Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE COMPLIANCE REVIEW OF NORTON HEALTHCARE, INC., FOR THE PERIOD JANUARY 1, 2011, THROUGH JUNE 30, 2012

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Office of Inspector General

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EXECUTIVE SUMMARY

Norton Healthcare, Inc., did not fully comply with Medicare requirements for billing inpatient and outpatient services, resulting in overpayments of at least $3 million over 1 ½ 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 Norton Healthcare, Inc. (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 a not-for-profit organization, located in Louisville, Kentucky. It consists of five acute care facilities: Norton Hospital, a 642-bed hospital; Norton Audubon Hospital, a 432-bed hospital; Norton Suburban Hospital, a 373-bed hospital; Norton Brownsboro Hospital, a 127-bed hospital; and Kosair Children's Hospital, a 263-bed hospital. According to CMS's National Claims History data, Medicare paid the Hospital approximately $408 million for 35,562 inpatient and 155,289 outpatient claims for services provided to beneficiaries during January 1, 2011, through June 30, 2012.

Our audit covered $22,508,511 in Medicare payments to the Hospital for 2,354 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 230 claims with payments totaling $3,950,255. These 230 claims had dates of service in the period January 1, 2011, through June 30, 2012 (audit period), and consisted of 138 inpatient and 92 outpatient claims.

WHAT WE FOUND

The Hospital complied with Medicare billing requirements for 166 of the 230 inpatient and outpatient claims that we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 64 claims, resulting in overpayments of $385,891 for the

audit period. Specifically, 52 inpatient claims had billing errors resulting in overpayments of $325,703, and 12 outpatient claims had billing errors resulting in overpayments of $60,188. 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 $3,002,136 for the audit period.

WHAT WE RECOMMEND

We recommend that the Hospital:

- refund to the Medicare program $3,002,136 in estimated overpayments for the audit period claims that it incorrectly billed and

- strengthen controls to ensure full compliance with Medicare requirements.

NORTON HEALTHCARE COMMENTS

In written comments on our draft report, the Hospital agreed that 45 of the 64 claims were billed incorrectly and described the actions it had taken and planned to take to address them. However, the Hospital contended that the calculated error rate substantially overstated the overpayment amount. Specifically, the Hospital contended that the overpayment calculation for 10 inpatient services claims reflected total reimbursement for inpatient stays, instead of the net overpayment (after deducting "expected" Part B reimbursements). The Hospital also contended that the remaining 19 inpatient claims were not billed in error, and it intends to challenge those claims on appeal. The Hospital further stated that the use of extrapolation violated statutory mandates prescribed for CMS and its contractors, violated the Hospital's substantive due process rights and fundamental fairness, and could lead to duplicate refunds.

OFFICE OF INSPECTOR GENERAL RESPONSE

In response to the Hospital's concerns regarding rebilling for certain services that were denied as part of this review, we acknowledge its comments; however, the rebilling issue is beyond the scope of our audit. CMS has issued the final regulations on payment policies (78 Fed. Reg. 160 (Aug. 19, 2013)), and the Hospital should contact its Medicare Administrative Contractor (MAC) for rebilling instructions. As stated in the report, we were unable to determine the effect that billing Medicare Part B would have on the overpayment amount because the Hospital had not billed, and the MAC had not adjudicated, these services prior to the issuance of our draft report. In addition, the claim errors we identified were not merely the result of differing opinions; instead, they represented specific actionable items that warranted our recommendations.

Regarding the Hospital's objections to our statistical sampling and extrapolation, the use of statistical sampling and extrapolation have been established by the Federal courts as a viable audit technique [Chaves County Home Health Serv., Inc. v. Sullivan, 931 F.2d 914, 921 (D.C.

Cir. 1991)]. Furthermore, the Federal courts have approved the use of statistical sampling and extrapolation as part of audits related to Medicare provided that the auditee has an opportunity to refute the outcome of the audit [Ratanasen v. California, 11 F.3d 1467, 1471 (9th Cir. 1993)]. Our use of statistical sampling by no means removes the Hospital's right to appeal the individual determinations on which the extrapolation is based through the normal appeals process. We properly executed our statistical sampling methodology in that we have defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software to apply the correct formulas for the extrapolation.

With respect to the Hospital's concerns about duplicate refunds for reviews of the same claims in our sampling frame, we took steps to exclude all claims in our sampling frame from future Recovery Audit Contractor (RAC) review. However, to prevent repaying Medicare twice for claims that the Hospital has already repaid due to previous RAC review, it should tell CMS which claims in our sampling frame were previously adjusted and CMS can then reduce the amount we recommended the Hospital refund ($3,002,136) by the amount already repaid.

Therefore, we continue to recommend that Norton Healthcare refund to the Medicare program $3,002,136 in estimated overpayments and strengthen controls to ensure full compliance with Medicare requirements.

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INTRODUCTION

WHY WE DID THIS REVIEW

This review is part of a series of hospital compliance reviews. Using computer matching, data mining, and other data analysis techniques, we identified hospital claims that were at risk for noncompliance with Medicare billing requirements. For calendar year 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

The objective of this review was to determine whether Norton Healthcare, Inc. (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.[1] All services and items within an APC group are comparable clinically and require comparable resources.

Hospital Claims at Risk for Incorrect Billing

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

- inpatient short stays,
- inpatient claims paid in excess of charges,
- inpatient claims billed with high-severity-level DRG codes,
- inpatient same day discharge and readmission,
- inpatient and outpatient manufacturer credits for replaced medical devices,
- inpatient psychiatric facility (IPF) emergency department adjustments,
- outpatient claims with payments greater than $25,000,
- outpatient claims billed for Doxorubicin Hydrochloride, and
- outpatient claims billed with evaluation and management (E&M) services.

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)).

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

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

Norton Healthcare, Inc.

The Hospital is a not-for-profit organization located in Louisville, Kentucky. It consists of five acute care facilities: Norton Hospital, a 642-bed hospital; Norton Audubon Hospital, a 432-bed hospital; Norton Suburban Hospital, a 373-bed hospital; Norton Brownsboro Hospital, a 127-bed hospital; and Kosair Children's Hospital, a 263-bed hospital. For purposes of Medicare billing, the Hospital submits to Medicare for reimbursement using one unique provider identification that comprises all five acute care facilities. According to CMS's National Claims History data, Medicare paid the Hospital approximately $408 million for 35,562 inpatient and 155,289 outpatient claims for services provided to beneficiaries during January 1, 2011, through June 30, 2012.

HOW WE CONDUCTED THIS REVIEW

Our audit covered $22,508,511 in Medicare payments to the Hospital for 2,354 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 230 claims with payments totaling $3,950,255. These 230 claims had dates of service in the period January 1, 2011, through June 30, 2012 (audit period), and consisted of 138 inpatient and 92 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 26 claims to medical review to determine whether the services were medically necessary.

This report focuses on selected risk areas and does not represent an overall assessment of all claims submitted by 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 audit scope and methodology.

FINDINGS

The Hospital complied with Medicare billing requirements for 166 of the 230 inpatient and outpatient claims that we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 64 claims, resulting in overpayments of $385,891 for the audit period. Specifically, 52 inpatient claims had billing errors resulting in overpayments of

$325,703, and 12 outpatient claims had billing errors resulting in overpayments of $60,188. 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 $3,002,136 for the audit period.

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

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 52 of the 138 inpatient claims that we reviewed. These errors resulted in overpayments of $325,703.

Incorrectly Billed as Inpatient or Without a Valid Physician Order

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)). A payment for services furnished to an individual may be made only to providers of services that are eligible and only if, "with respect to inpatient hospital services … which are furnished over a period of time, 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)). Federal regulations state that Medicare Part A pays for inpatient hospital services only if a physician certifies and recertifies, among other things, the reasons for continued hospitalization (42 CFR § 424.13(a)). Section 1815(a) of the Act precludes payment to any provider without information necessary to determine the amount due the provider.

For 29 of the 138 inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for inpatient status and should have been billed as outpatient or outpatient with observation services. Specifically:

- For 24 claims, the Hospital incorrectly billed for beneficiaries whose level of care and services provided should have been billed as outpatient or outpatient with observation services. For example, one patient was scheduled for a VP Shunt placement. Vital signs remained stable during the procedure with no complications post procedure and patient was discharged. The services that the Hospital provided did not meet the intensity that is consistent with an inpatient level of care and could have been provided in an observation status. In addition, for two of these claims, the medical records indicated that an Advanced Registered Nurse Practitioner, rather than a physician, ordered inpatient admission.

- For five claims, the beneficiary met the level of care and services provided; however, the Hospital incorrectly billed for inpatient services when the medical records did not contain valid orders signed by a physician.

The Hospital stated that these overpayments occurred because staff members were not able to assess and review 1- to 2-day inpatient admissions prior to patient discharge, or the admitting physicians were not readily available to discuss the cases with the staff to ensure that patients were ordered into the appropriate status. As a result, the Hospital received overpayments of $198,518.[2]

Incorrectly Billed Diagnosis-Related Group Codes

Medicare payments may not be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (the Act, § 1862(a)(1)(A)). The Manual requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly (chapter 1, § 80.3.2.2).

For 10 of the 138 inpatient claims, the Hospital billed Medicare for incorrect DRG codes. For example, the Hospital submitted a claim with a diagnosis of unspecified psychosis. However, the medical records did not support the coding of this diagnosis. The psychiatry consultation revealed depression and anxiety, but no definitive diagnosis was made for unspecified psychosis. Therefore, medical review determined that the diagnosis coding should have been for altered mental status. The Hospital stated that these errors occurred because, at the time of coding a patient record, some information necessary to code the record may not have been clear or available to the coder. As a result of these errors, the Hospital received overpayments of $61,387.

Incorrectly Billed as Separate Inpatient Stays

The Manual, chapter 3, § 40.2.5, states: "When a patient is discharged/transferred from an acute care Prospective Payment System (PPS) hospital and is readmitted to the same acute care PPS hospital on the same day for symptoms related to, or for evaluation and management of, the prior stay's medical condition, hospitals shall adjust the original claim generated by the original stay by combining the original and subsequent stay onto a single claim."

For 6 of the 138 inpatient claims, the Hospital incorrectly billed Medicare separately for related discharges and readmissions in the same day. Hospital officials stated that these errors occurred because of inaccurate coder interpretations for the need to combine the stays. As a result of these errors, the Hospital received overpayments of $38,414.

[2] 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 administrative contractor prior to the issuance of our report.

Manufacturer Credits for Replaced Medical Devices Not Obtained or Reported

The CMS *Provider Reimbursement Manual* 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. If costs are determined to exceed the level that such buyers incur, in the absence of clear evidence that the higher costs were unavoidable, the excess costs are not reimbursable under the program" (Pub. No. 15, part I, § 2102.1).[3]

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). Federal regulations require all payments to providers of services must be based on the reasonable cost of services (42 CFR § 413.9). The Manual states that to bill correctly for a replacement device that was provided with a credit, the 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 3 of the 138 inpatient claims, the Hospital incorrectly billed Medicare for medical devices that were under warranty.

- For two claims, the Hospital did not obtain the credit for a replaced medical device for which a credit was available under the terms of the manufacturer's warranty.

- For one claim, the Hospital received a reportable credit from a manufacturer for a replaced device but did not adjust its inpatient claim with the proper condition and value code to reduce payment as required.

The Hospital stated that these errors occurred because it had an unwritten process in place that either failed to confirm or delayed confirmation of warranty credit information, and the Hospital did not ensure appropriate application of the credit to the claim. As a result, the Hospital received overpayments of $27,003.

Incorrect Source-of-Admission Code

CMS increases the Federal per diem rate for the first day of a Medicare beneficiary's IPF stay to account for the costs associated with maintaining a qualifying emergency department. CMS makes this additional payment regardless of whether the beneficiary used emergency department services; however, the IPF should not receive the additional payment if the beneficiary was

[3] 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."

discharged from the acute care section of the same hospital (42 CFR § 412.424 and the Manual, chapter 3, § 190.6.4). The Manual also states that IPFs report source-of-admission code "D" to identify patients who have been transferred to the IPF from the same hospital (chapter 3, § 190.6.4.1). An IPF's proper use of this code is intended to alert the Medicare contractor not to apply the emergency department adjustment.

For 4 of the 138 inpatient claims, the Hospital incorrectly coded the source-of-admission for beneficiaries who were admitted to its IPF upon discharge from its acute care section. Hospital officials stated that the errors occurred because staff did not correctly interpret the admission source. As a result, the Hospital received overpayments of $381.

BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 12 of the 92 outpatient claims that we reviewed. These errors resulted in overpayments of $60,188.

Manufacturer Credits for Replaced Medical Devices Not Reported

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). 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.[4]

For 2 of the 92 outpatient claims, the Hospital incorrectly billed Medicare for medical devices that were under warranty. The Hospital received full credit for replaced devices but did not report the "FB" modifier and reduced charges on its claims.

The Hospital stated that these errors occurred because it had an unwritten process in place that either failed to confirm or delayed confirmation of warranty credit information, and the Hospital did not ensure appropriate application of the credit to the claim. As a result, the Hospital received overpayments of $19,708. Prior to completion of our fieldwork, the Hospital took corrective action to improve communication and documentation among clinical staff, vendor representatives, and hospital departments and published a policy, effective May 2013, for replaced medical devices.

[4] CMS provides guidance on how a provider should report no-cost and reduced-cost devices under the OPPS (CMS Transmittal 1103, dated November 3, 2006, and the Manual, chapter 4, § 61.3).

Incorrectly Billed Number of Units

Section 1833(e) of the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider. The Manual, chapter 1, section 80.3.2.2, states: "In order to be processed correctly and promptly, a bill must be completed accurately." In addition, the Manual states: "The definition of service units ... is the number of times the service or procedure being reported was performed" (chapter 4, § 20.4). The Manual, chapter 17, section 90.2.A, further states: "It is … of great importance that hospitals billing for [drugs] make certain that the reported units of service of the reported HCPCS code are consistent with the quantity of a drug … that was used in the care of the patient." If the provider is billing for a drug, according to chapter 17, section 70, of the Manual, "[w]here HCPCS is required, units are entered in multiples of the units shown in the HCPCS narrative description. For example, if the description for the code is 50 mg, and 200 mg are provided, units are shown as 4 …."

For 3 of the 92 outpatient claims, the Hospital incorrectly billed Medicare for the number of units.

- For two claims, the Hospital incorrectly submitted claims to Medicare with the incorrect number of units of service. For example, rather than billing 1 unit for a right eye procedure, the Hospital billed 31 units. The Hospital indicated that one overpayment occurred because of a documentation error, and the other overpayment was caused by a change in the billing system and the intermittent failure of an established system edit. As a result, the Hospital received overpayments of $39,751.

- For one claim, the Hospital incorrectly submitted a claim to Medicare with an incorrect number of units for Doxorubicin Hydrochloride.[5] For this claim, rather than billing five units of Doxorubicin Hydrochloride, the Hospital billed six units. The Hospital indicated that this occurred as the result of human error when the pharmacist did not document waste in accordance with the normal procedure. As a result of this error, the Hospital received an overpayment of $407.

Insufficiently Documented Evaluation and Management Services

The Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§ 1833(e)).

For 7 of the 92 outpatient claims, the Hospital incorrectly billed Medicare for E&M services that were insufficiently documented in the medical records. The Hospital stated that these errors occurred because of system error and staff confusion. As a result of these errors, the Hospital received overpayments of $322.

[5] This drug is used in the chemotherapy treatment of a wide range of cancers.

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that the Hospital received overpayments of at least $3,002,136 for the audit period.

RECOMMENDATIONS

We recommend that the Hospital:

- refund to the Medicare program $3,002,136 in estimated overpayments for the audit period claims that it incorrectly billed and

- strengthen controls to ensure full compliance with Medicare requirements.

NORTON HEALTHCARE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

Norton Healthcare Comments

In written comments on our draft report, the Hospital agreed that 45 of the 64 claims were billed incorrectly and described the actions it had taken and planned to take to address them. However, the Hospital contended that the calculated error rate substantially overstated the overpayment amount. Specifically, the Hospital contended that the overpayment calculation for 10 inpatient services claims reflected total reimbursement for inpatient stays, instead of the net overpayment (after deducting "expected" Part B reimbursements). The Hospital also contended that the remaining 19 inpatient claims were not billed in error, and it intends to challenge those claims on appeal. The Hospital further stated that the use of extrapolation violated statutory mandates prescribed for CMS and its contractors, violated the Hospital's substantive due process rights and fundamental fairness, and could lead to duplicate refunds. The Hospital's comments are included as Appendix E.

Office of Inspector General Response

In response to the Hospital's concerns regarding rebilling for certain services that were denied as part of this review, we acknowledge its comments; however, the rebilling issue is beyond the scope of our audit. CMS has issued the final regulations on payment policies (78 Fed. Reg. 160 (Aug. 19, 2013)), and the Hospital should contact its Medicare Administrative Contractor (MAC) for rebilling instructions. As stated in the report, we were unable to determine the effect that billing Medicare Part B would have on the overpayment amount because the Hospital had not billed, and the MAC had not adjudicated, these services prior to the issuance of our draft report. In addition, the claim errors we identified were not merely the result of differing opinions; instead, they represented specific actionable items that warranted our recommendations.

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audit technique [Chaves County Home Health Serv., Inc. v. Sullivan, 931 F.2d 914, 921 (D.C. Cir. 1991)]. Furthermore, the Federal courts have approved the use of statistical sampling and extrapolation as part of audits related to Medicare provided that the auditee has an opportunity to refute the outcome of the audit [Ratanasen v. California, 11 F.3d 1467, 1471 (9th Cir. 1993)]. Our use of statistical sampling by no means removes the Hospital's right to appeal the individual determinations on which the extrapolation is based through the normal appeals process. We properly executed our statistical sampling methodology in that we have defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software to apply the correct formulas for the extrapolation.

With respect to the Hospital's concerns about duplicate refunds for reviews of the same claims in our sampling frame, we took steps to exclude all claims in our sampling frame from future Recovery Audit Contractor (RAC) review. However, to prevent repaying Medicare twice for claims that the Hospital has already repaid due to previous RAC review, it should tell CMS which claims in our sampling frame were previously adjusted and CMS can then reduce the amount we recommended the Hospital refund ($3,002,136) by the amount already repaid.

Therefore, we continue to recommend that Norton Healthcare refund to the Medicare program $3,002,136 in estimated overpayments and strengthen controls to ensure full compliance with Medicare requirements.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $22,508,511 in Medicare payments to the Hospital for 2,354 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 230 claims with payments totaling $3,950,255. These 230 claims had dates of service in the period January 1, 2011, through June 30, 2012 (audit period), and consisted of 138 inpatient and 92 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 26 claims to medical review to determine whether the services were medically necessary.

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 National Claims History file, but we did not assess the completeness of the file.

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

We conducted our fieldwork from April 2013 through January 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 National Claims History 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 other data analysis techniques to identify claims potentially at risk for noncompliance with selected Medicare billing requirements;
- selected a stratified random sample of 230 claims totaling $3,950,255 (Appendix C) for detailed review;
- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been cancelled or adjusted;

- reviewed the itemized bills and medical record documentation provided by the Hospital to support the sampled claims;

- requested the Hospital to conduct its own review of the sampled claims to determine whether the services were billed correctly;

- reviewed the Hospital's procedures for classifying hospital stays (outpatient, observation, or inpatient admission), case management, coding, and Medicare claim submission;

- used CMS's Medicare contractor medical review staff to determine whether 26 sampled claims met medical necessity 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 to estimate the Medicare overpayments to the Hospital (Appendix C); and

- discussed the results of the 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 was inpatient and outpatient claims paid to the Hospital for services provided to Medicare beneficiaries during January 1, 2011, through June 30, 2012.

SAMPLING FRAME

According to CMS's National Claims History data, for 36 risk areas, Medicare paid the Hospital $232,601,238 for 13,162 inpatient and 49,593 outpatient claims for services provided to beneficiaries during January 1, 2011, through June 30, 2012.

From these 36 risk areas, we selected 10 consisting of 41,071 claims totaling $161,688,067 for further review.

We then removed the following:

- $0 paid claims;
- claims duplicated within individual risk areas by assigning each inpatient claim that appeared in multiple risk areas to just one category based on the following hierarchy:
    - Inpatient Manufacturer Credits for Replaced Medical Devices,
    - Inpatient Claims Billed With High-Severity-Level DRG Codes,
    - Inpatient Claims Paid in Excess of Charges, and
    - Inpatient Short Stays; and
- claims under review by the RAC as of March 12, 2013.

This resulted in a sampling frame of 2,354 unique Medicare claims in 10 risk areas totaling $22,508,511.

Risk Area	Number of Claims	Amount of Payments
1. Inpatient Manufacturer Credits for Replaced Medical Devices	11	$245,741
2 Inpatient Claims Billed With High-Severity-Level DRG Codes	1,356	13,253,818
3. Inpatient Claims Paid in Excess of Charges	34	788,533
4. Inpatient Short Stays	722	5,259,149
5. Inpatient Same Day Discharge and Readmission	9	136,368
6. Inpatient Psychiatric Facility Emergency Department Adjustments	4	18,457
7. Outpatient Manufacturer Credits for Replaced Medical Devices	2	28,037
8. Outpatient Claims Billed With Evaluation and Management Services	98	16,220
9. Outpatient Claims with Payments Greater than $25,000	45	2,476,823
10. Outpatient Claims Billed for Doxorubicin Hydrochloride	73	285,365
Total	**2,354**	**$22,508,511**

SAMPLE UNIT

The sample unit was a Medicare paid claim.

SAMPLE DESIGN

We used a stratified random sample. We divided the sampling frame into 10 strata based on risk area.

SAMPLE SIZE

We selected 230 claims for review as follows:

Stratum	Risk Area	Claims in Sampling Frame	Claims in Sample
1	Inpatient Manufacturer Credits for Replaced Medical Devices	11	11
2	Inpatient Claims Billed With High-Severity-Level DRG Codes	1,356	50
3	Inpatient Claims Paid in Excess of Charges	34	34
4	Inpatient Short Stays	722	30
5	Inpatient Same Day Discharge and Readmission	9	9
6	Inpatient Psychiatric Facility Emergency Department Adjustments	4	4
7	Outpatient Manufacturer Credits for Replaced Medical Devices	2	2
8	Outpatient Claims Billed With Evaluation and Management Services	98	30

Stratum	Risk Area	Claims in Sampling Frame	Claims in Sample
9	Outpatient Claims With Payments Greater Than $25,000	45	30
10	Outpatient Claims Billed for Doxorubicin Hydrochloride	73	30
	Total	2,354	230

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the claims within strata 2, 4, 8, 9, and 10. After generating the random numbers for strata 2, 4, 8, 9, and 10, we selected the corresponding claims in each stratum. We selected all claims in strata 1, 3, 5, 6, and 7.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the total amount of Medicare overpayments paid to the Hospital during the audit period.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

SAMPLE RESULTS

Stratum	Frame Size (Claims)	Value of Frame	Sample Size	Value of Sample	Number of Incorrectly Billed Claims in Sample	Value of Overpayments in Sample
1	11	$245,741	11	$245,741	3	$27,003
2	1,356	13,253,818	50	487,163	11	52,794
3	34	788,533	34	788,533	9	102,622
4	722	5,259,149	30	194,144	18	103,039
5	9	136,368	9	136,368	7	39,864
6	4	18,457	4	18,457	4	381
7	2	28,037	2	28,037	2	19,708
8	98	16,220	30	5,579	7	322
9	45	2,476,823	30	1,924,301	2	39,751
10	73	285,365	30	121,932	1	407
Total	**2,354**	**$22,508,511**	**230**	**$3,950,255**	**64**	**$385,891**

ESTIMATES

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

Point Estimate	$4,102,213
Lower limit	$3,002,136[6]
Upper limit	$5,242,448

[6] In accordance with OAS policy, we did not use the results from strata 9 and 10 in calculating the estimated overpayments. Instead, we added the actual overpayments from strata 9 ($39,751) and 10 ($407) to the lower limit ($2,961,978), which resulted in an adjusted lower limit of $3,002,136.

APPENDIX D: RESULTS OF REVIEW BY RISK AREA

Risk Area	Selected Claims	Value of Selected Claims	Claims With Over-payments	Value of Over-payments
Inpatient				
Short Stays	30	$194,144	18	$103,039
Claims Paid in Excess of Charges	34	788,533	9	102,622
Claims Billed With High-Severity-Level DRG Codes	50	487,163	11	52,794
Same Day Discharge and Readmission	9	136,368	7	39,864
Manufacturer Credits for Replaced Medical Devices	11	245,741	3	27,003
Psychiatric Facility Emergency Department Adjustments	4	18,457	4	381
Inpatient Totals	**138**	**$1,870,406**	**52**	**$325,703**
Outpatient				
Claims with Payments Greater Than $25,000	30	$1,924,301	2	$39,751
Manufacturer Credits for Replaced Medical Devices	2	28,037	2	19,708
Claims Billed for Doxorubicin Hydrochloride	30	121,932	1	407
Claims Billed With Evaluation and Management Services	30	5,579	7	322
Outpatient Totals	**92**	**$2,079,849**	**12**	**$60,188**
Inpatient and Outpatient Totals	**230**	**$3,950,255**	**64**	**$385,891**

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.

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May 8, 2014

VIA Federal Express Overnight Delivery and Electronic Mail

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

Re: Provider's Response to Draft Report Number A-04-13-08024, Medicare Compliance Review of Norton Healthcare, Inc. for the Period January 1, 2011, Through June 30, 2012

Dear Ms. Pilcher:

We are in receipt of the U.S. Department of Health and Human Services, Office of Inspector General ("OIG") draft report entitled "Medicare Compliance Review of Norton Healthcare, Inc. for the Period January 1, 2011 Through June 30, 2012," ("Draft Report") and your accompanying letter, requesting Norton Healthcare, Inc.'s ("Norton" or "Hospital") response within thirty days. In compliance with your office's directive, this letter responds to the draft audit report, its findings and its recommendations.

Norton appreciates the opportunity to provide this response to your office to underscore its commitment to strengthening its internal controls to address the audit findings with which it concurs. We also appreciate the opportunity to advise your office of the findings with which we disagree, and to request that those findings and recommendations be reviewed and revised accordingly. In addition, we respectfully request that, prior to the determination of the Medicare Overpayment, the Hospital be allowed, pursuant to Medicare program guidance, to refund and rebill those claims with which it concurs, as the rebilling will greatly reduce the estimated overpayment amount. Completing the refunding and rebilling of claims for inpatient services that should have been billed as outpatient will result in a more accurate overpayment determination and reduce the costs of further administrative review, which benefits the Medicare program, its contractors and its beneficiaries.

I. FACTUAL BACKGROUND

Norton is a not-for-profit healthcare provider located in Louisville, Kentucky, and consists of five acute care campuses: Norton Hospital, a 624-bed hospital; Norton Audubon Hospital, a 432-bed hospital; Norton Suburban Hospital, a 373-bed hospital; Norton Brownsboro Hospital, a 127-bed hospital; and Kosair Children's Hospital, a 263-bed hospital. Norton is

dedicated to providing the highest-quality, compassionate care to its patients, their families, and the community we serve. In addition to providing the highest-quality care to our patients, Norton, through its compliance program, is committed to ensuring the integrity of our clinical documentation to support overall clinical decision making and accurate coding and billing of patient services and ensuring the services provided to our patients are both reasonable and necessary to best serve and meet our patients' needs and expectations. We routinely conduct internal and external audits of the clinical documentation, assess medical decision making, evaluate for the appropriate charging and the assignment of coding and diagnostic related groups ("DRG") indicators, perform ongoing monitoring of the billing of patient services, monitor reimbursement to ensure appropriateness of monies received for services provided, and modify our processes when necessary to ensure compliance with our standards of care, Medicare program guidance, and applicable regulatory guidance and laws.

As relevant here, in 2013 the OIG began an audit of the Hospital as part of a national auditing initiative. The audit sought to identify whether the Hospital was complying with government billing requirements for claims that the OIG had deemed to be at risk for noncompliance. Specifically, the audit focused on ten claim-risk areas: (1) inpatient claims for short stays; (2) inpatient claims paid in excess of charges; (3) inpatient claims billed with high-severity-level DRG codes; (4) inpatient same day discharges and readmissions; (5) inpatient claims involving medical device manufacturer credits for replaced devices; (6) outpatient claims involving medical device manufacturer credits for replaced devices; (7) inpatient psychiatric facility ("IPF") emergency department adjustments; (8) outpatient claims exceeding $25,000; (9) outpatient claims billed for Doxorubicin Hydrochloride; and (10) outpatient claims billed with evaluation and management ("E&M") services ("Risk Areas").

The Audit "covered $22,508,511 in Medicare payments to the Hospital for 2,354 claims that were potentially at risk for billing errors."[1] The OIG then selected and reviewed a stratified random sample of 230 claims (138 inpatient and 92 outpatient), whose Medicare payments totaled $3,950,255.[2] The OIG concluded that while the Hospital complied with Medicare billing requirements for 166 of the 230 inpatient and outpatient claims that it reviewed, it did not fully comply with billing requirements for 64 claims. According to the Draft Report, the 64 claims identified as errors by the OIG resulted in overpayments of $385,891. Specifically, the Draft Report concluded that "52 inpatient claims had billing errors resulting in overpayments of $325,703, and 12 outpatient claims had billing errors resulting in overpayments of $60,188." After extrapolation, the Draft Report estimates an overpayment in the amount of $3,002,136.[3]

Norton has carefully reviewed the Draft Report, and believes it grossly overstates the alleged overpayment by Medicare. As outlined below, the Hospital contends that the error rate calculated substantially overstates the overpayment amount, as the overpayment calculation for 10 claims for inpatient services that the Hospital agrees should be rebilled as outpatient services reflects total reimbursement for inpatient stays, not the net overpayment (after deducting

[1] Draft Rpt. at 3.
[2] Draft Rpt. at 3.
[3] Draft Rpt. at 4 & 9.

expected Part B reimbursement), and, therefore, must be set aside, or at a minimum, recalculated. The Hospital also challenges the Draft Report's conclusion that 19 other claims for inpatient services were billed in error. Given the complexity involved in determining the appropriate patient-care setting and the significant reversal rate for appeals of previously denied inpatient claims, the OIG's use of extrapolation has compounded an error rate that is questionable, at best, and is being contested in this response, and if not reviewed and revised before the final audit is released, will be challenged on appeal. For these reasons, Norton also contends that the use of extrapolation is legally unfounded, contravenes the Social Security Act, and is otherwise arbitrary and capricious.

II. RESPONSE TO EXTRAPOLATION AND OVERPAYMENT CALCULATIONS

A. OVERPAYMENT AMOUNTS ASSOCIATED WITH INPATIENT CLAIMS THAT SHOULD HAVE BEEN PAID AS OUTPATIENT CLAIMS AND ANY ATTENDANT EXTRAPOLATION MUST BE BASED ON THE DIFFERENCE BETWEEN THE PART A AND PART B PAYMENTS THAT WILL BE MADE WHEN THE CLAIM IS REBILLED, NOT ON THE FULL PART A PAYMENT.

As noted above, the OIG auditor's findings indicate that Norton complied with Medicare billing requirements for 166 of the 230 claims it reviewed. The OIG contends, however, that the Hospital did not fully comply with Medicare billing requirements for the remaining 64 claims, resulting in alleged overpayments of $385,891 for the audit period. The Draft Report claims that 52 inpatient claims had billing errors resulting in alleged overpayments of $325,703, and 12 outpatient claims had errors resulting in alleged overpayments of $60,188. It also alleged that Norton incorrectly billed 29 of 138 sampled claims to Medicare Part A for beneficiary inpatient stays that should have been billed as outpatient or outpatient with observation services. The Draft Report claims Norton received overpayments totaling $198,518 for the 29 claims erroneously billed as inpatient services.

The 29 inpatient claims the Audit determined should have been billed as outpatient services form the basis of the Hospital's objection to the use of extrapolation. The Hospital disagrees that extrapolation is appropriate here given that it challenges, on the merits, 19 out of the 29 claims, i.e., 65% of the alleged errors regarding inpatient/outpatient billing ("Contested Claims"). *See* Section III below, at 7-8. Moreover, for the 10 Uncontested Claims, i.e., those that the Hospital concurs should be rebilled as outpatient services ("Uncontested Claims"), the Hospital contends that its rebilling of the Uncontested Claims to Part B must offset the overpayment, and, therefore, further undermines the calculated overpayment and the use of extrapolation in this instance.

Pursuant to Medicare program guidance, the Hospital has already commenced the process of refunding and rebilling for the 10 Uncontested Claims, and it is actively working with its MAC to cancel, refund and rebill those claims for payment under Medicare Part B. The Hospital estimates that the difference between the original inpatient reimbursement payment and the outpatient reimbursement will substantially reduce the determined Overpayment for the

Uncontested Claims. This Inpatient/Outpatient Differential will confirm that the estimated overpayment is clearly erroneous. *See, e.g.*, 42 C.F.R. § 412.3; CMS 1455-F (Oct. 1, 2013); 78 Fed. Reg. 50496 (Aug. 19, 2013); CMS 1455-R (Mar. 13, 2013); 78 Fed. Reg. 16632 (Mar. 18, 2013); *O'Connor Hospital*, 2010 WL 425107, Med. & Med. GD (CCH) P 122133 (HHS Feb. 1, 2010); *Indiana Univ. Health Methodist Hosp.*, 2012 WL 3067987, at *10, Docket No. M-12-872 (HHS May 17, 2012) (upholding ALJ ruling that hospital was entitled to reimbursement for the full outpatient services under Medicare Part B even though hospital initially billed the claim as inpatient service under Medicare Part A). For those claims, the Draft Report shows the total reimbursement amount as an overpayment error when in fact this is not accurate. The overpayment error should be reflective of the "actual overpayment" amount, i.e., the net, not the gross, amount, which is consistent with current law. [4] Indeed, the Draft Report concedes at page 5, footnote 2, that the Part B payments should be offset against the overpayment.

Therefore, consistent with the Final Rule and the OIG's concession in its Draft Report, Norton respectfully requests that the OIG wait until all rebilling is completed for these Uncontested Claims before it recalculates the overpayment and modifies its recommendations, as it believes doing so is more accurately aligned with the law. That is, the recalculation of the alleged overpayment for the 10 Uncontested Claims should be held in abeyance until all of those claims have been reprocessed by the MAC. Thereafter, the overpayment may be recalculated by determining the difference between the original inpatient reimbursement and the outpatient reimbursement the Hospital received after it completed the rebilling of the Uncontested Claims. In doing so, the Hospital is properly compensated for medically necessary services provided to the Medicare Beneficiary. Failing to do the same before extrapolating an error rate is statistically invalid, contrary to federal law and obviously unfair.[5]

B. USE OF EXTRAPOLATION VIOLATES STATUTORY MANDATES.

The authority of CMS and its contractors to extrapolate is subject to strict statutory and regulatory limits. The Social Security Act provides that:

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[4] On March 13, 2013, CMS 1455-R was issued, in which the Administrator of CMS referred to the above-noted ALJ decision and endorsed hospitals being paid "under Medicare Part B following a denial of a Medicare Part A hospital inpatient claim . . . [if] an inpatient admission was [found] not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act." Centers for Medicare & Medicaid Services, Ruling No. CMS-1455-R (Mar. 13, 2013), at 1. CMS Ruling 1455-R remains applicable to these claims pursuant to Final Rule CMS-1455-F, as these inpatient claims have dates of admission before October 1, 2013, and were denied after September 30, 2013, on the ground that the medical care was reasonable and necessary but the inpatient admission allegedly was not.

[5] Norton continues to maintain that given the decline in the error rate once the Part B repayments on the rebilled claims are taken into account, the OIG should abandon the Audit's use of extrapolation altogether, and confine the overpayment demand to actual overpayments on those claims.

> a Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that (A) there is a sustained or high level of payment error; or (B) documented educational intervention has failed to correct the payment error.

42 U.S.C. § 1395ddd(f)(3). While neither the Act nor the applicable regulations define the term "high error rate," or suggest the criteria for identifying those instances where "educational intervention has failed," the preamble to the implementing regulations addressing extrapolation explains that extrapolation is merely a method of determining an overpayment. It further provides that "the determination of a sustained or high error rate will be used as the basis for a contractor undertaking further review of claims submitted by the provider or supplier." 74 Fed. Reg. 65296, 65303-04 (Dec. 9, 2009).

Decisions from the Office of Medicare Hearings and Appeals confirm that no basis for extrapolation exists in the absence of either documentation concerning a finding of a high error rate or a documented failure of response to education. *See, e.g., Cabarrus Podiatry Clinic Claim for Part B Benefits*, All Appeal No. 1-127356701 (Dec. 14, 2007). At a minimum, therefore, the OIG must document its findings that there exists a high rate of error or a failure of education before extrapolating the findings of a statistical sample to a broader universe of claims. Because the OIG failed to address either of the statutory criteria required for use of extrapolation, no basis existed for the application of its use in the instant case. Norton therefore objects to the recommendation that an extrapolated overpayment of $3,002,136 be recouped from the Hospital.

C. EXTRAPOLATION VIOLATES NORTON'S SUBSTANTIVE DUE PROCESS RIGHTS AND VIOLATES FUNDAMENTAL FAIRNESS.

A review of the 90 Medicare Compliance Review audit reports the OIG has issued publicly in the past three years demonstrates that all but 10 of them were based on a "judgmental" sampling methodology. Additionally, those hospitals that had the "judgmental" sampling methodology applied had to refund only the overpayments for the claims actually reviewed as part of the audit. In other words, in contrast to what has been recommended here, the OIG did not require repayment based on extrapolation of the audit results from 80 of the other hospitals subject to these compliance audits.

While Norton acknowledges that the OIG has authority to perform the Medicare Compliance Review audits, it believes, under the circumstances presented, which involve medical necessity determinations, it is unfair to extrapolate the sample results here. The process of determining "medical necessity" for inpatients is a "complex decision making process" and is a "gray area" at best. *See, e.g.*, CMS, *The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-Year Demonstration* at 14-15 (June 2008) ("Project Evaluation"). Indeed, billing reviews conducted over the past three years by the Recovery Audit Contractors on behalf of the Center for Medicare and Medicaid Services ("CMS") have proven that many claims identified as being inappropriate for inpatient status have been subsequently appealed and reversed through the administrative appeal process. The American Hospital Association has

reported that 41% of medical necessity denials were for 1-day stays where the care was allegedly provided in the wrong setting. Of those cases appealed, 72% of the appeals have been reversed in the providers' favor. *See American Hospital Association, Program Integrity*, available at http://www.aha.org/content/13/13-ProgInteg.pdf; *see also American Hosp. Ass'n v. Sebelius*, Case No. 12-cv-01770-CKK, D.D.C. 04/19/13, Complaint 11132-49, Doc. 26.

The administrative appeals processes and results concerning RAC audits throughout the country further substantiate the difficulty in applying the "complex medical decision" process to the appropriate setting. Norton therefore contends that the application of the "statistical" sampling methodology in this case is arbitrary and capricious and maintains that any demand for recoupment should be for only those claims that were actually audited, as has been the case with virtually all of the OIG's previously published hospital Medicare compliance reviews.

D. EXTRAPOLATION MAY LEAD TO DUPLICATE REFUNDS.

As a result of this review, we have additional concerns related to the identification of the cases pulled for the sample time frame. During our initial audit meeting, we were informed that the cases in the sample time frame would be excluded from reviews by other government contractors. To date we have had a total of 67 claims either pulled for another OIG review or Recovery Audit Contractor (RAC) review. Because of the failure to securely identify the accounts from the sample time frame, and the increasing RAC and other reviews, a potential exists that the Hospital could be required to repay Medicare twice for the same alleged error. The following examples illustrate our concerns:

- 19 Inpatient Cases from the sample frame were requested in February 2014 for part of a RAC review. After extensive communication with Cigna Government Services (CGS) and the assistance of the OIG, we were finally able to have those cases removed from the RAC review, but those cases should not have been selected at all in the frame of cases reviewed.
- 1 Cardiac Implant Case overlapped with an OIG audit of implants, and, again, with the assistance of the OIG, we were able to have the case removed from review.
- 47 Cases were reviewed on prior RAC audits.

We would request that the OIG re-evaluate the frame file to ensure that all cases that have been requested by any RAC review are removed and to ensure the cases are labeled so that they cannot be selected for another review, i.e., removed from the RAC Warehouse altogether.

Further, we request that, in light of this inaccurate labeling, extrapolation be abandoned by the OIG because no assurances have been made that these cases will not be pulled for additional auditing. We believe that, under the circumstances, it would be statistically invalid and unfair for the OIG to adhere to the extrapolation as recommended in the Draft Report.

III. RESPONSE TO FINDINGS AND RECOMMENDATIONS IN THE DRAFT REPORT

A. THE DRAFT REPORT BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS.

The Draft Report states that Norton incorrectly billed Medicare for 52 of the 138 inpatient claims that it audited, and concludes that the errors resulted in an overpayment of $325,703. As explained above, the Hospital does not totally agree with both the findings and recommendations in the Draft Report.

1. Claims Incorrectly Billed as Inpatient or Without a Valid Physician Order.

The Draft Report states that for 29 of 138 sampled claims, Norton incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for inpatient status and should have been billed as outpatient or outpatient with observation services. As a result, it concludes the Hospital received overpayments totaling $198,518.

Although Norton concurs that 10 claims, identified above as the Uncontested Claims, were billed in error, it contests on the merits that the remaining 19 claims were incorrectly billed with inpatient status.[6] Norton contends that the medical records for the Contested Claims, discussed in detail below, clearly support its inpatient admission determinations, and the OIG auditors erroneously concluded otherwise.

Furthermore, as discussed above in Section A, at 3-4, Norton maintains that overpayment calculation for the Uncontested Claims is erroneous because it does not account for the Hospital's cancellation, refunding, and rebilling of those claims for Part B payment. Hence, as the Draft Report even acknowledges, the rebilling of Uncontested Claims for payment under Part B will have dramatic effect on the overpayment analysis and error rate extrapolation. Therefore, Norton respectfully requests that the OIG hold in abeyance any recalculation of the overpayment until the Hospital has completed its reprocessing of those claims with its MAC.

a. Each of the Contested Claims Met Medicare Coverage Criteria; Therefore, No Overpayment Occurred.

Norton disagrees with the Draft Report's findings regarding the 19 Contested Claims, and believes further adjudication of those claims will establish that they met Medicare coverage criteria, and, therefore, were properly submitted and paid under Medicare Part A. Accordingly, no basis exists for recoupment of these specific payments, and more importantly, the claim-errors should be removed from the extrapolation.

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[6] The Uncontested Claims are Patient Sample Nos.: 28, 60, 99, 101, 104, 105, 106, 112, 122, 124; the Contested Claims are Patient Sample Nos.: 14, 19, 25, 30, 40, 42, 46, 58, 74, 87, 98, 102, 109, 114, 115, 119, 121, 123, 125.

Medicare program guidance provides that the "decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors," including the patient's medical history, current medical needs, types of facilities available, hospital bylaws, admission policies, and the relative appropriateness of treatment in each setting. MEDICARE BENEFIT POLICY MANUAL, IOM Pub. 100-02, Ch. 1, § 10. Program guidance also states that the decision to admit a patient for inpatient services must be assessed based on the evidence that was available to the doctor at the time the decision was made. The fact that a patient does well during his or her inpatient stay is irrelevant to the evaluation of the admitting physician's decision to admit the patient for inpatient hospital services. Rather, the key factors for review are those that were known to the provider at the time of the admission, i.e., the patient's medical needs, medical history, co-morbidities, and the predictability of an adverse event. *See also* QUALITY IMPROVEMENT ORGANIZATION MANUAL, Ch. 4, § 4110.

In adherence to this guidance, Norton utilizes an external physician reviewer to assist in evaluating the medical decision making for patients classified as inpatient or outpatient or outpatient with observation services. In addition, our care managers use InterQual® Level of Care Criteria, for severity of illness and intensity of services, for screening patients to ensure placement in the proper status.

Upon patient admission or shortly thereafter, a member of the Care Management staff screens the episode of care and determines the expected needs as well as the appropriate level of service to best serve each patient on a case-by-case basis. The care manager, utilizing InterQual®, a nationally recognized standard of care criterion, reviews the medical record to assess for overall medical necessity, taking into consideration intensity of service, severity of illness and level of care required. For cases where the appropriate level of service cannot be absolutely determined, those cases are referred to an unbiased and independent physician reviewer for analysis. For each of the Contested Claims, with which the Hospital disagrees with the auditors' findings, the Hospital has either supporting documentation from that physician reviewer or supporting evidence from InterQual® criteria to confirm that the inpatient level of service was the most appropriate level of care and was medically necessary and reasonable in order to best serve our patient, pursuant to Medicare coverage criteria, regulations and policies.

In support of this response, we have appended as examples, at Exhibit A, a detailed clinical analysis of two Contested Claims, Patient Sample Nos. 14 and 114, which we believe support our position and require the OIG to review and reconsider its findings and recommendations.[7] We likewise believe the remaining Contested Claims, Patient Sample Nos. 19, 25, 30, 40, 42, 46, 58, 74, 87, 98, 102, 109, 115, 119, 121, 123, 125, met Medicare coverage criteria for inpatient admission; therefore, we intend to appeal those Contested Claims should the OIG not modify the finding here. Lastly, in the exercise of our appeal rights, we shall request at

[7] Pursuant to the OIG's directive, Exhibit A, which contains patient health information that cannot be redacted without altering the analysis, is being omitted from the electronic filing of this letter.

each level of appeal, the OIG's re-evaluation and recalculation of the overpayment for each reversal.[8]

2. Incorrectly Billed Diagnosis-Related Groups Codes.

The OIG auditors found that for 10 of 138 inpatient claims, Norton billed Medicare for incorrect DRG codes. As a result of these errors, the auditors contend that Norton received overpayments totaling $61,387.

Norton recognizes that coding assignment is a process open to coder interpretation of the documentation and guidelines available to the coder at the time of their review. After much discussion with the OIG auditors, Norton concurs that the 10 claims were in error and, as a result, we have resubmitted corrected claims to our MAC.

Norton remains committed to ensuring the most appropriate coding indicators are assigned to each claim for services provided. Norton maintains dynamic policies and procedures related to coding assignment to ensure organization-wide consistency and compliance with nationally recognized standards and guidelines available at the time of the assignment. We will continue with our current practice of using internal and third-party audits, identifying potential areas of concern or patterns of errors and, in addition, we will continue to provide ongoing coder education to ensure accuracy of diagnostic and procedural coding and DRG assignment.

3. Incorrectly Billed as Separate Inpatient Stay.

The OIG auditors found that for 6 of the 138 sampled claims, Norton incorrectly billed Medicare separately for related discharges and readmissions on the same day. As a result of these errors, the Draft Report states that Norton received overpayments totaling $38,414.

Norton concurs that the 6 claims were billed in error. It should be noted Norton has appropriate measures in place for reviewing and identifying potential same day readmissions. For the records in question, the report identified each of these cases as potential combined accounts and, prior to billing, the individual reviewing the cases determined the accounts should remain separate.

As a result of these findings, Norton has resubmitted corrected claims to our MAC.

Norton is confident that its recent completion of coder re-education will reduce the likelihood of such errors. Norton will continue reviewing, training and educating its staff to strive to eliminate such errors in the future.

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[8] The Hospital maintains that extrapolation at this state of the proceedings is premature and unfounded. The Hospital intends to appeal the Contested Claims, and may prevail on most, if not all, of them. As a result, the number of errors will keep shifting downward at each level of adjudication requiring repeated monetary adjustments and reconciliations between the MAC, the OIG and the Hospital. Hence, the MAC and the OIG will be called upon to not only recalculate the alleged overpayment, but also continue to try to justify the legality of extrapolation as the error rate declines.

4. Incorrect Reporting of Medical Device Credits.

The auditors found that for 3 of 138 inpatient claims, Norton incorrectly billed Medicare for medical devices that were under warranty. The draft report claims that, as a result of these errors, Norton received overpayments totaling $27,003.

Norton concurs that 3 claims were billed in error. Corrected claims are currently being reprocessed with the MAC.

During this audit, we identified a then current informal process related to the pursuit and reporting of applicable manufacturer rebates for medical devices. We found these measures insufficient to meet the Medicare requirement related to billing and reporting such rebates, thereby resulting in delays in obtaining manufacturer credit information and inconsistently communicating warranty or credit information to the Hospital's billing department, causing errors to occur. As a result of our self-audit, a new formal policy was implemented. The policy was the result of a meeting with all medical device vendor representatives, and with hospital billing, coding, materials management and clinical staff present to ensure proper charging and coding and reporting of applicable credits across all involved. As a result of this review, the new policy and procedure for explanted and/or replaced medical devices was put into place in May 2013.

5. Incorrect Source-of-Admission Code.

The OIG auditors found that for 4 of the 138 inpatient claims, Norton incorrectly coded the source-of-admission for beneficiaries who were admitted to its Inpatient Psychiatric Facility upon admission from its acute care setting or emergency services department. As a result, it received overpayments of $381.

Norton concurs with these findings and has submitted corrected claims with our MAC.

Norton is confident that recent changes to the electronic medical record along with the change of the inpatient psychiatric unit to the same hospital provider number will reduce the likelihood of source-of-admission code errors. Norton will also conduct periodic reviews to ensure compliance with Medicare coding and program guidance.

B. THE DRAFT REPORT BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS.

The Draft Report states that Norton incorrectly billed Medicare for 12 of the 92 outpatient claims, resulting in overpayments of $60,188.

1. Incorrect Reporting of Medical Device Credits.

The OIG auditors found that for 2 of 92 outpatient claims, Norton incorrectly billed Medicare for medical devices that were under warranty. The Draft Report estimates that, as a result, Norton received overpayments totaling $19,708.

Norton concurs that 2 claims were billed in error. See the corrective actions implemented for inpatient medical device credits. Norton has submitted corrected claims to our MAC.

2. Incorrectly Billed Number of Units.

The OIG auditors found that for 3 of 92 outpatient claims, Norton incorrectly billed Medicare for the number of units.

Norton concurs that these 3 claims were billed incorrectly.

In one instance, there was an incorrect number of units for the drug Doxorubicin Hydrochloride, resulting in an overpayment of $407. Though we believe the dosage charged was appropriate and correct, we found the documentation insufficient to justify the additional one unit of billable and reimbursable pharmaceutical waste.

In the second instance, we believe the medication was prepared and charged correctly, as the patient's medical record indicated a change of dosage related to the date of service; however, the documentation reflected the administration of the original, lower dosage as having been administered.

Norton has provided education to its pharmacy staff regarding the importance of waste documentation and accuracy of medication documentation.

In the third instance, a computer system-edit update caused the system to stop the conversion of surgery minutes to a single procedure for the purpose of billing. Although the Hospital concedes the errors occurred, it notes that the system-edit error had been identified prior to this review and all other accounts had been corrected.

Norton has submitted corrected claims to our MAC.

3. Insufficiently Documented Evaluation and Management Services.

The OIG auditors also found that for 7 of 92 outpatient claims, Norton incorrectly billed Medicare for Evaluation and Management Services that were insufficiently documented in the medical records, resulting in an overpayment of $322.

Norton concurs that these 7 claims were billed incorrectly. Norton has submitted corrected claims to our MAC.

The account errors noted were inadvertent, and resulted from inadequacies in the patient care system to identify new versus established patients across healthcare settings, when patients received services at one of our hospitals and subsequently received services in one of our physician or outpatient settings. The errors occurred due to the complexity of the coding rules and Hospital coders' subjective interpretation of their meaning. Norton has retrained and educated its staff on the documentation and the billing requirements to avoid further error and to ensure system-wide understanding of the currently applicable regulations and guidelines.

IV. NORTON'S INTERNAL CONTROL STRUCTURE AND CORRECTIVE ACTION PLANS

As part of our Compliance Program, the Hospital is committed to operating in compliance with all the applicable rules and regulations governing the healthcare industry. Norton's System Compliance Program has the infrastructure to allow for necessary education and training with ongoing auditing and monitoring of the various at-risk areas. The hospital routinely conducts internal coding audits on hospital and physician coders and also engages an external audit firm to perform an independent assessment on coding compliance. Even as strong and effective as our Compliance Program is, exceptions will occur at times given the complexity of medical decision making and interpretation of clinical documentation leading to accurate coding and billing of patient claims.

When exceptions are identified, the Hospital takes appropriate corrective action as may be necessary, including refunding claims to its MAC, retraining its staff, conducting follow-up review either internally or by an external audit firm.

To ensure that patients are correctly assigned to the appropriate clinical setting (categorized as either inpatient or outpatient or outpatient observation), the Hospital will continue to engage an external physician reviewer to assist in evaluating the medical decision making and our care managers will continue to use InterQual® Level of Care Criteria for severity of illness and intensity of services, for screening patients to ensure placement in the most appropriate clinical setting for the patient medical needs.

To ensure accurate claims regarding credits of medical devices, we have appointed a compliance staff, knowledgeable in the area of medical devices, who will receive medical device credit reports on a monthly basis, and the Compliance Department will conduct periodic audits to confirm billing accuracy.

Norton takes the audit findings very seriously, and has taken affirmative steps to strengthen internal control structure, increase auditing to better scrutinize claims, and re-educate staff where opportunities exist to improve accuracy and eliminate confusion. We therefore accept the opportunity this audit process has provided us to further enhance our commitment to a strong and effective Compliance Program.

V. CONCLUSION

For the reasons set forth herein, the Hospital requests that the OIG reconsider its overpayment calculation and its basis for extrapolation. As the Draft Report acknowledges, a portion of the alleged overpayment is properly billable under Medicare Part B, and therefore, those payments, once received, will reduce the current estimated overpayment. Further, we maintain that several of the Contested Claims will be found to have been properly paid under Medicare Part A, which will also reduce the estimated overpayment. For these reasons, the Hospital believes extrapolating overpayment damages from these claims is inappropriate, and requests that the OIG abandon its use here.

We thank you in advance for your consideration of the concerns raised in this response.

If you have any questions on the content of this letter, please contact John Sass, System Vice President of Compliance/Audit at (502) 629-8422.

Sincerely,

/Michael W. Gough/

Michael W. Gough
System Senior Vice-President of Operations
Chief Financial Officer

Encl.: Exhibit A—Medical Necessity Analysis of Patient Sample Nos. 14 & 114
(*omitted from electronic submission*)

cc: John Sass, Norton Healthcare, Inc.