the UNC Hospitals. Because these “short stay” claims sampled include a large number of patient admissions that spanned several days of both outpatient and inpatient care, it is unclear why these cases were included in the sample.

Importantly, for the 2011-2012 claims reviewed here, the applicable Medicare Benefit Policy Manual, Chapter 1, Section 10 stated that generally, a hospital “inpatient” is someone formally admitted to a hospital “with the expectation that he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred...” CMS has confirmed repeatedly that observation care should “usually” last under 24 hours, “and should rarely take longer than 48 hours.” (See, e.g., CMS Memorandum Report, Hospitals’ Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries (EI-02-12-00040) (July 29, 2013). In applying this standard and reviewing the spectrum of care
delivered, the Provider believes that the patients were correctly admitted as inpatients when their conditions did not improve after appropriate outpatient treatments.

For example, several of the patients whose claims were reviewed presented to the UNC Hospitals’ emergency room (“ED”) for a period of several hours (for some, 24 hours or more) before their conditions worsened, or they had evidence of acute conditions for which inpatient care was ordered appropriately. In multiple cases, the patients presented to the ED with acute symptoms for which they were evaluated and treatments delivered. When the patients were treated over time as outpatients, some had further declines for which inpatient admissions were appropriately ordered. Although some were treated on an outpatient basis for up to 48 hours and were not able to be safely discharged, in accordance with the Manual guidance, the physicians admitted them as inpatients based on the severity of their illnesses and intensity of services required to care for each.

Although many sampled claims were for patients who initially were treated in the emergency room, there are instances where an attending surgeon or interventionalist ordered inpatient care after the patient had complications that required more extensive inpatient medical treatments appropriately delivered to inpatients. Because the physicians have documented concerns about their patients’ conditions, including the need for inpatient care for more than 24 hours, it is unclear why determined that the claim was improperly billed.

- **Applying Hindsight Standards, Medical Reviewers Improperly Denied Inpatient Admissions For Certain Claims.**

In CMS’ own words and in accordance with its guidelines, when making inpatient admission determinations, treating physicians should consider the “medical predictability of something adverse happening to the patient.” (MBPM, CMS Pub. 100-2, Ch. 1, § 10) (emphasis added). Accordingly, any evaluation of a physician’s medical decision to admit a
patient must consider the medical facts available at the time of the decision. (See HCFA Ruling No. HCFAR-93-1; see also In the Case of Sacred Heart Hospital, DAB-MAC, (Nov. 10, 2009) at 10) (the “foreseeable adverse effects” related to the patient’s health condition were of such severity to support inpatient hospital care). Blurred statements explaining that certain denials were based on what did or did not happen to a patient after admission suggest that their decisions were not based on what was known when the physician admitted the beneficiary for inpatient care.

Similarly, in denying reimbursement for inpatient care for other claims, narratives explain that inpatient admissions were inappropriate because there was “no worsening of the patient’s condition” or because there was no “further” complication for the patient after admission. Knowing long after care was provided that a patient’s condition did not worsen as the basis for a denial is inconsistent with program standards that the medical necessity of inpatient admissions is based on the patient information available to the attending physician at the time of admission.

- For Several Of The Sampled Cases, Patients Presented With Conditions That Required Inpatient Hospital Admissions In Accordance With InterQual Guidelines.

As required by Medicare, UNC Hospitals employs an extensive system of utilization reviews to ensure that patients are appropriately admitted for hospital care. To ensure accuracy, we employ case managers who have ongoing training regarding Medicare standards for admission reviews, including how to apply the relevant InterQual criteria to assess the severity of a patient’s illness, together with the intensity of services required to care for the condition. Although not developed by CMS, the InterQual criteria are used by CMS and its contractors to determine coverage for inpatient care and have been afforded “substantial deference” by the
Medicare Appeals Council in admission determinations. (See, e.g., Sacred Heart Hospital v. First Coast Service Options at 8 (DAB Nov. 10, 2009); Triumph Hospital Detroit v. MPRO (QIO) at 6 (DAB Oct. 27, 2009)).

For several cases reviewed in the audit, objective criteria using the InterQual standard supports the attending physicians’ decisions to admit patients for inpatient care. Indeed, in several sampled cases, patients presented with objective signs of clinical acuity (e.g., abnormal lab results, etc.) and required an inpatient intensity of care so they were admitted. In other instances, patients were treated initially in outpatient observation status in the ED for 24-48 hours before their physicians decided to admit them when clinical findings did not support discharge, lab tests documented significant findings or patient conditions worsened.

UNC Hospitals recognizes that there can be instances in which reviewers may not have considered the same InterQual screening tool that its case managers may have used, leading to a different outcome in certain cases. For instance, if a patient presents with complex symptoms that could arise from an acute cardiac injury or be related to acute congestive heart failure, case managers and physicians could reference InterQual screening criteria for either condition as the primary concern to assess whether an admission was supported for the patient. It is possible that the patient’s condition and care requirements are consistent with the criteria for inpatient admission under the clinical guideline for acute cardiac concerns but not satisfy criteria for admission if the standard for heart failure were applied. For this reason, the opportunity to discuss findings with could help clarify how determinations should be made.

**Conclusion: Medical Necessity Denials**

As explained, we believe that we have strong internal controls to support appropriate billing for Medicare inpatient admissions. We have devoted extensive resources and education
to ensuring that its inpatient admissions are billed in compliance with CMS standards. Although the decision to admit each patient is a fact-specific, prospective determination for a physician, our case management team reviews those decisions using appropriate standards of care as well as recognized standards. Both internal and external, independent reviews are conducted to confirm accurate billings. Because UNC Hospitals believes its billing for inpatient care satisfied applicable Medicare coverage requirements, we renew our request for an opportunity to engage in a peer-to-peer discussion with medical reviewers before the Report is finalized.

**OIG Finding: Incorrectly Billed Diagnosis-Related Group Codes**

OIG auditors asserted that for 19 of the 244 inpatient claims, UNC Hospitals submitted claims to Medicare with incorrect DRG codes, resulted in an alleged overpayment of $144,958.

**UNC Hospitals Response: Incorrectly Billed Diagnosis-Related Group Codes**

Although we acknowledge that human error resulted in incorrect coding in limited instances, we dispute downcoding of claims in the remaining cases based on our understanding and application of guidelines in the *ICD-9-CM Official Guidelines for Coding and Reporting* as well as guidance and examples provided in the American Hospital Association’s *Coding Clinic* guidelines, both of which are considered by CMS to be the standard used to ensure accurate ICD coding and DRG assignment.

For instance, several of the claims were identified as having improper coding for patients who were admitted to UNC Hospitals for treatment for acute renal failure. Because there are specific directives regarding how clinical information documented in a patient’s record is sequenced to determine appropriate coding in these complex cases, our staff followed the *Coding Clinic* guidelines to submit claims. It appears, however, that determinations were
based on a different sequencing method that resulted in a determination that particular claims were overpaid.

Different interpretations regarding how the *Coding Clinic* should be applied resulted in overpayment assessments in other sampled claims. For instance, although the *Coding Clinic*, First Quarter 2001, pp. 5-6 and Second Quarter 2000, pp.17-18, permits coders to consider medical information about a patient’s hospitalization from lab reports issued after a patient is discharged (as well as all documentation noted in the patient chart, etc.) to support accurate coding, reviewers did not factor post-discharge lab results into its adverse determination in at least one case. Although we recognize that we have the right to appeal these denials, we request the opportunity to meet with reviewers to discuss their findings in view of the different interpretations of the *Coding Clinic* guidance.

**Conclusion: Incorrectly Billed Diagnosis-Related Group Codes**

UNC Hospitals acknowledges that despite strong internal controls to prevent errors in claim submission, human error was identified as the cause of mistaken coding. As discussed in the course of this audit and at the August 2014 exit conference, we have multiple levels of coding review as part of our internal controls to support compliance efforts. Indeed, in addition to regular training sessions with staff in both group and one-on-one settings, we employ experienced staff to work as internal auditors of coded claims. In addition, we retain independent, nationally recognized external coding experts who conduct prepayment reviews of a large portion of its Medicare claims on a daily basis to ensure accurate billing. In addition, we use a proprietary software system that reviews all coded claims on a prepayment basis and flags any items of concern for additional review prior to billing. To further enhance and improve
coding accuracy, we have an active documentation improvement program. Accordingly, we believe that we have a system of strong controls to prevent incorrect billing of claims.

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

For 2 of the 244 inpatient claims, UNC Hospitals 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, resulting in an overpayment of $11,600.

**UNC Hospitals Response: Manufacturer Credits for Replaced Medical Devices Not Reported**

UNC Hospitals agrees with the finding on the two cases identified. To ensure ongoing compliance, we have adopted additional internal controls to prevent recurrence. Staff has had focused training on identifying and reporting instances in which manufacturer credits could apply. This training was performed for staff scheduling cases, clinicians involved in procedures, as well as those responsible for accurate billing. As part of these efforts, workflows in multiple areas were modified to support accurate reporting and education focused to identify such credits before claims are submitted. In addition, we worked with our electronic health record (EHR) vendor to install a mechanism to permit clinical staff to readily “flag” patient claims for which credit may be received so that information can be confirmed before claims are submitted. Moreover, as a means to verify the accuracy of internal processes, we now receive monthly credit reports from device vendors to verify compliance.

**OIG Finding: Incorrect Discharge Status**

OIG asserts that for 1 of the 244 inpatient claims reviewed, UNC Hospitals incorrectly billed the beneficiary’s discharge status with a disposition to the beneficiary’s home instead of a
transfer to a home health agency. As a result, OIG states that UNC Hospitals was overpaid $1,624.

**UNC Hospitals Response: Incorrect Discharge Status**

UNC Hospitals disputes that it incorrectly billed a beneficiary’s discharge status when days *after* the patient was discharged, her primary care physician ordered that she receive home health services. In this case, there is no mention in any part of the patient’s medical record, including entries from her attending physician, her nurses, case managers, discharge planning staff or anyone else that the patient needed, requested or was being considered for home health services. Therefore, when we billed her inpatient claim, we coded her discharge status as “home” as documented in the patient’s chart.

We had no means to know that the patient’s primary care doctor ordered home health services *after* she left our care. Accordingly, we respectfully request that this finding be removed from the Report. CMS itself has acknowledged that it did not make edits to its own processes to identify cases where beneficiaries received home health care after hospital discharge until 2013, long after this claim was processed. *(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), (“CMS made updates to the common working file (CWF) edits in 2013, resolving some of the vulnerabilities identified.”)).*

**Billing Errors Associated with Outpatient Claims**

**OIG Finding: Manufacturer Credits for Replaced Medical Devices Not Reported or Obtained**

OIG reported that UNC Hospitals incorrectly billed Medicare for 1 of the 7 outpatient claims that were reviewed. Specifically, OIG reported that UNC Hospitals incorrectly billed
Medicare for medical devices that were under warranty and failed to report an “FB” modifier on the claim to reduce the charges appropriately.

UNC Hospitals Response: Manufacturer Credits for Replaced Medical Devices Not Reported or Obtained

We agree with the finding for the outpatient case identified. As explained in response to the similar finding above for inpatient claims, we have adopted new measures to ensure ongoing compliance in device credit reporting for all claims, whether provided in the inpatient or outpatient setting. Staff involved in multiple aspects of patient care including those scheduling procedures, staff assisting physicians during procedures, physicians and coding employees have been trained regarding the new processes. In addition, staff has adopted processes to identify possible cases in which device credits may apply and document the information using new procedures. In addition, we worked extensively with its EHR vendor to adopt a user-friendly means to flag claims for which credits may be issued so that appropriate information is communicated to billing staff. Before claims are submitted, coders verify receipt of credits with appropriate staff. In addition, to confirm proper billing, we receive monthly credit reports from vendors to verify its coding.

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

With regard to the proposed decision to extrapolate findings to assert that we refund $2,492,687 in estimated overpayments to Medicare, even assuming [[redacted]] decisions downcoding claims or determining that sampled claims were not properly billed as inpatient admissions, we respectfully request that no extrapolation be done in this case. If an overpayment demand is calculated, however, we request that the OIG recommend that any calculations of
overpayment in each case be modified in accordance with CMS billing and reimbursement policies at a minimum, as explained below.

The draft Report includes a footnote stating that the proposed extrapolated overpayment does not take into account partial payments that CMS would have reimbursed UNC Hospitals for medically necessary services as contemplated in Ruling 1599-F. Although we realize that OIG itself may not be able to perform the per-claim calculations, we request that the final Report recommend that those calculations be done before any extrapolated amount is calculated as being owed.¹

Moreover, to ensure consistency in reimbursement, the per-claim calculations should be revised for those patients whose care includes treatments and procedures that were performed for each on an outpatient basis before they were admitted for inpatient care. Therefore, when UNC Hospitals initially submitted the claims for reimbursement in 2011 and 2012, outpatient charges that could have been filed under Medicare Part B but were related to the inpatient admissions were “bundled” into the Part A claims in accordance with the CMS 3-day payment window requirements. Based on current conclusions that the care in certain cases should all have been billed on an outpatient basis, the 3-day window rule is inapplicable and the separately billable outpatient care should be calculated to reduce the overpayment assessment in affected cases.

¹ As stated, UNC Hospitals plans to appeal any denials processed on the basis of a final OIG report; however, since the administrative hearing process is backlogged, that process could take years to complete. Although we recognize that CMS has attempted to address the backlog by offering settlement to hospitals for “status” cases that are in dispute here, any denials finalized as a result of this audit would not be eligible for the 68% per claim settlement payment. Accordingly, UNC Hospitals could have funds recouped long before the appeals process is complete.
Legal Due Process Standards As Well As CMS Guidelines Require That Valid Statistical Methods Be Used As A Basis For An Extrapolated Overpayment.

Although statistical sampling to extrapolate overpayments may be acceptable where universal review is not possible, samples that are used as the basis for a large potential recoupment must be representative 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)).

The CMS Program Integrity Manual (PIM) directs that statistically valid samples be drawn and that statistically valid methods be used to project any overpayment. (See, PIM, Chapter 8.4.1.1). As CMS observes, probability testing is not a “one size fits all” for sampling. Continuing, CMS observes that use of the 90% confidence interval is appropriate to correct for study bias that can occur in simple random sampling. Notably, however, if the sampling method used in a particular circumstance is not a simple random method, the Manual suggests that consultation with experts be done to ensure projections are appropriately calculated using other methods.

In addition, the PIM notes that when stratified sampling is used,

*Generally, one defines strata to make them as internally homogenous as possible with respect to overpayment amounts... [and the] main objective of stratification is to define the strata in a way that will reduce the margin of error in the estimate [to obtain an] unbiased estimate [of an alleged overpayment].*

(PIM 8.4.11.1). (emphasis added). Therefore, when designing strata to be used in sampling, if the range of overpayments that could be identified is from $5,000 to $7,500, results for sampled claims within that level should be fairly consistent.

As explained below, because the simple random sampling was not done in this review, the 90% confidence interval used in the draft Report to estimate the alleged overpayment does not necessarily correct for imprecise sampling results. Moreover, because each stratum that OIG
used for the proposed calculation includes sampled claims with vastly different overpayment (and even underpayment) amounts, using a calculated “average” multiplied by the number of admissions sampled does not reliably predict an extrapolated overpayment. For these reasons and as briefly discussed below, we request that the final report not include an extrapolated overpayment demand.

**Sampling Claims Associated With A Beneficiary’s Inpatient Admission Is Not A “Simple Random Sample.”**

The draft Report states that the sampling unit supporting the extrapolated demand is a Medicare-paid claim. Based on the PIM, however, since auditors pulled all claims billed for an entire inpatient admission for sampled beneficiaries, the sampling “unit” is a beneficiary admission. (PIM 8.4.3.2.2) This distinction is important since when this sort of cluster sampling is used instead of simple random sampling of each claim line, the resulting estimate of any overpayment in one admission may not predict what the overpayment (if any) will be for another beneficiary whose admission is reviewed. Intuitively, this makes sense since two beneficiaries whose admissions were included in the sampling could have had very different diagnoses or treatments that would impact the coding and reimbursement for each.

**The Strata Identified Include Claims Whose Payment Ranges Were Too Variable To Calculate A Reliable Extrapolated Overpayment Amount For The Provider**

The draft Report states that multiple strata were used to calculate the extrapolated overpayment amount. Use of stratified sampling can lead to calculations to support overpayment demands where, *within the strata, any identified error in payment falls within a narrow range.* Because the identified error amounts per strata here vary tremendously, averaging the findings in the sample and multiplying it by all the claims in the frame fails to correct for any bias in sampling.
Specifically, Stratum 2 contains patients whose associated claims included codes for major complications or comorbidities (MCC). For sampled claims within this Stratum, the draft Report includes one claim with an overpayment of nearly $70,000, a few claims that were underpaid by a few thousand dollars each and a majority of claims that were coded and billed properly.

Stratum 3 included those admissions for which Medicare payments for the care delivered were greater than the charges recorded on the individual claim. Because each patient’s claim could include charges for treatments for any condition, the sample results in this stratum could vary anywhere from a conclusion that the claim was significantly underpaid to a determination that claims were overpaid up to nearly $70,000.

The last level sampled is Stratum 4, which is identified in the draft Report as claims for admissions associated with a “Short Stay” for each beneficiary in that level. The identified “error” in payment for each admission reviewed could be anywhere from an underpayment up to more than $44,000 per case.

The range of values per stratum sampled—from negative amounts to tens of thousands of dollars—is extremely broad. Accordingly, use of an average figure per stratum is too imprecise to support an extrapolated overpayment.

**Conclusion**

UNC Hospitals has a strong compliance program to which we have committed appropriate resources to support accurate billing and coding. Our case management and utilization review processes and professionals monitor the appropriateness of admissions in accordance with recognized standards and in accordance with sound medical judgment. Our coding department uses extensive internal and external means to support accurate billing;
however, we acknowledge that human error can result in inaccurate billing. Because we believe our controls are consistent with CMS billing requirements, we respectfully renew our request to meet with [redacted] auditors to correct any misunderstandings before the report is finalized.

To address the complex process to identify and properly bill credits for replaced devices, UNC Hospitals has enhanced its policies and adopted internal and external controls going forward to avoid erroneous submissions.

With regard to the calculations used to extrapolate the overpayment demand, UNC Hospitals requests that no extrapolation be performed since the calculation relies on widely variable parameters to predict an amount. In the event OIG determines an extrapolation is required, we respectfully request that the final report recommend that any calculation be modified to compensate the Provider for medically necessary care as contemplated in CMS Ruling 1599-R as well as for all outpatient services received as explained above.

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

Sincerely,

/Margaret B. Dardness/

Margaret B. Dardess, Ph.D., JD
Senior Advisor to the Chief Executive Officer, University of North Carolina Health Care System
Interim Chief Audit & Compliance Officer for UNCHCS

cc: Gary L. Park