July 13, 2012

TO: Peter Budetti  
Deputy Administrator and Director  
Center for Program Integrity  
Centers for Medicare & Medicaid Services

Deborah Taylor  
Director and Chief Financial Officer  
Office of Financial Management  
Centers for Medicare & Medicaid Services

FROM: /Brian P. Ritchie/  
Assistant Inspector General for the  
Centers for Medicare & Medicaid Audits

SUBJECT: Medicare Compliance Review of Singing River Hospital for Calendar Years 2008 Through 2010 (A-04-11-03069)

Attached, for your information, is an advance copy of our final report on our most recent hospital compliance review. We will issue this report to Singing River Hospital within 5 business days.

This report is part of a series of the Office of Inspector General’s hospital compliance initiative, designed to review multiple issues concurrently at individual hospitals. These reviews of Medicare payments to hospitals examine selected claims for inpatient and outpatient services.

If you have any questions or comments about these reports, please do not hesitate to contact me at (410) 786-7104 or through email at Brian.Ritchie@oig.hhs.gov, or your staff may contact Lori S. Pilcher, Regional Inspector General for Audit Services, Region IV, at (404) 562-7750, or through email at Lori.Pilcher@oig.hhs.gov. Please refer to report number A-04-11-03069.

Attachment

cc: Daniel Converse  
Office of Strategic Operations and Regulatory Affairs  
Centers for Medicare & Medicaid Services
July 18, 2012

Report Number: A-04-11-03069

Mr. Chris Anderson
Chief Executive Officer
Singing River Health System
2101 Highway 90
Gautier, MS 39553

Dear Mr. Anderson:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled Medicare Compliance Review of Singing River Hospital for Calendar Years 2008 Through 2010. We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.


If you have any questions or comments about this report, please do not hesitate to call me, or contact John T. Drake, Audit Manager, at (404) 562-7755 or through email at John.Drake@oig.hhs.gov. Please refer to report number A-04-11-03069 in all correspondence.

Sincerely,

/Lori S. Pilcher/
Regional Inspector General
for Audit Services

Enclosure
Direct Reply to HHS Action Official:

Ms. Nanette Foster Reilly
Consortium Administrator
Consortium for Financial Management & Fee for Service Operations
Centers for Medicare & Medicaid Services
601 East 12th Street, Room 355
Kansas City, MO 64106
MEDICARE COMPLIANCE REVIEW OF SINGING RIVER HOSPITAL FOR CALENDAR YEARS 2008 THROUGH 2010
The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

**Office of Audit Services**

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

**Office of Evaluation and Inspections**

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

**Office of Investigations**

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

**Office of Counsel to the Inspector General**

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG’s internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.
Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC at http://oig.hhs.gov

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.
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 inpatient hospital 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. The DRG payment is, with certain exceptions, payment in full to the hospital for all inpatient costs associated with the beneficiary’s stay.

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 ambulatory payment classification.

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

Singing River Hospital (the Hospital) is a 435-bed hospital located in Pascagoula, Mississippi. According to CMS’s National Claims History data, Medicare paid the Hospital approximately $277 million for 23,407 inpatient and 209,417 outpatient claims for services provided to beneficiaries during calendar years (CY) 2008, 2009, and 2010.

Our audit covered $3,409,995 in Medicare payments to the Hospital for 100 inpatient and 269 outpatient claims that we identified as potentially at risk for billing errors. These 369 claims had dates of service in CYs 2008, 2009 and 2010.

OBJECTIVE

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

SUMMARY OF FINDINGS

The Hospital complied with Medicare billing requirements for 177 of the 369 claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for selected inpatient and outpatient claims. Specifically, 192 claims had billing errors that resulted
in overpayments totaling $515,651 for CYs 2008, 2009, and 2010. Overpayments occurred primarily because the Hospital did not have adequate controls to prevent incorrect billing of Medicare claims and did not fully understand the Medicare billing requirements.

RECOMMENDATIONS

We recommend that the Hospital:

- refund to the Medicare contractor $515,651, consisting of $121,289 in overpayments for 31 incorrectly billed inpatient claims and $394,362 in overpayments for 161 incorrectly billed outpatient claims and
- strengthen controls to ensure full compliance with Medicare billing requirements.

SINGING RIVER HEALTH SYSTEM COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Hospital generally disagreed with our first recommendation and did not specifically comment on our second recommendation. However, the Hospital said it implemented several measures to strengthen its processes and controls to reduce the risk of similar errors recurring in the future. The Hospital also provided additional documentation that it believed would show that two of its medical device claims were not overpaid. Based on our review of the additional documentation, we revised our findings and recommendations accordingly. The Hospital’s comments are included in their entirety as the Appendix.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>BACKGROUND</strong></td>
<td>1</td>
</tr>
<tr>
<td>Hospital Inpatient Prospective Payment System</td>
<td>1</td>
</tr>
<tr>
<td>Hospital Outpatient Prospective Payment System</td>
<td>1</td>
</tr>
<tr>
<td>Hospital Payments at Risk for Incorrect Billing</td>
<td>2</td>
</tr>
<tr>
<td>Medicare Requirements for Hospital Claims and Payments</td>
<td>2</td>
</tr>
<tr>
<td>Singing River Hospital</td>
<td>3</td>
</tr>
<tr>
<td><strong>OBJECTIVE, SCOPE, AND METHODOLOGY</strong></td>
<td>3</td>
</tr>
<tr>
<td>Objective</td>
<td>3</td>
</tr>
<tr>
<td>Scope</td>
<td>3</td>
</tr>
<tr>
<td>Methodology</td>
<td>3</td>
</tr>
<tr>
<td><strong>FINDINGS AND RECOMMENDATIONS</strong></td>
<td>5</td>
</tr>
<tr>
<td><strong>BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS</strong></td>
<td>5</td>
</tr>
<tr>
<td>Inpatient Short Stays</td>
<td>5</td>
</tr>
<tr>
<td>Inpatient Manufacturer Credit for Replaced Medical Devices</td>
<td>5</td>
</tr>
<tr>
<td><strong>BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS</strong></td>
<td>6</td>
</tr>
<tr>
<td>Outpatient Billing for Lupron Injections</td>
<td>6</td>
</tr>
<tr>
<td>Outpatient Manufacturer Credit for Replaced Medical Devices</td>
<td>7</td>
</tr>
<tr>
<td><strong>RECOMMENDATIONS</strong></td>
<td>8</td>
</tr>
<tr>
<td><strong>SINGING RIVER HEALTH SYSTEM COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE</strong></td>
<td>8</td>
</tr>
<tr>
<td>Billing Errors Associated With Inpatient Claims</td>
<td>8</td>
</tr>
<tr>
<td>Billing Errors Associated With Outpatient Claims</td>
<td>9</td>
</tr>
<tr>
<td><strong>APPENDIX</strong></td>
<td></td>
</tr>
<tr>
<td>Singing River Health System Comments</td>
<td></td>
</tr>
</tbody>
</table>
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\(^1\) 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 inpatient hospital 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, payment in full to the hospital for all inpatient costs associated with the beneficiary’s stay.

Hospital Outpatient Prospective Payment System

CMS implemented an outpatient prospective payment system (OPPS) 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.\(^2\) The OPPS was 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 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.\(^3\) All services and items within an APC group are comparable clinically and require comparable resources.

---

\(^1\) Section 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, required CMS to transfer the functions of fiscal intermediaries and carriers to Medicare administrative contractors (MAC). This transition occurred between October 2005 and October 2011. Most, but not all, of the MACs are fully operational; for jurisdictions where the MACs are not fully operational, the fiscal intermediaries and carriers continue to process claims. For purposes of this report, the term “Medicare contractor” means the fiscal intermediary, carrier, or MAC, whichever is applicable.

\(^2\) In 2009, SCHIP was formally redesignated as the Children’s Health Insurance Program.

\(^3\) HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.
Hospital Payments at Risk for Incorrect Billing

Prior Office of Inspector General (OIG) audits, investigations, and inspections identified certain payments to hospitals that are at risk for noncompliance with Medicare billing requirements. OIG identified these types of payments to hospitals using computer matching, data mining, and analysis techniques. The types of payments to hospitals reviewed by this and related audits included payments for claims billed for:

- inpatient short stays,
- inpatient and outpatient claims involving manufacturer credits for replaced medical devices,
- inpatient claims with payments greater than $150,000,
- inpatient claims paid in excess of charges,
- inpatient claims for blood clotting factor drugs,
- outpatient claims billed for Lupron injections,
- outpatient evaluation and management services,
- outpatient claims billed during an inpatient stay,
- outpatient surgeries billed with units greater than one, and
- outpatient claims billed with Modifier -59.

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 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 and services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” 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 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.

Singing River Hospital

Singing River Hospital (the Hospital) is a 435-bed hospital located in Pascagoula, Mississippi. According to CMS’s National Claims History data, the Hospital received approximately $277 million for inpatient and outpatient services provided to Medicare beneficiaries during calendar years (CY) 2008, 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 claims.

Scope

Our audit covered $3,409,995 in Medicare payments to the Hospital for 369 claims that we judgmentally selected as potentially at risk for billing errors. These 369 claims had dates of service in CYs 2008 through 2010 and consisted of 100 inpatient and 269 outpatient claims.

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

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

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

We conducted our fieldwork at the Hospital during July and August 2011.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
extracted the Hospital’s inpatient and outpatient paid claim data from CMS’s National Claims History file for CYs 2008, 2009, and 2010;

obtained information on known credits for replacement cardiac medical devices from the device manufacturers;

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 369 claims (100 inpatient and 269 outpatient) for detailed review;

reviewed available data from CMS’s Common Working File for the sampled claims to determine whether the claims had been cancelled or adjusted;

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

reviewed the remittance advices the Hospital provided to determine the charges reimbursed by Medicare;

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

utilized Medicare contractor medical review staff to determine whether a limited selection of sampled claims met medical necessity requirements;

reviewed the Hospital’s procedures for assigning HCPCS codes and submitting Medicare claims;

discussed the incorrectly billed and/or coded claims with the Hospital personnel to determine the underlying causes of noncompliance with Medicare requirements;

calculated the correct payments for those claims requiring adjustments; and

discussed the results of our review with the 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 objective.
FINDINGS AND RECOMMENDATIONS

The Hospital complied with Medicare billing requirements for 177 of the 369 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 192 claims, resulting in overpayments totaling $515,651 for CYs 2008 through 2010. Specifically, 31 inpatient claims had billing errors, resulting in overpayments totaling $121,289, and 161 outpatient claims had billing errors, resulting in overpayments totaling $394,362. Overpayments occurred primarily because the Hospital did not have adequate controls to prevent incorrect billing of Medicare claims and did not fully understand the Medicare billing requirements.

Only risk areas with errors are listed in the findings and recommendations section.

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 31 of 100 sampled inpatient claims that we reviewed. These errors resulted in overpayments totaling $121,289.

Inpatient Short Stays

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 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.

For 30 of the 34 sampled claims for inpatient short stays, the Hospital incorrectly billed Medicare Part A for beneficiary stays that it should have billed as either “outpatient” or “outpatient with observation” services. Pinnacle Business Solutions (Pinnacle), the Hospital’s MAC, reviewed each of the 30 claims for medical necessity. For 29 claims, Pinnacle determined from a review of the patients’ medical records that the inpatient admission was not medically necessary and the patient could have been treated in a less intensive setting. For one claim, the medical record documentation had conflicting information and the admission date was unclear. As a result of these errors, the Hospital received overpayments totaling $120,789.4

Inpatient Manufacturer Credit for Replaced Medical Devices

Federal regulations (42 CFR § 412.89) require reductions in the IPPS payments for the replacement of an implanted device if (1) the device is replaced without cost to the provider.

---

4 The Hospital may bill Medicare Part B for a limited range of services related to some of these incorrect Medicare Part A short-stay claims. 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 MAC prior to the issuance of our report.
(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.

Billing Requirements for Medical Device Credits

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 codes 49 or 50, along with value code “FD.”

For 1 of the 42 sampled claims for replaced medical devices, the Hospital did not comply with Medicare requirements. Specifically, the Hospital received a reportable credit for a replaced device but did not report the proper value and condition code on its claim. The Hospital stated that the overpayments occurred because it lacked the knowledge and controls to report the appropriate billing codes. As a result of this, the Hospital received an overpayment totaling $500.

BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 161 of 269 sampled outpatient claims. These errors resulted in overpayments totaling $394,362.

Outpatient Billing for Lupron Injections

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

Leuprolide acetate (Lupron) is a drug commonly used to treat hormone-dependent cancers. The U.S. Food and Drug Administration (FDA) approved different dosages of Lupron for the treatment of different diagnoses. During our audit period, the 3.75 mg dosage of Lupron, HCPCS code J1950, was FDA-approved for the treatment of disorders relating to the uterus. In addition, the FDA approved the 7.5 mg dosage of Lupron, HCPCS code J9217, solely for the treatment of advanced prostatic cancer. The billing code for the smaller dosage of Lupron has a higher Medicare reimbursement rate than the billing code for the larger dosage.

For all of the 160 sampled claims for Lupron injections, the Hospital incorrectly billed HCPCS code J1950. Specifically, of the 160 claims sampled, the Hospital billed 154 of these claims using a multiple of J1950 for the use of the 3.75 mg dosage of Lupron, although the 7.5 mg dosage was administered. For the remaining six claims, the Hospital made other billing errors associated with the number of units billed for J1950.

The Hospital stated that it was unaware of the proper use of HCPCS code J1950 because no relevant CMS or Pinnacle guidance instructed them on how to bill. Thus the Hospital disagreed with our determination.
As a result of these errors, the Hospital received overpayments totaling $390,276.

Outpatient Manufacturer Credit for Replaced Medical Devices

Federal regulations (42 CFR § 419.45) require a reduction in the OPPS payment for the replacement of an implanted device if (1) the device is replaced without cost to the provider or the beneficiary, (2) the provider receives full credit for the cost of the replaced device, or (3) the provider receives partial credit equal to or greater than 50 percent of the cost of the replacement device.

Billing Requirements for Medical Device Credits

The Manual and CMS guidance in Transmittal 1103, dated November 3, 2006, explain how a provider should report no-cost and reduced-cost devices under the OPPS. For services furnished on or after January 1, 2007, CMS requires the provider to use the modifier “FB” and reduce 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.

Prudent Buyer Principle

Federal regulations (42 CFR § 413.9) state: “All payments to providers of services must be based on the reasonable cost of services ….” The prudent buyer principle, is defined in CMS’s Provider Reimbursement Manual, part 1, section 2102.1, and states:

Implicit in the intention that actual costs be paid to the extent they are reasonable is the expectation that the provider seeks to minimize its costs and that its actual costs do not exceed what a prudent and costs conscious buyer pays for a given item or service. If costs are determined to exceed the level that such buyers incur, in the absence of clear evidence that the higher costs were unavoidable, the excess costs are not reimbursable under the program.

Section 2103 of the Provider Reimbursement Manual states that CMS expects Medicare providers to pursue free replacements or reduced charges under warranties. Section 2103(C)(4) provides the following example:

Provider B purchases cardiac pacemakers or their components for use in replacing malfunctioning or obsolete equipment, without asking the supplier/manufacturer for full or partial credits or payments available under the terms of the warranty covering the replaced equipment. The credits or payments that could have been obtained must be reflected as a reduction of the cost of the equipment supplied.

For 2 of the 29 sampled claims for replaced medical devices, the Hospital did not comply with Medicare requirements. For the first claim, the Hospital received a reportable credit for a replaced medical device but did not report the appropriate “FB” modifier or reduced charges on its claim. However, during the course of our audit, the Hospital resubmitted this claim with the correct modifier and the Medicare contractor adjusted the Hospital’s claim. For the second claim, the Hospital did not obtain a credit that was available under the terms of the
manufacturer’s warranty. The Hospital stated that these overpayments occurred because it lacked the knowledge and controls to report the appropriate modifiers, and it relied on the device manufacturers to issue device credits. As a result of not obtaining a credit that was available under the terms of the manufacturer’s warranty, the Hospital received an overpayment totaling $4,086.

**RECOMMENDATIONS**

We recommend that the Hospital:

- refund to the Medicare contractor $515,651, consisting of $121,289 in overpayments for 31 incorrectly billed inpatient claims and $394,362 in overpayments for 161 incorrectly billed outpatient claims, and
- strengthen controls to ensure full compliance with Medicare billing requirements.

**SINGING RIVER HEALTH SYSTEM COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, the Hospital generally disagreed with our first recommendation and did not specifically comment on our second recommendation. However, the Hospital said it implemented several measures to strengthen its processes and controls to reduce the risk of similar errors recurring in the future. The Hospital’s comments are included in their entirety as the Appendix.

In regards to our first recommendation, the Hospital said that the majority of claims that we identified as erroneous were billed in accordance with published guidelines in effect during the service dates of the claims.

**Billing Errors Associated With Inpatient Claims**

*Hospital Comments – Inpatient Short Stays*

The Hospital disagreed with the results of Pinnacle’s medical necessity review for inpatient short-stay claims. The Hospital said that, during its utilization review process, it had procedures in place to review the status of admissions based on guidance it received from Interqual and Executive Health Resources. The Hospital also stated that the physician is ultimately responsible for deciding the admission status of a patient.

*Office of Inspector General Response – Inpatient Short Stays*

The Hospital did not provide any additional information that would cause us to change our recommendation. Based on Pinnacle’s medical review of the 30 claims, we continue to recommend that the Hospital refund to the Medicare contractor $120,789 for these 30 claims.
Hospital Comments – Inpatient Manufacturer Credit for Replaced Medical Devices

For one of the two inpatient manufacturer credit for replaced medical device claims, the Hospital stated that it did not bill for the replaced device. Therefore, the Hospital did not include the “FD” value code, did not receive reimbursement for the replacement device, and did not receive an overpayment. For the second claim, the Hospital summarized the medical situation that resulted in the replacement of the device and provided the original device implantation date. The Hospital stated that, according to the warranty information provided by Biotronick, the replaced device was no longer under warranty and a credit was not available. The Hospital stated that it had procedures in place to report credits and was strengthening these procedures.

Office of Inspector General Response – Inpatient Manufacturer Credit for Replaced Medical Devices

Under IPPS, inpatient claims are reimbursed through the DRG payment mechanism. Because the DRG bundles the cost of the device within the payment, the Hospital did receive reimbursement. For the first claim, we continue to recommend that the Hospital resubmit the claim using the “FD” value code.

For the second claim, the Hospital provided additional information that showed the claim was allowable. Accordingly, we revised the report and excluded this claim from our findings.

Billing Errors Associated With Outpatient Claims

Hospital Comments – Outpatient Billing for Lupron Injections

The Hospital said that our finding concerning its outpatient billing for Lupron injections was not factually based on clear documentation in the medical record and that its “physicians did not use Lupron off-label.” The Hospital said that the only issue was the code it used for billing. The Hospital also said that based on guidance at the time, billing lower dosages with a multiple of the J code was in accordance with published HCPCS codes in 2008, 2009, and 2010, and that the OIG was applying guidance in effect subsequent to the time being reviewed. The Hospital further said that the guidance did not specify gender-specific requirements for the Lupron J1950 code and did not specify the 3.75 mg dose was for females. According to the Hospital, the guidance provides that the J1950 code should be used for Lupron-3 and Lupron-4, the alternative code, J9217, did not include this level of specificity, and neither code was gender-specific. The Hospital said it was unreasonable to hold it to a later clarification of an ambiguous code.

Office of Inspector General Response – Outpatient Billing for Lupron Injections

We agree that the medical record does not provide a basis to question the clinical practices of the Hospital’s physicians, and we have, therefore, removed language in the report that would suggest that Lupron was prescribed off-label. However, we maintain that the Hospital’s use of multiple J1950 codes for 3.75mg of Lupron to bill for a single dose of 7.5mg administered to advanced prostatic cancer patients was improper, given that code J9217 applies to 7.5mg. (Since 1989, the FDA has approved the 7.5mg Lupron dose solely for advanced prostatic cancer, and, since 2001,
the FDA has approved the 3.75mg dose specifically for uterine disorders.) Therefore, we continue to recommend the Hospital refund $390,276 related to the 160 claims in error.

**Hospital Comments – Outpatient Manufacturer Credit for Replaced Medical Devices**

For one of the two outpatient manufacturer credit for replaced medical device claims, the Hospital filed a corrected claim on October 14, 2011, and, on November 7, 2011, the Medicare contractor recouped the overpayment. For the other claim, the Hospital said that the device depleted more quickly than normal, which resulted in it not being covered under the warranty.

**Office of Inspector General Response – Outpatient Manufacturer Credit for Replaced Medical Devices**

We adjusted our report based on the Medicare contractor’s recoupment of the $13,196 overpayment. With respect to the second claim, the Hospital did not provide any documentation from the manufacturer indicating the device was not under warranty. Therefore, we continue to recommend the Hospital pursue the warranty credit and refund any overpayment.
APPENDIX
APPENDIX: SINGING RIVER HEALTH SYSTEM COMMENTS

May 31, 2012

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

Re: Singing River Health System DRAFT Report No.: A-04-11-03069

Dear Ms. Pitcher:

Singing River Health System (SRHS) is in receipt of the U.S. Department of Health and Human Services, Office of Inspector General (OIG) draft report entitled Medicare Compliance Review of Singing River Hospital for Calendar Years 2008 Through 2010 (Report). SRHS has had an opportunity to review the Report and offers the following comments on the Report and the OIG’s recommendations.

The Report makes two recommendations, each of which is addressed below:

- **Recommendation 1:** Refund to the Medicare contractor $545,547, consisting of $137,989 in overpayments for 32 incorrectly billed inpatient claims and $407,558 in overpayments for 162 incorrectly billed outpatient claims.

SRHS respectfully disagrees with this recommendation. The majority of claims identified as erroneous were billed in accordance with published CMS guidelines and other guidelines during the time of service of the claims. The rationale for denial provided by OIG relies upon publications since the dates of service of the claims that have been retroactively applied. Additionally, the factual basis upon which OIG finds overpayments is in error.

**Inpatient Short Stays**

For 22 of the 34 sampled claims for inpatient short stays, the report stated Pinnacle determined from a review of the patients’ medical records that the inpatient admission was not medically necessary and the patient could have been treated in a less intensive setting. Additionally, the rationale provided to SRHS for each account stated the following:
Ms. Lori S. Pilcher
May 31, 2012
Page 2 of 5

“There was no documentation in the medical record to support the medical
necessity of an inpatient admission and no rationale was offered as to why this
patient could not have been evaluated and treated in a less intensive setting.”

“[A] verbal order was written by an RN case manager to change to Inpatient
Admission.”

“There was no physician documentation of risk assessment or rationale for
changing the admission status.”

“There was documentation of an “Observation Initial Review Determination”
by a physician advisor from Executive Health Resources included with the
medical records that recommended “Inpatient Appropriate”; however, this is
only a second opinion. Per the Medicare Benefit policy Manual, the physician
or other practitioner responsible for the patient’s care at the hospital is
ultimately responsible for deciding whether the patient should be admitted as
an inpatient, not a secondary reviewer.”

As discussed during the initial interview with SRHS and the initial response, dated
October 26, 2011, SRHS has procedures in place to review the status of admission based on
the guidance provided by Interal and Executive Health Resources. The information
received from Executive Health Resources is used for utilization review/utilization
management/claims purposes only and does not serve as the decision to change the status
of admission. The attending physician is involved in the decision regarding any change to status
and is ultimately responsible for deciding whether the patient should be admitted as an
inpatient. The attending physician consults with Executive Health Resource physician and
considers the Executive Health Resource physician’s risk assessment during the utilization
review consult. Additionally, if the attending physician does not agree with the Executive
Health Resource physician’s recommendation, no change to status is made. No change can
be made to the status without an order from the attending physician. The RN Case Manager
cannot and does not make this decision independently. Per the SRHS Bylaws, all verbal
orders must be initiated and authenticated by the SRHS physician. The decision to change
the patient’s status to Inpatient Admission is made by an SRHS physician after a medical
necessity review under the utilization review process has been made. All appropriate
physician documentation is within the medical record. SRHS has met the requirements to
meet medical necessity.

Inpatient Manufacturer Credit for Replaced Medical Devices

For the Inpatient 2010 claim, dated October 21, 2010, the OIG audit revealed the “FD”
value code be placed for a replacement device that was provided with a credit. Yet for that
claim, SRHS did not bill for the device and did not receive reimbursement for the
replacement device. Accordingly, although SRHS did not include the modifier code, SRHS did
not receive reimbursement for the replacement and thus no overpayment resulted.

For the Inpatient 2010 claim, dated September 15, 2010, the OIG audit revealed the
device was replaced due to a low battery and the device was eligible for credit due to battery
depletion. Based on the clinical review of the patient’s record, the patient’s device indicated a
Ms. Lori S. Pilcher  
May 31, 2012  
Page 3 of 5

lead fracture. The new lead could not be placed on the left due to an occluded left subclavian vessel pathway in the patient. The device settings were then updated on the original device and the following day, after interrogation of the device, it was found that reseting the device did not correct the problem and the decision was made by the physician to explant the device from the left subclavian and implant a new single lead AICD to the right. The lead from the left subclavian was from the original implanted device dated from June 12, 2003 and was no longer under warranty, according to the warranty information provided by Biotronik on the device. There was no credit available and no resulting overpayment. The supporting documentation has been provided during the audit.

SRHS has procedures in place to report credits. In addition, SRHS is strengthening its ongoing programs to document that it appropriately requests manufacturer credits for devices under warranty.

Outpatient Billing for Lupron Injections

OIG's finding that that SRHS billed code J1950 for the off-label use of Lupron 3.75 mg for male patients is not factually based upon the clear documentation in the medical record. SRHS physicians did not use Lupron off-label—the physician order was for 7.5 mg for a male patient, the dosage administered was 7.5 mg for a male patient, and the packaging for the drug administered (and included in the medical record) clearly provided that it was a 7.5 mg dosage. The only issue for review is the code applied once billing occurred. The OIG's characterization of the clinical practices of the physicians involved is not supported by the medical record and is not accurate. Additionally, there are several drugs (e.g., Leucovorin, Procrit, Crestor, Protonix, and Lovenox) which are administered in single dosages as clinically indicated yet billed in multiple units.

Based on the guidance that was issued during that time period and other circumstances when a drug is available in lower dosages to use a multiple of the J code when multiple dosages of the drug is administered, SRHS billed in accordance with the HCPCS published in 2008, 2009 and 2010 (which remained in 2011 and 2012). The OIG is applying interpretations and guidance that was not available at the time the services were rendered.

As discussed in the draft response, dated October 26, 2011, based on the guidance provided in 2008, 2009, and 2010 HCPCS Coding System, SRHS billed the J1950 Lupron per 3.75 mg administered for male patients with prostate conditions. The guidance did not specify gender specific requirements for the Lupron J1950, but only indicated to use the J1950 code “(for depot suspension), per 3.75 mg”. The guidance specifies “per 3.75 mg” and does not specify for 3.75 mg dose with female indication. The HCPCS legend has symbols for “female only” and “male only.” Neither of these symbols is provided for either the J1950 or the J9217. There is no HCPCS gender-specific code for Lupron from 2008 - 2012. There is a “quantity alert” symbol. Quantity alert symbol are used where "HCPCS reports quantities that may not coincide with quantities available in the market place. ... This symbol indicates that care should be taken to verify quantities in this code."

Furthermore, the guidance provides that the J1950 code should be used for Lupron-3 and Lupron-4. The alternative code available, J9217, did not include this level of specificity
Ms. Lori S. Pilcher  
May 31, 2012  
Page 4 of 5

for the treatment administered. Neither code was gender specific. It is unreasonable to hold SRIS to a later clarification of an ambiguous code. SRIS was not "unaware of the proper use of HCPCS code J1950." SRIS reasonably applied the HCPCS code indicated for Lupron-3 and Lupron-4 (See 2008 HCPCS p. 83; 2009 HCPCS p. 78; and 2010 HCPCS p. 77). This availability remains to date.

Although Pinnacle published an LCD in August 2011, the prior Medicare Contractor, Tri-Span had not published any LCDs regarding the appropriate J Codes during the years 2008, 2009 nor 2010.

SRIS continually evaluates, updates, and strengthens its processes to remain compliant with CMS requirements and guidelines. In May of 2010, our internal review process revisited the use of J1950 and J9217. After further research, SRIS began using J9217 in June 2010 and ultimately discontinued the use of Lupron in June 2010. The Pharmacy and Therapeutics Committee recommended the sole use of Eligard 7.5mg, 22.5mg, 30mg, and 45mg.

SRIS is in the process of implementing an electronic health record. Upon implementation, SRIS will be restricting the use of certain drugs to the prescribed diagnosis to provide additional controls to reduce the risks of errors from occurring in the future.

Outpatient Manufacturer Credit for Replaced Medical Devices

For the Outpatient 2009 claim, dated December 18, 2009, SRIS has filed a corrected claim on October 14, 2011. We have removed the charge for the device and appended the modifier "FB" to the surgery CPT code. The adjustment claim was processed on the Remittance Advice on November 7, 2011 which Medicare has recouped the overpayment.

For the Outpatient 2009 claim, dated November 15, 2010, SRIS responded in the initial response, dated October 26, 2011. Based on the clinical review of the patient’s record, the patient had an underlying rhythm of a complete third degree heart block and there was no communication between the atrial and ventricular conduction, therefore, the patient was totally dependent on the device. This was an example of an aged, diseased muscle that could not conduct well and required greater energy to conduct and maintain a rhythm compared to a patient with a healthy tissue. The device amplitude was set at maximum and resulted in depleting the generator more quickly than a normal situation which resulted in not being eligible for the warrant of the device. There was no credit received.

- **Recommendation 2**: Strengthen controls to ensure full compliance with Medicare billing requirements.

SRIS regularly conducts coding and compliance education, monitoring and auditing. To strengthen the efforts raised by the OIG's findings, we have implemented several measures, including the following:

- Review and update process related to Inpatient and Outpatient Manufacturer Credits for Medical Devices;
Ms. Lori S. Pilcher
May 31, 2012
Page 5 of 5

- Conduct additional coding education and auditing;

- Implementing stronger internal controls aimed at reducing the risks of these types of errors from occurring in the future.

We thank you for the professionalism and courtesy displayed by your staff during the review. We also appreciate the opportunity to review and strengthen our process.

SRHS takes great pride in providing world-class healthcare services and is equally committed to ensuring that all legal and regulatory requirements are met. If you have any questions or feedback, please do not hesitate to contact me at (228) 497-7494.

Very truly yours,

[Signature]
Stephanie Barnes Taylor
Chief Compliance Officer