

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE COMPLIANCE REVIEW
OF NEW YORK-PRESBYTERIAN
HOSPITAL FOR 2011 AND 2012**

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Office of Inspector General

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EXECUTIVE SUMMARY

New York-Presbyterian Hospital did not fully comply with Medicare requirements for billing inpatient and outpatient services, resulting in overpayments of at least \$14.2 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 New York-Presbyterian 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 pre-determined rates for patient discharges. The rates vary according to the diagnosis-related group (DRG) to which a beneficiary's stay is assigned and the severity level of the patient's diagnosis. The DRG payment is, with certain exceptions, intended to be payment in full to the hospital for all inpatient costs associated with the beneficiary's stay. CMS pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification. CMS contracts with Medicare contractors to, among other things, process and pay claims submitted by hospitals.

Providers are responsible for reporting and returning overpayments within 60 days of identifying that overpayment (the 60-day repayment rule). Providers are required to exercise reasonable diligence to investigate credible information of potential overpayments to determine whether they have received an overpayment and to quantify the amount of the overpayment over the entire 6-year lookback period.

The Hospital is a 2,508-bed acute-care teaching hospital located in New York, New York. According to CMS's National Claims History data, Medicare paid the Hospital approximately \$1.5 billion for 76,437 inpatient and 579,761 outpatient claims for services provided to beneficiaries during CYs 2011 and 2012 (audit period).

Our audit covered \$32,829,323 in Medicare payments to the Hospital for 3,884 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 285 claims (102 inpatient and 183 outpatient) with payments totaling \$3,346,750. These 285 claims had dates of service in our audit period.

WHAT WE FOUND

The Hospital complied with Medicare billing requirements for 162 of the 285 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 123 claims, resulting in overpayments of \$819,803 for the audit period. Specifically, 56 inpatient claims had billing errors, resulting in overpayments of \$697,996, and 67 outpatient claims had billing errors, resulting in overpayments of \$121,807. 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 \$14,200,773 for the audit period.

WHAT WE RECOMMEND

We recommend that the Hospital:

- exercise reasonable diligence to investigate the potential overpayments outside of the Medicare reopening and recovery periods and work with the Medicare contractor to return any identified overpayments—which we calculate to be as much as \$14,200,773 during our audit period—in accordance with the 60-day repayment rule; and
- strengthen its controls to ensure full compliance with Medicare requirements.

HOSPITAL COMMENTS AND OUR RESPONSE

In written comments on our draft report, the Hospital, through its attorneys, disagreed with two of our initial recommendations and agreed with our third initial recommendation. Specifically, the Hospital indicated that the 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 therefore do not need to be returned. The Hospital also 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 agree that it incorrectly billed 16 inpatient claims and 16 outpatient claims with a total overpayment amount of \$143,920.

The Hospital disagreed that it improperly billed 91 of the 123 claims for which we determined it 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; therefore, the Hospital believes the extrapolation of overpayments is improper and statistically unsound. Finally, the Hospital indicated that it will continue to strengthen its controls to fulfill its commitment to compliance with Medicare requirements.

After reviewing the Hospital's comments, we maintain that our findings are valid. However, we revised our initial recommendations (combined two financial recommendations) to address the specifics of the 60-day repayment regulation, which became effective after the issuance of our draft report, 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 they have received an overpayment and to quantify the amount of the overpayment. In exercising reasonable diligence, providers are expected to determine whether or not overpayments of a similar type existed during a 6-year lookback period. Providers are obligated to quantify the entire amount of the 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 OIG’s conclusions concerning the 16 inpatient claims and 16 outpatient claims billed incorrectly, with an accumulated overpayment of \$143,920.”

Regarding the Hospital’s disagreement that it improperly billed 91 claims and that our review misapplied Medicare requirements, we note that we obtained an independent medical review of these claims for medical necessity and coding errors, and our report reflects the results of that review. Regarding our extrapolation methodology and the statistical validity of our results, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means 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 New York-Presbyterian 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 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 rehabilitation facility claims,
- inpatient and outpatient manufacturer credits for replaced medical devices,
- inpatient psychiatric facility emergency department adjustments,
- inpatient claims with same-day discharges and readmissions,
- outpatient claims billed with modifier -59,
- outpatient intensity-modulated radiation therapy (IMRT) planning services,
- outpatient claims billed for doxorubicin hydrochloride,
- outpatient claims billed for the drug Herceptin, and
- outpatient billing for dental services.

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

Medicare Requirements for Hospital Claims and Payments

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

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

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

Under section 1128J(d) of the Social Security Act and 42 CFR part 401 subpart D providers are responsible for reporting and returning overpayments within 60 days of identifying that overpayment (the 60-day repayment rule). Providers are required to exercise reasonable diligence to investigate credible information of potential overpayments to determine whether they have received an overpayment and to quantify the amount of the overpayment. In exercising reasonable diligence, providers are expected to determine whether or not overpayments of a similar type existed during a 6-year lookback period. In addition, providers such as the Hospital are obligated to quantify the entire amount of the overpayment for the 6-year lookback period and may do so by using a statistically valid extrapolation methodology. (42 CFR §§ 401.305(a)(2) and (f) and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016)).

New York-Presbyterian Hospital

The Hospital is a 2,508-bed acute-care teaching hospital in New York, New York. Medicare paid the Hospital approximately \$1.5 billion for 76,437 inpatient and 579,761 outpatient claims for services provided to beneficiaries during CYs 2011 and 2012 (audit period) based on CMS's National Claims History data.

HOW WE CONDUCTED THIS REVIEW

Our audit covered \$32,829,323 in Medicare payments to the Hospital for 3,884 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 285 claims (102 inpatient and 183 outpatient) with payments totaling \$3,346,750. These 285 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 120 claims to medical and coding review to determine whether the services were medically necessary and properly coded.

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

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

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

FINDINGS

The Hospital complied with Medicare billing requirements for 162 of the 285 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 123 claims, resulting in overpayments of \$819,803 for the audit period. Specifically, 56 inpatient claims had billing errors, resulting in overpayments of \$697,996, and 67 outpatient claims had billing errors, resulting in overpayments of \$121,807. 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 \$14,200,773 for the audit period.²

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

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 56 of 102 selected inpatient claims, which resulted in overpayments of \$697,996.³

Incorrectly Billed as Inpatient

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

For 46 of the 102 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. The Hospital did not provide a cause for the errors identified because it disagreed with this finding. As a result of these errors, the Hospital received overpayments of \$665,371.⁴

² 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.

³ During our review we identified 10 Inpatient Psychiatric Facility (IPF) claims in our sample that were incorrectly billed due to an Incorrect Source-of-Admission Code. For four IPF claims, the Hospital refunded the overpayments to the Medicare contractor. However, of the six remaining overpayments, the Hospital did not refund the overpayments for four IPF claims, and underpaid the required refund amount for two IPF claims. The difference between the underpaid refund and the required refund amount are reported as an overpayment to the Hospital.

⁴ 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.

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).⁵

For 4 of the 102 selected inpatient claims, the Hospital either (1) received reportable credits from manufacturers for replaced devices but did not adjust the claim with the appropriate condition and value codes to reduce payment as required (2 claims) or (2) did not obtain credits for replaced devices for which credits were available under the terms of the manufacturer's warranty (2 claims). 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. As a result of these errors, the Hospital received overpayments of \$32,138.

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 6 of the 102 selected inpatient claims, the Hospital incorrectly coded the source-of-admission for beneficiaries who were admitted to its IPF upon discharge from its acute care section. For four of the six claims, the Hospital did not refund the overpayments. For two of the six claims, the Hospital initiated corrective action to refund Medicare for the incorrectly coded source-of-admissions; however the Hospital underpaid the required refund amount due to Medicare.⁶

⁵ The PRM states: "Implicit in the intention that actual costs be paid to the extent they are reasonable is the expectation that the provider seeks to minimize its costs and that its actual costs do not exceed what a prudent and cost conscious buyer pays for a given item or service" (part I, § 2102.1). Section 2103 further defines prudent buyer principles and states that Medicare providers are expected to pursue free replacements or reduced charges under warranties. Section 2103(C)(4) provides the following example: "Provider B purchases cardiac pacemakers or their components for use in replacing malfunctioning or obsolete equipment, without asking the supplier/manufacturer for full or partial credits available under the terms of the warranty covering the replaced equipment. The credits or payments that could have been obtained must be reflected as a reduction of the cost of the equipment."

⁶ The overpayment for these two claims is the difference between the partial refund and the required refund amount.

Hospital officials stated that the errors occurred because of a clerical error during the design of the automatic source-of-admission code assignment process. As a result of these errors, the Hospital received overpayments of \$487.

BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 67 of 183 selected outpatient claims, which resulted in overpayments of \$121,807.⁷

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 7 of the 183 selected outpatient claims, the Hospital either did not obtain a credit for a replaced device that was available under the terms of the manufacturer's warranty (5 claims), received full credit for a replaced device but did not report the -FB modifier and reduce charges on its claim (1 claim), or received full credit for a replaced device and reported the -FB modifier but did not reduce charges on its claim (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. As a result of these errors, the Hospital received overpayments of \$68,891.

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).

⁷ During our review, we identified 30 outpatient IMRT planning service claims in our sample that were incorrectly billed. Seven IMRT claims contained two types of errors. Therefore, the number of errors exceeds the number of incorrectly billed claims.

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).

For 27 of the 183 selected outpatient claims, the Hospital incorrectly billed Medicare for HCPCS codes, appended with modifier -59, which were already included in the payments for other services billed on the same claim. Hospital officials did not provide a cause for the errors identified because they disagreed with this finding. As a result of these errors, the Hospital received overpayments of \$42,669.

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 30 of the 183 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 disagreed with this finding and asserted that all 30 claims complied with applicable coding and billing guidelines. As a result of these errors, the Hospital received overpayments of \$6,818.

Insufficiently Documented Procedures

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

For 5 of the 183 selected outpatient claims, the Hospital incorrectly billed Medicare with certain procedure codes that were unsupported in the medical records. Hospital officials stated that these errors occurred because of clerical error. As a result of these errors, the Hospital received overpayments of \$2,502.

Incorrect Billing for Dental Services

The Act states: “No payment may be made under Medicare Part A or Part B for any expenses incurred for items or services where such expenses are for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth...” (§ 1862(a)(12)).

For 1 of the 183 selected outpatient claims, the Hospital incorrectly billed Medicare for the treatment or removal of teeth. Hospital officials stated that this error occurred because of a clerical error. As a result of this error, the Hospital received an overpayment of \$584.

Medically Unnecessary Procedures

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

For 4 of the 183 selected outpatient claims, the Hospital incorrectly billed Medicare for HCPCS procedure codes that were medically unnecessary. The Hospital disagreed with this finding and stated that the associated procedures were appropriately provided and that the claims complied with applicable coding and billing guidelines. As a result of these errors, the Hospital received overpayments of \$343.

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$14,200,773 for the audit period.

RECOMMENDATIONS

We recommend that the Hospital:

- exercise reasonable diligence to investigate the potential overpayments outside of the Medicare reopening and recovery periods and work with the Medicare contractor to return any identified overpayments—which we calculate to be as much as \$14,200,773 during our audit period—in accordance with the 60-day repayment rule; and
- strengthen its 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, through its attorneys, disagreed with two of our initial recommendations and agreed with our third initial recommendation. Specifically, the Hospital indicated that the overpayments 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 therefore do not need to be returned. The Hospital also 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 agree that it incorrectly billed 16 inpatient claims and 16 outpatient claims with a total overpayment amount of \$143,920.

The Hospital disagreed that it improperly billed 91 of the 123 claims for which we determined it 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; therefore, the Hospital believes the extrapolation of overpayments is improper and statistically unsound. Finally, the Hospital indicated that it will continue to strengthen its controls to fulfill its commitment to compliance with Medicare requirements.

After reviewing the Hospital's comments, we maintain that our findings are valid. However, we revised our initial recommendations (combined two financial recommendations) to address the specifics of the 60-day repayment regulation, which became effective after the issuance of our draft report, 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 they have received an overpayment and to quantify the amount of the overpayment. In exercising reasonable diligence, providers are expected to determine whether or not overpayments of a similar type exist during a 6-year lookback period. Providers are obligated to quantify the entire amount of the 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 OIG’s conclusions concerning the 16 inpatient claims and 16 outpatient claims billed incorrectly, with an accumulated overpayment of \$143,920.”

Regarding the Hospital’s disagreement that it improperly billed 91 claims and that our review misapplied Medicare requirements, we note that we obtained an independent medical review of these claims for medical necessity and coding errors, and our report reflects the results of that review. Regarding our extrapolation methodology and the statistical validity of our results, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare.

The Hospital’s comments are included as Appendix E. We did not include attachments to the Hospital’s comments because they contained personally identifiable information and were too voluminous.

STATUTE OF LIMITATIONS AND THE 60-DAY RULE

Hospital Comments

The Hospital stated that section 1870(b) of the Act bars 2011 and 2012 claims from recovery by CMS. The Hospital also cited limits on the ability of Medicare contractors to reopen claims with potential overpayments after 4 years of the date of the claims’ initial payment determinations, as set by 42 CFR § 405.980(b). In addition, the Hospital contested its responsibility to refund the estimated overpayments to comply with the 60-day rule. The Hospital stated that it believes the February 2016 publication of the final regulations interpreting the 60-day rule clarified that our findings do not qualify as “overpayments.” Instead, the Hospital views these overpayments as a “fact-based inquiry” for which the Hospital stated that it “has conducted the reasonable diligence required by the Overpayment Rule and disputed in large part that overpayments exist.”

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 OIG’s conclusions concerning 16 inpatient claims and 16 outpatient claims, with an accumulated overpayment of \$143,920.”

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 provider’s or supplier’s 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 provider (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 32 of our sample claims are in fact overpayments, that is only the beginning of the inquiry. Our audit period (CYs 2011 and 2012) 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).

Importantly, the claims which the Hospital identified as overpayments in its response to our draft report were only sample claims representative of a much larger population. As a result, the value of the overpayment identified by the Hospital (\$143,920) is incorrect. To properly quantify the value of the overpayments would require extrapolation to that population. “[I]t is not appropriate for a provider or supplier to only return a subset of claims identified as overpayments and not extrapolate the full amount of the overpayment” (81 Fed. Reg. at 7664). Further, as discussed above, the population that we sampled was far more limited than the 6-year lookback period required by the 60-day rule. As a result, we are recommending that the Hospital exercise reasonable diligence to quantify the value of any additional overpayments it received for the years outside of our audit period as required by the 60-day rule (81 Fed. Reg. at 7667).

CONTESTED DETERMINATIONS OF CLAIMS

Hospital Comments

The Hospital disagreed that it improperly billed 91 of the 123 claims that we determined did not fully comply with Medicare billing requirements. Specifically, the Hospital disagreed with our determinations for 16 of the 21 inpatient short stay claims, 24 of the 25 inpatient rehabilitation claims, 27 of the 30 outpatient IMRT claims, and 24 of the 28 outpatient modifier -59 claims. However, the Hospital acknowledged that it improperly billed 16 inpatient and 16 outpatient claims and stated that it believes the amount that should be refunded is \$143,920.

The Hospital disagreed with the findings of 40 inpatient claim determinations, all of which the Hospital stated were reasonable and necessary, and met Medicare coverage criteria. In its rationale for disagreeing with these claims, the Hospital cited “limitations of post-hoc evaluations of inpatient admissions,” physician judgement at the time of inpatient admission,

inconsistent medical review determinations, and inflated overpayments due to claims that may be rebilled under Part B. The Hospital disagreed with the inpatient rehabilitation claims on the basis of its internal and external medical reviews of the sampled claims, along with a 2015 audit conducted by National Government Services (NGS), the Hospital's Medicare contractor, which found that all 10 claims sampled by NGS met Medicare coverage and documentation requirements. The Hospital stated that Medicare criteria, and its policies and procedures for admitting patients, have not materially changed since 2011, when our audit period began.

The Hospital also disagreed with our determinations regarding 51 outpatient claims, all of which it stated met Medicare coding and coverage guidance. Specifically, the Hospital disagreed with the outpatient IMRT determinations based on its interpretation of Medicare and American Medical Association (AMA) guidance, and Medicare contractor Local Coverage Determinations (LCDs). The Hospital stated the services were "performed as an initial evaluation of the patient" and "appropriately billed for the initial set-up of the patient." In addition, the Hospital disagreed with the outpatient modifier -59 determinations due to its interpretation of the National Correct Coding Initiative Manual, AMA guidance, and Medicare contractor LCDs. The Hospital stated that the LCDs allow for separate reimbursement of claims when a medically necessary diagnostic procedure occurs that results in data not previously available.

Office of Inspector General Response

We obtained an independent medical review of these claims for medical necessity and coding requirements, and our report reflects the results of that review. The contractor 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. On the basis of the contractor's conclusions, we determined that the Hospital should have billed the 40 inpatient claims as outpatient or outpatient with observation services, and that, for the 51 outpatient claims, Medicare coding and coverage requirements were not met. We continue to stand by those determinations.

Additionally, the Medicare contractor LCDs cited by the Hospital to justify, in part, its rationale for billing certain IMRT services were not issued by the Hospital's Medicare contractor, NGS, and therefore, were outside of the Hospital's jurisdiction. CMS confirmed that an LCD only applies to that Medicare contractor's jurisdiction.⁹

Finally, we acknowledged the fact that the Hospital's Medicare contractor allows for separate billing of diagnostic services under certain circumstances. However, while our independent medical review found that these diagnostic services were medically necessary, medical review

⁹ Chapter 13 of the Program Integrity Manual (PIM) (Pub. 100-08) outlines the LCD process which Medicare contractors must follow. Chapter 13 § 13.1.3 of the PIM states: "The LCDs specify under what clinical circumstances an item or service is considered to be reasonable and necessary. They are administrative and educational tools to assist providers in submitting correct claims for payment. Contractors publish LCDs to provide guidance to the public and medical community within their jurisdictions."

also found that they were not separate and distinct procedures. Therefore, these services do not meet CMS' definition of modifier -59.¹⁰

STATISTICAL SAMPLING AND EXTRAPOLATION

Hospital Comments

The Hospital stated that the use of statistical sampling and extrapolation to estimate the overpayment was arbitrary and not required. It objected that we identified the entire amount as having been overpaid for each of the improperly billed inpatient short stay claims, without offsetting the claims by the amount the Hospital would have been paid had it been correctly billed. The Hospital believes the lack of a payment offset and statutory limits of section 1870(b) of the Act bar our overpayment estimate and, therefore, our initial recommendation lacked sufficient and appropriate evidence to support our findings. Finally, the Hospital stated that certain strata should be exempt from extrapolation due to low financial error rates in those strata.

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.

We acknowledge that the Hospital may rebill Medicare 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.

¹⁰ 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).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$32,829,323 in Medicare payments to the Hospital for 3,884 claims that were potentially at risk for billing errors. We selected a stratified random sample of 285 claims (102 inpatient and 183 outpatient) totaling \$3,346,750 for review. These 285 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 120 claims to medical and coding reviews to determine whether the services were medically necessary and properly coded.

We limited our review of the Hospital's internal controls to those applicable to the inpatient and outpatient areas of review because our objective did not require an understanding of all internal controls over the submission and processing of claims. We established reasonable assurance of the authenticity and accuracy of the data obtained from the 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 from May 2013 through November 2015.

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 285 claims (102 inpatient and 183 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 120 sampled claims met medical necessity and coding requirements;
- discussed the incorrectly billed claims with Hospital personnel to determine the underlying causes of noncompliance with Medicare requirements;
- calculated the correct payments for those claims requiring adjustments;
- used the results of the sample to estimate the Medicare overpayment to the Hospital for our audit period (Appendix C);
- discussed the results of our review with Hospital officials.

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

APPENDIX B: SAMPLE DESIGN AND METHODOLOGY

POPULATION

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

SAMPLING FRAME

According to CMS's National Claims History data, Medicare paid the Hospital \$1,484,468,372 for 76,437 inpatient and 579,761 outpatient claims for services provided to beneficiaries during the audit period.

We obtained a database of claims totaling \$916,565,667 for 38,689 inpatient and \$91,255,897 for 99,690 outpatient claims in 37 risk areas. From these 37 areas, we selected 11 areas consisting of 76,977 claims totaling \$498,074,817 for further review.

We performed data analyses of the claims within each of the 11 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:
 - Inpatient Short Stays,
 - Inpatient Rehabilitation Facility Claims,
 - Inpatient Manufacturer Credits for Replaced Medical Devices,
 - Inpatient Psychiatric Facility Emergency Department Adjustments,
 - Inpatient Claims with Same-Day Discharges and Readmissions,
 - Outpatient Claims Billed with Modifier -59,
 - Outpatient IMRT Planning Services,
 - Outpatient Claims Billed for Doxorubicin Hydrochloride,
 - Outpatient Manufacturer Credits for Replaced Medical Devices,
 - Outpatient Claims Billed for the Drug Herceptin, and
 - Outpatient Billing for Dental Services; and
- claims under review by the Recovery Audit Contractor (RAC), as of May 31, 2013.¹¹

Removing these claims resulted in a sampling frame of 3,884 unique Medicare claims in 11 risk areas totaling \$32,829,323 as follows:

¹¹ To ensure that our overpayment extrapolation is valid, any sample items that a RAC has reviewed or is currently reviewing will be 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 will be subtracted from the total overpayments.

Table 1: Risk Areas Sampled

Risk Area	Number of Claims	Amount of Payments
Inpatient Short Stays	1887	\$9,592,012
Inpatient Rehabilitation Facility Claims	500	13,793,564
Inpatient Manufacturer Credits for Replaced Medical Devices	97	4,165,692
Inpatient Psychiatric Facility Emergency Department Adjustments	10	246,498
Inpatient Claims with Same-Day Discharges and Readmissions	2	10,359
Outpatient Claims Billed with Modifier -59	1015	3,297,335
Outpatient Intensity-Modulated Radiation Therapy Planning Services	250	1,005,992
Outpatient Claims Billed for Doxorubicin Hydrochloride	80	245,423
Outpatient Manufacturer Credits for Replaced Medical Devices	24	425,201
Outpatient Claims Billed for the Drug Herceptin	13	40,610
Outpatient Billing for Dental Services	6	6,637
Total	3,884	\$32,829,323

SAMPLE UNIT

The sample unit was a Medicare paid claim.

SAMPLE DESIGN

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

SAMPLE SIZE

We selected 285 claims for review as follows:

Table 2: Sampled Claims by Stratum

Stratum	Risk Area	Claims in Sampling Frame	Claims in Sample
1	Inpatient Short Stays	1887	30
2	Inpatient Rehabilitation Facility Claims	500	30
3	Inpatient Manufacturer Credits for Replaced Medical Devices	97	30
4	Inpatient Psychiatric Facility Emergency Department Adjustments	10	10
5	Inpatient Claims with Same-Day Discharges and Readmissions	2	2
6	Outpatient Claims Billed with Modifier -59	1015	30
7	Outpatient Intensity-Modulated Radiation Therapy Planning Services	250	30
8	Outpatient Claims Billed for Doxorubicin Hydrochloride	80	80
9	Outpatient Manufacturer Credits for Replaced Medical Devices	24	24
10	Outpatient Claims Billed for the Drug Herceptin	13	13
11	Outpatient Billing for Dental Services	6	6
	Total Sampled Claims	3,884	285

SOURCE OF THE RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the claims within strata one, two, three, six, and seven. After generating the random numbers for these strata, we selected the corresponding claims in each stratum. We selected all claims in strata four, five, eight, nine, ten, and eleven.

ESTIMATION METHODOLOGY

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

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

TOTAL MEDICARE OVERPAYMENTS

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	1887	\$9,592,012	30	\$124,108	21	\$83,160
2	500	13,793,564	30	786,713	25	582,211
3	97	4,165,692	30	1,227,158	4	32,138
4	10	246,498	10	246,498	6	487
5	2	10,359	2	10,359	0	0
6	1015	3,297,335	30	98,362	28	43,763
7	250	1,005,992	30	135,681	30	7,986
8	80	245,423	80	245,423	0	0
9	24	425,201	24	425,201	7	68,891
10	13	40,610	13	40,610	0	0
11	6	6,637	6	6,637	2	1,167
Total	3,884	\$32,829,323	285	\$3,346,750	123	\$819,803

ESTIMATES

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

Point Estimate	\$16,655,925
Lower Limit	\$14,200,773
Upper Limit	\$19,111,077

APPENDIX D: RESULTS OF REVIEW BY RISK AREA

Risk Area	Selected Claims	Value of Selected Claims	Claims With Over-payments	Value of Overpayments
Inpatient				
Rehabilitation Facility Claims	30†	\$786,713	25	\$582,211
Short Stays	30†	124,108	21	83,160
Manufacturer Credits for Replaced Medical Devices	30	1,227,158	4	32,138
Psychiatric Facility Emergency Department Adjustments	10	246,498	6	487
Same-Day Discharges and Readmissions	2	10,359	0	0
Inpatient Totals	102	\$2,394,836	56	\$697,996
Outpatient				
Claims Billed with Modifier -59	30†	\$98,362	28	\$43,763
Manufacturer Credits for Replaced Medical Devices	24	425,201	7	68,891
Intensity-Modulated Radiation Therapy Planning Services	30†	135,681	30	7,986
Dental Services	6	6,637	2	1,167
Doxorubicin Hydrochloride	80	245,423	0	0
Herceptin	13	40,610	0	0
Outpatient Totals	183	\$951,914	67	\$121,807
Inpatient and Outpatient Totals	285	\$3,346,750	123	\$819,803

† 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

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February 12, 2016

VIA FEDEX

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

Re: NewYork-Presbyterian Hospital's Response to Draft Report A-02-13-01027 by the U.S. Department of Health & Human Services Office of Inspector General

Mr. Edert:

In response to the December 18, 2015 correspondence and the above-captioned draft report issued by the U.S. Department of Health and Human Services Office of Inspector General ("OIG"), NewYork-Presbyterian Hospital, through its counsel, Latham & Watkins LLP, respectfully submits the attached response.

Regards,



Stuart S. Kurlander
of LATHAM & WATKINS LLP

cc: NewYork-Presbyterian Hospital
Eric C. Greig, Latham & Watkins LLP

NEW YORK-PRESBYTERIAN HOSPITAL

RESPONSE TO DRAFT NO. A-02-13-01027 ISSUED BY
THE DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

LATHAM & WATKINS LLP
February 12, 2016

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I. INTRODUCTION & SUMMARY OF RESPONSE

On behalf of NewYork-Presbyterian Hospital (“NYPH” or the “Hospital”), Latham & Watkins LLP respectfully submits this response to the above-captioned draft report issued by the U.S. Department of Health and Human Services Office of Inspector General (“OIG”), dated December 2015 (the “Draft Report”). The Draft Report addressed the results of an OIG audit of 285 claims submitted by NYPH for services provided to Medicare beneficiaries in 2011 and 2012. The Draft Report concluded that 162 of the 285 inpatient and outpatient claims reviewed complied with Medicare billing requirements. Conversely, OIG concluded that the remaining 123 claims did not meet requirements for Medicare coverage, with 56 inpatient claims and 67 outpatient claims allegedly containing billing errors.

On the basis of the 123 allegedly deficient claims, OIG calculated an overpayment of \$819,803. Extrapolating the results of the 285-claim sample to a universe of 3,884 claims, OIG estimated that the Hospital received overpayments of \$14,200,773 for the audit period. Recognizing that, as of the December 2015 date of the Draft Report, the Hospital’s 2011 claims were outside of the statutory 3-year recovery period applicable to Medicare claims, OIG recommended that: (i) NYPH refund to the Medicare program an estimated \$6,977,864 in overpayments related to claims incorrectly billed during the 3-year recovery period; and (ii) NYPH work with its Medicare contractor to return overpayments outside of the 3-year recovery period, estimated to be as much as \$7,222,909, in accordance with the 60-day repayment rule. The Draft Report also recommended that NYPH strengthen controls to ensure full compliance with Medicare requirements.

In light of numerous disagreements with OIG concerning these claims’ compliance with applicable coverage, coding, and documentation requirements—as well as the passage of time that has resulted in all claims reviewed by OIG extending beyond the 3-year recovery period—NYPH respectfully disagrees with both of OIG’s recommendations concerning overpayments. **First**, NYPH is not required to refund \$6,977,864 to the Medicare program because many of the claims in question met Medicare coverage and documentation requirements, and all of the Hospital’s 2011 and 2012 claims are subject to statutory and regulatory administrative finality limitations. **Second**, the 60-day repayment rule does not require NYPH to return \$7,222,909, and the Hospital has been and continues to be compliant with its responsibilities under the 60-day repayment statute. **Third**, NYPH recognizes the need for constant evaluation and strengthening of controls to ensure compliance with ever-changing Medicare requirements. While the Hospital concurs with this recommendation, it disagrees strongly with OIG’s finding that the “errors” identified by OIG 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 the errors.

II. ALL CLAIMS REVIEWED BY OIG ARE TIME-BARRED AND DO NOT CONSTITUTE OVERPAYMENTS.

Although OIG correctly recognized in the Draft Report that Section 1870(b) of the Social Security Act barred 2011 claims from recovery by CMS, that same law now bars recovery of any amounts associated with 2012 claims. In addition, OIG fails to recognize the limit on the ability of CMS contractors to reopen claims alleged to be errors more than four years after the date of

the claims' initial determinations. Finally, OIG incorrectly characterizes claims more than four years after their date of initial determination as "overpayments," when these claims were correctly determined to be appropriate and are no longer subject to reopening and recovery.

It is important to recognize the sound public policy motivations underlying the application of time limits after which certain actions cannot be taken. Both Congress and CMS adopted time limitations to prevent providers from being subject to a never-ending process of claim denials and recoveries. Instead, as CMS has explained, "wherever possible, a party must have a reasonable expectation as to the administrative finality of a decision on a claim or claims in question."¹ In the same publication, CMS noted that "the underlying goal of the reopening process is to pay claims appropriately, subject to considerations of administrative finality."² The failure to recognize either of these limitations in the final report would result in an unfairly prejudicial audit report, inconsistent with the decisions by Congress and CMS to grant providers some degree of reassurance that long-ago claims would not be resurrected in an endless loop of payments and repayments.

A. The Recovery Law Acts as a Statutory Time Bar to Recovering 2011 and 2012 Claims.

As OIG has acknowledged in numerous other hospital compliance audit reports³ and the Draft Report, Section 1870 of the Social Security Act (42 U.S.C. § 1395gg) (the "Recovery Law") restricts the ability of a Medicare contractor to recover an overpayment after the contractor has reopened the claim and adjusted payment. The Recovery Law bars the recovery of overpayments from providers that are "without fault" for the overpayment.⁴ Under the law in effect during 2011 and 2012, the Recovery Law deemed a provider to be "without fault" for overpayments being recovered three years after the year in which the original payment was made.⁵ For 2011 claims, the third year after the year in which the claims were paid ended on December 31, 2014; for 2012 claims, the third year after the year in which the claims were paid ended on December 31, 2015.

NYPH concurs with OIG that as of January 1, 2015, recovery of amounts related to 2011 claims was barred by the Recovery Law. Now that 2015 has ended, NYPH is deemed to be without fault for 2012 payments, and amounts associated with the initial determinations for the

¹ See CMS, *Medicare Program: Changes to the Medicare Claims Appeal Procedures*, 70 Fed. Reg. 11420, 11452 (Mar. 8, 2005).

² *Id.* at 11451 (emphasis added).

³ See, e.g., OIG, *Medicare Compliance Review of Boca Raton Regional Hospital, Inc., for 2011 and 2012* (A-04-14-07048) (Oct. 20, 2015) (acknowledging statutory limits on reopening); OIG, *Medicare Compliance Review of Mary Hitchcock Memorial Hospital for 2009 through 2012* (A-01-13-00513) (July 30, 2015) (recommending refund to the Medicare program only for claims within 3-Year Recovery Period); OIG, *Medicare Compliance Review of University of Kentucky Healthcare for 2011 and 2012* (A-04-13-08026) (June 17, 2015) (recommending refund to the Medicare program only for claims within 3-Year Recovery Period); OIG, *Medicare Compliance Review of Loma Linda University Medical Center for 2011 and 2012* (A-09-13-02056) (May 27, 2015) (recommending refund to the Medicare program only for claims within 3-Year Recovery Period).

⁴ 42 U.S.C. § 1395gg(c).

⁵ *Id.* § 1395gg(b) and (c) (2011).

2012 claims under review are now beyond the limit of the Recovery Law. For this reason, NYPH requests that OIG revise the findings of the report to state that the entire estimated amount associated with the Hospital's 2011 and 2012 claims is outside of the 3-year recovery period. In addition, the Hospital requests that OIG revise its recommendations to remove the recommendation that NYPH refund to the Medicare program \$6,977,864, since that amount is associated with claims statutorily barred from recovery.

B. OIG Should Recognize That the Reopening Rule Provides Administrative Finality to the Hospital's 2011 Claims and a Portion of the 2012 Claims.

While OIG correctly summarized the effect of the Recovery Law on 2011 claims, the Draft Report fails to recognize the separate time limit adopted by CMS to grant providers assurance that long-ago claims would not be subject to arbitrary and endless reopening and recovery actions. In order to collect an overpayment based on a post-payment review of a previously-paid Medicare claim, the Medicare contractor responsible for processing the claim must reopen the determination that the claim was approved and revise the determination to deny the claim.⁶ CMS has instructed contractors to not attempt recovery actions on certain claims, including situations in which "the carrier has not taken action to reopen the payment decision within 4 years (48 months) after the date of the initial payment determination."⁷ The regulatory time limits that prevent a contractor from reopening stale claims are set by 42 C.F.R. § 405.980(b) (the "Reopening Rule"). Under this regulation and related guidance from CMS, a contractor may only reopen an initial determination:

- for any reason within one year after initial payment; and
- for "good cause" within four years of the initial determination.⁸

All of the claims from 2011 are time barred from reopening because it has been at least four years since the initial determinations on the claims were made. In addition, a number of the Hospital's claims with dates of service in 2012 are beyond the four-year reopening limitation. While the exact impact of the Reopening Rule on NYPH's 2012 claims cannot yet be determined with certainty, the impact of the Reopening Rule on OIG's findings and recommendations is not at issue, since the Recovery Law already instructs OIG to revise the Draft Report's findings and recommendations to recognize that all 2011 and 2012 claims share the same limitation under the Recovery Law. The Hospital respectfully requests, however, that OIG recognize in the final report that the Reopening Rule prevents a Medicare contractor from reopening all 2011 claims and all 2012 claims with initial determination dates more than four years after the date on which a Medicare contractor would attempt to reopen the claims.

⁶ See CMS, Medicare Claims Processing Manual ("MCPM"), Pub. 100-04, ch. 34, § 10.

⁷ See Medicare Financial Management Manual, Pub 100-06, ch. 3, § 170.2.B.

⁸ See 42 C.F.R. § 405.980(b); see also CMS, MCPM, ch. 34, § 10.6. 1. The regulation also allows CMS contractors to reopen a claim after four years if there is reliable evidence that the provider procured the initial determination by fraud or similar fault. No such fraud or similar fault has been alleged by OIG or is present in the Hospital's claims, eliminating the possibility of an unlimited reopening period.

C. Time-Barred Claims and Disputed Claims Are Not Overpayments.

Although OIG rightly recognized the 2011 claims as barred from recovery under the Recovery Law, the Draft Report then recommends that the Hospital “work with the Medicare contractor to return overpayments outside of the 3-year recovery period...in accordance with the 60-day repayment rule...”⁹ At the time of the Draft Report, although NYPH would have strongly disagreed with the characterization, OIG may have had some discretion to interpret the 60-day repayment rule to suggest that estimated amounts outside of the 3-year recovery period were “overpayments,” or that NYPH had a responsibility to refund or return these amounts to comply with the 60-day repayment rule. Upon the February 2016 publication of the final regulations interpreting the repayment statute, however, it has become clear that the amount referenced by OIG neither qualifies as an “overpayment” nor requires refund by NYPH to comply with the 60-day repayment rule. Throughout the course of this audit, NYPH conducted careful review and analysis of each claim identified by OIG as potentially problematic, including the Hospital’s retention of outside clinical experts to evaluate the claims. NYPH agreed with OIG’s evaluations regarding a limited number of claims in which OIG identified alleged billing issues, and the Hospital plans to refund promptly the amounts related to those claims.¹⁰ For the significant number of claims in which the opinions of OIG and NYPH diverge, however, it is inaccurate for OIG to characterize actual or estimated amounts beyond the 3-year recovery period as “overpayments” required to be refunded to comply with the 60-day repayment rule. Instead, OIG must limit its findings to identifying the number of claims OIG alleges contain billing errors, and limit any refund recommendation to the claims in which NYPH did not dispute OIG’s claim determination.

1. The Overpayment Rule Conflicts With OIG’s Recommendation That NYPH Refund Disputed Claim Amounts.

The “60-day repayment rule” referred to by OIG is an amendment to the Social Security Act under Section 1128J(d), which was recently interpreted by CMS in a final rule set to become effective March 13, 2016 (the “Overpayment Rule”).¹¹ Pursuant to the Overpayment Rule, if a person “identifies” a circumstance resulting in the receipt of an overpayment from Medicare, the person must report and return the overpayment to an appropriate government agency or contractor within sixty (60) days from the date the overpayment was identified. The Overpayment Rule defines an “overpayment” as “any funds that a person receives or retains [under Medicare] to which the person, after applicable reconciliation, is not entitled.”¹²

When CMS adopted final regulations interpreting the statute, the agency addressed the responsibility of a provider in the exact situation as NYPH. CMS stated that the receipt of the results of a government audit “is an example of credible information of a potential overpayment”

⁹ See Draft Report at *ii*.

¹⁰ NYPH does not dispute OIG’s conclusions concerning 16 inpatient claims and 16 outpatient claims, with an accumulated overpayment of \$143,919.72.

¹¹ 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 and 405).

¹² See 42 U.S.C. § 1320a-7k(d)(4)(8).

that requires the provider to conduct reasonable diligence to “confirm or contest” the audit’s findings.¹³ When questioned whether the determination from a government auditor that a claim constitutes an overpayment means that the provider should report and return the payment associated with the questioned claim, CMS declined to provide that confirmation, explaining instead that the provider’s “overpayment” determination is a fact-based inquiry dependent on the provider reviewing specific facts and circumstances and billing and coverage rules to determine the scope of reasonable diligence.¹⁴ At no point in the Overpayment Rule does CMS state or suggest that the mere determination by a non-Medicare entity, like OIG, that a claim may contain a billing error results in the creation of an “overpayment” required to be refunded under the Overpayment Rule.

Given that NYPH actively disputes the accuracy of the amounts identified by OIG as alleged “overpayments” and has expressed this dispute through this letter and prior communications with OIG, NYPH is not disregarding or ignoring any potential overpayments. To the contrary, NYPH has conducted the reasonable diligence required by the Overpayment Rule and disputed in large part that overpayments exist. OIG’s prior interpretation of the Overpayment Rule is inconsistent with the regulations adopted after publication of the Draft Report, and as such, must be adjusted to comply with those new regulations.

2. Time-barred Claims Are Not Overpayments.

As discussed above, Congress and CMS adopted certain time limits on the reopening and recovery of amounts related to stale claims, granting providers some measure of certainty and administrative finality on claims submitted by the provider in good faith. A Medicare contractor’s initial claim determination is binding on all parties unless and until a Medicare contractor reopens and revises the initial determination within certain prescribed timeframes.¹⁵ CMS clarified that “a reopening is an action to change a final determination or decision that *results in* either an overpayment or an underpayment.”¹⁶ This language makes clear that unless a provider self-identifies an overpayment in accordance with the Overpayment Rule described above, it is only *after* reopening that a revised determination can create an overpayment or underpayment. As such, it is not accurate to refer to a claim outside the four-year Reopening Rule period as an “overpayment” when it is not subject to a reopening and revised determination.

Without reopening, the initial determinations made by NYPH’s Medicare contractor in 2011 and 2012 stand as final. With respect to all of the claims subject to the OIG’s audit, the Medicare contractor determined that the payment was authorized. That determination remains binding unless the claim is reopened and the initial determination revised within the allotted regulatory timeframes. Even if some portion of the 2012 claims could be reopened by a contractor, NYPH is without fault for this amount and thus not financially liable for any amounts related to reopened claims denied outside of the 3-year recovery period that ended on December

¹³ Overpayment Rule, 81 Fed. Reg. at 7667.

¹⁴ *Id.*

¹⁵ See 42 C.F.R. § 405.928(a).

¹⁶ See 70 Fed. Reg. at 11451 (emphasis added).

31, 2015. Since Congress and CMS have chosen to limit Medicare contractors' ability to reopen and recover stale claims, the initial determinations for these claims stand as final and no overpayment exists for NYPH to identify and refund under the Overpayment Rule.

III. OIG'S REVIEW MISAPPLIED MEDICARE COVERAGE, CODING, AND DOCUMENTATION REQUIREMENTS, RESULTING IN AN INCORRECT ERROR RATE.

NYPH respectfully disagrees with the OIG's findings and conclusions regarding multiple categories of inpatient and outpatient claims reviewed. As confirmed through internal and external expert evaluations of the Hospital's inpatient and outpatient claims, NYPH maintains that the following inpatient and outpatient services were reasonable and necessary, provided in accordance with Medicare coverage criteria, and adhered to the highest standard of medical practice to which NYPH holds itself.

A. NYPH Disagrees with OIG's Determinations Regarding Acute Inpatient Admissions.

The Medicare Benefit Policy Manual ("MBPM") establishes the definition of an inpatient for the Medicare Part A benefit, stating "[g]enerally, 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."¹⁷ CMS's longstanding guidance has been that "Medicare review contractors should evaluate the physician's expectation [of an overnight stay] based on the information available to the admitting practitioner at the time of the inpatient admission."¹⁸ This determination involves a complex medical judgment that includes consideration of not only the patient's medical history and current medical needs, but also the types of facilities available to inpatients and to outpatients at the hospital.¹⁹ Courts have recognized that patients' treating physicians—not post-payment review auditors evaluating the services years after the fact—are "unquestionably" in the best position to certify the necessity of the inpatient stay:

In demonstrating to us that substantial evidence underlies his determination that inpatient hospitalization was not reasonable and necessary, the Secretary of course is at an immediate disadvantage, because none of his representatives ever personally examined [the patient]. To reach his determination, 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

¹⁷ See CMS, Medicare Benefit Policy Manual, Ch. 1, §10 (emphasis added).

¹⁸ See CMS, *Frequently Asked Questions*, available at <https://questions.cms.gov/faq.php?id=5005&faqId=9230> (last visited Jan. 29, 2016).

¹⁹ See CMS, MBPM, Ch. 1, §10.

must necessarily demand that his review of the record be probing, precise and accurate.²⁰

The Hospital has confirmed the accuracy of physicians' clinical judgment to admit the vast majority of patients questioned by OIG's medical review contractor in the sampled claims. In each of these disputed cases, the admitting physician determined that the patient's clinical condition created the expectation that the patient would remain at least overnight and occupy a bed. Unlike the OIG's contracted medical reviewers, these physicians did not "patch together discrete findings and observations in records" to reach an admission determination; they directly observed the myriad clinical conditions and considerations that influenced these medical determinations.

CMS recently reaffirmed the deference that must be paid to the admitting physician's decision to certify a patient for inpatient care. After years of uncertainty and changing admission standards adopted after the dates of service reviewed by OIG here, CMS has once again returned to the exact same recognition of, and deference to, the admitting physician's medical judgment. A complicated narrative of "two midnight stays" dominated discussion of the appropriate admission standard for acute inpatient stays from 2013 to 2015, with feedback and pronouncements from patients, providers, regulators, and Congress all culminating in a final decision from CMS published in the most recent Medicare Hospital Outpatient Prospective Payment System ("OPPS") Final Rule for calendar year 2016. Specifically recognizing lessons learned from stakeholder input and from probe reviews of "short" inpatient admissions conducted by the Medicare Administrative Contractors ("MACs"), CMS adopted a policy under which patients expected to need less than two midnights of hospital care may be payable as an inpatient admission based on "the physician's determination . . . that the patient requires formal admission to the hospital on an inpatient basis."²¹ CMS acknowledged in the 2016 OPPS Final Rule that it "continues to recognize the important role of physician judgment and individual patient needs in the hospital admission decision-making process."²² While CMS reiterated that a physician would be unlikely to expect beneficiaries undergoing a minor surgical procedure or other treatment to require formal admission, the vast majority of NYPH's "short stay" admissions involved patients admitted from the emergency department who required evaluation in an inpatient setting for at least an overnight stay. The propriety of these admissions was confirmed by a second clinical review conducted by physicians affiliated with Columbia University Medical Center and Weill Cornell Medical College, and then verified by the NYPH Chief Medical Officer. These experts concluded that twenty four (24) of the twenty eight (28) admissions characterized by OIG as appropriate only for outpatient or observation care were actually characterized by a justified expectation of an overnight admission, qualifying these claims for inpatient care.

In contrast to the Hospital's clinical review, the review papers provided by OIG's medical necessity review contractor contain contradictory and confusing reasoning and conclusions. For example, the beneficiary described in Sample A-09, a 90-year-old woman with

²⁰ See *State of New York on behalf of Bodnar v. Sec'y of Health & Human Servs.*, 903 F.2d 122 (2d Cir. 1990).

²¹ See 80 Fed. Reg. § 70298, 70541.

²² *Id.*

a history of diastolic dysfunction and angina who had a pacemaker implanted in June 2011, presented to the Hospital with recurrent syncope (temporary loss of consciousness). The patient's telemetry monitoring demonstrated the presence of arrhythmia, showing moderately frequent supraventricular premature complexes with short runs of supraventricular tachycardia. Consistent with the standard of care, her physician concluded that it was medically necessary to admit the patient for evaluation and diagnostic testing, with the expectation that she would remain in the hospital at least overnight due to the high risk of a short-term adverse health outcome due in large part to the patient's concurrent syncope and arrhythmia. Admission in this situation is consistent with the accepted standard of care, as acknowledged by the OIG contractor in sample claim A-29, where the reviewer explicitly states that when a patient has syncope and "the physical examination shows signs of arrhythmia . . . the standard of care is generally inpatient admission." Despite this acknowledgment in claim A-29, the OIG reviewer responsible for claim A-09 concluded that inpatient care for a patient with a recently implanted pacemaker, syncope, and arrhythmia was "not warranted." Inconsistencies such as this are present throughout the reviews and undermine the conclusions reached by OIG's medical necessity review contractor.

A further inconsistency relates to the calculation used by OIG to estimate the "overpayment" associated with NYPH's inpatient short stay claims. Although OIG recognizes that NYPH "may be able to bill Medicare Part B for all services . . . that would have been reasonable and necessary had the beneficiary been treated as a hospital outpatient rather than admitted as an inpatient," the report fails to acknowledge that this fact undermines any finding or recommendation that includes an overpayment amount for short stay claims. The Inspector General Act of 1978 requires OIG to ensure that their audits comply with the Generally Accepted Government Auditing Standards (the "Yellow Book"), published by the U.S. Government Accountability Office.²³ These standards require OIG auditors to "obtain sufficient, appropriate evidence to provide a reasonable basis for their findings and conclusions."²⁴ By acknowledging that OIG is actually unable to determine the amount of the overpayment attributable to short stay admissions that are eligible for rebilling under Part B, OIG implicitly acknowledges that it is not able to obtain sufficient evidence to support its inflated overpayment amount. Without a reasonable basis for the overpayment amount associated with these claims, OIG should include neither a finding nor recommendation with an overpayment amount attributable to inpatient short stay claims. The inclusion of such a finding would deviate materially from OIG's statutory responsibility to use sufficient evidence to address the audit objectives and support its findings and conclusions.²⁵

Due to the recognized limitations of post-hoc evaluations of inpatient admissions without any exposure to the patient, the recognition by CMS after years of input and experience that the decision of the admitting physician deserves deference, and the inconsistent evaluations conducted by OIG's review contractor, NYPH respectfully disagrees with OIG's conclusions concerning sixteen (16) of the twenty-one (21) inpatient "short stay" claims. The lack of uniform

²³ See 5 U.S.C. App. § 4(b)(1)(C) *see also* Government Auditing Standards, United States Government Accountability Office, GAO-12-331G § A.102(a) (Dec. 2011) (recognizing that the Inspector General Act of 1978 includes these requirements).

²⁴ See Yellow Book § 6.56.

²⁵ See Yellow Book § 6.67.

analysis and misinterpretation of the relevant Medicare criteria for admission by the OIG contractor suggest OIG's findings and recommendations are undermined by the failure to abide by mandatory supervisory standards that require OIG to properly supervise audit staff, including providing sufficient guidance and direction to "follow applicable requirements" and reviewing the work performed by the audit staff.²⁶ For these reasons, and due to OIG's inability to calculate actual overpayment amounts because of Part B rebilling options, the Hospital requests that OIG remove any amounts related to inpatient short stay admissions from its findings and recommendations.

B. The Hospital Disagrees with OIG's Determinations Regarding the Admission of Patients into Inpatient Rehabilitation.

Medicare regulations and guidance set forth in Medicare manuals detail CMS's medical necessity and documentation criteria for coverage under Medicare's inpatient rehabilitation facility ("IRF") benefit.²⁷ Generally, to be determined reasonable and necessary for IRF care, there must be a "reasonable expectation" that the patient meets all of the following requirements at the time of the patient's admission:

1. The patient requires active and ongoing intervention of multiple therapy disciplines, one of which is physical or occupational therapy;
2. The patient requires an intensive rehabilitation therapy program;
3. The patient is reasonably expected to actively participate in, and benefit from, the intensive rehabilitation therapy program;
4. The patient requires physician supervision by a rehabilitation physician; and
5. The patient requires an intensive and coordinated interdisciplinary approach to providing rehabilitation.²⁸

CMS has imposed specific criteria necessary for providers to adequately document their expectation that admission is necessary, including documentation of a comprehensive preadmission screening, post-admission physician evaluation, and an individualized overall plan of care.²⁹ CMS has indicated 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,"³⁰ signifying that consideration of the IRF file's documentation may be sufficient but is not the exclusive means of assessing the medical necessity of inpatient rehabilitation.

²⁶ See Yellow Book §§ 6.53 and 6.54.

²⁷ See 42 C.F.R. §§ 412.622(a)(3)-(4); CMS, MBPM, Ch. 1, §§ 110-110.2.2.

²⁸ See 42 C.F.R. § 412.622(a)(3); CMS, MBPM, Ch. 1, § 110.2.2.

²⁹ See 42 C.F.R. § 412.622(a)(4); CMS, MBPM, Ch. 1, § 110.2.2.

³⁰ See CMS, MBPM, Ch. 1, § 110.2.1.

After thorough internal review and an independent external review of the sample claims, the Hospital is confident that the clinical circumstances of these patients justified admission to the IRF and qualified for payment under applicable coverage criteria. In addition to performing its own review of the sampled claims, the Hospital engaged FTI Consulting (“FTI”)—a nationally recognized consulting firm experienced in the review of Medicare claims—to evaluate the claims identified as problematic by OIG’s medical review contractor (the “OIG Contractor”). FTI’s review team of preeminent, nationally-known psychiatrists and an experienced registered nurse with prior experience in IRF reviews performed an extensive review of the claims, ultimately concluding that 24 out of the 25 admissions the OIG Contractor found inappropriate were, in fact, medically necessary and reasonable. FTI concluded that the difference in results between FTI and the OIG Contractor “appears to be the result of [the OIG Contractor] failing to apply the correct Medicare standards to IRF admissions. . . .” FTI’s claim reviews included the preparation of individual patient narratives describing the clinical circumstances of the admission, the course of treatment, and a response to the observations or conclusions of Maximus, which are included at [Appendix B](#) to FTI’s report attached as [Exhibit 1](#) to this response.

FTI’s review team identified instances in which the OIG Contractor often cited invalid reasons for denial that were not consistent with Medicare regulations or general medical practice.³¹ In some cases, the OIG Contractor inaccurately claimed that key documentation was missing or incomplete when, in fact, such information was in the medical record.³² In other cases, the OIG Contractor cited broad and non-specific issues as reasons for denial even though the issues were not supported by the medical record.³³ For example, in its review of claim B-06, the OIG Contractor stated, “[t]here was no evidence of complex medical issues that required acute physical medicine and rehabilitation care.” However, the patient’s IRF file indicated that this patient had several ongoing complex medical needs that required medical management and oversight, including the risk of complications related to chronic thrombotic thrombocytopenic purpura, deep vein thrombosis, pulmonary embolism, seizure and stroke. NYPH’s board-certified rehabilitation physicians and FTI’s expert team concluded that these ongoing complex medical needs indicated a need for the patient to be admitted to inpatient rehabilitation.

The results of the FTI review and NYPH’s system of controls were recently corroborated by an audit conducted by National Government Services (“NGS”), the MAC responsible for administration of the Hospital’s IRF claims. This thorough review of a sample of ten IRF claims in 2015 concluded that one hundred percent (100%) of the reviewed files met Medicare coverage and documentation requirements for inpatient rehabilitation admission and services. The NGS audit report, attached at [Exhibit 2](#), specifically noted that the NYPH files were “well organized and easy to navigate,” and that NYPH “continues to strive for excellence” in the provision and documentation of inpatient rehabilitation services. Importantly, neither the Medicare coverage and documentation criteria for IRF services, nor the Hospital’s process for evaluating and admitting patients or documenting their IRF care, have changed materially since the 2011 and

³¹ See OIG Contractor Medical Review Summaries for OIG Samples B-02, B-12, B-13, B-24.

³² See OIG Contractor Medical Review Summaries for OIG Samples B-12, B-17, B-18, B-28.

³³ See OIG Contractor Medical Review Summaries for OIG Samples B-03, B-06, B-08, B-10, B-11, B-13, B-17, B-27, B-28, B-29.

2012 dates of service covered by OIG's audit. The 2015 NGS audit, conducted by the entity with the most experience and expertise in evaluating IRF coverage and documentation criteria, confirms the validity of services provided by the Hospital's IRF and contradicts the conclusions of OIG and its contract reviewer.

The Hospital respectfully disagrees with the OIG's conclusions regarding twenty-four (24) of the twenty-five (25) inpatient rehabilitation claims. As the FTI Report and NGS audit make clear, the Hospital held a reasonable expectation at the time of the admissions that these patients met the coverage criteria established by CMS.

C. The Denied Services Provided to Patients that Received Intensity-Modulated Radiation Therapy ("IMRT") at NYPH Were Unrelated to the IMRT Planning Procedure Service.

The Hospital disagrees with OIG's findings related to IMRT planning procedures for twenty seven (27) out of thirty (30) of the sample claims. Although NYPH recognizes that the procedure code describing the creation of an IMRT treatment plan includes a variety of tasks and services, applicable coding guidance authorized NYPH to bill for separate procedures provided outside of the creation of this plan. Under Medicare guidance, certain imaging services, treatment simulations, and treatment calculations should not be billed separately when performed as part of developing an IMRT treatment plan.³⁴ In contrast, these services may be appropriately billed in addition to IMRT planning services when they "are not provided as part of developing the IMRT treatment plan."³⁵ Medicare and American Medical Association ("AMA") guidance documents note that developing the IMRT plan is one step in the typical patient's process of IMRT treatment, during which: (1) a physician contours the target area and develops the gross tumor volume (GTV), clinical target volume (CTV), and planning target volume (PTV); and (2) a physicist or dosimetrist utilizes a treatment planning computer to develop a complex, multibeam treatment plan to deliver the prescription dose to the PTV while satisfying normal tissue dose constraints, resulting in the computerized treatment plan.³⁶ Only by incorrectly expanding the scope of this service to include *all* potential services provided to IMRT patients does OIG reach the conclusion that the sample claims were billed in error.

NYPH contends that it properly billed for computed tomography services, described by CPT code 77014, because in each of the sample claims, the CT scan was performed as an initial evaluation of the patient, prior to any decision being made to treat the patient with IMRT, let alone as part of developing the Medicare beneficiary's IMRT treatment plan. Similarly, simple and complex therapeutic radiology simulation-aided field setting services provided by NYPH (described by CPT codes 77280 and 77290) were used to physically align the radiation therapy patient outside of the development of the IMRT treatment plan.³⁷ These procedures are

³⁴ See CMS, MCPM, Ch. 4, § 200.3.2. These services are identified by CPT codes 77014, 77280-77295, 77305-77321, 77331, 77336, and 77370.

³⁵ CMS, MCPM, ch. 4, § 200.3.1.

³⁶ See, e.g., AMA, CPT Assistant 09:11, "Intensity Modulated Radiation Therapy (IMRT): CPT Codes 77301, 77418, 77338" (Nov. 2009).

³⁷ See *id.*

appropriately billed for the initial set-up of the patient where an immobilization device may be constructed, isocenter(s) and volume of interest determined, and CT or other imaging is obtained.³⁸ In each of the sample claims in which NYPH billed therapeutic radiology simulation-aided field settings in addition to IMRT planning services, the simulation services were performed prior to the decision to proceed with IMRT treatment. Because the simulation procedures were used for purposes other than the planning of Medicare beneficiaries' IMRT treatment, the Hospital appropriately billed for these services in addition to the beneficiaries' IMRT planning services.

Beyond the claims identified as errors due to inclusion of the codes listed above, NYPH believes that its claims were supported by adequate and appropriate documentation. The Hospital would assert its appeal rights and expects to support these claims if any attempt at recovery were made.

D. The Hospital Disagrees with the OIG's Determinations Regarding the Use of Modifier -59.

NYPH also disagrees with OIG's findings regarding the Hospital's billing for outpatient services billed with modifier -59 for twenty four (24) of the twenty eight (28) claims. Similar to the IMRT coding analysis described above, NYPH believes that the OIG Contractor ignored published coding and coverage guidance to adopt an overly-simplistic coding analysis for outpatient claims involving modifier -59, resulting in incorrect denials. These claims generally involve the same clinical circumstances, with post-heart transplant patients receiving services consisting of a cardiac tissue biopsies to evaluate the heart for tissue rejection and right heart catheterization ("RHC") procedures to evaluate the heart's hemodynamic data for sufficient output and pressure. Both of these procedures were reasonable and necessary services for this select group of high-risk Medicare patients, and as such, were eligible for separate billing and reimbursement through the use of modifier -59. Because the RHC procedures reported on the sampled claims were eligible for separate payment in accordance with Medicare coding and coverage policies, NYPH disagrees with OIG's conclusion that the Hospital incorrectly billed outpatient services with modifier -59.

CMS has adopted a system of "automatic edits" that automatically denies certain procedure codes when they are reported with other procedure codes that typically should not be reported together.³⁹ For certain procedure codes that may be eligible for separate reimbursement in limited circumstances, CMS allows providers to override these automatic edits in some cases by using modifiers, such as modifier -59, to enable separate payment for the procedures in accordance with Medicare coverage and coding policies.⁴⁰ While the procedure codes for RHC services and endomyocardial biopsy procedures are paired codes that are typically not available for separate reimbursement, CMS designated this pairing as one of the procedure combinations

³⁸ See, e.g., Local Coverage Determinations L24318, L29200, and L29352.

³⁹ See CMS, National Correct Coding Initiative ("NCCI") Manual, Ch.1, § A.

⁴⁰ See *id.* §§ A; E.1

potentially eligible for separate reimbursement, allowing providers to use a modifier to bypass the edit when separate payment is appropriate for both procedure codes.⁴¹

Medicare coverage guidance indicates that reimbursement is available for both of these procedures when the RHC is a medically necessary diagnostic procedure that results in hemodynamic data not previously available.⁴² The automatic edit denying separate reimbursement for these procedures is in place for situations when “an endomyocardial biopsy is performed without obtaining hemodynamic data not previously available.”⁴³ The AMA coding guidance specifies separate coding for the RHC and biopsy should not occur in this instance because the RHC would be performed “only as a means of obtaining the endomyocardial biopsy,” not as a separate diagnostic procedure.⁴⁴

Importantly, the necessary nature of each aspect of these cardiac procedures is not in dispute: The OIG Contractor confirmed in each cover sheet that the RHC procedures were distinctly reasonable and necessary diagnostic procedures. In each of the sample claims, the cardiologist ordered a diagnostic RHC to evaluate hemodynamics to provide separate diagnostic information from the endomyocardial biopsy provided to the patient. These RHC procedures were performed as distinct diagnostic procedures to provide the physician with necessary hemodynamic measurements, including pressures, arterial and venous oxygen saturation, and cardiac output, rather than merely as a means of obtaining the biopsy. Since both procedures were reasonable and necessary diagnostic procedures, the Hospital respectfully disagrees with OIG’s findings, and instead asserts that the coding and billing for these procedures were proper and consistent with Medicare guidance.

IV. EXTRAPOLATION OF OIG’S REVIEW RESULTS WOULD BE IMPROPER AND STATISTICALLY UNSOUND.

Beyond the procedural and substantive disagreements noted above, NYPH believes that OIG’s use of extrapolation to calculate an estimated overpayment amount would be arbitrary, premature, and inconsistent with OIG’s obligation to support its audit findings and conclusions with sufficient, appropriate evidence. NYPH requests that OIG revise its findings and recommendations to reference only amounts associated with claims actually reviewed during the audit, as summarized in Appendix C on page 15 of the Draft Report.

OIG’s prior response to numerous hospitals’ comments against OIG’s arbitrary use of extrapolation in the hospital compliance audit process has been that “each hospital review is

⁴¹ See CMS, Hospital PTP Edits (designating 93505 and 93451 with modifier indicator “1”).

⁴² See NGS, *Local Coverage Determination: Cardiac Catheterization and Coronary Angiography* (L26880); NGS, *Local Coverage Article: Cardiac Catheterization and Coronary Angiography – Supplemental Instructions Article* (A50603); AMA, *CPT Assistant* 00:10, Q&A on CPT Code 93505.

⁴³ See NGS, *Local Coverage Article: Cardiac Catheterization and Coronary Angiography – Supplemental Instructions Article* (A50603).

⁴⁴ See AMA, *CPT Assistant* at 10 (Apr. 2000).

unique” and audit methodologies will vary.⁴⁵ This audit, however, raises unique concerns that weigh against the ability of OIG to meet its statutory obligations under the IG Act to meet the standards set forth in the Yellow Book. Most critically, an extrapolated estimation of an “overpayment” in this case conflicts with OIG’s obligation to obtain reasonable assurance that “evidence is sufficient and appropriate to support the auditors’ findings and conclusions in relation to audit objectives.”⁴⁶ As described above, referencing any amount as an overpayment in the findings, or recommending the return of any amounts due to the audit results—let alone an extrapolated amount—would ignore the plain application of the Recovery Law and Reopening Rule. In the last five years, both CMS and OIG are on record as acknowledging the limitations these two timing restrictions place on the ability of OIG to make findings and recommendations supported by applicable law when the Recovery Law and Reopening Rule apply to long-past claims.⁴⁷ To the knowledge of NYPH, OIG has not examined any other hospital in which the entirety of the claims reviewed exceeds the statutory bar against recovery. Therefore, at most, OIG’s findings should be limited to identifying certain claims that OIG determines did not fully comply with Medicare billing requirements, with a corresponding recommendation that NYPH communicate with CMS to determine whether any of the claims could be subject to reopening and recovery.

In any case, the proposed extrapolation method and calculations described on pages 11 through 18 of the Draft Report are already deficient and contrary to OIG Office of Audit Services policy. Due to the application of the Recovery Law to the Hospital’s 2011 claims, the sample sizes of the sampled strata fall below the minimum sample sizes required by Chapter 20-02 of the OAS Audit Policies and Procedures Manual. As explained in Section 20-02-50-05, for stratified random sampling, “the minimum sample size is 100 randomly selected sample units with a minimum of 30 sample units per random stratum.”⁴⁸ While the chart of claims at Table 5 of the Draft Report purports to show Medicare overpayments within the 3-year recovery period, OIG has failed to adjust the strata sample sizes to reflect the fact that half (or more) of the sample claims in each strata fall outside of the 3-year period. Retaining the sample size number at thirty claims, while recognizing that the Recovery Law excluded approximately half of those claims from consideration, is an artificial attempt to retain minimum sample size units for extrapolation. OIG should recognize that claims beyond the Recovery Law and Reopening Period must be excluded from consideration of extrapolation, and OAS policy instructs that extrapolation may not proceed on the reduced strata sizes. The Reopening Rule also applies to a majority of the claims review, including an unknown portion of the 2012 claims, which have yet to be reopened by the Medicare contractor. The uncertainty created by the application of this rule to a yet-to-be-determined number of claims makes extrapolation impossible.

In addition to the unique status of this audit report under the Recovery Law and Reopening Rule, NYPH’s unique position in the healthcare market weighs against extrapolation. Extrapolation of hospital compliance audit results is already a rare event: In more than 130

⁴⁵ See, e.g., OIG, Medicare Compliance Review of Naples Community Hospital for 2011 and 2012 at 8 (Oct. 2015).

⁴⁶ See Yellow Book § 6.01.

⁴⁷ See OIG, *Obstacles to Collection of Millions in Medicare Overpayments*, A-04-10-03059 at ii (May 2012).

⁴⁸ OIG, *OAS Audit Policies and Procedures Manual*, TN 2015.03, Ch. 20-02, “Statistical Sampling and Mathematical Calculation Estimation Techniques in Auditing” (Mar. 16, 2015).

hospital compliance reviews released in the last five (5) years that incorporated more than one risk area under review, only twenty-seven (27) audit reports included an extrapolated estimation of the overpayment—approximately twenty percent (20%) of all hospital compliance audits. There is no requirement that OIG perform any extrapolation, and comparisons to prior audit reports of peer institutions support the elimination of extrapolation from this Draft Report. For instance, as an academic medical center affiliated with two of the nation’s leading medical schools, NYPH’s commitment to medical education is rare among other hospitals that have been subject to extrapolation. While the number of the claims under direct review in NYPH’s audit (285) roughly corresponds with the number of claims reviewed by the OIG in audits of similarly-styled teaching hospitals such as the University of Pennsylvania (208), NYU Langone Medical Center (367), Indiana University Hospital (198), Georgetown University Hospital (265), Medstar Washington Hospital Center (313), and Brigham and Women’s Hospital (359), none of these institutions were subject to extrapolation despite significant error rates. The imposition of an extrapolated overpayment amount would result in an arbitrary penalty being applied to NYPH, with no rationale or explanation to differentiate between this audit and the audits cited here. Similarly, when OIG examined such a large number of risk areas in similarly-situated hospitals, the audit reports rarely adopted an extrapolated overpayment method.⁴⁹

The same Yellowbook standard cited above weighs strongly against OIG’s extrapolation of the claims included within the stratum of inpatient “short stays” since OIG acknowledges that NYPH may be able to bill Medicare Part B for all services reasonable and necessary to these patients’ treatment, and that OIG is “unable to determine the effect that billing Medicare Part B would have on the overpayment amount.”⁵⁰ OIG’s Deputy Inspector General for Audit Services has gone one step further, recognizing that OIG “cannot judge the value or allowability of Part B claims that have yet to be submitted.”⁵¹ While Ms. Jarmon uses this observation to conclude that OIG cannot provide an offset to the Part A overpayment with Part B reimbursement figures, OIG fails to recognize that this observation also means that a finding or recommendation based on an “estimated” overpayment related to inpatient short stay claims has no basis in fact or law when all parties recognize that the overpayment amount is subject to rebilling and offset. Consistent with OIG’s obligations to support its findings and recommendations with appropriate evidence consistent with the laws and regulations applicable to the program under which it is auditing,⁵² the final report should limit any findings or recommendations related to inpatient short stays to an identification of the number of claims reviewed by OIG that it feels did not meet Medicare coverage criteria for the inpatient admission.

⁴⁹ See, e.g., OIG, *Medicare Compliance Review of New York University Langone Medical Center for the Period July 1, 2008, through December 31, 2010* (Dec. 2012); OIG, *Medicare Compliance Review of the Hospital of the University of Pennsylvania for Calendar Years 2008 through 2011* (July 2013); OIG, *Medicare Compliance Review of MedStar Washington Hospital Center* (Oct. 2013); OIG, *Medicare Compliance Review of Indiana University Health for the Period October 2008 through September 2010* (May 2012). In each of these reviews, OIG utilized judgmental sampling and no extrapolation.

⁵⁰ See Draft Report at 4, n.5.

⁵¹ See Letter from Gloria L. Jarmon, Deputy Inspector Gen. for Audit Servs., to Melinda Reid Hatton, Senior Vice President and Gen. Counsel, Am. Hosp. Assoc. (Jan. 15, 2015), available at <http://oig.hhs.gov/about-oig/about-us/files/AHA-review-letter.pdf> (last visited Feb. 8, 2016).

⁵² See Yellow Book § 2.07(b).

Finally, the low error rate demonstrated in certain claim categories mandates against extrapolation of those strata. The Social Security Act, as well as Medicare and OIG policies, limit the use of extrapolation to instances in which a high level of payment error exists.⁵³ With financial error rates of approximately 5%, at least two strata are not eligible for extrapolation: (1) manufacturer credits for inpatient replaced medical devices; and (2) IMRT planning services. In a number of prior audits, OIG declined to extrapolate results of statistically sampled strata when the audited entity demonstrated similar rates of compliance. For example, in OIG's Medicare Compliance Review of the Medical University of South Carolina, OIG identified four out of thirty-five claims in error (11.4%) for inpatient claims billed with high-severity-level DRG codes, resulting in a financial error rate of 4.6%.⁵⁴ OIG explained that when calculating its estimated overpayment, it only added the actual overpayments from that stratum to the lower limit of the extrapolation rather than include the results in calculating the estimated overpayments, citing "OAS policy." Similarly, OIG declined to include in its extrapolated results a statistically sampled stratum in the Medicare Compliance Review of Northwestern Memorial Hospital when it observed only five of thirty-eight claims in error, resulting in a financial error rate of 4.6%.⁵⁵ In NYPH's audit, even before application of the Recovery Law, OIG identified only four out of thirty errors in stratum 3, resulting in a financial error rate of 2.6%, and only identified a financial error rate of 5.9% in stratum 7.⁵⁶ Yet, with these error rates lower than or approximating the prior audit reports mentioned, OIG determined to include these strata in the extrapolated results. NYPH should be entitled to the same, consistent treatment applied by OIG in other hospital compliance audits, requiring OIG to exclude strata 3 and 7 from any extrapolated estimate of overpayments.

V. NYPH IS COMMITTED TO COMPLIANCE WITH MEDICARE REQUIREMENTS.

NYPH has a longstanding and deep commitment to operating in compliance with Medicare requirements. The Hospital performs ongoing and routine audits of its coding and billing practices to constantly evaluate its compliance and, where necessary, improve the accuracy of those processes. The current compliance processes are effective, emphasizing adherence to applicable coverage criteria and regulations and constant re-evaluation to identify new potential risk areas and enhance oversight of the Hospital's compliance efforts. If an audit or other evidence informs NYPH of a potential billing issue, the Hospital engages in the necessary diligence to evaluate the issue and any relevant claims, and if an overpayment is identified, NYPH immediately refunds any identified amount. NYPH will continue to strengthen its controls to fulfill its commitment to compliance with Medicare requirements.

⁵³ 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 high level of payment error; or (B) documented educational intervention has failed to correct the payment error."); See also CMS, MPIM, ch. 8, § 8.4.1.2.

⁵⁴ OIG, *Medicare Compliance Review of Medical University of South Carolina for the Period January 1, 2011 Through June 30, 2012* at 14, A-04-13-03075 (Jan. 2014).

⁵⁵ OIG, *Medicare Compliance Review of Northwestern Memorial Hospital* at 17, A-05-13-00051 (Mar. 2015).

⁵⁶ Draft Report at 15.