Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE COMPLIANCE REVIEW OF MOUNT SINAI HOSPITAL FOR 2012 AND 2013

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

Gloria L. Jarmon
Deputy Inspector General
for Audit Services

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EXECUTIVE SUMMARY

Mount Sinai Hospital did not fully comply with Medicare requirements for billing inpatient and outpatient services, resulting in overpayments of at least $41.9 million over 2 years.

WHY WE DID THIS REVIEW

This review is part of a series of hospital compliance reviews. Using computer matching, data mining, and data analysis techniques, we identified hospital claims that were at risk for noncompliance with Medicare billing requirements. For calendar year (CY) 2012, Medicare paid hospitals $148 billion, which represents 43 percent of all fee-for-service payments; therefore, the Office of Inspector General must provide continual and adequate oversight of Medicare payments to hospitals.

The objective of this review was to determine whether Mount Sinai Hospital (the Hospital) complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) pays inpatient hospital costs at predetermined rates for patient discharges. The rates vary according to the diagnosis-related group (DRG) to which a beneficiary's stay is assigned and the severity level of the patient's diagnosis. The DRG payment is, with certain exceptions, intended to be payment in full to the hospital for all inpatient costs associated with the beneficiary's stay. CMS pays inpatient rehabilitation services at a predetermined rate according to the distinct case-mix group (CMG). The CMG is based on the beneficiary's clinical characteristics and expected resource needs. CMS pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification. CMS contracts with Medicare contractors to, among other things, process and pay claims submitted by hospitals.

Under section 1128J(d) of the Social Security Act and 42 CFR part 401 subpart D (the 60-day rule), upon receiving credible information of a potential overpayment, providers must: (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify the overpayment amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (42 CFR § 401.305(a)(2), (f) and 81 Fed. Reg. 7654, 7663) (Feb. 12, 2016)). OIG believes that this audit report constitutes credible information of potential overpayments.

The Hospital is a 1,171-bed acute-care teaching hospital located in New York, New York. According to CMS's National Claims History data, Medicare paid the Hospital approximately $842.4 million for 36,262 inpatient and 361,784 outpatient claims for services provided to beneficiaries during CYs 2012 and 2013 (audit period).

Our audit covered $74,679,543 in Medicare payments to the Hospital for 6,369 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 261

claims (144 inpatient and 117 outpatient) with payments totaling $4,375,619. These 261 claims had dates of service in our audit period.

WHAT WE FOUND

The Hospital complied with Medicare billing requirements for 151 of the 261 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 110 claims, resulting in overpayments of $1,374,339 for the audit period. Specifically, 78 inpatient claims had billing errors, resulting in overpayments of $1,200,390 and 32 outpatient claims had billing errors, resulting in overpayments of $173,949. These errors occurred primarily because the Hospital did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

On the basis of our sample results, we estimated that the Hospital received overpayments totaling at least $41,869,783 for the audit period. As of the publication of this report, this unallowable amount may include claims outside of the 4-year claims reopening period.

WHAT WE RECOMMEND

We recommend that the Hospital:

- refund to the Medicare program the portion of the estimated $41,869,783 overpayment for claims incorrectly billed that are within the reopening and recovery periods;

- for the remaining portion of the estimated $41,869,783 overpayment, which is outside of the Medicare reopening and recovery periods, exercise reasonable diligence to identify and return overpayments. When returning overpayments, payments should be identified as being made in accordance with this recommendation;

- exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule. When returning overpayments, payments should be identified as being made in accordance with this recommendation; and

- strengthen controls to ensure full compliance with Medicare requirements.

HOSPITAL COMMENTS AND OUR RESPONSE

In written comments on our draft report, the Hospital generally disagreed with our findings and recommendations. Specifically, the Hospital indicated that the majority of overpayments we identified in our draft report can no longer be recovered by CMS and that some of these claims are also outside of a 4-year reopening period and do not need to be returned. The Hospital indicated that it believes the potential overpayments we identified are time-barred; therefore, the Hospital is not obligated to return them under the 60-day repayment rule. However, the Hospital did not dispute our determination that it incorrectly billed 4 inpatient claims and 21 outpatient

claims with a total overpayment amount of $219,523, and stated that it will submit refunds for some of these claims that are within the reopening and recovery periods.

The Hospital disagreed that it improperly billed 85 of the 110 claims that we determined did not fully comply with Medicare billing requirements. The Hospital stated that our review misapplied Medicare coverage, coding, and documentation requirements, resulting in an incorrect error rate. In addition, the Hospital stated that it believes the extrapolation of overpayments is premature, improper, and statistically unsound. Finally, the Hospital indicated that it would strengthen its controls through continual oversight of potential risk areas for Medicare noncompliance.

After reviewing the Hospital's comments, we maintain that our findings are valid and continue to recommend that the Hospital return any identified overpayments. Providers who identify overpayments are required to return them within 60 days. In addition, providers must exercise reasonable diligence to determine whether overpayments of a similar type existed during a 6-year lookback period. Providers are obligated to quantify the entire amount of overpayment for this period and may do so by using a statistically valid extrapolation methodology. The Hospital, itself, identified overpayments when it did not dispute our determinations concerning the 4 inpatient claims and the 21 outpatient claims it billed incorrectly and stated that it will submit refunds for some of these claims that are within the reopening and recovery periods.

Regarding the Hospital's disagreement with our determination that it improperly billed 85 claims and that our review misapplied Medicare requirements, we note that we obtained independent medical review for 77 of these claims for medical necessity and coding errors. Additionally, in response to the Hospital's concerns about 29 inpatient elective procedure determinations, a second medical review consultation was conducted. We subjected these claims to focused medical reviews to determine whether services met medical necessity and coding requirements and our report reflects the results of these reviews. For the remaining eight disputed inpatient manufacturer credits for replaced medical device claims, we reiterate that section 2103 of the CMS *Provider Reimbursement Manual* defines prudent buyer principles and states that Medicare providers are expected to pursue free replacements or reduced charges under warranties. Finally, regarding our extrapolation methodology and the statistical validity of our results, Federal courts have consistently upheld statistical sampling and extrapolation as a valid method to determine overpayment amounts in Medicare.

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INTRODUCTION

WHY WE DID THIS REVIEW

This review is part of a series of hospital compliance reviews. Using computer matching, data mining, and data analysis techniques, we identified hospital claims that were at risk for noncompliance with Medicare billing requirements. For calendar year (CY) 2012, Medicare paid hospitals $148 billion, which represents 43 percent of all fee-for-service payments; therefore, the Office of Inspector General (OIG) must provide continual and adequate oversight of Medicare payments to hospitals.

OBJECTIVE

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

BACKGROUND

The Medicare Program

Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge, and Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

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

Hospital Inpatient Prospective Payment System

Under the inpatient prospective payment system (IPPS), CMS pays hospital costs at predetermined rates for patient discharges. The rates vary according to the diagnosis-related group (DRG) to which a beneficiary's stay is assigned and the severity level of the patient's diagnosis. The DRG payment is, with certain exceptions, intended to be payment in full to the hospital for all inpatient costs associated with the beneficiary's stay.

Hospital Inpatient Rehabilitation Facility Prospective Payment System

Inpatient rehabilitation facilities provide rehabilitation for patients who require a hospital level of care, including a relatively intense rehabilitation program and an interdisciplinary, coordinated team approach to improve their ability to function. Section 1886(j) of the Social Security Act (the Act) established a Medicare prospective payment system for inpatient rehabilitation facilities. CMS implemented the payment system for cost-reporting periods beginning on or after January 1, 2002. Under the payment system, CMS established a Federal prospective payment rate for each of the distinct case-mix groups (CMG). The assignment to a CMG is based on the beneficiary's clinical characteristics and expected resource needs. 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), which is effective for services furnished on or after August 1, 2000, for hospital outpatient services. Under the OPPS, Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification (APC). CMS uses Healthcare Common Procedure Coding System (HCPCS) codes and descriptors to identify and group the services within each APC group.[1] All services and items within an APC group are comparable clinically and require comparable resources.

Hospital Claims at Risk for Incorrect Billing

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

- inpatient short stays,
- inpatient claims billed with high severity level DRG codes,
- inpatient rehabilitation facility (IRF) claims,
- inpatient and outpatient manufacturer credits for replaced medical devices,
- inpatient psychiatric facility (IPF) emergency department adjustments,
- inpatient claims with same-day discharges and readmissions,
- outpatient claims billed with modifier -59,
- outpatient claims billed with modifier -25,
- outpatient evaluation and management services billed at a higher level than physician,
- outpatient claims billed for the drug Herceptin, and
- outpatient intensity-modulated radiation therapy (IMRT) planning services.

For the purposes of this report, we refer to these areas at risk for incorrect billing as "risk areas." We reviewed these risk areas as part of this review.

[1] The health care industry uses HCPCS codes to standardize coding for medical procedures, services, products, and supplies.

Medicare Requirements for Hospital Claims and Payments

Medicare payments may not be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (the Act, § 1862(a)(1)(A)). In addition, payments may not be made to any provider of services or other person without information necessary to determine the amount due to the provider (§ 1833(e)).

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

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

Under section 1128J(d) of the Act and 42 CFR part 401 subpart D (the 60-day rule), upon receiving credible information of a potential overpayment, providers must: (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify the overpayment amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (42 CFR § 401.305(a)(2), (f) and 81 Fed. Reg. 7654, 7663) (Feb. 12, 2016)). OIG believes that this audit report constitutes credible information of potential overpayments.

Mount Sinai Hospital

The Hospital is a 1,171-bed acute-care teaching hospital in New York, New York.[2] Medicare paid the Hospital approximately $842.4 million for 36,262 inpatient and 361,784 outpatient claims for services provided to beneficiaries during CYs 2012 and 2013 (audit period) based on CMS's National Claims History data.

HOW WE CONDUCTED THIS REVIEW

Our audit covered $74,679,543 in Medicare payments to the Hospital for 6,369 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 261 claims (144 inpatient and 117 outpatient) with payments totaling $4,375,619. These 261 claims had dates of service in our audit period.

We focused our review on the risk areas identified as a result of prior OIG reviews at other hospitals. We evaluated compliance with selected billing requirements and subjected 188 claims to medical and coding review to determine whether the services were medically necessary and properly coded.

[2] The hospital is one of seven hospitals and a medical school that comprise The Mount Sinai Health System.

During our exit conference with the Hospital, Hospital officials raised concerns about our review of inpatient stays. We subsequently met with the Hospital two more times so that we could gain a full understanding of the Hospital's position. We also subjected claims for which the Hospital expressed concerns to a second medical review.

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

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

See Appendix A for the details of our audit scope and methodology.

FINDINGS

The Hospital complied with Medicare billing requirements for 151 of the 261 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 110 claims, resulting in overpayments of $1,374,339 for the audit period. Specifically, 78 inpatient claims had billing errors, resulting in overpayments of $1,200,390 and 32 outpatient claims had billing errors, resulting in overpayments $173,949. These errors occurred primarily because the Hospital did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors. On the basis of our sample results, we estimated that the Hospital received overpayments of at least $41,869,783 for the audit period.[3] As of the publication of this report, this unallowable amount may include claims outside of the 4-year claims reopening period.[4]

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

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 78 of 144 selected inpatient claims, which resulted in overpayments of $1,200,390.

[3] To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner will be less than the actual overpayment total at least 95 percent of the time.

[4] 42 CFR § 405.980(b)(2).

Incorrectly Billed as Inpatient

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

A payment for services furnished to an individual may be made only to providers of services that are eligible and only if, "with respect to inpatient hospital services … which are furnished over a period of time, a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment…" (the Act, § 1814(a)(3)). Federal regulations state that Medicare Part A pays for inpatient hospital services only if a physician certifies and recertifies, among other things, the reasons for continued hospitalization (42 CFR § 424.13(a)). In addition, the *Medicare Benefit Policy Manual* provides that a patient is an inpatient only "if admitted … for purposes of receiving inpatient hospital services" and "if formally admitted … with the expectation that he or she will remain at least overnight …" Furthermore, "the physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient (Pub. No. 100-02, chapter 1 § 10)."

For 36 of the 144 selected inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that it should have billed as outpatient or outpatient with observation services (33 claims) or the medical record did not contain a valid physician order (3 claims). The 36 errors were in two risk areas (1) electives procedures (26 claims) and (2) high severity level DRG codes (10 claims). The Hospital disagreed with our findings and stated that its patients met utilization review criteria and that the Hospital followed its utilization review plan process. As a result of these errors, the Hospital received overpayments of $637,692.[5]

Inpatient Rehabilitation Facility Services Incorrectly Billed as Inpatient

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

The *Medicare Benefit Policy Manual* states that the IRF benefit is designed to provide intensive rehabilitation therapy in a resource intensive inpatient hospital environment for patients who, due to the complexity of their nursing, medical management, and rehabilitation needs, require and can reasonably be expected to benefit from an inpatient stay and an interdisciplinary team approach to the delivery of rehabilitation care (Pub. No. 100-02, chapter 1, § 110-110.1).

In addition, the *Medicare Benefit Policy Manual* states that in order for IRF care to be considered reasonable and necessary, the documentation in the patient's IRF medical record must demonstrate a

[5] The Hospital may be able to bill Medicare Part B for all services (except for services that specifically require an outpatient status) that would have been reasonable and necessary had the beneficiary been treated as a hospital outpatient rather than admitted as an inpatient. We were unable to determine the effect that billing Medicare Part B would have on the overpayment amount because these services had not been billed and adjudicated by the Medicare contractor prior to the issuance of our report.

reasonable expectation that at the time of admission to the IRF the patient 1) required the active and ongoing therapeutic intervention of multiple therapy disciplines, 2) generally required an intensive rehabilitation therapy program, 3) actively participated in, and benefited significantly from, the intensive rehabilitation therapy program, 4) required physician supervision by a rehabilitation physician, and 5) required an intensive and coordinated interdisciplinary approach to providing rehabilitation (Pub. No. 100-02, chapter 1, § 110.2).

Furthermore, the *Medicare Benefit Policy Manual* states that a primary distinction between the IRF environment and other rehabilitation settings is the intensity of rehabilitation therapy services provided in an IRF. For this reason, the information in the patient's IRF medical record must document a reasonable expectation that at the time of admission to the IRF the patient generally required the intensive rehabilitation therapy services that are uniquely provided in IRFs (Pub. No. 100-02, chapter 1, § 110.2.2).

For 21 of the 144 selected inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for acute inpatient rehabilitation and should have been billed at a lower level of care. The Hospital disagreed with our findings and stated that its patients met utilization review criteria and that the Hospital followed its utilization review plan process.

As a result of these errors, the Hospital received overpayments of $357,364.

Manufacturer Credits for Replaced Medical Devices Not Obtained or Reported

Federal regulations require a reduction in the IPPS 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 the device, or (3) the provider receives a credit equal to 50 percent or more of the device cost (42 CFR § 412.89(a)). The Manual states that to correctly bill for a replacement device that was provided with a credit, hospitals must code Medicare claims with a combination of condition code 49 or 50 (which identifies the replacement device) and value code FD (which identifies the amount of the credit or cost reduction received by the hospital for the replaced device) (chapter 3, § 100.8). The CMS *Provider Reimbursement Manual* (PRM) reinforces these requirements in additional detail (Pub. No. 15-1).[6]

For 8 of the 144 selected inpatient claims, the Hospital did not obtain credits for replaced devices for which credits were available under the terms of the manufacturer's warranty. The Hospital disagreed with this finding and stated that it is exempt from the prudent buyer principle set forth in the CMS *Medicare Benefit Policy Manual* because it is reimbursed under the IPPS, whereas

[6] The PRM states: "Implicit in the intention that actual costs be paid to the extent they are reasonable is the expectation that the provider seeks to minimize its costs and that its actual costs do not exceed what a prudent and cost conscious buyer pays for a given item or service" (part I, § 2102.1). Section 2103 further defines prudent buyer principles and states that Medicare providers are expected to pursue free replacements or reduced charges under warranties. Section 2103(C)(4) provides the following example: "Provider B purchases cardiac pacemakers or their components for use in replacing malfunctioning or obsolete equipment, without asking the supplier/manufacturer for full or partial credits available under the terms of the warranty covering the replaced equipment. The credits or payments that could have been obtained must be reflected as a reduction of the cost of the equipment."

the prudent buyer principle is applicable only to cost-based reimbursed hospitals and exempt units.[7] As a result of these errors, the Hospital received overpayments of $121,732.

Incorrectly Billed Diagnosis Related Group Code

Section 1862(a)(1)(A) of the Act states that no Medicare payment may be made for items or services that "… are not reasonable and necessary for diagnosing or treating illness or injury or for improving the functioning of a malformed body member." The Manual, chapter 1, section 80.3.2.2, states: "In order to be processed correctly and promptly, a bill must be completed accurately."

For 6 of the 144 selected claims, the Hospital billed Medicare with an incorrectly assigned DRG code. The Hospital stated that errors because (1) two claims were coded incorrectly due to documentation inconsistencies not initially identified by the Hospital's DRG validators and (2) one claim was coded incorrectly due to a typographical error. The Hospital did not provide a cause for the remaining three errors because it did not agree with the findings. As a result of these errors, the Hospital received overpayments of $74,531.

Incorrectly Billed as a Separate Inpatient Stay

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

For 1 of the 144 selected claims, the Hospital billed Medicare separately for a related discharge and readmission within the same day. The Hospital did not provide a cause because it did not agree with this finding. As a result of this error, the Hospital received an overpayment of $7,282.

Incorrectly Billed Case Mix Group

Section 1886(j)(2)(D) of the Act requires IRFs to transmit sufficient patient data to allow CMS to administer the IRF PPS. These data are necessary to assign beneficiaries to the appropriate CMG to monitor the effects of the IRF PPS on patient care. Each CMG is assigned a relative weight. In addition, the Manual states: "In order to be processed correctly and promptly, a bill must be completed accurately" (chapter 1, § 80.3.2.2).

[7] Section 40.4 of Chapter 16 of the *Medicare Benefit Policy Manual* is not applicable to these claims. Section 40.4 was issued in 2003, several years before the promulgation of the payment adjustment rule in 42 CFR § 412.89. Consequently, section 40.4 does not accurately describe the OPPS's payment adjustment policy for replaced devices. We note that section 40.4 addresses exclusions from coverage for replaced devices in the reasonable cost reimbursement context. To the extent that anything in section 40.4 could apply under the OPPS, the regulation at 42 CFR § 412.89 and manual provisions cited in this report are superseding.

For 1 of the 144 selected claims, the Hospital billed Medicare with an incorrect CMG code. The Hospital stated that the CMG code was incorrectly billed due to human error. As a result of this error, the Hospital received an overpayment of $1,266.

Incorrect Source-of-Admission Code

CMS increases the Federal per diem rate for the first day of a Medicare beneficiary's IPF stay to account for the costs associated with maintaining a qualifying emergency department. CMS makes this additional payment regardless of whether the beneficiary used emergency department services; however, the IPF should not receive the additional payment if the beneficiary was discharged from the acute care section of the same hospital (42 CFR § 412.424 and the Manual, chapter 3, § 190.6.4). The Manual also states that IPFs report source-of-admission code "D" to identify patients who have been transferred to the IPF from the same hospital (chapter 3, 190.6.4.1). An IPF's proper use of this code is intended to alert the Medicare contractor not to apply the emergency department adjustment.

For 5 of the 144 selected claims, the Hospital incorrectly coded the source-of-admission for beneficiaries who were admitted to its IPF upon discharge from its acute-care section. The Hospital stated that the miscoding occurred because hospital staff misinterpreted Medicare billing requirements for applying IPF source-of-admission codes. As a result of these errors, the Hospital received overpayments of $523.

BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 32 of 117 selected outpatient claims, which resulted in overpayments of $173,949.

Manufacturer Credits for Replaced Medical Devices Not Obtained or Reported

Federal regulations require a reduction in the OPPS payment for the replacement of an implanted device if (1) the device is replaced without cost to the provider or the beneficiary, (2) the provider receives full credit for the cost of a replaced device, or (3) the provider receives partial credit equal to or greater than 50 percent of the cost of the replacement device (42 CFR § 419.45(a)). As described in footnote 6 of this report, the PRM reinforces these requirements in additional detail.

For services furnished on or after January 1, 2007, CMS requires the provider to report the modifier -FB and reduces 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.[8]

For 11 of the 117 selected claims, the Hospital (1) did not obtain a credit for a replaced device that was available under the terms of the manufacturer's warranty (9 claims), (2) received a

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

credit but did not report the credit by indicating an "FB" code on the claim (1 claim), or (3) received a credit but did not reduce the cost of charges (1 claim). The Hospital stated that these errors occurred due to possible miscommunication or disagreement among the parties involved in the process of obtaining the medical device credits and agreed with the findings in this section. As a result of these errors, the Hospital received overpayments of $167,469.

Incorrectly Billed Outpatient Services With Modifier -59

The Manual states: "The '-59' modifier is used to indicate a distinct procedural service…. This may represent a different session or patient encounter, different procedure or surgery, different site, or organ system, separate incision/excision, or separate injury (or area of injury in extensive injuries)" (chapter 23, § 20.9.1.1). In addition, the Manual states: "In order to be processed correctly and promptly, a bill must be completed accurately" (chapter 1, § 80.3.2.2).

For 11 of the 117 selected claims, the Hospital incorrectly billed Medicare for HCPCS codes, appended with modifier -59, which were already included in the payment for other services billed on the same claim. Hospital officials agreed with 5 of these 11 errors and disagreed with the remaining errors. The Hospital did not provide a cause for the claims it agreed with; however, indicated it will continue to educate its staff on billing claims with modifier -59. As a result of these errors, the Hospital received overpayments of $5,619.

Incorrect Billing for Intensity-Modulated Radiation Therapy Planning Services

The Manual states: "In order to be processed correctly and promptly, a bill must be completed accurately" (chapter 1, § 80.3.2.2). The Manual also states that certain services should not be billed when they are performed as part of developing an IMRT plan (chapter 4, § 200.3.2).

For 2 of the 117 selected outpatient claims, the Hospital incorrectly billed Medicare for services that were already included in the payment for IMRT planning services billed on the same claim. These services were performed as part of developing an IMRT plan and should not have been billed in addition to the HCPCS code for IMRT planning. The Hospital stated that this finding was due to human error. As a result of these errors, the Hospital received overpayments of $472.

Incorrectly Billed Evaluation and Management Level of Service

The Manual, Pub. No. 100-04, chapter 1, section 80.3.2.2, requires that claims be completed accurately to be processed correctly and promptly. The Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§ 1833(e)). Further, in guidance to hospitals, CMS stated that it expects hospitals' coding guidelines to follow the intent of the Current Procedural Terminology code descriptor in that the guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the assigned procedure code.[9]

For 8 of the 117 selected claims, the Hospital incorrectly billed Medicare with certain higher level-of-service procedure codes that were not supported in the medical records. Specifically,

[9] 72 Fed. Reg. 66580, 66805 (Nov. 27, 2007).

the Hospital billed Medicare for an incorrect level of service (6 claims) and case files lacked the necessary documentation to support the level of service billed (2 claims). The Hospital generally concurred with our findings and indicated that in certain circumstances the provider may have selected an incorrect level of service. As a result of these errors, the Hospital received overpayments of $389.

RECOMMENDATIONS

We recommend that the Hospital:

- refund to the Medicare program the portion of the estimated $41,869,783 overpayment for claims incorrectly billed that are within the reopening and recovery periods;

- for the remaining portion of the estimated $41,869,783 overpayment, which is outside of the Medicare reopening and recovery periods, exercise reasonable diligence to identify and return overpayments. When returning overpayments, payments should be identified as being made in accordance with this recommendation;

- exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule. When returning overpayments, payments should be identified as being made in accordance with this recommendation; and

- strengthen controls to ensure full compliance with Medicare requirements.

HOSPITAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Hospital generally disagreed with our findings and recommendations. Specifically, the Hospital indicated that the majority of overpayments we identified in our draft report can no longer be recovered by CMS and that some of the claims are also outside of a 4-year reopening period and do not need to be returned. The Hospital indicated that it believes the potential overpayments we identified are time-barred; therefore, the Hospital is not obligated to return them under the 60-day repayment rule. However, the Hospital did not dispute our determination that it incorrectly billed 4 inpatient claims and 21 outpatient claims with a total overpayment amount of $219,523, and stated that it will submit refunds for some of these claims that are within the reopening and recovery periods.

The Hospital disagreed that it improperly billed 85 of the 110 claims that we determined did not fully comply with Medicare billing requirements. The Hospital stated that our review misapplied Medicare coverage, coding, and documentation requirements, resulting in an incorrect error rate; in addition, the Hospital stated that it believes the extrapolation of overpayments is premature, improper, and statistically unsound. Finally, the Hospital indicated that it would strengthen its controls through continual oversight of potential risk areas for Medicare noncompliance.

After reviewing the Hospital's comments, we maintain that our findings are valid and continue to recommend the Hospital return any identified overpayments. Providers who identify

overpayments are required to return them within 60 days. In addition, providers must exercise reasonable diligence to determine whether overpayments of a similar type existed during a 6-year lookback period. Providers are obligated to quantify the entire amount of overpayment for this period and may do so by using a statistically valid extrapolation methodology. The Hospital, itself, identified overpayments when it did not dispute our determinations concerning the 4 inpatient claims and the 21 outpatient claims it billed incorrectly and stated that it will submit refunds for some of these claims that are within the reopening and recovery periods.

Regarding the Hospital's disagreement with our determination that it improperly billed 85 claims and that our review misapplied Medicare requirements, we note that we obtained independent medical review for 77 of these claims for medical necessity and coding errors. Additionally, in response to the Hospital's concerns about 29 inpatient elective procedure determinations, a second medical review consultation was conducted. We subjected these claims to focused medical reviews to determine whether services met medical necessity and coding requirements and our report reflects the results of these reviews. For the remaining eight disputed inpatient manufacturer credits for replaced medical device claims, we reiterate that section 2103 of the *Provider Reimbursement Manual* defines prudent buyer principles and states that Medicare providers are expected to pursue free replacements or reduced charges under warranties. Finally, regarding our extrapolation methodology and the statistical validity of our results, Federal courts have consistently upheld statistical sampling and extrapolation as a valid method to determine overpayment amounts in Medicare.

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

CONTESTED DETERMINATION OF CLAIMS

Hospital Comments

The Hospital disagreed that it improperly billed 85 of the 110 claims that we determined did not fully comply with Medicare billing requirements. Specifically, the Hospital disagreed with our determinations for all 29 inpatient elective procedure claims, 10 of the 13 inpatient claims billed with high severity level DRG codes, 21 of the 22 IRF claims, all 8 inpatient manufacturer credits for replaced medical device claims, the 1 inpatient claim with a same day discharge and readmission, 8 of the 11 outpatient modifier -59 claims, and all 8 outpatient evaluation and management level of service claims. However, the Hospital did not dispute our determination that it incorrectly billed 4 inpatient claims and 21 outpatient claims and stated that it will submit refunds for some of these claims within the reopening and recovery period.

The Hospital disagreed with our findings for 69 inpatient claim determinations. Specifically, the Hospital disputed 54 inpatient claims that we determined were incorrectly billed as inpatient. The Hospital stated that all of the claims were reasonable, necessary, and met Medicare coverage criteria.[10] In its rationale for disagreeing with the medical necessity determinations for these claims, the Hospital cited physician judgement at the time of inpatient admission, improper and inconsistent medical review determinations, and stated that a lower level of care would have

[10] The Hospital disputed 33 sample claims in categories A (Elective Procedures Billed as Inpatient) and B (Inpatient Claims Billed with High Severity Level DRG Codes), and 21 sample claims in category C (IRF Claims).

been inadequate for the health and safety of its Medicare patients. The Hospital also disputed our determinations for IRF claims, and stated that the medical reviewer failed to follow the applicable CMS rules governing whether a patient's admission for IRF care was reasonable and necessary. In addition, the Hospital disputed our findings for eight inpatient manufacturer credits for replaced medical device claims, and stated that the provisions of 42 CFR § 412.89 and chapter 3, § 100.8 of the Manual do not impose a reduction in reimbursement to the Hospital if a device manufacturer refuses to provide a credit or the Hospital does not seek a credit. While the Hospital disputes these findings, it described actions it has taken or plans to take to improve policies and procedures regarding inpatient manufacturer credits for replaced medical devices. The Hospital also disagreed with our determinations regarding three inpatient claims that lacked a physician's order to admit. The Hospital stated that CMS did not require a physician's order to admit until October 1, 2013, and that it is unaware of Medicare requirements that were in effect for the three disputed claims that were billed prior to that date. Finally, the Hospital added that, for three inpatient elective procedure claims, it correctly coded DRG assignments because the cases were on CMS's list of inpatient-only procedures and there was no requirement that an inpatient admission be ordered prior to the procedure.[11]

The Hospital also disagreed with our determination for 16 outpatient claims, all of which it stated met Medicare coding and coverage guidance. Specifically, the Hospital disagreed with eight outpatient modifier -59 claim determinations, stating its certified coders and physicians included the modifier -59 because the procedures and/or services were separate, distinct, and warranted separate reimbursement. In addition, the Hospital disagreed with the coding determinations for eight evaluation and management services billed at a higher level than physician findings, stating that nearly all of these claims were disputed by only one level. The Hospital added that these one level disagreements are differences of opinion that should not rise to the level of a finding.

Office of Inspector General Response

We obtained an independent medical review for 77 disputed claims for medical necessity and coding requirements, and our report reflects the results of that review.[12] Contractors examined all of the medical records and documentation submitted by the Hospital and carefully considered this information to determine whether the Hospital billed the claims in compliance with Medicare requirements. Further, in response to the Hospital's concerns regarding our determinations for 29 inpatient elective procedures, we initiated a second medical review consultation. On the basis of the contractors' conclusions, we determined that 61 inpatient claims did not meet medical necessity or coding requirements, and for 16 outpatient claims, Medicare coding and coverage requirements were not met. We continue to stand by those determinations.

[11] The Hospital also disputed our determination for one inpatient claim with a same-day discharge and readmission; however, it did not comment on this finding in its comments on our draft report.

[12] Of these 77 disputed claims, our medical review contractor determined or re-determined 76 inpatient and outpatient claims and the Hospital's Medicare contractor determined one inpatient claim. Of the 76 claims, our medical review contractor reviewed claims in the following categories: Inpatient elective procedures, inpatient claims billed with high severity level DRG codes, IRF claims, outpatient evaluation and management services billed at a higher level than physician, and outpatient modifier -59. The Hospital's Medicare contractor determined one inpatient claim with a same day discharge and readmission.

Regarding the inpatient claims that lacked a physician's order, we note that requirement for a physician's order is supported by legal authority in effect during our audit period. CMS regulations stated that Medicare pays for inpatient hospital services only if a physician certifies the reason for hospitalization. In addition, the *Medicare Benefit Policy Manual* provides that a patient is an inpatient only "if admitted … for purposes of receiving inpatient hospital services" and "if formally admitted … with the expectation that he or she will remain at least overnight …"[13] Also, in its 2013 regulations regarding this requirement, CMS described it as a "longstanding policy."[14] Accordingly, CMS required hospitals to have a physician's order authorizing the inpatient admission to properly bill for Medicare Part A services. We updated our report with the relevant criteria, which were in effect during our audit period, to reiterate CMS's longstanding policy.

Finally, regarding the eight disputed inpatient manufacturer credits for replaced medical device claims, section 2103 of the *Provider Reimbursement Manual* states that Medicare providers are expected to pursue free replacements or reduced charges under warranties; therefore, the Hospital should have requested manufacturer credits and accordingly adjusted the replaced inpatient medical device claims.[15]

STATUTE OF LIMITATIONS AND 60-DAY RULE

Hospital Comments

The Hospital disagreed with our first two recommendations and stated that the Medicare contractor is barred from reopening and recovering CY 2012 claims.[16] The Hospital stated that claims paid after 1 year are only subject to reopening for good cause within 4 years of the initial determination, and accordingly, the Hospital rejects the contention that any claim outside the reopening and recovery period constitutes an overpayment. In addition, the Hospital stated that it is unclear which CY 2013 claims may be beyond the reopening and recovery period. The Hospital also rejected our third recommendation to return overpayments outside the audit period for which it disputes "virtually" every overpayment we identified and intends to appeal. By reviewing our audit findings, the Hospital believes it has conducted a comprehensive review and that this qualifies as reasonable diligence under the 60-day rule. The Hospital stated that since it contests the findings of each claim, it does not believe it has "identified" any overpayments, and therefore contested claims are not subject to the 60-day rule. However, the Hospital also stated that, for claims that are within the reopening and recovery period, and for which the Hospital is not contesting, it will refund overpayments.

[13] Pub. No. 100-02, chapter 1 § 10.

[14] 78 Fed. Reg. 160 (Aug. 19, 2013).

[15] The PRM states: "Implicit in the intention that actual costs be paid to the extent they are reasonable is the expectation that the provider seeks to minimize its costs and that its actual costs do not exceed what a prudent and cost conscious buyer pays for a given item or service" (part I, § 2102.1).

[16] Specifically, the Hospital cited 42 U.S.C. § 1395gg, 42 CFR § 405.980(b), and the *Medicare Claims Processing Manual* (Pub. 100-4 Ch. 34 § 10) in its comments to our draft report.

Office of Inspector General Response

Under the 60-day rule, providers who identify overpayments are required to return them within 60 days (section 1128J(d) of the Act and 42 CFR § 401.305(b)(i)). In addition, providers must exercise reasonable diligence to determine whether they have received an overpayment and to quantify the amount of the overpayment (42 CFR § 401.305(a)(2)). In exercising reasonable diligence, providers are expected to determine whether or not overpayments of a similar type exist during a 6-year lookback period (42 CFR § 401.305(f) and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016)). In addition, the provider is obligated to quantify the entire amount of the overpayment for this lookback period and may do so by using a statistically valid extrapolation methodology (42 CFR § 401.305(d)(1)). The Hospital, itself, identified overpayments when it did not dispute our determinations concerning the 4 inpatient claims and the 21 outpatient claims it billed incorrectly, with a total overpayment amount of $219,523, and stated that it will submit refunds for some of these claims that are within the reopening and recovery periods.

Through our draft report, the Hospital was informed of actual and potential overpayments. As a result, the Hospital "has a duty to accept the finding or make a reasonable inquiry. If [the] inquiry verifies the audit results, then it has identified an overpayment and … has 60 days to report and return the overpayment" (81 Fed. Reg. at 7659). In conducting a reasonable inquiry, the Hospital must determine that it has received an overpayment and quantify the overpayment amount (42 CFR § 401.305(a)(2)).

While the Hospital acknowledges that 25 of our sample claims are overpayments, that is only the beginning of the inquiry. Our audit period (CYs 2012 and 2013) is well within the 6-year lookback period required by the 60-day rule. Thus, "it is appropriate to inquire further to determine whether there are more overpayments on the same issue before reporting and returning the … overpaid claim" (81 Fed. Reg. at 7663). Accordingly, we are recommending that the Hospital exercise reasonable diligence to determine whether it received additional similar overpayments during the entire 6-year lookback period now that it has been informed of potential overpayments during our limited audit period and agreed (at least in part) with that finding (81 Fed. Reg. at 7667).

STATISTICAL SAMPLING AND EXTRAPOLATION

Hospital Comments

The Hospital stated that extrapolation is premature until the completion of the appeals process and objected to the extrapolation of certain strata due to low financial error rates. In addition, it objected to inpatient claim determinations that identified the entire amount as having been overpaid because it may be able to rebill the claims through Medicare Part B. Therefore, until the appeals process is exhausted, the Hospital believes it is inappropriate to calculate an extrapolated overpayment amount. The Hospital also stated statistical sampling and extrapolation are unreliable for claims with complex medical judgements and defective because claims in different strata are too similar. Furthermore, it alleged that the statistical sampling is flawed because our sample contained claims outside the reopening and recovery period, and for

strata subject to random sampling, sample sizes should have been proportional to the number and value of each stratum despite meeting the minimum sample size requirements.

Office of Inspector General Response

Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare. See *Momentum EMS, Inc. v. Sebelius*, 2014 WL 199061 at *9 (S.D. Tex. 2014); Anghel v. Sebelius, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010). Additionally, the legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology. See *John Balko & Assoc. v. Sebelius*, 2012 WL 6738246 at *12 (W.D. Pa. 2012), aff'd 555 F. App'x 188 (3d Cir. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enter., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012). We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. These formulas accurately account for the number of claims selected from each of the strata. It remains OIG's statutory obligation to determine, using the tools available to us, the accuracy of payments to Medicare providers. Furthermore, our use of statistical sampling by no means removes the Hospital's right to appeal the individual determinations on which the estimation is based through the normal appeals process. See *Pruchniewski v. Leavitt*, No. 08:04-CV-2200-T-23TBM (M.D. Fla 2006).

We acknowledge that the Hospital may bill Medicare Part B for the incorrectly billed inpatient claims; however, rebilling is beyond the scope of our audit. CMS has issued the final regulations on payment policies (78 Fed. Reg. 160 (Aug. 19, 2013)), and the Hospital should contact its Medicare contractor for rebilling instructions. As stated in the report, we were unable to determine the effect that billing Medicare Part B would have had on the overpayment amount because the Hospital had not billed, and the Medicare contractor had not adjudicated, these services prior to the issuance of our report.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $74,679,543 in Medicare payments to the Hospital for 6,369 claims that were potentially at risk for billing errors. We selected a stratified random sample of 261 claims (144 inpatient and 117 outpatient) totaling $4,375,619 for review. These 261 claims had dates of service during the audit period. 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 188 claims to medical and coding reviews to determine whether the services were medically necessary and properly coded.

During our exit conference with the Hospital, Hospital officials raised concerns about our review of inpatient stays. We subsequently met with the Hospital two more times so that we could gain a full understanding of the Hospital's position. We also subjected claims for which the Hospital expressed concerns to a second medical review.

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

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

We conducted fieldwork at the Hospital and at our offices.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Hospital's inpatient and outpatient paid claims data from CMS's National Claims History file for the audit period;
- obtained information on known credits for replacement medical devices from the device manufacturers;
- used computer matching, data mining, and data analysis techniques to identify claims potentially at risk for noncompliance with selected Medicare billing requirements;
- selected a stratified random sample of 261 claims (144 inpatient and 117 outpatient claims) for detailed review (Appendix B);

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

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

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

- used an independent contractor and the Medicare contractor to determine whether 188 of the 261 sampled claims met medical necessity and coding requirements, and subjected 29 sampled claims (elective procedures) for which the Hospital expressed its concerns to additional medical review;

- discussed the incorrectly billed claims with Hospital personnel to determine the underlying causes of noncompliance with Medicare requirements;

- calculated the correct payments for those claims requiring adjustments;

- used the results of the sample to estimate the total Medicare overpayments to the Hospital during the audit period; and

- discussed the results of our review with Hospital officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

POPULATION

The population contained inpatient and outpatient claims paid to the Hospital for services provided to Medicare beneficiaries during the audit period.

SAMPLING FRAME

According to CMS's National Claims History data, Medicare paid the Hospital $842,370,802 for 36,262 inpatient and 361,784 outpatient claims for services provided to beneficiaries during the audit period.

We obtained a database of claims totaling $506,884,798 for 21,515 inpatient and $96,993,921 for 70,155 outpatient claims in 36 risk areas. From these 36 areas, we selected 12 high risk areas consisting of 84,747 claims totaling $412,105,975 for further review.

We performed data analyses of the claims within each of the 12 risk areas and removed the following:

- $0 paid claims;

- claims duplicated within individual risk areas by assigning each claim that appeared in multiple risk areas to just one category based on the following hierarchy:

    - Elective Procedures Billed as Inpatient
    - Inpatient Claims Billed with High Severity Level DRG Codes,
    - IRF Claims,
    - Inpatient Manufacturer Credits for Replaced Medical Devices,
    - IPF Emergency Department Adjustments,
    - Inpatient Claims with Same-Day Discharges and Readmissions,
    - Outpatient Claims Billed with Modifier -25
    - Outpatient Claims Billed with Modifier -59,
    - Outpatient Evaluation and Management Service Billed at a Higher Level than Physician
    - Outpatient Manufacturer Credits for Replaced Medical Devices,
    - Outpatient Claims Billed for the Drug Herceptin, and
    - Outpatient IMRT Planning Services; and

- claims under review by the Recovery Audit Contractor (RAC), as of September 29, 2014.[17]

[17] To ensure that our overpayment extrapolation is valid, any sample items that a RAC has reviewed or is currently reviewing were treated as non-errors. This adjustment results in a valid overpayment estimate regardless of when the RAC claims are identified. As an extra precaution, repayment of claims reviewed by the RAC that are in the sampling frame was subtracted from the total overpayments.

Removing these claims resulted in a sampling frame of 6,369 unique Medicare claims in 12 risk areas totaling $74,679,543 as follows:

Table 1: Risk Areas Sampled

Risk Area	Number of Claims	Amount of Payments
Elective Procedures Billed as Inpatient	2,407	$42,238,335
Inpatient Claims Billed with High Severity Level DRG Codes	1,027	18,736,980
IRF Claims	363	8,541,747
Inpatient Manufacturer Credits for Replaced Medical Devices	41	1,772,794
Inpatient Claims with Same Day Discharge and Readmissions	8	85,471
IPF Emergency Department Adjustments	5	32,342
Outpatient Claims Billed with Modifier -59	639	1,964,150
Outpatient Claims Billed with Modifier -25	1,616	712,256
Outpatient Manufacturer Credits for Replaced Medical Devices	20	520,834
Outpatient Evaluation and Management Services Billed at a Higher Level Than Physician	236	51,861
Outpatient Claims Billed for the Drug Herceptin	5	14,661
Outpatient IMRT Claims	2	8,112
Total	**6,369**	**$74,679,543**

SAMPLE UNIT

The sample unit was a Medicare paid claim.

SAMPLE DESIGN

We used a stratified random sample. We stratified the sampling frame into 12 strata based on risk area. All claims were unduplicated, appearing in only one area and only once in the entire sampling frame.

SAMPLE SIZE

We selected 261 claims for review as follows:

Table 2: Sampled Claims by Stratum

Stratum	Risk Area	Claims in Sampling Frame	Claims in Sample
1	Elective Procedures Billed as Inpatient	2,407	30
2	Inpatient Claims Billed with High Severity Level DRG Codes	1,027	30
3	IRF Claims	363	30
4	Inpatient Manufacturer Credits for Replaced Medical Devices	41	41
5	Inpatient Claims with Same Day Discharge & Readmissions	8	8
6	IPF Emergency Department Adjustments	5	5
7	Outpatient Claims Billed with Modifier -59	639	30
8	Outpatient Claims Billed with Modifier -25	1,616	30
9	Outpatient Manufacturer Credits for Replaced Medical Devices	20	20
10	Outpatient Evaluation and Management Services Billed at a Higher Level Than Physician	236	30
11	Outpatient Claims Billed for the Drug Herceptin	5	5
12	Outpatient IMRT Claims	2	2
	Total Sampled Claims	**6,369**	**261**

SOURCE OF THE RANDOM NUMBERS

We generated the random numbers using the OIG/Office of Audit Services (OAS) statistical software random number generator.

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the claims within strata 1, 2, 3, 7, 8, and 10. After generating the random numbers for these strata, we selected the corresponding claims in the sample frame. We selected for review all claims in strata 4, 5, 6, 9, 11, and 12.

ESTIMATION METHODOLOGY

We used the OAS statistical software to calculate our estimate. We estimated the total amount of Medicare overpayments made to the Hospital during the audit period at the lower-limit of the 90-percent confidence interval.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 3: Sample Results

Stratum	Frame Size (Claims)	Value of Frame	Sample Size	Value of Sample	Number of Incorrectly Billed Claims in Sample	Value of Claim Over-payments in Sample
1	2407	$42,238,335	30	$509,988	29	$465,532
2	1027	18,736,980	30	687,951	13	246,690
3	363	8,541,747	30	635,370	22	358,631
4	41	1,772,794	41	1,772,794	8	121,732
5	8	85,471	8	85,471	1	7,282
6	5	32,342	5	32,342	5	523
7	639	1,964,150	30	88,861	11	5,619
8	1616	712,256	30	11,786	0	0
9	20	520,834	20	520,834	11	167,469
10	236	51,861	30	7,449	8	389
11	5	14,661	5	14,661	0	0
12	2	8,112	2	8,112	2	472
Total	**6,369**	**$74,679,543**	**261**	**$4,375,619**	**110**	**$1,374,339**

ESTIMATES

Table 4: Estimated Value of Overpayments
Limits calculated for a 90-Percent Confidence Interval

Point Estimate	$50,555,871
Lower Limit	$41,869,783
Upper Limit	$59,241,958

APPENDIX D: RESULTS OF REVIEW BY RISK AREA

Risk Area	Selected Claims	Value of Selected Claims	Claims With Overpayments	Value of Overpayments
Inpatient				
Elective Procedures Billed as Inpatient	30†	$509,988	29	$465,532
IRF Claims	30†	635,370	22	358,631
Inpatient Claims Billed with High Severity Level DRG Codes	30†	687,951	13	246,690
Inpatient Medical Device Claims	41	1,772,794	8	121,732
Inpatient Same Day Discharge & Readmissions	8	85,471	1	7,282
Inpatient Psych - Emergency Room Admissions	5	32,342	5	523
Inpatient Totals	144	3,723,916	78	1,200,390
Outpatient				
Outpatient Medical Devices	20	520,834	11	$167,469
Claims Billed with Modifier -59	30†	88,861	11	5,619
IMRT Claims	2†	8,112	2	472
Outpatient Evaluation and Management Service Billed at a Higher Level Than Physician	30†	7,449	8	389
Outpatient Claims Billed with Herceptin	5	14,661	0	0
Outpatient Claims Billed with Modifier -25	30†	11,786	0	0
Outpatient Totals	117	651,703	32	173,949
Inpatient and Outpatient Totals	**261**	**$4,375,619**	**110**	**$1,374,339**

† We submitted these claims to a focused medical review to determine whether the services were medically necessary and properly coded.

Notice: The table above illustrates the results of our review by risk area. In it, we have organized inpatient and outpatient sample units by risk areas we reviewed. However, we have organized this report's findings by the types of billing errors we found at the Hospital. Because we have organized the information differently, the information in the individual risk areas in this table does not match precisely with this report's findings.

APPENDIX E: HOSPITAL COMMENTS

Frank Cino, MPH, CPA
Chief Risk Officer
Senior Vice President
Audit & Compliance Services
The Mount Sinai Health System
150 East 42nd Street – Suite 3- B19
New York, NY 10017
Phone – 646 - 605-7101
Fax - 212-731-3128

December 20, 2016

Mr. James P. Edert
Regional Inspector General for Audit Services
Office of Audit Services, Region II
Jacob K. Javits Federal Building
26 Federal Plaza, Room 3900
New York, NY 10278

Re: Response of Mount Sinai Hospital to Draft Report No. A-02-14-01019

Dear Mr. Edert:

In this submission, Mount Sinai Hospital ("Mount Sinai") provides its response and objections to the Department of Health and Human Services Office of Inspector General ("OIG")'s draft report issued in October 2016 ("Draft Report"). The Draft Report sets forth preliminary findings on a review of certain categories of Medicare services provided to Medicare beneficiaries in 2012 and 2013.

I. Introduction and Summary

The OIG's determination that certain of the reviewed claims were unsupported (and were thus overpayments to Mount Sinai) is based on erroneous interpretations of the applicable Medicare coverage, documentation and coding rules that were in effect during the audit period. In addition, most of the claims are now beyond the applicable limitations periods for claims reopening and recovery. Accordingly, the draft report should be substantially revised, as nearly all the reviewed claims complied with the applicable Medicare rules and, in any event, are beyond the permissible scope of retroactive review.

Most of the alleged overpayment relates to claims that the OIG contends involved medically unnecessary inpatient care. The OIG reviewed a random sample of 30 claims from each of Category A[1] and Category B[2], and now opines that 33 of those 60 patients should not have been

[1] OIG describes Category A as including 2,407 Medicare claims for elective inpatient services rendered during the period of January 1, 2012 through September 30, 2013, where the patient was discharged on or before the calendar day following the calendar day of admission. These are referred to as "short-stay" cases. *See* Draft Report at 2 (describing the first category, *i.e.*, Category A, as "inpatient

admitted to Mount Sinai for inpatient care. Likewise, for Category C, which covers claims for inpatient rehabilitation, the OIG contends that 22 of the 30 sample claims involved rehabilitation services that were medically unnecessary. But in each of these cases, a Mount Sinai physician appropriately determined and documented that the patient had medical conditions, symptoms, comorbidities and deficits that required the level of intensive treatment, rehabilitation, and assessment that was only available on an inpatient basis. These medical judgments were in the patients' best interests and were fully supported by (and compliant with) the operative Medicare rules for coverage of inpatient care. The contrary view reached by the private corporation contracted by OIG to review these patients' medical charts – namely, that none of these patients' conditions and illnesses warranted inpatient treatment and that these patients could have been observed or rehabilitated on an outpatient basis – is a dangerous proposition that second-guesses sound physician judgment years after the fact and risks putting Medicare patients' health and wellbeing in serious peril.

Compounding this unfairness is the OIG's recommendation that the contract reviewers' denials on the sample claims be "extrapolated" to the entire claims universe. In prior reviews on the very same issue of medical necessity, performed by the very same private corporation that conducted the current review, Mount Sinai prevailed on appeal ***over 85% of the time*** in reversing the contract reviewers' denials. Further, in a recent audit of Mount Sinai's short-stay cases, Livanta (Mount Sinai's Quality Improvement Organization) agreed with Mount Sinai's determinations ***in every single case***. This impressive track record underscores the unreliability of the contract reviewers' findings of medical necessity on this review. Before any extrapolation of those findings is recommended or performed, Mount Sinai should be afforded a full and fair opportunity to contest those findings before impartial Administrative Law Judges.

II. Mount Sinai Has a Robust and Effective Medicare Compliance Program

Mount Sinai has implemented a rigorous program for ensuring compliance with Medicare coverage, documentation and coding requirements, including medical necessity requirements for inpatient care. During the audit period, case managers were stationed in the Emergency Department care areas and were trained to ensure that inpatient admissions decisions satisfied

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short stays"). Notably, 98 of the 2,407 cases included in Category A were not short-stays. They were cases where the day of discharge was two or more calendar days after the day of admission. This irregularity in the design of Category A, and its implications for extrapolation, is discussed further below. *See infra*, Section V, Subsection B.

[2] OIG further describes Category B as including 1,027 Medicare claims billed with high-severity-level DRG codes. Many of the Category B claims are also short-stay cases.

Medicare requirements. Evidence-based care guidelines, developed by multidisciplinary workgroups within our organization, were also used to support clinical decision-making on level-of-care determinations. Treating physicians were educated on using these guidelines when deciding whether to admit.

Mount Sinai has also implemented a centralized, case-management review process whereby case types identified by the OIG as "high risk" areas, such as same-day discharges and short-stays, are closely reviewed, prior to claim issuance, to ensure that medical necessity is satisfied. Further, during the latter part of the audit period, Mount Sinai engaged an outside vendor to provide concurrent physician review of medical necessity.

An integral component of Mount Sinai's compliance function is continual oversight of potential risk areas for Medicare noncompliance. Thus, Mount Sinai's Utilization Review Committee meets monthly to review all areas identified in the OIG workplans and other similar publications to protect against potential improper resource utilization. Further, the Committee uses several tools, including the PEPPER (Program for Evaluating Payment Patterns Electronic Report) system, as a primary resource to guide monitoring and internal auditing efforts. Departments and physicians are provided with continuous monitoring and education based on these tools and reviews.

Mount Sinai's compliance and oversight programs are effective as seen by the very cases included in this audit. Many of the sample claims involved patients who received inpatient care following a surgical procedure in Mount Sinai's cardiac catheterization lab. Mount Sinai's cath lab treats more complex patients and performs more high-risk procedures than most other hospitals in the nation precisely because it is universally regarded as one of the highest quality centers in the nation. Indeed, many hospitals often refer their most complex and high-risk cases to Mount Sinai's cath lab because the referring hospital lacks the expertise and resources to provide optimal care. But despite performing a much higher rate of high-risk procedures on high-risk patients, Mount Sinai has one of the lowest mortality rates in the State of New York and, as shown in the PEPPER report, ***Mount Sinai performs a greater proportion of the subject procedures on an outpatient basis than virtually every other hospital in the State***. Mount Sinai achieves these outcomes through the development and use of evidence-based clinical standards that help to identify which cases can be safely performed on an outpatient basis versus those that require acute, inpatient care.

As noted, Mount Sinai has an exceptionally strong appellate track record on the issue of medical necessity in its inpatient setting. Time and again, independent ALJs vindicate the clinical judgments of Mount Sinai physicians to admit patients for inpatient care. As with this review, prior reviews resulted in denials of inpatient claims for a host of improper reasons, such as that the patient remained in stable condition *following* admission and that outpatient-with-observation care would have provided an equivalent level of treatment and evaluation. But when tested on

appeal before an impartial ALJ, those denial rationales are consistently rejected, and the ALJs repeatedly uphold the clinical judgments of Mount Sinai's physicians. Thus, the ALJs rule in favor of Mount Sinai with observations such as the following:

> [T]he ALJ agrees with the Appellant and finds that [the patient's] health would have been significantly threatened in a less intensive setting[3]
>
> * * *
>
> First, serious complications after surgery were possible given his comorbidities. ... Second, because of the medical predictability of an adverse reaction if he was released before his post-surgical condition was fully stabilized, the ALJ agrees with the Appellant and finds that his health would have been significantly threatened in a less intensive setting.[4]
>
> * * *
>
> Given the Beneficiary's medical history and presenting status, the undersigned is convinced that an inpatient admission was both medically necessary and reasonable.[5]
>
> * * *
>
> [I]n the estimation of his physician, the possibility of an adverse outcome warranted his admission as an inpatient .... Given the Beneficiary's medical history and presenting status, the undersigned is convinced that an inpatient admission was both medically reasonable and necessary.[6]

As described in the next Section, the reasoning of these independent judges applies equally to the inpatient cases that were reviewed on this OIG audit.

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[3] HIC 4162A, ALJ 1-1169588498 (ALJ Pastrana).

[4] IA HIC 3482m ALJ 1-1169589172 (ALJ Pastrana).

[5] HIC # 0859A No 1-14144043 (ALJ Knapp).

[6] DH. HIC #1-141393632 (ALJ Knapp).

III. The OIG's Contract Reviewers Misapplied Medicare's Rules for Coverage, Coding and Documentation

A. Inpatient Admissions in Categories A and B Were Reasonable and Necessary

Mount Sinai disputes the OIG's assertion that 33 sample claims in Categories A and B involved medically unnecessary inpatient services.[7] For each of the 33 claims, the admitting physician appropriately determined that the patient required ongoing, intensive evaluation, treatment and monitoring in an inpatient hospital setting and that treating the patient on an outpatient basis would pose an unacceptable risk of an adverse outcome. As discussed below, those admissions decisions were in the best interests of the Medicare patients and were supported by the Medicare rules governing coverage for inpatient services. Mount Sinai fully stands by them.

Each of the 33 patients presented with acute conditions, symptoms and signs requiring a level of intensive treatment and evaluation that could only have been rendered on an inpatient basis. Most of the patients were severely medically compromised with multiple co-morbidities and were admitted for essential, post-operative care following a significant surgical procedure, such as cardiac catheterization, pacemaker implantation, transurethral resection of the prostate or bladder, and total thyroidectomy. The rest of the patients (all in Category B) presented to the Emergency Department with serious conditions requiring treatment and stabilization.

The OIG predicates its denials on three fundamentally incorrect standards – standards that have been explicitly rejected by CMS, the ALJs and the federal courts. These criteria can best be distilled as the following: (1) the level of inpatient and outpatient care was interchangeable so it did not matter whether the patient was placed in an observation setting or admitted to an inpatient unit; (2) actual length of stay constituted a key factor in determining whether the patient warranted admission; if the patient remained in the hospital for less than twenty-four hours, the physician's expectations at the time of admission were irrelevant ; and, (3) the patient's post-admission recovery comprised another key factor; if the patient recovered without complications *ipso facto* they didn't require admission , despite that the physicians had no crystal ball to **ever** consider these facts in their admission decisions.

With regard to the levels of care, the OIG's position that these patients could have received adequate care on an outpatient basis simply confuses the purposes and benefits of two very different care levels. Indeed, CMS has explicitly recognized that inpatient and 'outpatient with

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[7] The 33 claims at issue are A-3 through A-9, A-11 through A-21, A-23, A-24, A-26 through A-30, B-2, B-5, B-9, B-13, B-14, B-22, B-27 and B-30.

observation' services are not interchangeable.[8] Moreover, the ALJs and courts reviewing this issue, in the context of an overwhelming number of hospital appeals of short-stay cases, have repeatedly reaffirmed this position.[9] And these distinctions are recognized for good reason. The inpatient setting provides lower nurse-to-patient ratios, more advanced telemetry capabilities, and more frequent and comprehensive physician rounding. Further, in the event of an emergent situation, inpatients will receive immediate, and potentially life-saving, medical attention.

With respect to the 33 cases at issue, the outpatient-with-observation level of care would have been inadequate and potentially dangerous to the health and safety of these Medicare patients. These patients were generally very elderly, underwent complex surgical procedures, presented to the ED with significant illnesses and injuries, had extensive histories of prior serious illness and / or had significant comorbidities. For example, nearly all the patients had a history of a major illness or condition, such as AIDS, prior stroke, prior heart attack, COPD, chronic renal failure, advanced coronary artery disease, advanced systolic heart failure, liver failure and various malignancies.

The physician judgments to admit these patients for the more intensive level of inpatient care fully complied with the Medicare guidelines for coverage of inpatient services. Chapter 1 of the Medicare Benefit Policy Manual sets forth the governing standard applicable during the audit period (emphasis added):

> An inpatient is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. ***Generally, a patient is considered an inpatient if formally admitted as inpatient with the expectation that he or she will remain at least overnight and occupy a bed*** even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight. …
>
> Physicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis. However, the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors …
>
> ***Admissions of particular patients are not covered or noncovered solely on the basis of the length of time the patient actually spends in the hospital.***

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[8] *See, e.g.*, Centers for Medicare and Medicaid Services; Interim and Final Rule with Comment Period, 72 Fed. Reg. 66814 (Nov. 27, 2007).

[9] As noted in the prior section, the ALJs who heard Mount Sinai's appeals of short-stay denials in prior Medicare billing reviews consistently found in favor of Mount Sinai on this issue.

In applying this standard, reviewing agencies are required by law to give an appropriate degree of deference to the clinical judgments of the health care professionals who were "on the scene" providing treatment:

> To reach his determination [that inpatient care was not reasonable and necessary], the Secretary had to patch together discrete findings and observations in records made by the very same health care professionals who were on the scene examining and caring for [the patient] and who were ***unquestionably in the best position*** to certify the necessity of the patient stay. Given the Secretary's second-hand knowledge, we must necessarily demand that his review be probing, precise and accurate.[10]

On this review, not only did the OIG's third-party contract reviewers fail to give any deference to the physicians' judgments, but they failed to undertake the kind of "probing, precise and accurate" assessment that the law requires. For many of the cases, the reviewers recited selective facts from the medical record and then supplanted the judgment of the admitting physician with their own conclusory, single-sentence statement that inpatient care was unnecessary.

Further, the reviewers improperly considered the length of a patient's stay at Mount Sinai as a major consideration, and sometimes a dispositive one, for denying coverage. This was impermissible for several reasons. First, as quoted above, the Medicare Benefit Policy Manual expressly states that length of stay is not determinative. It is the admitting physician's expectation that the patient will require acute care overnight, not the subsequent length of stay that is determinative. Second, on this review, all 33 patients ***did, in fact, stay overnight***. Finally, most of the 33 patients stayed for over 24 hours or close to 24 hours, demonstrating that the admitting physicians were appropriately using a 24-hour benchmark in forming their expectations.[11] Given that the operative guidance permits Medicare coverage even in cases where the patient did not stay overnight (provided that the admitting physician had a legitimate expectation of an overnight stay at the time), it is inexplicable how, on this review, OIG can

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[10] State of N.Y. on Behalf of Bodnar v. Sec. of Health and Human Services, 903 F.2d 122, 126 (2d Cir. 1990) (emphasis added) (upholding district court's reversal of the Secretary's determinations that inpatient services were not necessary and that the Medicare beneficiary should have been treated on an outpatient basis instead).

[11] Of the 33 patients, 17 stayed 24 hours or longer, another five stayed between 22 and 23.5 hours, and another nine stayed between 18 and 21.5 hours. Hence, 30 of the 33 patients at issue occupied a bed for at least 18 hours.

often cite the lengths of the patients' stays at Mount Sinai as a reason to deny coverage – especially when, in each case, *the patient actually stayed overnight at Mount Sinai*.[12]

Finally, the reviewers often improperly considered facts and circumstances that arose after the patient had been admitted. As stated in the Medicare Benefit Policy Manual, a physician's decision to admit a patient will necessarily be based on various factors, such as the patient's age, the signs and symptoms of the patient's condition, the predictability of an adverse event, the patient's medical history and family and social situation, as well as the seriousness and complexity of the surgical procedure. As the decision can only be based on information that was available to the physician at the time of the decision, any review of that decision must, of course, be limited to such information.[13]

Ignoring this rule of simple fairness, the third-party reviewers often invoked the fact that the patient fared well after admission (for example, the risk of serious post-operative complication did not actually materialize), and thus could be discharged the next calendar day, as a reason for concluding that inpatient care was unnecessary. For example, the contract reviewers repeatedly concluded that the admission decision was unsupported based on such observations as:

- "There were no postoperative complications"
- "The patient remained stable overnight"
- "The patient remained stable throughout the hospital stay"

This kind of backwards logic – a logic which considers things that the physician could not have known at the time of admission and penalizes the hospital for good outcomes following admission – is akin to stating that it is "unnecessary" and "unreasonable" to wear a seatbelt except on those occasions when one is actually involved in a car accident.

Below are four examples of claims that the reviewers determined involved inpatient care that was not reasonable and necessary. The examples show how the reviewers improperly considered facts and circumstances that arose after admission, improperly took into account the length of the stay (even though the stay met the expectation of an overnight bed occupancy), failed to

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[12] Two glaring examples are claims A-3 and A-9. In each case, the patient stayed at the hospital for over 29 hours, which period included, of course, an overnight stay. Despite this, in each case, the contract reviewer cited the fact that the patient was discharged the next calendar day as a reason to deny coverage.

[13] Thus, the Medicare Benefit Policy Manual recognizes that, in reviewing claims for payment, reviewers should "consider only the medical evidence which was available to the physician at the time an admission decision had to be made. They do not take into account other information (e.g., test results) which became available only after admission, except in cases where considering the post-admission information would support a finding that an admission was medically necessary."

appreciate the serious risks of the patient's illness and of post-operative complications, and failed to give any deference to the clinical judgments of the admitting physicians who were "on the scene" and "were unquestionably in the best position to certify the necessity of the patient stay."

- Claim A-8: This case involved a 72-year-old patient who underwent three complex coronary interventions (specifically, two venous grafts to the left-anterior descending artery and a third venous graft to the circumflex artery) as well as an aortic valvuloplasty. The entire procedure lasted 1 hour and 45 minutes; this duration is well above-average and reflects the complexity of the procedure. The patient had a significant history of coronary artery disease, including a prior myocardial infarction (heart attack), a prior three-vessel coronary artery bypass graft, severe aortic stenosis, severe left ventricular hypertrophy and congestive heart failure. In addition, the patient had several comorbidities, including a prior stroke, bladder cancer, kidney disease, hypertension and obesity. The medical chart reflects that, in light of the patient's prior history and comorbidities, as well as the complexity of the procedure, the treating physician believed inpatient care was warranted given the elevated risk for short-term adverse events. Consistent with that expectation, the patient stayed at the hospital overnight and was discharged 22 hours following admission. Further, in this case, an adverse event actually materialized: during the patient's overnight hospital stay, the patient's troponin level peaked at *ten times* the upper limit of normal. Despite this, the contract reviewer characterized the inpatient care as not reasonable and necessary. Impermissibly considering post-admission events, the reviewer stated that there were "no postoperative complications" and that the "patient remained stable throughout the hospital stay."

- Claim A-18: This case involved a 77-year-old patient who underwent a complex coronary intervention (stent placement) involving a bypass graft that had been placed in 1997. The procedure lasted 1 hour and 20 minutes, which is well above-average and reflects the complexity of a stent placement in an artery graft that is more than 15-years old. The patient had a significant medical history, including coronary artery disease, having undergone major bypass surgery in 1997 and a cardiac intervention in 2005. The patient also had longstanding diabetes, lower extremity edema, chronic kidney disease, hypertension and high cholesterol. By using the evidence-based risk assessment tool at the time of admission (following the procedure), it was determined that the patient had a 26% risk of contrast-induced kidney injury, a 6.5% risk of an in-hospital myocardial infarction or emergent artery bypass graft, and a 2.3% risk of an in-hospital death. The admitting physician documented these risks in his note and admitted the patient with the expectation that the patient would need to occupy a bed overnight and receive care over a 24-hour period. Consistent with that expectation, the patient did stay overnight and was discharged 23.5 hours after admission. Giving no deference to the admitting physician's clinical judgments, the contract reviewer found that the decision to admit was unsupported and not reasonable. The principal reason given by the reviewer for this

conclusion was that the patient "remained stable overnight" and thus was able to be discharged the following calendar day. The reviewer also claimed there was no documentation supporting the admission, even though the patient's medical chart contains fulsome detail of the patient's condition, signs, symptoms and history as well as a document specifically reflecting the physician's recommendation to admit with express reference to such facts and circumstances.

- Claim A-27: This case involved a 68-year-old patient who underwent a total thyroidectomy requiring "extensive dissection" as well as excision of a mass at the tongue bass. The patient had a significant prior medical history, including multiple prior surgeries and high cholesterol. The attending physician described the patient as cachectic. As stated in the medical record, the attending physician and other treating personnel were concerned of risk of post-operative complications, including severe oral bleeding, shortness of breath, hematoma, and hypocalcemia. In deciding to admit the patient, the physician made the following note: "Patient underwent extensive dissection which puts [patient] at increased risk of post-op hematoma. Based on my extensive clinical experience with similar patients, I feel that [patient] requires inpatient admission for the reasons discussed above. [Patient] is at high risk for short-term adverse events and requires acute level close monitoring to allow for rapid evaluation and treatment as needed." In this instance, the primary concern was that post-operative bleeding could lead to an expanding "post-op hematoma", a complication which can rapidly occlude the patient's airway leading to death unless an immediate intervention is performed. During the patient's overnight stay, the patient received intravenous hydration and pain management and received periodic ionized calcium checks; the patient's incision was also regularly checked for hematoma, swelling and erythema. The patient was discharged the following day (18 hours after admission) when the patient was tolerating liquids well and had stabilized. Ignoring the serious risks of post-operative complication (as clearly set forth in the medical record) – risks that the physician determined required the higher intensity level of care only provided in an inpatient setting – and providing no deference to this carefully considered clinical judgment of the admitting physician, the contract reviewer determined that the decision to admit was unsupported and not reasonable because the procedure is "routinely performed as an outpatient."

- Claim B-5: This case involved an 85-year-old patient suffering from dementia and other behavioral health conditions. The patient also had a history of heart failure. The patient presented to the Emergency Department after a fall at home and was initially admitted to "outpatient for observation" status. Based on such observation, the attending physician determined that the patient would require intensive care for a period of at least 24 hours. The patient was admitted and remained hospitalized for nearly a month because of severe issues arising from dementia with behavioral disturbance. Ignoring the hundreds of

pages in the medical record documenting the patient's incapacity and mental health deficits, the OIG reviewer claimed that the patient should never have been admitted in the first place and thus should have been sent home from the Emergency Department in a state of dementia.

It is also useful to review the facts of the cases that the contract reviewers upheld as involving reasonable and necessary inpatient care, as the relevant features of those cases are barely distinguishable from those of the cases they denied -- highlighting the arbitrary and capricious nature of this review. For example, claim A-25, which was upheld by the reviewer, involved a 71-year-old patient who underwent cardiac catheterization with rotational atherotomy and placement of a stent in the right coronary artery. The patient had a serious medical history of coronary artery disease and prior cardiac interventions; the patient also had serious comorbidities, such as prior strokes, hypertension, hyperlipidemia and history of tobacco use. The OIG reviewer noted that the "patient tolerated the procedure well" and that "there were no postoperative complications and the patient remained stable throughout the stay." The patient stayed overnight and was discharged 17 hours after admission. The reviewer concluded that "the record supports the reasonableness of acute inpatient status given the patient's acuity and the risk of adverse outcome at a lesser level of care." Mount Sinai fully endorses that conclusion. But the very same facts supporting that conclusion (complex cardiac procedure, serious risk of post-operative complication, extensive medical history, significant comorbidities, etc.) also appear in the numerous cases that the contract reviewers denied. There is no principled basis by which the reviewers could uphold the care given in A-25 but deny it in A-8, A-18 and many other similar cases.

In short, the OIG has employed a review process on these claims lacking even a semblance of objectivity and fairness. The Hospital intends to pursue all of its appeal rights on the grounds that it had a reasonable expectation at the time of admission that these patients met the CMS coverage criteria. Finally, to the extent that these claims are time-barred pursuant to 42 CFR 405.980(b) and not subject to re-opening, then they do not constitute overpayments and are not subject to repayments as explained in our section discussing these issues.

B. Admissions for Inpatient Rehabilitation Facility Services Were Reasonable and Necessary

For many of the same reasons noted in the above section, the Hospital disagrees with the OIG's findings that 21 of the patients admitted to the Inpatient Rehabilitation Facility ("IRF") did not meet the Medicare criteria for admission. As an initial matter, we dispute the OIG's rote review of select portions of the medical records and its failure to follow the applicable CMS rules governing whether these patients' admissions for IRF care were "reasonable and necessary." In this regard, CMS has delineated specific criteria for providers to document supporting their

"reasonable expectation" that the patient meets the requirements for IRF care.[14] However, CMS has also clarified that this specific templated documentation is not the exclusive means of determining the medical necessity of the inpatient rehabilitation admission. In the governing manual, CMS recognized that "Medicare requires determinations of whether IRF stays are reasonable and necessary to be based on an assessment of each beneficiary's individual care needs."[15] (Emphasis added). The manual goes on to specify that "Medicare contractors must consider the documentation contained in a patient's IRF medical record when determining whether an IRF admission was reasonable and necessary."[16] (Emphasis added). This provision makes clear that consideration of the documentation is an important, but not exclusive basis of determining the "individual care needs" and, therefore, the appropriateness of the admission. The determination must incorporate the individual complex medical needs and comorbidities that require medical management and oversight and present serious risk of complications warranting admission to inpatient rehabilitation. These issues were routinely ignored by the reviewers. More often than not, in many of their denials, the reviewers once again ignored the comorbidities and medical risks plaguing these patients and, instead, relied on the excellent post admission progress to conclude that the patients could have been treated in a lower level of care facility. On the opposite spectrum, when the patients failed to progress as anticipated, the OIG reviewers concluded that the patients would never have benefited from IRF services and should have been discharged immediately to a long-term care facility. In addition, for several of the claims, the OIG contract reviewers incorrectly asserted that key documentation was missing, when in fact the documentation was in the medical chart and the reviewers had been advised of that prior to issuing their findings. In short, the reviewers seized on conclusory and improper reasons to reject coverage rather than review the individual circumstances of each patient and conduct an appropriate comprehensive analysis of each patient's needs at the time of admission.

For example, the patient in sample C-03 was admitted to the IRF following a total knee replacement. The patient had a complicated medical history of hypertension, hyperlipidemia, morbid obesity and osteoarthritis. As an initial matter, the contract reviewer claimed that there was no initial PT evaluation and markedly few PT notes. This is simply incorrect. Not only did the reviewer apparently miss the medical documentation, but they ignored the substantial medical risks facing this complex patient. As our physician reviewer made clear in his review of the case, this was the ideal patient who required oversight for her complex medical history only available in an IRF and also greatly benefited from short term IRF intensive services so she could maximize her return to functionality and independence.

Similarly, in Sample C-19, the OIG contract reviewer denied the patient's admission following a total hip replacement based almost entirely on her post admission steady progress. This

[14] 42 CFR 412.622(a) (4); CMS MBPM Ch. 1. Section 110.22.

[15] CMS MBPM, Introduction Section 110.

[16] *Id.* at 110.2.1.

information only available in hindsight and not obviously available to the treating physician making the admission decision is not an appropriate basis for reversing the admission decision. Again, not only did this reviewer rely on inadmissible information, but the reviewer ignored the fact that this patient was over 85 years old (itself a qualifying diagnosis) as well as the patient's constellation of co-morbidities including atrial fibrillation, gastrointestinal bleeds and hypothyroidism. Given her age and medical history, she was at a heightened risk for post-operative medical complications and required close medical monitoring throughout her rehab stay. Indeed, her successful post-operative recovery and return to functional mobility and independence was likely due to the intensive monitoring only available in an inpatient rehab unit.

On the other side of the equation, the OIG reviewers rejected the admission of the patient in sample C-21 on the grounds that this patient was too sick to benefit from acute inpatient rehab. The reviewers again improperly relied on the post admission recovery which they claimed was slower than expected, to conclude that the physicians' expectations were unrealistic and they therefore could not have properly considered the patient's multiple medical issues. To the contrary, the physicians were very careful in evaluating this patient and determining that this patient required the entire medical and rehab services only available in an inpatient rehabilitation facility to achieve the necessary improvements to enable him to manage in a long term rehab facility for patients with brain injuries. Indeed, the documentation clearly shows that the physiatrist carefully and safely managed the patient's multiple medical problems in concert with the consulting physicians who were readily available as part of the IRF setting, thus preventing a readmission to the acute care hospital. And, through this concentrated oversight the patient's medical status improved so that he could steadily increase his toleration and participation in therapy and make steady, demonstrable gains in all aspects of function and cognition, including attention and comprehension, swallowing, bed mobility, transfers, ambulation and basic self-care. Again, this was the ideal patient for the specialized services only available in an IRF.

Patient C- 09 provides another excellent example of the reviewers' failure to consider the full circumstances of the patient, and instead seize upon an isolated comment within a clinician's note to disallow the services. This case involved a patient admitted to the IRF after suffering from an ischemic stroke. The reviewers partially denied the admission relying upon an isolated social worker's note discussing potential discharge options to conclude that the patient was ready and should have been discharged that very day rather than one week later. Yet, that note[17] simply documented the introduction of a discussion of the referral process with the family. The social worker did not have the clinical expertise to determine whether the patient was medically ready to be discharged that day. And, the subsequent notes from the treating physicians make clear that the patient was not ready for discharge that day or even the following few days. In fact, that very same day, the treating physician documented that the patient "needs to continue interdisciplinary rehabilitation therapy program, due to persistent deficits in self-care and mobility." Furthermore, the patient experienced a number of medical issues over the course of

[17] Social Work note dated 7/31/12.

the next few days that required treatment before she was ready to be discharged to a long term care facility. Finally, even if the patient were ready for discharge that day, the process for transferring a patient to a long-term care facility is virtually impossible to accomplish in a single day. Thus, this case is a good example of the reviewers' profound failures to incorporate the full circumstances of these patients and the IRF processes.

The Hospital disputes the OIG's conclusions regarding the 21 denials out of the 30 inpatient rehabilitation claims and intends to pursue all of its appeal rights on the grounds that it had a reasonable expectation at the time of admission that these patients met the CMS coverage criteria. Finally, to the extent that these claims are time-barred pursuant to 42 CFR 405.980(b) and not subject to re-opening, then they do not constitute overpayments and are not subject to repayments as explained in our section discussing these issues.

C. Lack of a Request to Secure Manufacturer Credits for Replaced Medical Devices does not Constitute an Overpayment

The Hospital disagrees with the OIG's conclusion that a failure to pursue manufacturer credits for replaced medical devices constitutes an overpayment. The OIG predicates its conclusion on the federal regulation that requires payment adjustments for devices replaced **without cost** to the hospital. This provision, 42 C.F.R. 89, provides that a hospital must credit the Medicare Program **if**: "(1) a device is replaced **without cost** to the hospital; (2) The provider **received full credit** for the cost of the device; or (3) The provider **receives a credit** equal to 50% or more of the cost of the device.(emphasis added)" The regulation is very clear in that it **only** requires the hospital to credit the Medicare Program if its **actual** costs are off-set by tangible and specific credits. Similarly, the pertinent Medicare Manual provision (chapter 3, Section 100.8) specifies that CMS will reduce Medicare payment "when a replacement device is **received by the hospital at a reduced cost or with a credit** that is 50 percent greater than the cost of the device. (Emphasis added)" There is nothing in the pertinent regulations or manual provisions that require an off-set when the hospital does not receive a credit and otherwise incurs the full cost for the replacement device. Accordingly, we do not believe that the OIG has the authority to convert the actual costs incurred by the hospital for these devices into overpayments due the Medicare Program. These provisions do not impose a reduction in reimbursement if the manufacturer improperly refuses to provide a credit or the hospital neglects to seek one. In such a case, the hospital provided the device to the patient, paid out of pocket fully for the device and the Medicare Program is obligated to pay the hospital without any reduction for a credit that the hospital never received.[18]

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[18] It is worth noting that manufacturers have been prosecuted for failing to grant promised warranty credits and rebates. *See* 2011 Settlement in *U.S. ex rel Fry v. Guidant Corp et al.*, No. 3:03-0842, 2006 WL 2633740 (M.D. Tenn. Sept. 13, 2006). This underscores that even when a hospital pursues a credit, it is not always received.

While the hospital disputes the OIG's conclusion that the actual costs incurred for these replacement devices constitute overpayments, it has incorporated new policies and procedures to improve the tracking of these replacement devices so that it can actively pursue any potential credit available to the hospital. Under these revised policies, the Hospital now reviews all explanted devices on a quarterly basis to ensure that all requests for credits and warranties have been submitted. If it receives such credit, then it will apply the appropriate modifier so that the credit is passed on to the Medicare Program.

D. Mount Sinai's Documentation and Coding was Accurate and Compliant

1. Prior to October 2013, There Was No Requirement for a Physician Order to Admit

Three of the 60 claims in Categories A and B were denied because the medical record purportedly lacked a physician order for admission.[19]

These denials are improper for the simple reason that, at the time of these inpatient stays, there was no obligation for a provider to memorialize an inpatient admission by a written physician order. Effective October 1, 2013, CMS amended its regulations to add a new section stating that a "physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A," that the order "must be furnished by a qualified and licensed practitioner who has admitting privileges at the hospital as permitted by State law, and who is knowledgeable about the patient's hospital course, medical plan of care, and current condition," and that the order be "furnished at or before the time of the inpatient admission."[20]

Each of the three cases involved inpatient care prior to the October 1, 2013 effective date of the new regulation (specifically, the cases involved care in August 2013 (A-10) and March 2012 (B-8 and B-11). Accordingly, the regulation cannot be the basis for the purported obligation in

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[19] The three claims are A-10, B-8 and B-11. In A-10, the reviewer cited lack of medical necessity as an additional reason for denying the claim. But the reviewer's statement strongly implied that the absence of a physician order was deemed to be an independent and sufficient ground for denying the claim. In each of B-8 and B-10, the only ground cited for denial was the absence of a physician order.

[20] *See* 78 Fed. Reg. 50,495, 50,939-43, 50,965 (Aug. 19, 2013) (codified at 42 C.F.R. § 412.3(a)). CMS also amended its regulation that sets forth the requirements for inpatient services by adding a new physician certification requirement for every inpatient admission occurring on or after October 1, 2013. *See* 78 Fed. Reg. at 50,940, 50,941 (codified at 42 C.F.R. § 424.13(a)). But CMS subsequently amended its regulations again, dropping the requirement for a physician certification except for hospital stays that last 20 inpatient days or more and cost outlier cases. 79 Fed. Reg. 66,770, 66,998 (Nov. 10, 2014).

these cases to generate and maintain a written physician order. Further, while Section 1841(a)(3) of the Social Security Act requires that a physician certify that inpatient services are required where the services are "furnished over a period of time", that same provision states such certification shall be required to be made only where regulations have been enacted specifying the kinds of cases in which certification shall be required, the frequency of the certification, and the supporting materials to accompany the certification. Mount Sinai is unaware of any regulations that were in effect during March 2012 and August 2013 that would have required the existence of a physician order as a precondition to Medicare payment in the three cases at issue, and no such regulation is cited by the contract reviewers who denied the claims or by the OIG in the draft report. As such, the OIG reviewers appear to have denied these three claims on the basis of a made-up condition to payment requiring a physician order for admission when no such condition existed at the time of these inpatient admissions.

2. Mount Sinai Used the Correct DRG Codes

OIG contends that three claims in each of Category A and Category B were coded with the wrong DRG code.[21] Mount Sinai acknowledges that the three claims in Category B were incorrectly coded and to the extent that these claims are within the reopening period, Mount Sinai shall process the appropriate refunds.

With respect to the three claims in Category A, the reviewers determined that the DRG coding was incorrect because, in each case, the medical chart reflects that the patient was admitted to inpatient care upon completion of the surgical procedure. According to the reviewers, the surgical procedure in each case was on CMS's list of inpatient-only procedures, and therefore admission should have been ordered no later than the start of the procedure.

The reviewers' denial rationales are incorrect for at least three reasons. First, there was simply no requirement during the audit period that inpatient admission be ordered prior to commencement of a surgical procedure appearing on CMS's list of inpatient-only procedures. Second, because these procedures were inpatient-only, it is obvious that the inpatient services rendered in these three cases included the inpatient-only procedure at issue. The admission time appearing in these three charts indicated when the patient was physically transferred from the operating room to an inpatient bed. Thus, the admission time entry was never intended to convert these patients' status from outpatient to inpatient. Moreover, reliance on this data point would render the categorization of the in-patient only surgeries secondary and potentially superfluous. Simply put, there is no basis for the reviewers to use the admission time entry to exclude the procedure from the reimbursable costs of inpatient care. Finally, as noted above, during the audit period there was no requirement for a physician to issue a written order for inpatient care. As such, the timing of an order that was not even required cannot be

[21] The six claims are A-1, A-2, A-22, B-1, B-7 and B-28.

determinative of the DRG code and level of payment. Mount Sinai intends to appeal these denials.

3. Mount Sinai Correctly Billed for Outpatient Services with Modifier "59"

As noted in the first section, Mount Sinai maintains a vigorous compliance program that includes extensive education, training and monitoring on various coding requirements, including the use of Modifier 59. The compliance program's effectiveness is particularly evident in the hospital's appropriate use of modifier 59 for the claims in the OIG's sample.[22] The standard for the use of Modifier 59 seems undisputed; it is appropriately used when the procedure and/or services are performed on the same day, but are separate and distinct and, therefore, separately payable. While it is more frequently used in the context of procedures, it is also appropriately used for behavioral services, when a patient receives multiple mental health services in a single day.

The Hospital disputes the OIG's denial of the majority of the 12 claims in this category and maintains that the certified coders and physicians who included modifier 59 did so because the procedures and/or services were separate and distinct and warranted separate reimbursement. It is important to note that the bulk of these denials related to psychotherapy services. In these cases, the OIG reviewers appeared to disallow any individual psychotherapy services provided on the same day as group therapy solely because the patients received both services on the same day. The reviewers paid no attention to the mental health needs of the individual patients, the comprehensive care plans developed by the treating psychiatrists and the medical necessity for these discrete services. Indeed, if these services were simply performed on sequential days, presumably the reviewers would have never questioned the appropriateness of the services. Yet, although these services were provided to the patients on the same day, they were clearly distinct and different sessions. They were often performed by separate clinicians (generally the psychiatrist performing the individual psychotherapy was not the same person providing the group therapy), provided in separate rooms, at separate times and addressed different issues. Moreover, these patients were under the care of a psychiatrist who developed comprehensive plans of care that deliberately included distinct group psychotherapy as well as individual psychotherapy. These patients were severely compromised, suffering from post-traumatic stress disorder, personality disorders, and/or paranoid schizophrenia and the clinicians determined that each of these patients required both individual and group sessions to manage their symptoms, alleviate stress, and develop health coping strategies to improve functionality. These decisions to provide both forms of therapy is well supported by the literature in the field which underscores the value of combining individual psychotherapy with group therapy for patients

[22] It is also worth noting that the OIG found no errors on the Hospital's use of the modifier 25 in the 30 sample claims reviewed. Both Modifier 59 and Modifier 25 are used to identify a separate and distinct service provided on the same day. (Modifier 25 is used for separate and distinct E & M services).

with more severe mental illness and co-occurring disorders. There is no question that the patients received both of these services and use of the modifier 59 was entirely appropriate.

The Hospital also disputes several of the OIG denials for the procedural cases. For example, the patient in sample G-09 initially received a heart biopsy to assess the status of his prior heart transplant and determine whether he was a candidate for a diagnostic catheterization. The diagnostic procedure was necessary to inform the physician whether to proceed with the procedure itself. As such, each was a distinct service and the modifier 59 was entirely appropriate in this instance. The hospital intends to appeal all of these denials in this category with the exception of sample numbers G-16, G-17 and G-26. To the extent, however that these three claims are time-barred pursuant to 42 CFR 405.980(b) and not subject to re-opening, then they do not constitute overpayments and are not subject to repayments as explained in our section discussing these issues.

4. Mount Sinai Correctly Billed for Intensity-Modulated Radiation Therapy Planning Services

The OIG denied two payments embedded in claims related to IMRT planning, claiming that these codes are always part of the bundled IMRT claim and never subject to separate payment. While we do not necessarily refute these two specific claims, we note that the issue of billing separately for the IMRT planning codes, CPT 77290 and 77014 has been the subject of much controversy and confusion during the period that these services were performed. As an initial matter, even CMS guidance allows for the billing of these codes separately when they are performed as part of an initial evaluation of a patient to assess whether the patient is a suitable candidate for IMRT.[23] So contrary to the OIG's report, these codes can be billed discretely Moreover, the guidance issued by several of the Medicare contractors during the timeframe for this audit created further confusion regarding the appropriateness of billing separately for these codes when they are performed as part of the planning process. Although our contractor, NGS had not issued any Local Coverage Determinations on this issue, several other contractors had issued written guidance explicitly permitting the separate billing of simulation codes for the initial setup of the patient *even when this setup was part of the overall IMRT planning.*[24] CMS recognized the confusion engendered by its contractors and in October 2015 explicitly addressed this confusion and published a final rule making clear that these two codes should not be separately billed and were otherwise included in the IMRT planning code CPT 77301. In making this clarification, CMS acknowledged that it would be "revis[ing] and update[ing] the Medicare Claims Processing Manual and coding guidance … to ensure that this policy is more

[23] CMS, MCPM Ch. 4 section 200.3.1.

[24] First Coast Service Options, Inc. LCD L28892; Wisconsin Physician Insurance Corporation LCD L30316; Noridian Health Care Solutions LCD L24318.

directly stated."[25] Thus, the submission of these two claims in 2013, two years before CMS clarified the rules on these codes were entirely supportable given the confusing, but prevailing guidance from the carriers.

Finally, to the extent that these claims are time-barred pursuant to 42 CFR 405.980(b) and not subject to re-opening, then they do not constitute overpayments and are not subject to repayments as explained in our section discussing these issues.

5. Mount Sinai Had a Comprehensive Process for Determining the Appropriate Evaluation and Management ("E & M") Level of Service

The Hospital had a structured process for determining the appropriate level of E & M service for its Hospital Outpatient Departments and followed these processes to bill compliantly. In all but two of the outpatient departments the Hospital utilized the 1997 CPT E & M guidelines for physician services to determine the appropriate hospital levels taking into account the patient's history, physical examination, medical decision-making, counseling, coordination of care, nature of the patient's presenting problem and time spent with the patient. In the other select departments, the Hospital adopted a point system that incorporated the range of services most frequently provided in those clinics and trained the clinicians to mark the specific services provided to each patient as a methodology for documenting the service. Each of these services correlated to a specific number of points depending on the acuity of the service. Both systems were designed to measure the intensity of the services provided to the patient. Moreover, the Compliance department trained the clinicians on the E & M code levels and monitored these services on a regular basis.

While we firmly believe that our procedure and oversight structure promoted accurate billing, we also note that CMS eliminated the multi-level service codes as of 2014 and adopted a single G code for reimbursement of Hospital E & M services. Therefore, when the OIG commenced this Audit, these coding standards had already been eliminated. Accordingly, the OIG's continued auditing of this issue serves no value for purposes of educating providers or improving billing practices relating to this discrete issue.

With respect to the audit review, the OIG rejected eight out of the one hundred and seventeen claims reviewed on this issue. In virtually all of these eight denials, the OIG disagreed with the Hospital's coding selection by one level, determining that the Hospital should have billed a 99214 instead of a 99215. Yet, CMS has repeatedly acknowledged that even the most experienced reviewers often have differences of opinion on the coding of E & M services by one level when it entails a scale of five code levels. In fact, various studies establish that these experienced reviewers disagree by at least a one level difference about half the time.[26] This

[25] 80 Fed Reg.70401 (Nov. 13, 2015).

[26] King MS, Lipsky MS, Sharp L., Expert Agreement in Current Procedural Terminology Evaluation and Management Coding, Arch Int Med 162:316-320, 2002; Chao J et al. Billing for Physician

underscores the fact that these disagreements are differences of opinion that should not rise to the level of a denial finding. A good example of this disagreement is claim J- 25 involving a patient being treated in the outpatient cancer department for chronic myelomonocytic leukemia who presented with increased monocytes and spleen size. The service was extraordinarily extensive and involved the comprehensive assessment of the patient and the decision whether to commence a new form of cancer therapy in light of the patient's deteriorating clinical condition. The clinical staff documented their extensive review of systems, comprehensive history, medication evaluation, complete physical exam; review of multiple laboratory testing (that was critical to the determination of alternative therapies), the complex medical decision making, and forty-five minutes in time spent explaining the onset of conditions and various options available to the patient. The Hospital billed a 99215 for this unusually extensive service pursuant to its point system structure. The OIG reviewer disagreed with this code by one level claiming that the Hospital should have billed a 99214 because allegedly there was no documentation in the record for reassessment after the patient received their vaccination. The Reviewer is simply wrong. Indeed, the documentation is squarely in the record and states that the patient "tolerated [the vaccine] well....education given for 5 minutes regarding common side effects, management and when to report." Indeed, the nurse included additional documentation on the patient's receptivity to education on the potential longer term side effects of the vaccine. Clearly the clinicians could not have documented that the patient "tolerated" the vaccine "well" if they hadn't reassessed the patient after the patient received the vaccination. More to the point, however, this is a patient who received the very highest intensity level of services.[27] To reduce the level for an alleged failure to reassess the patient post vaccination trivializes the entire coding process. Virtually all of the other denials are plagued with similar mistakes and one level disagreements and the Hospital intends to appeal these denials. For those isolated claims where the Hospital agrees with the OIG's determination and the services were provided within the reopening period, the Hospital will submit refunds.

IV. Claims Outside the Statutory Re-Opening Period are Time-Barred

The Audit period encompasses claims with dates of services in 2012 and 2013. Pursuant to the pertinent re-opening and recovery rules in effect during this time period, claims paid after more than one year are only subject to reopening for "good cause" within four years of the initial

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Services: a Comparison of Actual Billing with CPT Codes Assigned by Direct Observation, J Fam Pract 47:28-32, 1998; Kikano GE, Goodwin MA, Stange KC, Evaluation and Management Services: A Comparison of Medical Record Documentation with Actual Billing in a Community Family Practice, Arch Fam Med 9:68-71, 2000; Zuber TJ et al., Variability in Code Selection Using the 1995 and 1998 HCFA Documentation Guidelines for Office Services, J Fam Pract 49:642- 645, 2000.

[27] Under the Hospital's point system, this service reflected 112.5 points, well above the 85 points necessary for billing a level 5. Moreover, even if the OIG reviewers deducted the 10 points for the lack of documentation for the reassessment, the service still qualified to be billed as a level 5.

determination, and once reopened, the contractor is only permitted to recover claims within three years of determination. [28] The OIG has acknowledged in numerous other hospital compliance audit reports that these Reopening and Recovery Rules prevented the Medicare Contractor from recovering overpayments outside of this regulatory framework.[29] In these Audits and in numerous others, the OIG recommended refund to the Medicare Program solely for claims within the applicable three year recovery period and eliminated all claims outside that time frame from its refund recommendations. This position is consistent with the law and the public policy rationales underpinning these Reopening and Recovery provisions. Congress and CMS explicitly adopted this statute of limitation provisions to protect providers from being subject to a perpetual, never-ending process of claim reopening and recoveries. Indeed, CMS has specifically described the purpose of these rules when it adopted a unified appeals process in 2005 by noting that "the underlying goal of the reopening process is to pay claims appropriately, subject to considerations of administrative finality."[30] In the same section, CMS further noted "for purposes of administrative finality and efficiency, CMS cannot sanction an endless cycle of reopening requests and appeals." Given the OIG's past practice and acceptance of the CMS rules on reopening and recovery, the OIG should remove its recommendations for recovery of any claims that fall outside the four year reopening limit and three year recovery limits. [31] Once these reopening and recovery periods have passed, the provider is deemed to be "without fault" and payment is final and not subject to correction.[32]

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[28] The governing statute and implementing CMS regulations and manual provisions are the following: 42 U.S.C. 1395gg, 42 CFR 405.980(b), and MCPM Pub. 100-4 Ch. 34 section 10. The regulations permit a contractor to reopen a claim beyond the four years only if there is "reliable evidence that the provider procured the initial determination by fraud." There is no such allegation of fraud. In fact, the OIG's Draft Report is replete with references to "incorrect" billing and billing "errors" but absolutely no allegation or basis for contending that these alleged billing mistakes, which the Hospital largely disputes, have any grounding in fraud. Therefore, there is no basis to reopen under this provision.

[29] *See, e.g.*, OIG, *Medicare Compliance Review of Boca Raton Regional Hospital, Inc.* for 2011 and 2012 (A-04-14-07048) (Oct. 20, 2015*); OIG Medicare Compliance Review of Mary Hitchcock Memorial Hospital* for 2009 through 2012 (A-01-13-00513) (July 30, 2015); *OIG Medicare Compliance Review of Loma Linda University Medical Center* for 2011 and 2012 (A-09-13-02056) (May 27, 2015).

[30] CMS, *Medicare Program: Changes to the Medicare Claims Appeal Procedures,* 70 Fed. Reg 11420, 11453 (March 8, 2005).

[31] All of the claims from 2012 are time-barred from re-opening because it has been at least four years since the initial determinations on these claims were made. In addition, it is as yet unclear which claims with dates of service in 2013 may be beyond the re-opening period.

[32] *See* 42 U.S.C. 1395gg (b).

In that regard, the Hospital rejects the OIG's two-fold recommendation set forth on page 10 of its Draft Audit Report that (1) The Hospital identify and return overpayments for claims that are part of the audit period but outside the Medicare reopening and recovery periods and (2) identify and return any additional similar overpayments outside the audit period in accordance with the 60-day rule. First and foremost, we reject the contention that any claims outside of the reopening and recovery periods constitute "overpayments" under the applicable statute.[33] As explained above, federal law imposes specific statute of limitations on the reopening and recovery of alleged overpayments. Under these provisions, the Medicare contractor's initial claim determination is binding on **all** parties, unless the claim is properly reopened and adjusted within the prescribed timeframes. Once these timeframes have passed, the determination of payment becomes final and the Hospital is "entitled" to the payment. Indeed, any other interpretation of these interlacing rules would render the reopening and recovery rules superfluous. For the same reasons, we reject the OIG's recommendation to return similar "overpayments" outside the audit period. In the first instance, the Hospital actively disputes virtually every claim denial deemed by the OIG as an "overpayment," and intends to appeal all of these denials based on this review. In reaching this conclusion, (and as more fully explained in each of the category sections in our response) the Hospital has conducted a comprehensive review of all the relevant materials related to each of the claim denials and based on this review, it has made good faith determinations that virtually all of these medical services as billed were appropriate and medically necessary for the patients. This review certainly qualifies as "reasonable diligence" under the Overpayment Rule.[34] Since the Hospital vigorously contests the audit findings based on the specific facts and circumstances of each claim, it has not "identified" any overpayments and, therefore, these contested claims are not subject to repayment under the 60-day rule.[35]

V. Extrapolation is Premature and Methodologically Unsound

Mount Sinai opposes the OIG's recommendation for extrapolation of the alleged overpayments. As discussed below, extrapolation is premature at this juncture and based on a deeply flawed statistical methodology. As a consequence, the extrapolation amount calculated by OIG in the draft report drastically overstates Mount Sinai's potential repayment obligations to CMS, and

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[33] An "overpayment is defined as "any funds that a person receives or retains [under Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled." 42 USC 1320a-7k (d) (4) (8).

[34] 42 U.S.C. 1320a-7k (d) see also CMS, *Reporting and Returning Overpayments*, 81 Fed. Reg. 7654 (Feb. 12, 2016) (codified at 42 C.F.R. parts 401 & 405).

[35] For those handful of claims that are within the re-opening period and the hospital is not contesting, the hospital is making all the appropriate refunds.

publication of the inflated amount will needlessly cause Mount Sinai irreparable reputational and operational harm.

A. Extrapolation is Premature Prior to Exhaustion of Appeals and Determination of Part B Offset

As a threshold matter, extrapolation as a means of recovering overpayments is appropriate only where CMS has found that either a high level of payment error exists or documented educational intervention has failed to correct the payment errors.[36] In its Draft Report, the OIG calculates an extrapolated overpayment amount in a select number of audit categories where the auditors purportedly selected a random sample of claims, but the OIG has not determined, or even alleged, that an educational intervention has failed. Accordingly, the OIG's use of extrapolation appears to be predicated on an unstated finding of a high level of payment error.

It is, however, premature at this point in the process to make any finding of a payment error rate, much less one that is significant enough to allegedly warrant extrapolation. Following issuance of the report, CMS and its Medicare contractors will determine the sample claims (if any) for which they will demand recoupment from Mount Sinai, and Mount Sinai will be entitled to appeal each such demand. As noted, Mount Sinai has a remarkably strong track record on prior appeals of allegedly overpaid claims that raised the very same issues involved with this review – prevailing over 85% of the time before impartial ALJs on questions of medical necessity in short-stay cases. Given that track record and the unprincipled manner by which the OIG's contract reviewers conducted the medical necessity reviews in each of the categories[37] in this audit, Mount Sinai is confident that it will prevail in the significant majority of the appeals stemming from this audit. That has two important implications for extrapolation. First, each successful appeal will significantly reduce the extrapolated overpayment amount. For every dollar of a disputed sample claim that Mount Sinai shows on appeal to have been validly paid, the extrapolation amount will be reduced by around thirty dollars. Second, it will only be possible to calculate an accurate payment error rate following completion of those appeals. And in the likely event that the error rate is not ultimately found to be sustained or high, then *any* extrapolation will be unfounded. Thus, until the appeals are exhausted, it is not possible to

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[36] *See* 42 U.S.C. § 1395ddd ("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."). *See also* Medicare Program Integrity Manual, Ch. 8, §§ 8.4.1.2 and 8.4.1.4.

[37] The denials in the elective inpatient procedure category, the high severity DRG category, the IRF category, the Modifier 59 category and the E & M level of services all were predicated on a disagreement over the medical necessity for the various services. In each of these cases, the auditors substituted their judgment regarding the patients' needs for that of the treating physicians.

determine whether extrapolation is even appropriate, let alone to calculate the correct extrapolated overpayment amount.

Moreover, we further object to the OIG's recommendation to extrapolate in every category where it performed a random sample regardless of its determined error rate. Indeed, certain of the claim categories, specifically Stratum seven (modifier 59) and ten (E & M level of service) had a low error rate even by the OIG's own measure (we believe the error rates in these categories are even lower since we believe the OIG's denial determinations are wrong). Accordingly, even if one were to accept the OIG's determinations in these categories, then both the law and OIG's own practices preclude extrapolation. In fact, in the OIG's audit report of Northwestern Memorial Hospital, the OIG specifically declined to recommend extrapolation for its review of Modifier 59 claims because the error rate was negligible.[38] But the financial error rate on this review of modifier-59 claims is nearly the same as that in the Northwestern review. The OIG should make the same choice in this audit both as a matter of law and equity.

With respect to the decision whether to recommend extrapolation at all, it is important to note that recommendations to extrapolate the findings in these hospital audits are relatively uncommon. And there is no requirement that the OIG conduct an extrapolation audit. In fact, in the vast majority of these compliance audits entailing multiple risk areas of similarly situated teaching hospitals with similar findings, the OIG has chosen not to recommend extrapolation.[39] Moreover, the OIG has offered no principled basis for recommending extrapolation in this case. Indeed as explained throughout this response, we have identified numerous reasons that mitigate against extrapolation. Simply put, the OIG should use its discretion and adhere to its overwhelming past practices to refrain from pursuing any extrapolation against Mount Sinai.

Further, the extrapolated overpayment amount is known to be a grossly inflated figure as it fails to incorporate the Part B off-set to which Mount Sinai would be entitled for those inpatient claims that OIG contends should have been billed on an outpatient basis. As most of the extrapolated overpayment amount is tied to such claims, the off-set will be very substantial. In the draft report, the OIG responds to this point by acknowledging that Mount Sinai may be entitled to a Part B off-set.[40] But the OIG further contends that it cannot consider an off-set when calculating the total overpayment amount because Mount Sinai has not submitted the

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[38] See, OIG, *Medicare Compliance Review of Northwestern Memorial Hospital* A-05-00051 (Mar. 2015) where the OIG chose not to extrapolate the errors for the category Modifier 59 because the financial error rate was 4.6%.

[39] For example, Extrapolation was not pursued in the following OIG Medicare Compliance Reviews: *Review of New University York Langone Medical Center* (Dec. 2012); *Hospital of the University of Pennsylvania* (July 2013); *Medstar Washington Hospital Center* (October 2013); *Indiana University Health* (May 2012)

[40] *See* Draft Report at p. 5 fn. 5.

claims at issue for reimbursement as outpatient services and, accordingly, the OIG cannot know how the Medicare contractor will process such claims for Part B coverage.[41] The OIG thus acknowledges that the extrapolated overpayment amount is subject to significant downward adjustment based on future determinations of Part B coverage, but the OIG refuses to include the adjustment as an element in the calculation because the adjustment is too speculative. But that acknowledgment highlights precisely why the OIG cannot possibly determine an "estimated" overpayment and, therefore, must refrain from publishing *any* extrapolated overpayment amount at this point: it is simply too soon to calculate an extrapolation figure, when crucial elements of the calculation (i.e., the Part B off-set and the final payment error rate) are not yet knowable. Indeed, the OIG's anticipated publication of an overpayment figure based on incomplete and uncertain information will conflict with the ethical principles set forth in the Government Auditing Standards manual (i.e., the "Yellow Book") requiring that audits be conducted with integrity and objectivity.[42]

Accordingly, the OIG should refrain from recommending an extrapolated overpayment amount. Extrapolation should be undertaken only by CMS and its Medicare contractors, and only when appeals of the individual cases have been completed, there exists a substantial error rate warranting extrapolation and a Part B off-set can be determined.[43]

B. Extrapolation is Based on Unsound Methodology

The OIG should withdraw its calculation of an extrapolated overpayment amount for the additional reason that the calculation was based on flawed methodology.

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[41] *See id.; see also* Letter from Gloria L. Jarmon, Deputy Inspector General for Audit Services, to Melinda Reid Hatton, Senior Vice President and General Counsel, American Hospital Association (Jan. 15, 2015) (stating that the OIG "cannot judge the value or allowability of Part B claims that have yet to be submitted.").

[42] The Yellow Book § 1.12 observes that "[i]ntegrity and objectivity are maintained when auditors perform their work and make decisions that are consistent with the broader interest of those relying on the auditors' report, including the public." But no interest is served by publication of an overpayment amount known to be inflated and subject to significant, downward adjustment – especially when the OIG does not print corrections or retractions of its published audit reports when those reports are later determined to be materially erroneous. Likewise, the Yellow Book § 2.07(b) requires that auditors obtain "sufficient, appropriate evidence" for their conclusions. In this case, the evidence is necessarily incomplete because certain elements of the extrapolation calculation cannot be known at this point in time.

[43] The Social Security Act contemplates that only "a Medicare contractor" can undertake extrapolation, and only where CMS has made the necessary predicate finding. *See* 42 U.S.C. § 1395ddd. This statutory language reflects Congress's judgment that the process of extrapolation should be reserved to these specific entities.

Most of the extrapolated overpayment amount is derived from sample claims in Categories A (elective procedures billed as inpatient), B (inpatient claims billed with high severity level DRG codes), and C (the IRF cases) that the OIG contends involved medically unnecessary inpatient care. As discussed above, the decision to admit a patient is a complex medical judgment based on the unique facts and circumstances of the patient's situation. In particular, the decision draws upon the physician's firsthand observations and interactions with the patient; the patient's specific medical history, condition, signs and symptoms; the availability of inpatient resources at the time; the patient's family and social situation; and various other relevant factors. As such, these medical judgments are unique to the specific facts of the respective cases, and they are not susceptible to generalization or extrapolation across an entire stratum. This is especially true where, as on this audit, a stratum contains claims involving different physicians in numerous departments and practices throughout the hospital. Each claim for Part A inpatient or IRF services turns on its specific facts, and the appropriateness of the physician's clinical judgment to admit can only be assessed by reference to those facts. In short, sampling and extrapolation is not a reliable method for determining the extent and quantum of potential overpayments on claims based on complex and individualized clinical judgments.

In addition, the design of the strata for Categories A and B was defective. As stated in the Medicare Program Integrity Manual, "the stratification scheme should try to ensure that a sampling unit from a particular stratum is more likely to be similar in overpayment amount to others in its stratum than to sampling units in other strata."[44] This criterion was not satisfied in the design of the strata for Categories A and B on this review: many of the claims that were assigned to Category A could have been assigned to Category B. Because of this design defect and the purportedly higher error rate for Category A than Category B, the extrapolated overpayment amount corresponding to Category A is much higher than it need be. That is, if the claims in Category A that also meet the definition for claims in Category B were in fact assigned to Category B instead of Category A, then the total extrapolated overpayment amount would be significantly less. This illustrates that the extrapolated overpayment amount is based on arbitrary considerations (e.g., the assignment of a particular claim to Category A versus Category B) and should not be the subject of any finding or recommendation by the OIG.

The design of the stratum for Category A is also flawed because it includes 98 claims that do not meet the category's definition. Category A is supposed to include cases of inpatient short-stays following an elective procedure. *See* draft OIG report at 2 (describing the first category (Category A) as including "inpatient short stays", which is one of the "risk areas" that the OIG "reviewed … as part of this review."). But 98 of the 2,407 claims in Category A are <u>not</u> short-stay cases. This is highly problematic because it means that 98 "non-risk-area" cases are included in a category that is meant to include only "risk-area" cases. And as these cases were for longer stays, it is likely they contribute a disproportionately greater share to the total

[44] MPIM § 8.4.4.1.3.

payments captured in Category A. Further, each of the 30 sample claims from Category A was short-stay cases. It is clearly improper for the OIG to extrapolate its findings from a sample of short-stay cases (a purported risk area) to a stratum containing 98 non-short-stay cases (which do not belong to the purported risk area), since, even by the OIG's own methodological assumptions, the sampled short-stay cases have a materially different risk profile compared to the 98 non-short-stay cases. This illustrates another serious flaw in the OIG's statistical model and is another reason for the OIG to refrain from recommending extrapolation.[45]

The sampling methodology is further defective because it includes numerous claims that are outside the reopening and recovery periods. In fact, once these claims are excluded from the samples, as they must be since the payments are final and not subject to recoupment, the sample sizes fall well below the minimum requirements specified in the OIG's own policy and procedure manual.[46] For example, there are thirteen cases with 2012 dates of service in Category A, short-stay cases, and twenty-four cases from 2012 in Category C, IRF cases. There is no question that these cases are all beyond the reopening period, leaving the sample size for the short-stay category at just seventeen, and a mere six for the IRF category. These small sample sizes cannot be subject to extrapolation by any measure and underscores how inflated and just plain wrong the extrapolated figure is in the OIG's draft report.

Finally, the OIG gave no regard to a stratum's significance, whether measured by number of claims in the stratum or by the total dollar amount of those claims, when deciding the sample size for review. For each of the six strata that was subject to random sampling, the OIG selected 30 claims to review, even though there were drastic variations in the number and value of the claims these strata – with stratum 1 (inpatient short-stays following an elective procedure) being most significant, with 2,407 claims constituting a total of $40,918,047 in payments, and with stratum 10 (outpatient E&M services) being least significant, with 236 claims constituting a total of $58,601 in payments. While the OIG's Audit Policies and Procedures Manual requires that at least 30 claims be reviewed in any random sampling of a stratum, it defies prudence and good practice for the OIG to adhere rigidly to this minimum requirement without regard to the scope and weight of the stratum under review. Further, as noted, the OIG has not even satisfied the minimum requirement because many of the claims are not subject to recoupment and thus are not properly included in the audit stratum.

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[45] At the very least, the 98 non-short-stay cases should be removed from the category and the extrapolation calculation should be re-performed.

[46] See, OIG, OAS Audit Policies and Procedures Manual, TN 2015, 03, Ch. 20-02 (Mar. 16, 2015) (requiring a minimum of "100 randomly selected sample units with a minimum of 30 sample units per random stratum.").

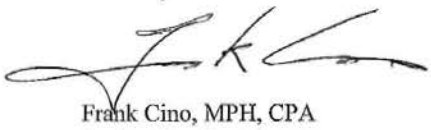
VI. Conclusion

Mount Sinai has provided the OIG with its comprehensive compliance program---a program that demonstrates an enduring and deep commitment to compliance in all facets of the Hospital's programs. The compliance program incorporates an extensive educational curriculum for all of its physicians and staff to keep up to date with the coding and billing rules and the compliance team performs regularly scheduled audits of the Hospital and physician coding and billing practices. The program incorporates strong internal controls to promote accurate and compliant billing and coding. Moreover, when mistakes in coding are identified, the compliance team re-educates the coders and providers and immediately refunds any identified overpayment. In short, Mount Sinai prides itself on having a strong culture of compliance and works hard to constantly re-evaluate and continually improve its programs to make them best in class.

We believe that any objective and fair review of the claims in this audit would reflect the strength of our compliance program and result in very few, if any, denials. In particular, the clinical judgments of Mount Sinai physicians to provide inpatient care were medically supported, made in furtherance of the patients' best interest, and complied in all respects with Medicare coverage rules. Given its strong commitment to compliance and its strong track record in prevailing on its appeals of claim denials, Mount Sinai respectfully requests that at a minimum, the OIG revise its Draft Report to recommend that CMS delay recoupment of any overpayments until the Hospital has had the opportunity to exhaust its appeal rights through the third level of the Medical claims appeal process (the administrative law judge hearing.)

Thank you in advance for your careful consideration of our comments and recommendations. We sincerely hope that you will accept our recommendations when preparing the Final Report.

Sincerely,



Frank Cino, MPH, CPA
Senior Vice President &
Chief Risk Officer