

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE COMPLIANCE  
REVIEW OF  
ST. VINCENT'S MEDICAL CENTER  
FOR CALENDAR YEARS  
2009 AND 2010**

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# *Office of Inspector General*

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## **EXECUTIVE SUMMARY**

### **BACKGROUND**

Title XVIII of the Social Security Act (the Act) established the Medicare program, which provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

Section 1886(d) of the Act established the inpatient prospective payment system (IPPS) for hospital inpatient services. Under the 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. In addition to the basic prospective payment, hospitals may be eligible for an additional payment, called an outlier payment, when the hospital's costs exceed certain thresholds.

CMS implemented an outpatient prospective payment system (OPPS) for hospital outpatient services, as mandated by the Balanced Budget Act of 1997, P.L. No. 105-33, and the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999, P.L. No. 106-113. Under the OPPS, Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification.

Prior Office of Inspector General (OIG) audits, investigations, and inspections identified certain hospital claims that are at risk for noncompliance with Medicare billing requirements. OIG identified these types of claims using computer matching, data mining, and analysis of claims. This review is part of a series of OIG reviews of Medicare payments to hospitals for selected types of claims for inpatient and outpatient services.

St. Vincent's Medical Center, Inc. (the Hospital), is a 528-bed acute care facility located in Jacksonville, Florida. Medicare paid the Hospital approximately \$279 million for 30,587 inpatient and 223,186 outpatient claims for services provided to beneficiaries during calendar years (CYs) 2009 and 2010 based on CMS's National Claims History data.

Our audit covered \$30,762,321 in Medicare payments to the Hospital for 4,087 claims that were potentially at risk for billing errors. We randomly selected a sample of 200 (197 inpatient and 3 outpatient) claims with payments totaling \$1,382,935 for review. Additionally, we judgmentally selected 7 (2 inpatient and 5 outpatient) claims involving replaced medical devices totaling \$65,022. These 207 claims had dates of service in CYs 2009 and 2010.

### **OBJECTIVE**

Our objective was to determine whether the Hospital complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims.

## **SUMMARY OF FINDINGS**

The Hospital complied with Medicare billing requirements for the majority of the claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for 52 claims resulting in overpayments totaling \$282,217. Specifically:

- 45 randomly selected inpatient claims had overpayments totaling \$246,316,
- 2 judgmentally selected inpatient claims had overpayments totaling \$15,084, and
- 5 judgmentally selected outpatient claims had overpayments totaling \$20,817.

Overpayments occurred primarily because the Hospital did not have adequate controls to prevent incorrect billing of Medicare claims within the selected risk areas that contained errors.

Based on our random sample results, we estimated that the Hospital received overpayments totaling at least \$3,248,566 for CYs 2009 and 2010. In addition, based on our judgmental sample results, the Hospital received overpayments totaling \$35,901 for 7 claims involving medical devices.

## **RECOMMENDATIONS**

We recommend that the Hospital:

- refund to the Medicare program \$3,248,566 in estimated overpayments for CYs 2009 and 2010 claims that it incorrectly billed,
- refund to the Medicare program \$35,901 in overpayments for CY 2009 that it incorrectly billed for medical device claims, and
- strengthen controls to ensure full compliance with Medicare requirements.

## **ST. VINCENT'S MEDICAL CENTER COMMENTS**

In written comments on our draft report, the Hospital did not agree with our first recommendation and stated that CMS is time-barred from recovering any claims paid in 2009. Section 1870(b) of the Act prohibits recovery of any paid claims subsequent to the third calendar year after the year of payment because providers are deemed to be “without fault.” For claims paid in 2009, the last day to recover an overpayment was December 31, 2012. In addition, even if the Hospital were not “without fault,” many of the 2009 claims could not be reopened beyond 4 years under Medicare’s reopening rules, even if CMS could establish “good cause.”

The Hospital contested that 31 inpatient claims were improperly billed. For these, it either did not agree with our error determinations or argued the claim was time-barred. The Hospital had further concerns over our use of both judgmental and statistical sampling approaches in this audit. It objected to the use of statistical sampling and extrapolation as being unwarranted as a

matter of law and statistical integrity and said that statistical sampling could result in repaying Medicare twice if claims under review by a Recovery Audit Contractor (RAC) were included in the sampling frame.

The Hospital also disagreed with our second recommendation. Specifically, the Hospital stated that all 7 judgmentally selected, medical device claims were time-barred from being recovered. In regard to our third recommendation, the Hospital discussed steps it had taken or planned to take to strengthen its internal controls to ensure compliance with Medicare billing requirements.

## **OFFICE OF INSPECTOR GENERAL RESPONSE**

### **Claims Remain Subject to Reopening and Recovery**

We disagree with the Hospital's assertion that the 2009 claims are time-barred. The claims from 2009 are eligible for reopening under the "similar fault" provisions of the reopening regulations at 42 CFR part 405, subpart I. The regulation at section 405.980(b) provides that an initial determination or redetermination can be reopened at any time if there is reliable evidence of fraud or similar fault. Although OIG is not alleging that the Hospital engaged in fraud, its improper billings are sufficient to establish "similar fault" under current Medicare guidance (42 CFR § 405.902 and 70 Fed. Reg. 11420 and 11450 (March 8, 2005)). Therefore, there is no time limit that would prohibit the reopening of the claims questioned in this report.

The Hospital is not "without fault" with respect to the claims questioned in the report and, therefore, recovery is not time-barred under the Act, section 1870(b). CMS guidance states that a provider is not without fault if, among other circumstances, the provider should have known that the underlying services were non-covered. Furthermore, a provider should know of a policy or rule if the policy or rule is in the provider manual or in Federal regulation (*Medicare Financial Management Manual*, Pub. 100-06, chapter 3, § 90.1). We questioned the claims in this report on the basis of criteria drawn from statutory, regulatory, and manual provisions with which the Hospital is expected to be familiar. Therefore, the Hospital is not "without fault" with respect to our findings above.

### **Contested Determinations of Claims**

After issuing our draft report, we obtained an independent medical review of all remaining inpatient claims for medical and coding errors. This information resulted in a reduction from 56 to 47 in the number of inpatient claims that we identified in our draft report as being in error. Our report now reflects the results of the additional medical review determinations, and we adjusted our first recommendation to reflect the reductions in the total estimated overpayment to \$3,248,566.

### **Statistical Sampling**

During the course of the audit, we discussed with a Hospital official our plans to use statistical sampling. As the hospital compliance review initiative has matured, we have refined our audit methodologies. Some reviews use statistical sampling and estimation techniques to draw

conclusions about a larger portion of a hospital's claims while other reviews use judgmental sampling. Each hospital review is unique, and the sampling method used in each of these reviews will vary. For this reason, we review different risk areas at different hospitals and use both statistical and non-statistical methods for selecting our samples.

We acknowledge that most previously published compliance reviews did not use statistical sampling and estimation. However, we maintain that the statistical sampling and estimation techniques planned and used for this review are statistically valid methodologies that we have successfully used to identify overpayments. In response to the Hospital's concerns over our use of both judgmental and statistical sampling approaches in this audit, we identified the seven judgmentally selected medical device claims prior to random sampling. We did not include these claims in the sampling frame for the statistically selected claims and did not use them as the basis for extrapolation. We did rely on a statistically valid sample.

With respect to the Hospital's concern about being potentially at risk more than once for reviews of the same claims in our sampling frame, we have taken steps to exclude all claims in our sampling frame from future RAC review. However, to prevent repaying Medicare twice for claims we audited, the Hospital should tell CMS which claims in our sampling frame were previously adjusted as a result of a RAC review. CMS can then reduce the amount we recommended the Hospital refund (\$3,248,566) by the amount already repaid as a result of any RAC review.

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D: ST. VINCENT'S MEDICAL CENTER COMMENTS

# INTRODUCTION

## BACKGROUND

Title XVIII of the Social Security Act (the Act) established the Medicare program, which provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program. Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge. Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services.

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

### **Hospital Inpatient Prospective Payment System**

Section 1886(d) of the Act established the inpatient prospective payment system (IPPS) for hospital inpatient services. Under the 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. In addition to the basic prospective payment, hospitals may be eligible for an additional payment, called an outlier payment, when the hospital's costs exceed certain thresholds.

### **Hospital Outpatient Prospective Payment System**

CMS implemented an outpatient prospective payment system (OPPS) for hospital outpatient services, as mandated by the Balanced Budget Act of 1997, P.L. No. 105-33, and the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999, P.L. No. 106-113.<sup>1</sup> The OPPS is effective for services furnished on or after August 1, 2000. 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.<sup>2</sup> All services and items within an APC group are comparable clinically and require comparable resources.

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<sup>1</sup> In 2009 SCHIP was formally redesignated as the Children's Health Insurance Program.

<sup>2</sup> HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

## **Hospital Claims at Risk for Incorrect Billing**

Prior Office of Inspector General (OIG) audits, investigations, and inspections identified certain hospital claims that are at risk for noncompliance with Medicare billing requirements. OIG identified these types of hospital claims using computer matching, data mining, and analysis of claims. The types of claims identified included:

- inpatient claims for short stays,
- inpatient claims billed with high-severity-level DRG codes,
- inpatient claims paid in excess of charges,
- inpatient and outpatient manufacturer credits for replaced medical devices,
- inpatient claims with same day discharges and readmissions, and
- outpatient claims greater than \$25,000.

For purposes of this report, we refer to these areas at risk for incorrect billing as “risk areas.” This review is part of a series of OIG reviews of Medicare payments to hospitals for selected types of claims for inpatient and outpatient services.

## **Medicare Requirements for Hospital Claims and Payments**

Section 1862(a)(1)(A) of the Act states that 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.” In addition, 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.

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

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.

## **St. Vincent’s Medical Center, Inc.**

St. Vincent’s Medical Center, Inc. (the Hospital), is a 528-bed acute care facility located in Jacksonville, Florida. According to CMS’s National Claims History (NCH) data, Medicare paid the Hospital approximately \$279 million for 30,587 inpatient and 223,186 outpatient claims for services provided to beneficiaries during calendar years (CYs) 2009 and 2010.

## **OBJECTIVE, SCOPE, AND METHODOLOGY**

### **Objective**

Our objective was to determine whether the Hospital complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims.

### **Scope**

Our audit covered \$30,762,321 in Medicare payments to the Hospital for 4,087 claims that were potentially at risk for billing errors from which we randomly selected a sample of 200 (197 inpatient and 3 outpatient) claims totaling \$1,382,935. Additionally, we judgmentally selected 7 (2 inpatient and 5 outpatient) claims involving replaced medical devices totaling \$65,022. These 207 claims had dates of service in CYs 2009 and 2010.

We focused our review on the risk areas that we had identified as a result of prior OIG reviews at other hospitals. We evaluated compliance with selected billing requirements and subjected 63 inpatient claims to focused medical review to determine whether the services met medical necessity and coding requirements. 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 February through November 2012.

### **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 CYs 2009 and 2010;
- obtained information on known credits for replaced cardiac medical devices from the device manufacturers for CYs 2009 and 2010;
- used computer matching, data mining, and analysis techniques to identify claims potentially at risk for noncompliance with selected Medicare billing requirements;
- selected a judgmental sample of 7 claims (2 inpatient and 5 outpatient) totaling \$65,022 (involving manufacturer credits for replaced medical devices) for detailed review;

- selected a random sample of 200 claims (197 inpatient and 3 outpatient) totaling \$1,382,935 for detailed review (Appendix A);
- 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, HCPCS and admission status codes for Medicare claims;
- discussed the incorrectly billed claims with Hospital personnel to determine the underlying causes of noncompliance with Medicare requirements;
- used an independent medical review contractor to determine whether 63 sampled claims met medical necessity and coding requirements;
- calculated the correct payments for those claims requiring adjustment;
- used OIG/Office of Audit Services (OAS) software to estimate the total overpayment to the Hospital (Appendix B); 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.

## **FINDINGS AND RECOMMENDATIONS**

The Hospital complied with Medicare billing requirements for the majority of the claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for 52 claims resulting in overpayments totaling \$282,217. Specifically:

- 45 randomly selected inpatient claims had overpayments totaling \$246,316,
- 2 judgmentally selected inpatient claims had overpayments totaling \$15,084, and
- 5 judgmentally selected outpatient claims had overpayments totaling \$20,817.

Overpayments occurred primarily because the Hospital did not have adequate controls to prevent incorrect billing of Medicare claims within the selected risk areas that contained errors.

Based on our random sample results, we estimated that the Hospital received overpayments totaling at least \$3,248,566 for CYs 2009 and 2010. See Appendix A for details on our sample design and methodology, Appendix B for our sample results and estimates, and Appendix C for the results of our review by risk area. In addition, based on our judgmental sample results, the Hospital received overpayments totaling \$35,901 for 7 claims involving medical devices.

## **BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS**

The Hospital incorrectly billed Medicare for 47 of the 199 inpatient claims that we reviewed. Some claims contained more than one type of error.<sup>3</sup> These errors resulted in overpayments totaling \$261,400.

### **Incorrectly Billed as Inpatient**

Section 1862(a)(1)(A) of the Act states that 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.” Section 1814(a)(3) of the Act states that 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....” Federal regulations (42 CFR § 424.13(a)) 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.

For 43 of 199 inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for inpatient status and either should have been billed as outpatient or outpatient with observation services, or did not have a valid physician’s order to admit the beneficiary to inpatient care.

- For 42 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. Additionally, some of these contained multiple errors such as the medical records contained conflicting or unclear admission information. For example, a physician wrote, “Change from inpatient to day-stay per care management (protocol),” and the Hospital defaulted to inpatient admission. Other claims were supported by medical records on which the care manager wrote a clarifying order from “observation” to “inpatient” status that was not subsequently authenticated by a physician, and the Hospital defaulted to inpatient admission. One judgmentally selected claim, totaling

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<sup>3</sup> For randomly sampled claims that contained more than one type of error, the total claim overpayment was used for error estimation. We did not estimate errors on the same claim twice.

\$11,484, also contained multiple errors. For this claim, the medical record contained a standing order indicating that the patient should “remain in the current status. The Care Manager to review and change status based on CM (Care Manager) protocol [*sic*],” and the Hospital defaulted to inpatient admission and incorrectly billed a warranty credit.

- For 1 claim, 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 a valid order signed by a physician.

The Hospital stated that these errors occurred because physicians were not always required to write or certify orders that designated the level of service required for treatment. Additionally, care manager shortages prevented screenings from being conducted before patients were discharged, and chart errors were not identified and corrected timely. As a result, the Hospital received overpayments totaling \$252,819.<sup>4</sup>

### **Incorrect Diagnosis-Related Group Codes**

Section 1862(a)(1)(A) of the Act states that 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.” Chapter 1, section 80.3.2.2, of the Manual requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly.

For 1 of 199 inpatient claims, the Hospital billed Medicare for incorrect DRG codes. The Hospital stated that this coding error occurred because its medical coders misinterpreted the code guidelines for correct sequencing and coding of the claim. As a result, the Hospital received an overpayment of \$1,874.

### **Incorrect Reporting of Medical Device Credit**

Federal regulations (42 CFR § 412.89) require reductions in the inpatient prospective payment 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. The Manual, chapter 3, section 100.8, 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.”

For 1 of 199 inpatient claims, the Hospital received a reportable medical device credit from a manufacturer for a replaced device but did not adjust its inpatient claim with the proper condition

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<sup>4</sup> With the exception of the claims that did not have a valid physicians order, 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 or adjudicated by the Medicare administrative contractor prior to the issuance of our report.

and value codes to reduce payment as required. The Hospital stated that this error occurred because the manufacturer did not receive the explanted device from the Hospital and the credit dollar amount was not known at the time of billing. As a result, the Hospital received an overpayment of \$3,600 on this judgmentally selected claim.

### **Incorrect Discharge Status**

Federal regulations (42 CFR § 412.4(c) and (f)) 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 a home under a written plan of care for the provision of home health services from a home health agency and those services begin within 3 days after the date of discharge. 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.

For 1 of 199 inpatient claims, the Hospital billed Medicare for a patient discharge that should have been billed as a transfer. For this claim, the Hospital should have coded the discharge status as a transfer to home under a written plan of care for the provision of home health services. However, the Hospital incorrectly coded the discharge status to home, thus the Hospital should have received the per diem payment instead of the full DRG. The Hospital stated that this error occurred because the medical record contained conflicting information that resulted in the medical coder selecting the incorrect discharge status. As a result, the Hospital received an overpayment of \$2,876.

### **Incorrect Charges Resulting in an Improper Outlier Payment**

Section 1815(a) of the Act precludes payment to any provider without information necessary to determine the amount due the provider. Chapter 3, section 10, of the Manual states that a hospital may bill only for services provided. Additionally, chapter 1, section 80.3.2.2, requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly.

For 1 of the 199 inpatient claims, the Hospital incorrectly billed Medicare for pharmacy services, supplies, and injection procedures that the medical records did not support as having ever been given to the patient. The Hospital indicated that this error occurred because its procedures did not provide information necessary to ensure that discrepancies between the billing system and the medical record documentation were identified and corrected. As a result, the Hospital received an overpayment of \$231.

## **BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS**

The Hospital incorrectly billed Medicare for 5 of the 8 outpatient claims that we reviewed. These errors resulted in overpayments totaling \$20,817.

## **Incorrect Reporting of Medical Device Credits**

Federal regulations (42 CFR § 419.45) require a reduction in the OPSS 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.

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 OPSS. 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 5 of the 8 outpatient claims, 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 the manufacturers did not always receive the explanted devices from the Hospital and the credit dollar amount was not known at the time of billing. As a result, the Hospital received overpayments totaling \$20,817 for these judgmentally selected claims.

## **OVERALL ESTIMATE OF OVERPAYMENTS**

Based on our random sample results, we estimated that the Hospital received overpayments totaling at least \$3,248,566 for CYs 2009 and 2010. See Appendix A for details on our sample design and methodology and Appendix B for our sample results and estimates. In addition, based on our judgmental sample results, the Hospital received overpayments totaling \$35,901 for 7 claims involving medical devices.

## **RECOMMENDATIONS**

We recommend that the Hospital:

- refund to the Medicare program \$3,248,566 in estimated overpayments for CYs 2009 and 2010 claims that it incorrectly billed,
- refund to the Medicare program \$35,901 in overpayments for CY 2009 that it incorrectly billed for medical device claims, and
- strengthen controls to ensure full compliance with Medicare requirements.

## **ST. VINCENT’S MEDICAL CENTER COMMENTS**

In written comments on our draft report, the Hospital did not agree with our first recommendation. In regard to our second recommendation, the Hospital stated that all 7

judgmentally selected medical device claims were time-barred from being recovered. In regard to our third recommendation, the Hospital discussed steps it had taken or planned to take to strengthen its internal controls to ensure compliance with Medicare billing requirements.

### **2009 Claims Are Time-Barred**

The Hospital stated that CMS is time-barred from recovering any claims paid in 2009. Section 1870(b) of the Act prohibits recovery of any paid claims subsequent to the third calendar year after the year of payment because providers are deemed to be “without fault.” For claims paid in 2009, the last day to recover an overpayment was December 31, 2012. In addition, even if the Hospital were not “without fault,” many of the 2009 claims could not be reopened beyond 4 years under Medicare’s reopening rules, even if CMS could establish “good cause.”

### **Contested Determinations of Claims**

The Hospital contested that 31 inpatient claims were improperly billed. For these, it either did not agree with our error determinations or argued the claim was time-barred.

### **Statistical Sampling**

The Hospital objected to the use of statistical sampling and extrapolation as being unwarranted as a matter of law and statistical integrity and said that statistical sampling could result in repaying Medicare twice if claims under review by a Recovery Audit Contractor (RAC) were included in the sampling frame.

#### *Matter of Law*

With respect to the matter of law, the Hospital noted that the authority of CMS and its contractors to extrapolate is subject to strict statutory and regulatory limits.

#### *Statistical Integrity*

The Hospital stated that including both judgmentally and statistically selected claims in the same audit invalidates the statistical estimations. Secondly, it had concerns with the decision to extrapolate the results of the audit using a post-stratification methodology. Thirdly, the Hospital contended that the integrity of the statistical sampling is harmed by the unacceptably high precision level of 30.72 percent at the 90-percent confidence level and recommended that OIG not use claims from Stratum 2 for extrapolation.

#### *Duplicate Refunds*

The Hospital said that our sample frame included several claims that the RAC had also reviewed. The Hospital believed that including RAC claims in our sample frame, especially claims that the Hospital had already repaid, would result in the Hospital repaying Medicare twice.

The Hospital's response is included as Appendix D. We excluded supporting schedules and reference material from the Hospital's response because it included personally identifiable information.

## **OFFICE OF INSPECTOR GENERAL RESPONSE**

### **Claims Remain Subject to Reopening and Recovery**

We disagree with the Hospital's argument that the 2009 claims are time-barred.

#### *Reopening*

The claims from 2009 are eligible for reopening under the "similar fault" provisions of the reopening regulations at 42 CFR part 405, subpart I. The regulation at section 405.980(b) provides that an initial determination or redetermination can be reopened at any time if there is reliable evidence of fraud or similar fault. Although OIG is not alleging that the Hospital engaged in fraud, its improper billings are sufficient to establish "similar fault" under current Medicare guidance (42 CFR § 405.902 and 70 Fed. Reg. 11420 and 11450 (March 8, 2005)). Therefore, there is no time limit that would prohibit the reopening of the claims questioned in this report.

#### *Recovery*

The Hospital is not "without fault" with respect to the claims questioned in the report and, therefore, recovery is not time-barred under section 1870(b). CMS guidance states that a provider is not without fault if, among other circumstances, the provider should have known that the underlying services were non-covered. Furthermore, a provider should know of a policy or rule if the policy or rule is in the provider manual or in Federal regulation (*Medicare Financial Management Manual*, Pub. 100-06, chapter 3, § 90.1). We questioned the claims in this report on the basis of criteria drawn from statutory, regulatory, and manual provisions with which the Hospital is expected to be familiar. Therefore, the Hospital is not "without fault" with respect to our findings above.

### **Contested Determinations of Claims**

After issuing our draft report, we obtained an independent medical review of all remaining inpatient claims for medical and coding errors. This information resulted in a reduction from 56 to 47 in the number of inpatient claims that we identified in our draft report as being in error. Our report now reflects the results of the additional medical review determinations, and we adjusted our first recommendation to reflect the reductions in the total estimated overpayment to \$3,248,566.

### **Statistical Sampling**

During the course of the audit, we discussed with a Hospital official our plans to use statistical sampling. As the hospital compliance review initiative has matured, we have refined our audit methodologies. Some reviews use statistical sampling and estimation techniques to draw

conclusions about a larger portion of a hospital's claims while other reviews use judgmental sampling. Each hospital review is unique, and the sampling method used in each of these reviews will vary. For this reason, we review different risk areas at different hospitals and use both statistical and non-statistical methods for selecting our samples.

We acknowledge that most previously published compliance reviews did not use statistical sampling and estimation. However, we maintain that the statistical sampling and estimation techniques planned and used for this review are statistically valid methodologies that we have successfully used to identify overpayments. Therefore, we recommend that the Hospital refund to the Medicare program \$3,248,566 in estimated overpayments for the audit period.

### *Matter of Law*

Courts have long held the validity of using sampling and extrapolation in audits of Federal health programs.<sup>5</sup> Furthermore, such statistical sampling and methodology may be used in cases seeking recovery against States, individual providers, and private institutions.<sup>6</sup>

### *Statistical Integrity*

In response to the Hospital's concerns over our use of both judgmental and statistical sampling approaches in this audit, we identified the seven judgmentally selected medical device claims prior to random sampling. We did not include these claims in the sampling frame for the statistically selected claims and did not use them as the basis for extrapolation. We did rely on a statistically valid sample.<sup>7</sup> In his book, *Sample Design in Business Research*, W. Edwards Deming (1960) states: "An estimate made from a sample is valid if it is unbiased or nearly so and if we can compute its margin of sampling error for a given probability." We select our samples according to principles of probability (every sampling unit has a known, nonzero chance of selection). We use the difference estimator (an unbiased estimator) for monetary recovery and recommend recovery at the lower limit of the 90-percent, two-sided confidence interval. After further medical review of Stratum 2 claims, we have not estimated errors related to claims in Stratum 2, but the dollar value of the claim overpayments from Stratum 2 have been added to the total estimated overpayments.

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<sup>5</sup> See, e.g., *State of Georgia v. Califano*, 446 F. Supp. 404, 409-410 (N.D.Ga. 1977) (ruling that sampling and extrapolation are valid audit techniques for programs under Title IV of the Social Security Act); *Ratanasen v. California Dept. of Health Servs.*, 11 F. 3d 1467, 1471-72 (9th Cir. 1993) (ruling that simple random sampling and subsequent extrapolation were valid techniques to calculate Medi-Cal overpayments); *Illinois Physicians Union v. Miller*, 675 F. 2d 151, 155-56 (7th Cir. 1982) (ruling that random sampling and extrapolation were valid statistical techniques for calculating Medicaid overpayments claimed against an individual physician).

<sup>6</sup> *Illinois Physicians Union v. Miller*, 675 F. 2d 151, 155-56 (7th Cir. 1982).

<sup>7</sup> See Puerto Rico Department of Health, DAB (Departmental Appeals Board) No. 2385 (2011) (DAB upholding disallowance of claims based on statistical sampling and statistical methodology).

### *Duplicate Refunds*

With respect to the Hospital's concern about being potentially at risk more than once for reviews of the same claims in our sampling frame, we have taken steps to exclude all claims in our sampling frame from future RAC review. However, to prevent repaying Medicare twice for claims we audited, the Hospital should tell CMS which claims in our sampling frame were previously adjusted as a result of a RAC review. CMS can then reduce the amount we recommended the Hospital refund (\$3,248,566) by the amount already repaid as a result of any RAC review.

# **APPENDIXES**

## **APPENDIX A: SAMPLE DESIGN AND METHODOLOGY**

### **POPULATION**

The population is inpatient and outpatient claims paid to the Hospital for services provided to Medicare beneficiaries during CYs 2009 and 2010.

### **SAMPLING FRAME**

According to CMS's National Claims History (NCH) data, Medicare paid the Hospital \$279,199,261 for 30,587 inpatient and 223,186 outpatient claims for services provided to beneficiaries during CYs 2009 and 2010.

We obtained a database of claims from the NCH data totaling \$156,645,074 for 14,369 inpatient and 59,566 outpatient claims in 30 high-risk areas. From the 30 high-risk areas, we selected 6 that consisted of 4,565 claims totaling \$35,061,476. The high-risk categories are: Inpatient Short Stays, Inpatient Claims With High-Severity-Level DRG Codes, Inpatient Claims Paid in Excess of Charges, Medical Devices, Outpatient Claims Greater Than \$25,000, and Inpatient Claims With Same Day Discharge and Readmission.

We combined claims from each of the high-risk areas into a single database. We then removed 478 claims totaling \$4,299,154 as follows:

- all claims that were \$0,
- all claims that were under review by the Recovery Audit Contractor, and
- all duplicate claims.

This resulted in 4,087 unique Medicare claims remaining, totaling \$30,762,321, from which we drew our sample.

### **SAMPLE UNIT**

The sample unit was a Medicare paid claim.

### **SAMPLE DESIGN**

We used simple random sampling to select the sample claims.

### **SAMPLE SIZE**

We selected 200 sample claims for review.

## SOURCE OF RANDOM NUMBERS

We generated 200 random numbers using the Office of Inspector General, Office of Audit Services, statistical software Random Number Generator.

## METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the claims in our sampling frame from 1 to 4,087. After generating the 200 random numbers, we selected the corresponding claims from our sampling frame.

## ESTIMATION METHODOLOGY

Post-stratification: After randomly selecting 200 sample claims from our sampling frame of 4,087 unique Medicare claims, we stratified these claims into one of three different strata:

**Sampled Claims by Stratum<sup>8</sup>**

<b>Stratum</b>	<b>Medicare High-Risk Area</b>	<b>Number of Claims in Sample Frame</b>	<b>Number of Claims in the Sample</b>
1	Inpatient Short Stays	2,307	110
2	Inpatient Claims With High-Severity-Level DRG Codes	1,275	73
3	Inpatient Claims Paid in Excess of Charges	286	11
	Medical Devices	158	4
	Outpatient Claims Greater Than \$25,000	46	2
	Inpatient Same Day Discharges and Readmissions	15	0
	<b>TOTAL</b>	<b>4,087</b>	<b>200</b>

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<sup>8</sup> Each claim can appear in only one stratum.

## APPENDIX B: SAMPLE RESULTS AND ESTIMATES

### SAMPLE RESULTS

Stratum	Frame Size (Claims)	Value of Frame	Sample Size	Value of Sample	Number of Improperly Billed Claims in Sample	Value of Overpayments in Sample
1	2,307	\$15,383,467	110	\$726,871	40	\$221,047
2	1,275	9,009,435	73	480,910	5	25,269
3	505	6,369,419	17	175,154	0	0
<b>Total</b>	<b>4,087</b>	<b>\$30,762,321</b>	<b>200</b>	<b>\$1,382,935</b>	<b>45</b>	<b>\$246,316</b>

### ESTIMATES

#### Estimated Value of Overpayments for CYs 2009 and 2010 *Limits Calculated for a 90-Percent Confidence Interval*

Point Estimate	\$4,635,969
Lower limit	\$3,248,566 <sup>9</sup>
Upper limit	\$6,048,642

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<sup>9</sup> In accordance with OAS policy, we did not use the results from Stratum 2 in calculating the estimated overpayments. Instead, we added the actual overpayment from Stratum 2 (\$25,269) to the lower limit (\$3,223,297), which resulted in an adjusted lower limit of \$3,248,566.

**APPENDIX C: RESULTS OF REVIEW BY RISK AREA**

<b>Risk Area for Random Sample</b>	<b>Selected Claims</b>	<b>Value of Selected Claims</b>	<b>Claims With Over-payments</b>	<b>Value of Over-payments</b>
<b>Inpatient</b>				
Short Stays	110	\$726,871	40	\$221,047
Claims Billed With High-Severity-Level DRG Codes	73	480,910	5	25,269
Claims Paid in Excess of Charges	11	79,411	0	0
Manufacturer Credits for Replaced Medical Devices	3	23,808	0	0
Same Day Discharges and Readmissions	0	0	0	0
<b>Inpatient Totals</b>	<b>197</b>	<b>\$1,311,000</b>	<b>45</b>	<b>\$246,316</b>
<b>Outpatient</b>				
Claims Greater Than \$25,000	2	\$51,642	0	\$0
Manufacturer Credits for Replaced Medical Devices	1	20,293	0	0
<b>Outpatient Totals</b>	<b>3</b>	<b>\$71,935</b>	<b>0</b>	<b>\$0</b>
<b>Inpatient and Outpatient Totals</b>	<b>200</b>	<b>\$1,382,935</b>	<b>45</b>	<b>\$246,316</b>
<b>Risk Area for Judgmental Sample</b>				
<b>Inpatient</b>				
Manufacturer Credits for Replaced Medical Devices	2	\$30,856	2	\$15,084
<b>Outpatient</b>				
Manufacturer Credits for Replaced Medical Devices	5	\$34,166	5	\$20,817
<b>Inpatient and Outpatient Totals</b>	<b>7</b>	<b>\$65,022</b>	<b>7</b>	<b>\$35,901</b>

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 St. Vincent's Medical Center. 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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## COMMENTS

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May 15, 2013

### BY Federal Express and Electronic Mail

Lori S. Pilcher  
Regional Inspector General for Audit Services  
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Re: Response to the Draft Report regarding the Medicare Compliance Review of St. Vincent's Medical Center, Jacksonville, Florida, Report Number: A-04-12-08013

Dear Ms. Pilcher:

Dentons US LLP respectfully submits this letter and the accompanying binder of exhibits on behalf of St. Vincent's Medical Center, Inc. ("St. Vincent's" or "Hospital"), a non-profit, faith-based, acute care hospital located in Jacksonville, Florida. Specifically, the letter responds to the draft audit report (the "Draft Report") — entitled, "St. Vincent's Medical Center Did Not Fully Comply With Some Medicare Billing Requirements," Draft Audit Report, No. A-04-12-0813 — that the U.S. Department of Health and Human Services, Office of Inspector General ("HHS-OIG") sent to St. Vincent's by letter dated March 14, 2013. It is the Hospital's hope that HHS-OIG will carefully review and seriously consider St. Vincent's response in its entirety because, for the reasons set forth below, the Hospital is of the view that both the Draft Report and the underlying audit are sufficiently flawed — as a combined matter of law, statistical validity and fairness — as to require that the Draft Report not be finalized and issued to the public at this time. Instead, the Hospital urges HHS-OIG to reconvene with St. Vincent's and its representatives at its earliest convenience for good faith discussions regarding appropriate solutions to the fundamental deficiencies in the HHS-OIG audit ("Audit").

#### I. Draft Report: Background

The Audit is part of a national auditing initiative in which HHS-OIG sought to identify whether hospitals were complying with Medicare billing requirements for certain types of claims that HHS-OIG believed were at risk for noncompliance. The Audit focused on six (6) claim categories: (1) inpatient claims for "short stays",<sup>1</sup> (2) inpatient claims with high-severity diagnosis-related group ("DRG") codes, (3) inpatient claims paid in excess of charges, (4) inpatient and outpatient claims involving medical device credits for replaced devices, (5) outpatient claims greater than \$25,000 and (6) inpatient claims with same day discharges and readmissions ("Risk Categories").<sup>2</sup>

<sup>1</sup> It is the Hospital's understanding that a "short stay" for purposes of the Audit included a claim with an admission and discharge on the same calendar day and a claim in which discharge occurred on the day immediately following the day of admission.

<sup>2</sup> Draft Report, at 2.

The Audit involved claims with dates of services in calendar years 2009 and 2010. In all, HHS-OIG identified a total universe of 4,087 claims within the six Risk Categories (the "Universe of Claims"), representing a total of \$30,762,321 in Medicare payments. HHS-OIG then selected for review a purportedly random sample of 200 claims (197 inpatient claims and three (3) outpatient claims), and seven (7) judgmentally selected claims (two (2) inpatient claims and five (5) outpatient claims), involving replaced medical devices. The randomly selected claims were subsequently consolidated into three strata: Stratum 1 covered inpatient short stays, Stratum 2 covered inpatient claims with high severity level DRG codes and Stratum 3 covered the remaining claims in the random sample of 200. HHS-OIG has not explained why or how it chose to use a sample size of 200 claims. Nor has HHS-OIG explained why it undertook post sampling stratification when doing so did not increase the reliability of the extrapolation in any meaningful sense, or why it went beyond the first draw of 200 claims and selected seven (7) judgmental claims, and, in any event, how doing so is appropriate from a statistical point of view or part of a well defined sampling strategy.

HHS-OIG has repeatedly assured the Hospital that the decision to use a random sample and extrapolate the results had nothing whatsoever to do with the Hospital or its conduct. In other words, the decision was made without reference to the Hospital's error rates, its cooperation with the Audit or its response to the educational components of the Audit or other external claim reviews. Rather, HHS-OIG stated that the decision to extrapolate was made internally by HHS-OIG and reflects the agency's decision to make some of the ongoing HHS-OIG hospital Medicare compliance audits more "efficient." Thus, HHS-OIG thanked the Hospital for its cooperation with the Audit and reiterated on more than one occasion that HHS-OIG did not find any evidence of fraud or anything approximating fraud in the Hospital's billing procedures and practices.

It appears that HHS-OIG initially set out to perform a simple random sampling without stratification. For reasons unknown to the Hospital, however, HHS-OIG changed the audit design in mid course — *i.e.*, post sampling — by introducing three strata for stratified estimation. Regardless of the rationale for this statistically *ad hoc*, and somewhat dubious, manner of proceeding, HHS-OIG's RAT-STATS post-stratification variable estimation shows that the variability for the overall point estimate is high (30.72 precision percent) as is the variability of both Stratum 1 and Stratum 2, individually — 31.44 and 142.79 precision percent at 90 percent confidence, respectively — casting material doubt about the reliability of the estimates. No errors were found in Stratum 3. Furthermore, compared to un-restricted variable appraisal, which would have been consistent with the HHS-OIG's original simple random sampling design, the HHS-OIG's post-stratification estimation failed to significantly improve the precision of the overall estimate for the universe — 32.32 precision percent at 90 percent confidence compared to HHS-OIG's 30.72 — further casting doubt on the sampling and estimation process.

## II. Draft Report: Findings

The above referenced statistical infirmities notwithstanding, the Draft Report sets forth the following findings:

**A. Inpatient Claims**

Fifty-six (56) of the one hundred ninety-nine (199) inpatient claims contained at least one error:<sup>3</sup> Fifty-four (54) of these claims were randomly selected and allegedly resulted in net overpayments of \$227,264; two (2) were judgmentally selected and allegedly resulted in net overpayments of \$15,084.<sup>4</sup> Of the fifty-four (54) randomly selected claims, forty-seven (47) were in Stratum 1 (representing alleged net overpayments of \$216,030) and the remaining seven (7) were in Stratum 2 (representing alleged net overpayments of \$11,234).

- Thirty-eight (38) of the fifty-six (56) inpatient errors involved claims that in HHS-OIG's view were incorrectly billed as inpatient stays.
  - Twenty-two (22) of the thirty-eight (38) were allegedly medically unnecessary. All twenty-two (22) were randomly selected and part of Stratum 1.<sup>5</sup>
  - The remaining sixteen (16) involved some perceived irregularity with the physician's admission order. Fifteen (15) of these claims had been randomly selected; one (1) was a judgmental claim.<sup>6</sup> Of the fifteen (15) randomly selected claims, fourteen (14) were in Stratum 1 and one (1) was in Stratum 2.
- Fifteen (15) of the fifty-six (56) inpatient errors were found to have incorrect DRG codes. All fifteen (15) claims were randomly selected. Nine (9) were in Stratum 1; six (6) were in Stratum 2.<sup>7</sup>
- One (1) of the fifty-six (56) inpatient errors involved an allegedly incorrect reporting of a medical device credit. The claim was a judgmental claim.<sup>8</sup>
- One (1) of the fifty-six (56) inpatient errors contained the incorrect discharge status. This claim was randomly selected and was in Stratum 1.<sup>9</sup>
- One (1) of the fifty-six (56) inpatient errors contained incorrect charges resulting in an improper outlier payment. This claim was randomly selected and was in Stratum 1.<sup>10</sup>

**B. Outpatient Claims**

- Five (5) of the eight (8) outpatient claim errors involved an reported medical device credit.<sup>11</sup> All five (5) claims were judgmentally selected and resulted in alleged net overpayments of \$20,817.<sup>12</sup>

<sup>3</sup> Of the 199 inpatient claims, 197 were randomly selected and two (2) were judgmental selections. Id. at i.

<sup>4</sup> Id. at 4.

<sup>5</sup> See id. at 5.

<sup>6</sup> See id.

<sup>7</sup> See id. at 6.

<sup>8</sup> See id.

<sup>9</sup> See id.

<sup>10</sup> See id.

### C. Summary of Findings

According to the Draft Report, the above referenced sixty-one (61) errors — fifty-six (56) inpatient and five (5) outpatient — resulted in net overpayments totaling \$242,348 for the inpatient claims (\$227,264 for randomly selected claims and \$15,084 for judgmental claims) and \$20,817 for the outpatient claims (all five (5) of which were judgmental). HHS-OIG extrapolated its findings with respect to the fifty-four (54) randomly selected claims to reach a net overpayment amount of \$3,275,032 (which represents the lower limit of the 90 percent confidence interval).

### D. HHS-OIG Recommendations

HHS-OIG recommends that the Hospital: (1) refund the extrapolated \$3,275,032 in overpayments, (2) refund the \$35,901 in overpayments allegedly received with respect to the seven incorrect judgmental claims and (3) strengthen its Medicare billing controls.<sup>13</sup>

## III. Hospital's Response

### A. Claims From 2009 Are Time Barred

Twenty-seven (27) — *i.e.*, 50 percent — of the fifty-four (54) randomly selected claims that allegedly gave rise to overpayments involve 2009 dates of service. All seven (7) — 100 percent — of the judgmental claims that allegedly gave rise to overpayments involve 2009 dates of service. A list of the thirty-four (34) claims for services that were furnished to the patient and adjudicated in 2009 is set forth in **TAB A**.

#### 1. Reopening and Recovery of Claims: An Overview

Under the Medicare program, contractors are permitted to recoup identified overpayments if certain criteria are met. A key criterion is the timeliness of the recoupment. Specifically, federal law places certain, firm time limits on the recovery of alleged overpayments, such as when the recovery would be against equity and good conscience.<sup>14</sup> As noted by the Secretary of Health and Human Services (the "Secretary"), Section 1870 of the Social Security Act ("SSA"), 42 U.S.C. § 1395gg, "provides a framework within which liability for Medicare overpayments is determined and recoupment of overpayments is pursued. This framework defines the process for pursuing the recoupment of Medicare overpayments."<sup>15</sup> Foremost among the constraints imposed by this framework are two separate, but related, sets of rules: the reopening rules and the recovery rules.

#### 2. Initial Determination

The Medicare program claim adjudication and decision-making processes commence with an "initial determination" that establishes whether the items and services are covered and otherwise

<sup>11</sup> Again, of the eight (8) outpatient claims, three (3) were randomly selected and five (5) were judgmental. *See id.* at i.

<sup>12</sup> *See id.* at 8.

<sup>13</sup> *Id.* at 8.

<sup>14</sup> *See* 42 U.S.C. § 1395gg(c); 42 C.F.R. § 405.358(b)(2).

<sup>15</sup> 63 Fed. Reg. 14506 (Mar. 25, 1998).

reimbursable.<sup>16</sup> Stated differently, the decision of a Medicare contractor to make payment to a provider of items and services (e.g., a hospital) constitutes an "initial determination," which is binding upon all parties to the claim, unless a party (whether the provider or contractor/adjudicator) reopens and revises the initial determination.<sup>17</sup> With respect to the sixty-one (61) allegedly erroneous claims at issue, the Medicare contractor initially determined that payment was authorized. By law, those initial determinations must stand unless revised by the contractor in compliance with legally mandated time frames and procedures. To change or alter the initial determination, the Medicare contractor (not HHS-OIG) must formally "reopen" the claim and initial payment determination. The contractor's revision to the initial determination constitutes a "reopening".<sup>18</sup>

### 3. Reopening Rules

The reopening rules permit a Medicare contractor to reopen a claim and revise a properly-determined overpayment "for any reason" within the first 12 months after initial payment.<sup>19</sup> This protects the Medicare program from inadvertent errors. (This 12 month time frame does not apply here, however, because all initial payment determination dates, the last of which was in 2010, occurred more than one year ago.) Claims that are more than one year old, but less than four years old, may be reopened only if the Medicare contractor establishes "good cause."<sup>20</sup> Finally, if more than four years have passed from the initial payment determination, the initial payment determination may be reopened by the contractor if and only if there is "reliable evidence . . . that the initial determination was procured by fraud or similar fault."<sup>21</sup>

### 4. Recovery Rules

The recovery rules govern the ability of Medicare contractors to recover overpayments after the contractor properly reopens a claim determination, consistent with the rules discussed above. Prior to January 2, 2013, the recovery rules deemed providers and suppliers to be "without fault," and thus not liable for overpayments, if the overpayment was discovered subsequent to the third calendar year after the year of initial payment.<sup>22</sup> In essence, this created a rebuttable presumption of no fault on the part of the provider or supplier (and hence no recovery) after the passage of three calendar years following the year of initial determination.<sup>23</sup> The Medicare manual clarifies that in calculating the three year limitations period:

Only the year of payment and the year it was found to be an overpayment enters into the determination . . . . The day and the month

<sup>16</sup> See 42 C.F.R. §§ 405.803, 405.920.

<sup>17</sup> *Id.* § 405.928.

<sup>18</sup> *Id.* § 405.980(a)(1).

<sup>19</sup> 42 C.F.R. § 405.980(b)(1); see also Medicare Claims Processing Manual (CMS Pub. 100-04) Ch. 34, § 10.6.1.

<sup>20</sup> 42 C.F.R. § 405.980(b)(2); see also Medicare Claims Processing Manual (CMS Pub. 100-04) Ch. 34, § 10.6.1.

<sup>21</sup> 42 C.F.R. § 405.980(b)(3); see also Medicare Claims Processing Manual (CMS Pub. 100-04) Ch. 34, § 10.6.1.

<sup>22</sup> See 42 U.S.C § 1395gg(b) (2003) (amended 2013); see also Medicare Financial Management Manual (CMS-Pub. 100-06) Ch. 3, §§ 80, 90.

<sup>23</sup> *Mt. Sinai Hospital of Greater Miami, Inc. v. Weinberger*, 517 F.2d 329, 342 (5th Cir. 1975).

are irrelevant. With respect to payments made in 2000, the third calendar year is 2003. For payments made in 2001, the third calendar year thereafter is 2004, etc. Thus, the rules apply to payments made in 2000 and discovered overpayments made after 2003, to payments made in 2001 and discovered to be overpayments after 2004, etc.<sup>24</sup>

Effective January 2, 2013, the recovery rules' statute of limitations was extended such that providers and suppliers are now deemed to be "without fault" if the overpayment is discovered and the initial determination is reopened subsequent to the *fifth* calendar year after the year of initial payment.<sup>25</sup>

## 5. Analysis

The January 2, 2013 statutory extension notwithstanding, all thirty-four (34) of the allegedly erroneous claims covered by the Draft Report from 2009 are time barred for two separate legal reasons.

First, the legal window to recover the 2009 claims permanently closed at midnight on December 31, 2012. Under federal law in full force and effect on January 1, 2013, any claim with an initial determination date of 2009 or earlier was no longer subject to recovery by virtue of the then applicable three year statute of limitations. In other words, the last day legally to recover a Medicare overpayment with a 2009 initial determination date was December 31, 2012.

St. Vincent's is aware that on January 2, 2013, a new law went into effect, extending the recovery limitations period from three (3) to five (5) years. The statutory amendment, however, is entirely silent with respect to the ability to apply the five (5) year period retroactively, let alone to apply it retroactively to claims that had expired under the pre-existing limitations period. To be clear, although an argument can be put forward that the five (5) year limitations period applies to claims adjudicated in 2010 forward — as opposed to from January 2, 2013 forward — there is no legal basis nor any legal precedent that an extension of a limitations period can somehow resuscitate previously time barred claims.

Second, even if, assuming *arguendo*, the new "fifth calendar year" limitations period were to apply retroactively and revive previously retired claims, a large portion of the 2009 claims still cannot be recovered under federal law. The reason for this is straightforward: an "overpayment" may only be recouped if the underlying claim has been reopened pursuant to the SSA § 1869 reopening rules. As set forth above, however, if more than one year has passed since the date of initial determination, a Medicare contractor may only reopen a claim: (1) if it possesses "reliable evidence" that the initial determination was "procured by fraud or similar fault", or (2) within four years from the initial determination, provided that the contractor establishes "good cause."<sup>26</sup>

As noted above, HHS-OIG has repeatedly confirmed the absence of fraud or similar fault. Thus, in the instant matter, the Medicare contractor is left with the four year limit test. In order to establish "good cause," the contractor would have to establish one of two things, neither of which is present here: (1) that the evidence that was considered in making the initial determination or decision clearly shows on its face

<sup>24</sup> See Medicare Financial Management Manual (CMS-Pub. 100-06), Chapter 3, Section 80.1.

<sup>25</sup> 42 U.S.C. § 1395gg(b)-(c) (2013) (emphasis added); American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 638, 126 Stat. 2313 (2013).

<sup>26</sup> 42 C.F.R. § 405.980(b).

that an obvious error was made at the time of the determination or decision,<sup>27</sup> or (2) that there is “new and material evidence” that was not available or known at the time of the initial determination and may result in a different conclusion.<sup>28</sup> (According to the Medicare Financial Management Manual, “good cause” does not exist if a provider complied with all pertinent regulations, made full disclosure of all material facts, and on the basis of the information available, had a reasonable basis for assuming that the payment was correct.<sup>29</sup>)

Even assuming for argument’s sake that the contractor were able to establish “good cause,” then many of the 2009 claims would still be time barred by the four year limitation period if and when the Medicare contractor decides to reopen the 2009 claims.

## 6. Summary

Thirty-four (34) of the sixty-one (61) allegedly erroneous claims at issue here are presumed to be “without fault” and hence not subject to recoupment as a matter of law. Moreover, even if the recoupment limitations period had not expired with respect to the thirty-four (34) claims from 2009, many of these claims cannot be recouped because, as a matter of law, they cannot be reopened.

### B. Contested Claims

#### 1. Inpatient Claims

##### a) Allegedly Incorrectly Billed as Inpatient

Separate and apart from establishing that the thirty-four (34) claims from 2009 (see **TAB A**) are time barred, the Hospital intends to contest — on the clinical merits — 28 of the 38 claims which HHS-OIG contends were incorrectly billed as inpatient. See **TAB B**. Of the 28, fifteen (15) are additionally contested as time barred for the reasons set forth in Section III.A. above. Of the remaining 10 claims, seven (7) are time barred. Thus, the Hospital concedes three (3) of the thirty-eight (38) claims. See **TAB C**.

##### (1) Level of Care

The Hospital contests on the merits seventeen (17) of the twenty-two (22) claims which HHS-OIG contends were “medically unnecessary” — i.e., that should have been billed as outpatient or outpatient with observation. See **TAB D**. Of these seventeen (17) claims, eleven (11) claims are additionally contested as time barred 2009 claims. Of the remaining five (5) claims in this category of twenty-two (22) claims, three (3) are contested as time barred 2009 claims. Thus, the Hospital concedes two (2) of the twenty-two (22) claims. See **TAB E**.

##### (2) Medical Record

The Hospital contests on the merits eleven (11) of the sixteen (16) claims which HHS-OIG contends were not supported by a valid order signed by the physician or contained conflicting admission information. See **TAB F**. Of these 11 claims, four (4) also are contested as being time barred 2009

<sup>27</sup> See 42 C.F.R. § 405.986(a)(2).

<sup>28</sup> See 42 C.F.R. § 405.986(a)(1).

<sup>29</sup> See Medicare Financial Management Manual (CMS-Pub. 100-06) Ch. 3, § 90.

claims. Of the remaining five (5) claims in this category, four (4) are contested as time barred 2009 claims. Thus, the Hospital concedes one (1) of the sixteen (16) claims. See TAB G.

**b) Allegedly Incorrect Diagnosis-Related Codes**

The Hospital contests eight (8) of the fifteen (15) claims which HHS-OIG concludes had incorrect Diagnosis-Related Codes: three (3) on the merits, see Tab H, and five (5) claims on the grounds that they are time barred 2009 claims. Thus, seven (7) of the claims in this category are not being contested. See TAB I.

**c) Allegedly Incorrect Reporting of Medical Device Credits**

The Hospital contests the one (1) inpatient claim which HHS-OIG concluded incorrectly reported a medical device credit on the grounds that it is a time barred 2009 claim. See TAB J.

**d) Allegedly Incorrect Discharge Status**

The Hospital is not contesting the one (1) claim which HHS-OIG concluded had an incorrect discharge status. See TAB K.

**e) Allegedly Incorrect Charges Resulting in Improper Outlier Payment**

The Hospital contests the one (1) claim which HHS-OIG concluded had incorrect charges resulting in improper outlier payment on the grounds that it is a time barred 2009 claim. See TAB L.

**2. Outpatient Claims**

The Hospital intends to contest all five (5) of the outpatient claims which HHS-OIG concluded had incorrect reporting of a medical device credit on the grounds that they are time barred 2009 claims. See TAB M.

**C. Extrapolation Concerns**

The Hospital has significant concerns with HHS-OIG's recommendation that its Audit determinations with respect to the fifty-four (54) randomly selected claims be extrapolated to the 4,087 claims that make up the Universe of Claims. The Hospital objects to extrapolation in the instant case because extrapolation is not warranted here as a matter of law, statistical integrity and fundamental fairness. Each of these grounds of objection is addressed sequentially.

**1. Extrapolation Is Inappropriate As a Matter of Law**

The authority of the Centers for Medicare & Medicaid Services ("CMS") and its contractors to extrapolate is subject to strict statutory and regulatory limits. Under the Social Security Act:

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.*<sup>30</sup>

Neither the Social Security Act nor any applicable regulation defines the term “high rate of error” or provides criteria for judging when a documented educational intervention has failed.

The preamble to the implementing regulations addressing extrapolation explains that extrapolation is merely a method of determining an overpayment and 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.”<sup>31</sup> Despite specific requests, CMS declined to define the term high error rate, referring the public to the Medicare Program Integrity Manual (CMS Pub. 100-08).<sup>32</sup> The Medicare Provider Integrity Manual (“PIM”), however, provides *methods* by which HHS may find that a high rate of error exists; it does not offer a *specific threshold*. Similarly, no guidance is provided for making a determination that a “documented educational intervention has failed.”

Although most courts addressing the definition of “high rate of error” have been asked to address the actual *merits* of CMS’ or the HHS-OIG’s finding of a high rate of error, such cases have been precluded from judicial review.<sup>33</sup> However, in at least one case, Cabarrus Podiatry Clinic, a Medicare Administrative Contractor (“MAC”) reversed an overpayment calculation based on extrapolation where neither the contractor nor CMS could produce *any documentation* concerning a finding of a high error rate or a documented failure of education.<sup>34</sup> Thus, at a bare minimum, the MAC, CMS or HHS-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.

To date, HHS-OIG has not met this burden – *i.e.*, it has not suggested, not even once, that its audit findings evidenced either a “sustained or high level of payment error” or that “educational intervention has failed.” The reason for this failure is straightforward: it has not made the requisite showing, because it cannot. Indeed, HHS-OIG has repeatedly assured the Hospital that the decision to extrapolate was made by HHS-OIG before the Audit commenced based on considerations — audit efficiencies — that had nothing whatsoever to do with the Hospital or its conduct. Although the use of extrapolation (rather than a claim-by-claim review) would arguably increase audit efficiency, “efficiency” is not one of the statutorily defined criteria for using extrapolation.

Even if it decided to reverse its position at this late stage, HHS-OIG would be hard pressed to establish that extrapolation is warranted because of the Hospital’s error rates or failure to respond to educational efforts. With respect to high error rates, HHS-OIG, as noted herein, has conducted several dozen “Medicare Compliance Review” audits over the past two years, and of the forty-eight (48) audit reports published thus far, HHS-OIG has yet to recommend extrapolation. Importantly, at least

<sup>30</sup> See 42 U.S.C. § 1395ddd(f)(3) (emphasis added).

<sup>31</sup> 74 Fed. Reg. 65296, 65303–04 (Dec. 9, 2009).

<sup>32</sup> *Id.*

<sup>33</sup> See Anghel v. Sebelius, No. 10-CV-4574, 2012 WL 6212843 (E.D.N.Y. Dec. 13, 2012); Gentiva Healthcare Corp. v. Sebelius, 857 F.Supp.2d 1, 13 (D.D.C. 2012); Morgan v. Sebelius, No. 11 Civ. 0300, 2012 WL 1231960, at \*1 (S.D.W.Va. Apr. 12, 2012); John Balko & Assocs. v. Sebelius, No. 12-CV-0572, 2012 WL 6738246 (W.D. Pa. Dec. 28, 2012).

<sup>34</sup> Cabarrus Podiatry Clinic (Appellant) (Beneficiaries) Claim for Part B Benefits, ALJ Appeal No. 1-127356701 (Dec. 14, 2007).

twelve (12) of these audits involved error rates of 50 percent or more, of which two (2) produced error rates in excess of 70 percent — more than double the (29.5 percent) error rate found at Hospital. As explained by the Secretary, extrapolation is a method of calculation, not an unchecked sanction. Thus, HHS-OIG must at the *very least* remain consistent in its application of the “high rate of error” criterion. Such consistency is seriously called into question if providers presenting nearly double the error rate of the Hospital are not found to have a “high rate of error” or are not, for some other undocumented reason, subject to extrapolation.

Similarly, HHS-OIG cannot maintain that previous educational attempts have failed to remedy the payment error. The Hospital cooperated fully in the educational components of the Audit, a fact that HHS-OIG acknowledged. Furthermore, the only documented “educational intervention” that could possibly be cited as a justification for extrapolation (*i.e.*, education which was directly targeted at addressing any errors found in the Audit) was introduced in the Audit itself and its effects have yet to be evaluated by HHS-OIG. Therefore, HHS-OIG cannot maintain that “documented educational intervention has failed to correct the payment error.”

In light of HHS-OIG’s failure to address, let alone satisfy, either of the specific statutory criteria required for use of extrapolation, HHS-OIG should reconsider and reverse its preliminary decision to recommend extrapolation.

## 2. Statistical Deficiencies

Even if, assuming *arguendo*, extrapolation of the fifty-four (54) randomly selected claims were legally appropriate, the post sampling decision to engage in stratification after initially selecting a simple random sample of 200 claims and to draw seven (7) judgmental claims, raises genuine concerns about the integrity of the numbers and HHS-OIG’s sampling planning. First, with respect to the seven (7) judgmental claims, they should not have been drawn in the first instance. Either the sampling and extrapolation are sound or they are not. By engaging in post sampling judgmental draws, HHS-OIG necessarily casts doubt regarding the precision of the extrapolated results. Unless HHS-OIG is willing to abandon extrapolation with respect to this Audit, all seven (7) judgmental claims, including the five (5) that allegedly are erroneous, should be removed from the Draft Report.

Second, with respect to post sampling stratification, HHS-OIG contends that it decided to group the fifty-four (54) claims into three strata for homogeneity purposes. This, however, could have, and indeed should have, been incorporated into the sample design prior to sampling. Moreover, stratification is employed by statisticians in order to reduce the overall variability of extrapolated results. This objective was simply not achieved by HHS-OIG in the instant case. The post stratification extrapolation generated an overall point estimate of \$4,726,962 and a lower limit \$3,237,032 with an unacceptably high precision level of 30.72 percent at the 90 percent confidence level — more than five (5) percent worse than the twenty-five (25) percent precision threshold established by HHS-OIG in its 1998 voluntary self disclosure protocol and widely used by Independent Review Organizations (“IRO”) auditing entities under HHS-OIG Corporate Integrity Agreements.

The imprecision of the extrapolated results is driven in large part by the extreme unreliability of Stratum 2. HHS-OIG reports a precision level of 142.79 percent, meaning that the lower limit of the two-sided 90 percent confidence interval for the Stratum reflects an underpayment of \$83,966, not an overpayment. Thus, the Hospital respectfully posits that none of the claims in Stratum 2 should be used for extrapolation purposes. (Stratum 3 was not used due to insufficient sampling items).

### 3. Extrapolation Would Violate Fundamental Notions of Fairness

In March 2011, HHS-OIG released its first "Medicare Compliance Review" report (South Shore Hospital in South Weymouth, MA), regarding whether the hospital complied with Medicare requirements for billing certain "high risk" inpatient and outpatient services. In contrast to most other HHS-OIG audit projects, this Medicare Compliance Review audit included several different types of claims. In addition, although the overall error rate was 64 percent, HHS-OIG recommended that the hospital refund *only* the overpayment amount attributable to the incorrectly billed claims. In other words, it did not propose a payment based on extrapolation.

Over the last two years, HHS-OIG has released a total of 48 Medicare Compliance Review audits. Each and every one of them has taken the approach described above, *i.e.*, no extrapolation. As at South Shore, others of the 48 facilities under review had overall error rates of 50 percent or more: Lahey Clinic (just released) (76 percent), Pacific Medical Center (1/10/13) (72 percent), University of Iowa (11/13/12) (69 percent), North Kansas City Hospital (10/18/12) (68 percent), South Shore Hospital (3/2/11) (64 percent), Brigham and Women's Hospital (3/16/12) (61 percent), Maine Medical Center (6/26/12) (61 percent), University of California, San Francisco (9/21/11) (55 percent), Cape Cod Hospital (7/11/11) (53 percent), Singing River Hospital (7/18/12) (52 percent), Georgetown University Hospital (4/9/12) (51 percent) and Norwood Hospital (11/30/11) (50 percent).

HHS-OIG has received widespread praise for its approach to these Medicare Compliance Reviews. For example, a 2012 article in *Modern Healthcare* reported numerous favorable comments from hospitals regarding the educational approach taken by HHS-OIG.<sup>35</sup> Moreover, Assistant Inspector General, Brian Ritchie, was reported stating that, "the goal is to pick a few and use them to instruct the hospital on best practices and prevent any future problems."

On February 29, 2012, HHS-OIG conducted an entrance conference for the audit of St. Vincent's, and the entrance memorandum stated that, "If you would like to have an idea of what our final report will look like, there are similar reports published on the <http://oig.hhs.gov> website: Tallahassee Memorial Hospital, Cape Cod, Fletcher Allen, Lighthouse, St. Vincent's [Bridgeport, CT]." None of the referenced audits contained recommendations to extrapolate, however.

In view of the above, St. Vincent's was shocked to realize in the fall of 2012 that HHS-OIG intended to extrapolate the Audit results. This was particularly the case in view of St. Vincent's overall error rate of 29.5 percent (assuming all HHS-OIG payment errors are upheld), which is dramatically lower than many other recent Medicare Compliance Review audits. The Hospital has been informed that there are other facilities undergoing Medicare Compliance Reviews for which extrapolation is contemplated, but (despite our request) neither St. Vincent's nor the industry has been told which criteria are used by HHS-OIG in deciding whether and when to extrapolate.

St. Vincent's does not question the legal authority of HHS-OIG to perform Medicare Compliance Review audits or to recommend extrapolation in compliance with established legal and statistical standards. But we respectfully suggest that it is unjust, arbitrary, and entirely unprincipled to precipitously recommend extrapolation for a facility with an "error rate" performance that is significantly lower than many other facilities.

<sup>35</sup> Modern Healthcare, *Audits said to put hospitals on track*, pp. 17-21 (Oct. 22, 2012).

**4. Extrapolation may lead to duplicate refunds and other inconsistencies due to overlap with RAC process.**

Throughout the course of the Audit, HHS-OIG representatives have assured the Hospital that they had instructed the Recovery Audit Contractor ("RAC") to cease requesting and auditing claims from the Universe of Claims. Failure of the RAC to do so would inevitably result in the Hospital paying twice for the same alleged error and result in a materially exaggerated extrapolation amount.

HHS-OIG's assurances notwithstanding, the RAC has delved deeply into the Universe of Claims, irretrievably infecting that Universe and making it entirely inappropriate for extrapolation. Here are the facts to the best of the Hospital's understanding:

- HHS-OIG identified all short stay claims from 2009 and 2010. (Short stays were defined as any inpatient claim that had a discharge date that was on the same day or one day after the patient's admission to the Hospital.)
- Next, HHS-OIG excluded any 2009 or 2010 short stay claim that had been pulled for review by the RAC, leaving 2,307 short stay claims.
- The 2,307 claims were made part of the Universe of Claims for purposes of this Audit.
- HHS-OIG then selected 110 claims from the pool of 2,307 for individual review by HHS-OIG, reducing the number of short stay claims in the Universe of Claims to 2,197.
- Since January 2012, the RAC has requested and received documentation relating to more than 700 (or 31 plus percent) of the remaining 2,197 short stay claims.

Under the circumstances, it would be statistically invalid and patently unfair to proceed with the extrapolation suggested in the Draft Report. Again, HHS-OIG should treat St. Vincent's just like the other hospitals that have had their reports published – i.e., it should abandon its present intention to extrapolate its findings.

**5. Extrapolation, if any, should be postponed until all claims have been fully adjudicated on their merits.**

As noted above, HHS-OIG has determined that fifty-four (54) claims (all inpatient) out of an allegedly random sample of 199 (or 27.1 percent) were erroneously paid in the course of the initial determination. According to HHS-OIG, this error rate should be extrapolated against the Universe of Claims in order to achieve audit efficiency. Separate and apart from all of St. Vincent's other arguments, as set forth elsewhere in this Response, the Hospital posits that extrapolation at this stage of the proceeding would be highly inefficient. In a nutshell, it is premature to extrapolate errors at this stage because St. Vincent's intends to contest many of the findings on a variety of grounds. Inevitably, the number of erroneous claims is likely to keep shifting (downward) at the various levels of adjudication and appeal, requiring repeated monetary adjustments and reconciliations between the Hospital and its Medicare contractor. Among other things, and as noted elsewhere in this Response, St. Vincent's believes in good faith that twenty-seven (27) of the fifty-four (54) allegedly random claims at issue are time barred, that thirty-one (31) of the fifty-four (54) claims were correctly adjudicated in the first instance (i.e., HHS-OIG audit findings are wrong), and that all seven (7) claims from Stratum 2 and use of Stratum

2 in extrapolation should be disregarded because considering a post stratification stratum with a precision level of 142.79% is unacceptable and represents a guesstimate, rather than a solid estimate, and is therefore unreasonable under universally accepted statistical principles and procedures. Accordingly, the Hospital requests that HHS-OIG either abandon the extrapolation recommendation in its entirety or, at a minimum, change the recommendation as follows:

We recommend that the Hospital refund to the Medicare program all overpayments using the following formulation: (the total dollar amount of actual overpayments remaining after each of the contested random claims has been fully adjudicated) applied across (the total dollar amount associated with the Universe of Claims) plus (the total dollar amount of actual overpayments remaining after each of the contested judgmentally selected claims has also been fully adjudicated).

- 6. The overpayment amounts associated with inpatient claims that should have been adjudicated as outpatient claims (and any attendant extrapolation) should be based on the difference between the Part A payment that was made and the Part B payment that would have been made if the claim was billed on an outpatient basis, not on the full Part A payment.**

HHS-OIG's determination that thirty-eight (38) claims (thirty-seven (37) randomly selected and one (1) judgmental) which had been processed as inpatient claims should have been processed as outpatients demonstrates that HHS-OIG does not dispute that the services at issue were furnished and medically necessary. As such, and consistent with both law and equity, HHS-OIG should recommend that once it is determined (*i.e.*, after full adjudication) which claims should have properly been paid by Medicare Part B (as opposed to Medicare Part A), the Medicare contractor should work in good faith with the Hospital to calculate and deduct from the Part A overpayment the amount that would have been paid by Part B.

The proposed recommendation would be consistent with Medicare guidance regarding similarly postured matters. Medicare guidance provides that a presiding administrative law judge ("ALJ") has the authority to order outpatient reimbursement following an inpatient admission.<sup>36</sup> As detailed in the O'Connor Hospital decision ("O'Connor"), the Medicare Appeals Council ("Council") upheld an ALJ's ruling that the hospital was entitled to reimbursement for full outpatient services under Medicare Part B even though the hospital initially billed the claim as an inpatient service under Medicare Part A.<sup>37</sup>

In O'Connor, CMS asserted that the ALJ "erred as a matter of law by ordering Medicare payment for 'the observation and underlying care' provided to the beneficiary because those services are not separately billable under Part A."<sup>38</sup> The Council disagreed with CMS, holding that the agency's argument

<sup>36</sup> See generally 42 C.F.R. § 405.1032.

<sup>37</sup> See In the case of O'Connor Hospital, Med & Med GD (CCH) P 122133 (H.H.S. Feb. 1, 2010), 2010 WL 425107, consistent with In the case of UMDNJ - University Hospital, 2005 WL 6290383 (H.H.S. Mar. 14, 2005) (directing the CMS contractor to reimburse the hospital for outpatient services pursuant to Medicare Part B after payment was denied for inpatient services pursuant to Medicare Part A). Copies of referenced cases are included at **Tab N**.

<sup>38</sup> O'Connor, at 2.

was inconsistent with guidance provided in multiple CMS manuals. In support of its conclusion, the Council quoted the Medicare Claims Processing Manual: "although providers may sometimes bill for services that are not covered as billed, they are nonetheless entitled to correct payment."<sup>39</sup>

Even more recently, in May 2012, in the Indiana University Health Methodist Hospital ("Indiana University") decision and the May 2011 Montefiore Medical Center ("Montefiore") decision, the Council confirmed the O'Connor decision, determining that Part B payment may be made if Part A payment is denied, following CMS's express guidance in the Medicare Benefit Policy Manual ("MBPM") and other manuals.<sup>40</sup>

Furthermore, in a July 13, 2012 Technical Direction Letter regarding ALJ Decisions, CMS instructed its contractors as follows:

There have been a number of Administrative Law Judge (ALJ) decisions in recent months that uphold a claims administration contractor's denial of inpatient services as not reasonable and necessary, but require the contractor to pay for the services on an outpatient basis and/or at an "observation level of care." ... Medicare pays for observation services under the outpatient prospective payment system (OPPS). However, observation services are generally bundled and not paid separately.

Therefore, CMS has reasoned that the ALJ's decision requires the claims administration contractor to pay for all services that would be separately payable under OPPS had the hospital initially billed Medicare for outpatient services on a 13x or 85x type of claim.

Given that Technical Direction Letters are not publicly available, CMS' first clear public pronouncement of its position was issued in CMS1455-R ("CMS Ruling") dated March 13, 2013. In it, the CMS Administrator specifically referred to the above noted ALJ decisions 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."<sup>41</sup>

CMS concurrently issued a proposed rule, entitled "Medicare Program; Part B Billing in Hospitals" addressing the policy of billing under Medicare Part B following the denial of a Medicare Part A hospital inpatient claim.<sup>42</sup> In the proposed rule, CMS acknowledged that the Medicare statute and regulations require CMS to pay hospitals under Medicare Part B for reasonable and necessary services furnished to beneficiaries. Specifically, CMS provides:

Having reviewed the statutory and regulatory basis of our current Part B inpatient payment policy, we believe that, under section 1832 of the

<sup>39</sup> Id. at 5.

<sup>40</sup> In the case of Indiana University Health Methodist Hospital, Docket No. M-12-872 (H.H.S. May 17, 2012), 2012 WL 3067987, at \*10; see also In the case of Montefiore Medical Center, Docket No. M-10-1121 (H.H.S. May 10, 2011), 2011 WL 6960290, at \*22; see also O'Connor, at 6.

<sup>41</sup> Centers for Medicare & Medicaid Services, Ruling No. CMS-1455-R (Mar. 13, 2013) (hereinafter, "CMS Ruling"), at 1.

<sup>42</sup> 78 Fed. Reg. 16632 (Mar. 18, 2013).

[Social Security] Act, Medicare should pay all Part B services that would have been reasonable and necessary (except for services that require an outpatient status) if the hospital had treated the beneficiary as a hospital outpatient rather than treating the beneficiary as an inpatient[.]<sup>43</sup>

The CMS Ruling is effective until such date as a final rule is issued.<sup>44</sup> Thus, the CMS Ruling applies to Part A inpatient claims that were denied because inpatient admission was not reasonable and necessary, as long as the denial was made: (1) while the CMS Ruling is in effect; (2) prior to the effective date of the CMS Ruling, but for which the timeframe to file an appeal has not expired; or (3) prior to the effective date of the CMS Ruling, but for which an appeal is pending.<sup>45</sup> CMS "acquiesce[d] to the approach taken in the aforementioned ALJ and Appeals Council decisions" and found that that when a Part A inpatient admission is denied because the inpatient admission was not reasonable and necessary, the hospital may submit a Part B inpatient claim for payment for the Part B services that would have been payable to the hospital had the beneficiary originally been treated as an outpatient, rather than admitted as an inpatient, except when those services specifically require an outpatient status.<sup>46</sup>

In short, consistent with the ALJ and Medicare Appeals Council Rulings and the recent CMS Ruling, HHS-OIG should (or recommend that CMS) calculate the overpayment at issue by determining the difference between the inpatient reimbursement received and the outpatient reimbursement the Hospital would have received. A recommendation that does not provide for this to be done prior to extrapolation, if any, will give rise to a logistical nightmare because once the Part A payments are extrapolated there will be no practical way to determine the Part B set-off. This would be inconsistent with the current state of the law and patently unfair.

Thus, the recommendation proposed in Section III.5 above should be further modified to read as follows:

We recommend that the Hospital refund to the Medicare program all overpayments using the following formulation: (the total dollar amount of actual Part A overpayments remaining after each of the contested random claims has been fully adjudicated) minus (the total dollar amount of Part B payments that would have been paid had the erroneous claims been processed as outpatient claims) applied across (the total dollar amount associated with the Universe of Claims) plus (the total dollar amount of actual overpayments remaining after each of the contested judgmentally selected claims has also been fully adjudicated).

#### IV. St. Vincent's Internal Controls

St. Vincent's is a responsible provider of healthcare items and services with a deep commitment to operating in compliance with applicable rules and regulations. As part of this commitment, the Hospital routinely examines its coding and billing practices and procedures with the objective of achieving ever-improved accuracy and completeness.

<sup>43</sup> Id. at 16636.

<sup>44</sup> CMS Ruling, at 2-3.

<sup>45</sup> Id. at 14.

<sup>46</sup> Id. at 4, 6.

In order to ensure that patients are properly categorized as either inpatients or outpatients, the Hospital uses outside clinical consultants to undertake a concurrent review of the medical record and the presence of medical necessity, thereby enabling adjustments before patient discharge. The HHS-OIG's determinations notwithstanding, the Hospital has an impressive record in connection with appealing and reversing RAC findings of error. To date, that track record has resulted in an appellate success rate in excess of 95 percent. This strongly suggests that the Hospital's internal controls are fully operational and highly efficient.

St. Vincent's has no intention of resting on its laurels, however. Thus, since the start of the Audit it has implemented a hospital-wide electronic medical record, which certainly should improve the ability to determine the presence of a valid physician order. In addition, the Hospital has engaged a courier service to better obtain timely physician signatures in those instances where a definitive signature is absent.

\* \* \*

On behalf of St. Vincent's, we thank you in advance for your consideration of our various arguments and concerns. We, and our client, will make ourselves available to you in the event that you have any questions or require further information.

Sincerely,

/Gadi Weinreich/

Gadi Weinreich  
Partner

cc: Bill Mayher  
Jeffrey Middlebrooks  
D. McCarty Thornton