

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE COMPLIANCE REVIEW OF
CAROLINAS MEDICAL CENTER**

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



Gloria L. Jarmon
Deputy Inspector General
for Audit Services

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Office of Inspector General

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The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: January 2018

Report No. A-04-16-04049

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Review

This review is part of a series of hospital compliance reviews. Using computer matching, data mining, and other data analysis techniques, we identified hospital claims that were at risk for noncompliance with Medicare billing requirements. For calendar year 2015, Medicare paid hospitals \$163 billion, which represents 46 percent of all fee-for-service payments to hospitals.

The objective of this review was to determine whether Carolinas Medical Center (the Hospital) complied with Medicare requirements for billing inpatient services on selected types of claims.

How OIG Did This Review

We selected for review a stratified random sample of 240 claims with payments totaling \$3.1 million for our 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.

Medicare Compliance Review of Carolinas Medical Center

What OIG Found

The Hospital complied with Medicare billing requirements for 157 of the 240 inpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 83 claims, resulting in net overpayments of \$331,831 for our audit period from January 1, 2014, through December 31, 2015. 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 \$1.7 million for the audit period.

What OIG Recommends and Hospital Comments

We recommend that the Hospital refund to the Medicare program \$1.7 million in estimated overpayments for the audit period for claims that it incorrectly billed; exercise reasonable diligence to identify and return any additional similar overpayments received outside of our audit period, in accordance with the 60-day repayment rule, and identify any returned overpayments as having been made in accordance with this recommendation; and strengthen controls to ensure full compliance with Medicare requirements.

The Hospital disagreed with our disallowance determinations on certain claims, and contended that the extrapolation of our results was invalid. The Hospital stated that, in accordance with the 60-day rule, it had identified and is refunding for one finding similar overpayments for claims outside of our audit period. However, it did not address whether it planned to do this for other claims it billed incorrectly, other than stating that it had reached out to CMS on one disputed finding. Also, the Hospital stated that it had a strong compliance program and has developed comprehensive policies, procedures, education, auditing, and other initiatives to improve its programs and acknowledged the importance of continuing improvements in compliance efforts.

After reviewing the Hospital's comments, we maintain that our findings and recommendations are valid. We used an independent medical reviewer to determine whether certain sampled claims were appropriately billed. Additionally, we used valid statistical sampling methodology in our sample selection and in determining the estimated Medicare overpayment.

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INTRODUCTION

WHY WE DID THIS REVIEW

This review is part of a series of hospital compliance reviews. Using computer matching, data mining, and other data analysis techniques, we identified hospital claims that were at risk for noncompliance with Medicare billing requirements. For calendar year 2015, Medicare paid hospitals \$163 billion, which represents 46 percent of all fee-for-service payments; accordingly, it is important to ensure hospital payments comply with requirements.

OBJECTIVE

Our objective was to determine whether Carolinas Medical Center (the Hospital) complied with Medicare requirements for billing inpatient services on selected types of claims from January 1, 2014, through December 31, 2015.

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 (PPS), 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 Claims at Risk for Incorrect Billing

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

- inpatient claims with same-day discharges and readmissions,
- inpatient claims with unreported discharges to home health services,

- inpatient claims paid in excess of charges, and
- inpatient claims billed with high-severity-level DRG codes.

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

Medicare Requirements for Hospital Claims and Payments

Medicare payments may not be made for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Social Security Act (the Act), § 1862(a)(1)(A)). In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§ 1815(a)).

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

The *Medicare Claims Processing Manual* (the Manual), Pub. No. 100-04, chapter 1, section 80.3.2.2, requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly.

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

Carolinas Medical Center

The Hospital is composed of two acute care facilities in Charlotte, North Carolina, with a total of 1,021 beds: Carolinas Medical Center and Carolinas Medical Center—Mercy. According to CMS’s National Claims History (NCH) data, Medicare paid the Hospital approximately \$369 million for 27,154 inpatient claims from January 1, 2014, through December 31, 2015 (audit period).

HOW WE CONDUCTED THIS REVIEW

Our audit covered \$31,093,729 in Medicare payments to the Hospital for 3,088 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of

240 inpatient claims with payments totaling \$3,066,432. Medicare paid these 240 claims during 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 153 claims to coding review to determine whether the services were 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 scope and methodology.

FINDINGS

The Hospital complied with Medicare billing requirements for 157 of the 240 inpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 83 claims, resulting in net overpayments of \$331,831 for the audit period. 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 \$1,659,619 for the audit period. See Appendix B for sample design and methodology, Appendix C for sample results and estimates, and Appendix D for results of review by risk area.

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 83 of the 240 inpatient claims that we reviewed. These errors resulted in net overpayments of \$331,831. Three of these claims contained errors that did not cause any overpayment, and five claims contained more than one error.¹

Incorrectly Billed Diagnosis-Related-Group Codes

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

¹ For sampled claims that contained more than one type of error, we used the total claim overpayment for error estimation. We did not estimate errors on the same claim twice.

to be processed correctly and promptly, a bill must be completed accurately” (chapter 1, § 80.3.2.2).

For 50 of the 240 inpatient claims, the Hospital submitted claims to Medicare with incorrect DRG codes. The Hospital did not agree that all 50 claims had errors. However, Hospital representatives acknowledged that human errors can occur despite the Hospital’s internal controls. Representatives also stated that, to support coding accuracy, they had adopted additional controls and training since the audit period.

As a result of these errors, the Hospital received net overpayments of \$144,179.

Incorrectly Billed Patient Discharge Status Codes

Federal regulations state that a discharge of a hospital inpatient is considered to be a transfer when the patient’s discharge is assigned to one of the qualifying DRGs and the discharge is to home under a home health agency’s written plan of care for home health services that begin within 3 days after the date of discharge (42 CFR § 412.4(c)). A hospital that transfers an inpatient under the above circumstance is paid a graduated per diem rate for each day of the patient’s stay in that hospital, not to exceed the full DRG payment that would have been paid if the patient had been discharged to another setting (42 CFR § 412.4(f)).

If a patient is discharged to home for the provision of home health services, but the continuing care is not related to the condition or diagnosis for which the individual received inpatient hospital services, the hospital can apply condition code 42 and receive the full DRG payment (65 Fed. Reg. 47081 (August 1, 2000) and Medicare Learning Network Matters SE1411). The hospital is responsible for coding the bill based on its discharge plan for the patient, or if it finds out subsequently that postacute care occurred, it is responsible for either coding the original bill as a transfer or submitting an adjustment bill (63 Fed. Reg. 40976, 40979, 40980 (July 31, 1998)).

For 29 of the 240 inpatient claims, the Hospital incorrectly billed Medicare for patient discharges that should have been billed as transfers to home health services. For example, the Hospital coded a discharge status as to “home” instead of to “home health.”

For 24 of the 29 inpatient claims, the Hospital incorrectly billed Medicare for patient discharges that should have been billed as transfers to home health services, and the services were related to the hospital stay. The Hospital received the full DRG payments instead of the graduated per diem payments that it would have received if it had correctly coded the patients’ discharge statuses.

For 5 of the 29 inpatient claims, the Hospital incorrectly billed Medicare for patient discharges that should have been billed as transfers to home health services, but the home health services

were not related to the hospital stays.² For these five claims, the Hospital could have applied condition code 42 and still have received the full DRG Payment. There are no overpayments due to the incorrectly billed patient discharge status codes for these five claims.

The Hospital did not agree that all 29 claims had errors. Hospital representatives acknowledged that human error caused some billing errors and that billing professionals sometimes completed bills without having all discharging information at their disposal. However, the representatives stated that a claim should only be considered a related transfer if the same hospital physician who discharged the patient also performed the qualifying face-to-face evaluation for the home health services. For example, if one hospital physician ordered the home health services and a different physician discharged the patient, the Hospital did not consider that to be a related transfer. Hospital representatives also disagreed that some of the home health services were related to the inpatient stay. For example, if a patient was already receiving home health services for chronic heart failure, was admitted to the Hospital for an acute exacerbation of the heart failure, then discharged with orders to continue home health services for heart failure, the Hospital did not consider that to be a related transfer. However, Medicare guidance does not make a distinction between new home health services and the continuation of services with regards to relatedness.

As a result of these errors, the Hospital received overpayments of \$98,781.

Incorrectly Billed as a Separate Inpatient Stay

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

For 8 of the 240 inpatient claims, the Hospital incorrectly billed same-day readmissions that should have been combined with the initial hospital stays. For each of these eight instances, the readmission was related to the prior stay's medical condition and should have been billed as one continuous stay. For example, two of these eight claims involved patients leaving against medical advice then returning the same day to continue treatment. Hospital representatives did not agree with all eight errors. However, they acknowledged that because the two acute care facilities, Carolinas Medical Center and Carolinas Medical Center—Mercy, operated under the same license, coordinating billing compliance for same-day readmissions can prove difficult. Also, four of these eight claims involved patients initially admitted to a substance abuse detoxification unit under 42 CFR part 2. The Hospital's billing professionals were not aware that treatments at the detox unit were part of the inpatient admissions. The

² One of the 30 claims in the "Inpatient Claims With Unreported Discharges to Home Health Services" stratum did not have an inpatient order. We did not assess the relatedness of any home health services for this claim.

Hospital treats substance abuse detoxification unit records differently because of different confidentiality standards under 42 CFR part 2.³ Also, Hospital representatives stated that they did not combine some claims because of their interpretation of an article by their Medicare contractor.

As a result of these errors, the Hospital received overpayments of \$81,129.⁴

Incorrectly Billed as Inpatient

Medicare payments may not be made for inpatient services unless “a physician certifies that such services are required to be given on an inpatient basis for such individual’s medical treatment . . .” (the Act, § 1814(a)(3)).

For 1 of the 240 inpatient claims, the Hospital incorrectly billed Medicare Part A for a beneficiary stay that did not have an inpatient order. Hospital representatives stated that this error was due to a bill processing error. The Hospital had internally identified that this claim should not have been billed as inpatient but did not follow its standard processes when trying to rebill the claim as outpatient.

As a result of this error, the Hospital received an overpayment of \$7,742.⁵

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$1,659,619 for the audit period.

RECOMMENDATIONS

We recommend that the Hospital:

- refund to the Medicare program \$1,659,619 in estimated overpayments for the audit period for claims that it incorrectly billed;

³ 42 CFR part 2 applies to an identified unit within a general medical facility that holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment. The regulation provides restrictions on disclosure that “would identify a patient as an alcohol or drug abuser”

⁴ This net overpayment includes the full payment for the eight subsequent claims and any changes to adjust the payment for the initial eight claims after combining the two.

⁵ The Hospital may be able to bill Medicare Part B for these outpatient services that were incorrectly billed as 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.

- exercise reasonable diligence to identify and return any additional similar overpayments received outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; and
- strengthen controls to ensure full compliance with Medicare requirements.

CAROLINAS MEDICAL CENTER COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Hospital disagreed with our findings on certain claims, and contended that the extrapolation of our results was invalid. The Hospital stated that, in accordance with the 60-day rule, it had identified and is refunding for one finding similar overpayments for claims outside of our audit period. However, it did not address whether it planned to do this for other claims it billed incorrectly, other than stating it had reached out to CMS on one disputed finding. Also, the Hospital stated that it had a strong compliance program and has developed comprehensive policies, procedures, education, auditing, and other initiatives to improve its programs and acknowledged the importance of continuing improvements in compliance efforts.

After reviewing the Hospital's comments, we maintain that our findings and recommendations are valid. We used an independent medical reviewer to determine whether certain sampled claims were appropriately billed. Additionally, we used statistically valid sampling methodology in our sample selection and in determining the estimated Medicare overpayment.

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

STATISTICAL SAMPLING AND EXTRAPOLATION

Hospital Comments

The Hospital alleged that we unknowingly drew the sample from a sample frame that included claims from two hospitals (that bill under the same provider number). The Hospital cited differences in the two locations and argued that, because our statistician did not initially consider these specific facts when approving our plan, our plan was not approved in accordance with CMS program standards and our extrapolation was invalid. The Hospital also objected to other aspects of our sampling methodology, such as excluding claims from our sampling frame that we identified as not likely having errors. In addition, the Hospital contended that our estimates were so imprecise that due process standards were not satisfied. Finally, the Hospital stated that, because there was only one claim without an inpatient order, this claim should not have been included in the extrapolation.

Office of Inspector General Response

We disagree with the Hospital's contention that the sample design process was flawed and that the extrapolation was not valid. We are aware that multiple locations can bill under one provider number and consider that possibility when designing and approving sample plans. Our methodology was appropriate for two acute care facilities with different patient populations. Our objective was to determine whether the Hospital complied with Medicare requirements for billing inpatient services on selected types of claims. Because the Hospital consisted of two acute care facilities that billed under the same provider number and were subject to the same criteria, our audit was consistent with our audit objective, and it was appropriate to include in our sample frame the claims paid during the audit period for both facilities. Before the entrance conference, we notified Hospital officials of our intent to treat all locations that bill under the same provider number as being part of a single entity.

The legal standard for use of sampling and extrapolation requires that it be based on a statistically valid methodology.⁶ We properly executed our statistical sampling methodology by defining our sampling frame and sampling unit, randomly selecting our sample, applying relevant criteria in evaluating the sample, and using statistical software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. We also appropriately used computer matching, data mining, and analysis techniques to identify claims potentially at risk for noncompliance to include in our sample frame and excluded other claims we considered low risk. We only reviewed claims included in our sample. Our overpayment estimate is unbiased and does not extend beyond the claims included in our sampling frame.

By recommending recovery at the lower limit of a 90-percent confidence interval, we accounted for any differences between the two facilities in a manner that generally favors the provider.⁷ In fact, our approach results in an estimate that is lower than the actual overpayment amount 95 percent of the time.

The use of statistical sampling and extrapolation to determine overpayment amounts in Medicare does not violate due process because the auditee is given the opportunity to appeal the audit results through the Medicare appeals process.⁸

⁶ See *John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052, at *34, 38 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 2016 U.S. Dist. LEXIS 6816 at *31-33, 37-39 (W.D. Tex. 2016); *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).

⁷ See *Pruchniewski v. Leavitt*, 2006 U.S. Dist. LEXIS 10218 at *51-52 (M.D. Fla. 2006); *Puerto Rico Dep't of Health*, DAB No. 2385, (2011); *Oklahoma Dep't of Human Servs.*, DAB No. 1436, (1993) (stating that the calculation of the disallowance using the lower limit of the confidence interval gave the State the "benefit of any doubt" raised by use of a smaller sample size).

⁸ See *Transyd Enter., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *34 (S.D. Tex. 2012).

INCORRECTLY BILLED CLAIMS

Hospital Comments

In response to our recommendation to refund to the Medicare program \$1,659,619 in estimated overpayments, Hospital officials disagreed with several specific findings in the report and requested that the proposed recommendations not be finalized. Hospital officials intend to appeal certain claims where we found incorrect coding determinations. Also, Hospital officials intend to appeal certain claim determinations where we found same-day readmissions should have been combined with the initial hospital stays.

Finally, Hospital officials disagreed with some of the determinations related to incorrect patient discharge status codes and also intends to appeal these claims. Hospital officials have also requested further guidance from CMS on this issue and on whether the Hospital should modify its processes. The Hospital alleged that we directed our medical reviewers to apply a much broader standard than the law requires and that we created and applied a new, unpublished standard that contradicts the law and CMS's guidance. Specifically, the Hospital stated that the transfer rule cannot apply unless a beneficiary's inpatient physician orders home health services. Further, when a beneficiary has home health services that pre-exist a PPS-admission and continue after discharge, the transfer rule cannot apply unless the post-hospital services include "new interventions." Hospital officials also stated that we could not satisfactorily explain the standards we used to evaluate the claims and that we mischaracterized the postacute care transfer rule and their understanding of the postacute care transfer rule in the report.

Office of Inspector General Response

We acknowledge that the Hospital disagrees with and plans to appeal many of our findings. As we indicated in Appendix A, during our audit we used an independent medical review contractor to determine whether certain claims in our sample were properly coded. The contractor examined all of the medical records documentation submitted for these claims, including home health records when applicable, and determined that the Hospital incorrectly billed Medicare Part A for these claims. On the basis of the contractor's conclusions, we maintain that the Hospital billed the disputed claims incorrectly. We provided our contractor's conclusions and rationales to the Hospital.

Specifically, regarding the disputed claims with incorrect patient discharge status codes, we neither directed our contractors to use a broader standard than the law required nor created or used any new, unpublished rule. Section 1886(d)(5)(J)(ii)(III) of the Social Security Act states that the postacute care transfer rule applies when a Medicare beneficiary in a PPS hospital stay is assigned to one of the CMS-designated DRGs and is "provided home health services from a home health agency, if such services relate to the condition or diagnosis for which such individual received inpatient hospital services from the . . . hospital, and if such services are provided within an appropriate period (as determined by the Secretary)." Federal regulations

(42 CFR § 412.4(c)(3)) implementing this statutory provision state that the policy applies when a patient's discharge is assigned one of the qualifying DRGs and the discharge is made "[t]o home under a written plan of care for the provision of home health services from a home health agency and those services begin within 3 days after the date of discharge." The Health Care Financing Administration (HCFA), predecessor to CMS, further addresses the definition of relatedness in the preamble to the final rule implementing the policy (42 CFR § 412.4(c)(3)). 63 Fed. Reg. 40954, 40976 (July 31, 1998). In essence, relatedness is presumed and the postacute care transfer rule applies when a beneficiary is discharged home under a written plan of care for home health services and those services begin within 3 days after discharge, but a hospital can rebut the presumption in specific cases by using Condition Code 42 when the home health services are not related to the condition or diagnosis for which the beneficiary received inpatient hospital services (MLN Matters Number SE0801 (Rev. Sept. 14, 2010), pp. 9 and 11; MLN Matters Number SE1411, pp. 3-4).

Insofar as the Hospital is asserting that a physician who treated the beneficiary during his or her inpatient stay needed to have ordered a specific home health intervention, HCFA rejected such an argument back in 1998. Specifically, the preamble to the final rule contains the following Comment and Response (63 Fed. Reg. at 40980):

Comment: One commenter stated that we should specify that the written plan of care for home health services should be defined clearly as "a specific order by the patient's physician in the hospital medical record that directs the hospital to arrange for home health services upon discharge."

Response: We do not believe that it is necessary to specify the precise definition of what a written plan of care for health services must entail. We note that we would deem a case to be a transfer if care related to the discharge was provided within 3 days after the date of discharge even if the hospital had no written plan of care.

Insofar as the Hospital is asserting that when a beneficiary has home health services that pre-exist a PPS-admission and continue after discharge, the transfer rule cannot apply unless the post-hospital services include "new interventions," there is no such requirement. Rather, it is a matter of medical judgment whether the post-hospital home health services are related to the hospitalization which should be documented in the Hospital's medical record⁹ (63 Fed. Reg. at 40979).

We provided our contractors with the criteria referenced in the body of the report and asked them to assess the claims based on that criteria. Regarding the alleged mischaracterization of

⁹ As stated in the body of the report, we found 29 claims that should have been coded as discharges to home health care. Nevertheless, our medical reviewers reviewed hospital and home health medical records and determined relatedness in each case, finding that 5 should have been coded with Condition Code 42 to rebut the initial presumption of relatedness.

the postacute care transfer rule and the Hospital's position on the postacute care transfer rule, we maintain that we have accurately described the postacute care transfer rule and accurately presented examples of the Hospital's objections to our findings during the course of this audit.

OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to HHS action officials. Action officials at CMS, acting through a MAC or other contractor, will determine whether a potential overpayment exists and will recoup any overpayments consistent with its policies and procedures. If a disallowance is taken, providers have the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). The Medicare Part A/B appeals process has five levels, including a contractor redetermination, a reconsideration by a Qualified Independent Contractor, and a hearing before an Administrative Law Judge. If a provider exercises its right to an appeal, it does not need to return funds paid by Medicare until after the second level of appeal. An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

60-DAY RULE

Hospital Comments

For disputed claims involving incorrect patient discharge status codes, the Hospital said that it had contacted CMS to receive the necessary guidance to determine whether they should conduct additional reviews. For claims involving the substance abuse detoxification clinic, the Hospital stated that it has identified and is refunding \$48,513 for additional, related claims outside of our audit period in accordance with the 60-day rule. The Hospital did not address what steps it planned to take for other claims it billed incorrectly.

Office of Inspector General Response

We acknowledge the Hospital's efforts related to claims involving the substance abuse detoxification clinic. We continue to recommend that the Hospital exercise reasonable diligence to identify and return any additional overpayments similar to those we identified that it received outside of our audit period, in accordance with the 60-day rule, and to identify any returned overpayments as having been made in accordance with this recommendation.

STRENGTHEN CONTROLS

Hospital Comments

The Hospital stated that it has a strong compliance program and has developed comprehensive policies, procedures, education, auditing, and other initiatives to improve its programs and acknowledged the importance of continuing improvements in compliance efforts.

Specifically, the Hospital said that it had:

- increased measures to improve coding accuracy since the time of our audit period,
- modified its practices to ensure that the billing department has information needed to correctly code same-day readmissions for individuals receiving substance abuse treatments, and
- re-educated staff to ensure appropriate billing and coding for patients who leave the Hospital against medical advice.

Office of Inspector General Response

We acknowledge the Hospital’s ongoing and planned efforts to strengthen its compliance with Medicare requirements.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$31,093,729 in Medicare payments to the Hospital for 3,088 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 240 claims with payments totaling \$3,066,432. Medicare paid these 240 inpatient claims from January 1, 2014, through December 31, 2015 (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 153 claims to coding review to determine whether the Hospital properly coded the services.

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

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

Our fieldwork included contacting the Hospital in Charlotte, North Carolina, from July 2016 through August 2017.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Hospital's inpatient paid claims data from CMS's NCH file for the audit period;
- used computer matching, data mining, and analysis techniques to identify claims potentially at risk for noncompliance with selected Medicare billing requirements;
- selected a stratified random sample of 240 inpatient claims totaling \$3,066,432 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;

- reviewed the itemized bills and medical record documentation provided by the Hospital to support the sampled claims;
- requested that the Hospital conduct its own review of the sampled claims to determine whether the services were billed correctly;
- reviewed the Hospital's procedures for assigning DRG and admission status codes for Medicare claims;
- used an independent medical review contractor to determine whether 153 claims met 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 review to calculate the estimated Medicare overpayment to the Hospital (Appendix C); and
- discussed the results of our review with Hospital officials.

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

APPENDIX B: SAMPLE DESIGN AND METHODOLOGY

TARGET POPULATION

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

SAMPLING FRAME

According to CMS's NCH data, Medicare paid the Hospital \$369,071,646 for 27,154 inpatient claims during the audit period.

We obtained a database of claims from the NCH data totaling \$267,844,757 for 17,991 inpatient claims in 14 risk areas. From these 14 areas, we selected 4 consisting of 5,069 claims totaling \$59,044,871 for further review. We then removed the following:

- claims billed with high-severity-level DRG codes with payment amounts less than \$3,000,
- claims under review by the Recovery Audit Contractor (RAC), and
- claims duplicated within individual risk categories.¹⁰

We assigned each claim that appeared in multiple risk areas to just one area on the basis of the following hierarchy: Inpatient Claims With Same-Day Discharges and Readmissions, Inpatient Claims With Unreported Discharges to Home Health Services, Inpatient Claims Paid in Excess of Charges, and Inpatient Claims Billed With High-Severity-Level DRG Codes. This assignment hierarchy resulted in a sample frame of 3,088 unique Medicare claims in 4 risk categories totaling \$31,093,729. We further separated Claims Billed With High-Severity-Level DRG Codes into three categories based on the amount paid.¹¹ (See Table 1.)

Table 1: Risk Categories

Medicare Risk Area	Number of Claims	Amount of Payments
1. Inpatient Claims With Same-Day Discharges and Readmissions	10	\$100,122

¹⁰ Any claims that were found to be under RAC review within the sample after it was pulled were treated as non-errors. This approach ensured that our estimates accurately accounted for these types of claims.

¹¹ Paid claims less than \$8,798 are in Stratum 4. Paid claims \$8,798 or greater and less than \$17,225 are in Stratum 5. Paid claims \$17,225 or greater are in Stratum 6.

Medicare Risk Area	Number of Claims	Amount of Payments
2. Inpatient Claims With Unreported Discharges to Home Health Services	91	1,304,171
3. Inpatient Claims Paid in Excess of Charges	274	3,208,160
4. Inpatient Claims Billed With High-Severity-Level DRG Codes—Low Dollar	1,803	12,437,062
5. Inpatient Claims Billed With High-Severity-Level DRG Codes—Medium Dollar	673	7,927,796
6. Inpatient Claims Billed With High-Severity-Level DRG Codes—High Dollar	237	6,116,418
Total	3,088	\$31,093,729

SAMPLE UNIT

The sample unit was a Medicare paid claim.

SAMPLE DESIGN

We used a stratified random sample. We stratified the sampling frame into six strata on the basis of the Medicare risk area and amount paid. All claims were unduplicated, appearing in only one area and only once in the entire sampling frame.

SAMPLE SIZE

We selected 240 claims for review as follows in Table 2:

Table 2: Claims by Stratum

Stratum	Medicare Risk Area	Claims in Sample Frame	Claims in Sample
1	Inpatient Claims With Same-Day Discharges and Readmissions	10	10
2	Inpatient Claims With Unreported Discharges to Home Health Services	91	30
3	Inpatient Claims Paid in Excess of Charges	274	30
4	Inpatient Claims Billed With High-Severity-Level DRG Codes—Low Dollar	1,803	80
5	Inpatient Claims Billed With High-Severity-Level DRG Codes—Medium Dollar	673	50
6	Inpatient Claims Billed With High-Severity-Level DRG Codes—High Dollar	237	40
	TOTAL	3,088	240

SOURCE OF 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 UNITS

We consecutively numbered the claims within each stratum two through six. After generating the random numbers, we selected the corresponding claims in each stratum. We selected all claims in stratum one.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to calculate our estimates. We used the lower-limit of the 90-percent confidence interval to estimate the amount of improper Medicare payments in our sampling frame during the audit period.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 3: Sample Results

Stratum	Frame Size (Claims)	Value of Frame	Sample Size	Total Value of Sample	Number of Incorrectly Billed Claims in Sample	Value of Overpayments in Sample
1	10	\$100,122	10	\$144,130	8	\$81,129
2	91	1,304,171	30	383,316	27	113,278
3	274	3,208,160	30	295,315	9	30,565
4	1,803	12,437,062	80	551,696	15	25,333
5	673	7,927,796	50	618,149	11	48,961
6	237	6,116,418	40	1,073,826	10	32,565
Total	3,088	\$31,093,729	240	\$3,066,432	80	\$331,831

ESTIMATES

Table 4: Estimates of Overpayments for the Audit Period
Limits Calculated for a 90-Percent Confidence Interval

Point Estimate	\$2,126,816
Lower limit	\$1,659,619
Upper limit	\$2,594,013

Notice: The table above illustrates the results of our review by risk area. In it, we have organized inpatient claims by the risk areas we reviewed. However, we have organized this report's findings by the types of billing errors we found at the Hospital. Because we have organized the information differently, the information in the individual risk areas in this table does not match precisely with this report's findings. The three claims with billing errors that did not affect the payment are not included in this table.

APPENDIX D: RESULTS OF REVIEW BY RISK AREA

Table 5: Sample Results by Risk Area

Inpatient Risk Area	Selected Claims	Value of Selected Claims	Claims With Underpayments/Overpayments	Value of Net Overpayments
Claims With Same-Day Discharges and Readmissions	10	\$144,130	8	\$81,129
Claims With Unreported Discharges to Home Health Services	30	383,316	27	113,278
Claims Paid in Excess of Charges	30	295,315	9	30,565
Claims Billed With High-Severity-Level DRG Codes—Low Dollar	80	551,696	15	25,333
Claims Billed With High-Severity-Level DRG Codes—Medium Dollar	50	618,149	11	48,961
Claims Billed With High-Severity-Level DRG Codes—High Dollar	40	1,073,826	10	32,565
Inpatient Totals	240	\$3,066,432	80	\$331,831

Notice: The table above illustrates the results of our review by risk area. In it, we have organized inpatient claims by the risk areas we reviewed. However, we have organized this report’s findings by the types of billing errors we found at the Hospital. Because we have organized the information differently, the information in the individual risk areas in this table does not match precisely with this report’s findings. The three claims with billing errors that did not affect the payment are not included in this table.



Carolinus HealthCare System

Edward J. Brown III
Chairman

Eugene A. Woods, FACHE
President and CEO

October 27, 2017

VIA ELECTRONIC MAIL (Lori.Pilcher@oig.hhs.gov)
AND USPS

Lori S. Pilcher
Regional Inspector General for Audit Services
Department of Health & Human Services, Region IV
61 Forsyth Street, S.W.
Suite 3T41
Atlanta, Georgia 30303

Re: Draft Report: Medicare Compliance Review of Carolinas Medical Center
OIG Report Number A-04-16-04049

Dear Ms. Pilcher:

Thank you for the opportunity to review the U.S. Department of Health and Human Services, Office of Inspector General (the "OIG") draft report entitled *Medicare Compliance Review of Carolinas Medical Center for Claims Paid From January 1, 2014, Through December 31, 2015* (the "Draft Report"). As requested, we are submitting responses to the proposed findings, including reasons for concurrence or nonconcurrence with each recommendation.

Carolinus Medical Center ("CMC Hospital") is part of the Carolinas Healthcare System ("CHS") and has a strong compliance program. Senior leadership supports our efforts to ensure accurate billing and coding for all claims filed. With management support, the CHS compliance team has developed comprehensive policies, procedures, education, auditing and other initiatives to continuously improve our programs. In the event we identify any areas of concern, our compliance staff focuses any needed resources to investigate problems and appropriately

remediate issues in a timely manner. Indeed, at the outset of our audit, the OIG confirmed that our compliance program is effective. Specifically, the OIG auditors stated that in constructing the strata for their pre-determined extrapolation, they excluded claims in the category of devices replaced under warranty/credit because they had reviewed CMC Hospital's data and not identified errors in any of our claims.¹

Despite acknowledging the strength in our compliance efforts, the OIG proceeded with its audit, constructing several different claims "strata" and applying its extrapolation "rule" to recommend that CMC Hospital refund the Medicare program \$1.7 million in estimated overpayments for the audit period. At its core, the recommendation is based on a unilateral determination that sampled claims were improperly paid. Astonishingly, for some of those denials, it appears that reviewers arbitrarily applied the law and could not articulate the standards used to disallow reimbursement. In addition, despite fundamental errors in design (including failure to inform the statistician who "approved" the method about what he or she was reviewing), the OIG applied a rote formula to calculate an extrapolated demand in violation of due process.

In a broadly worded recommendation, the OIG stated that CMC Hospital should "exercise reasonable diligence to identify and return any additional similar overpayments received outside of our audit period, in accordance with the 60-day repayment rule, identifying any repayment as having been made in accordance with the OIG recommendation." Finally, the OIG recommended that CMC Hospital strengthen its Medicare program controls, "to ensure full compliance with Medicare requirements."

Although we acknowledge the importance of continuing improvements in compliance efforts, we disagree with the OIG's findings and request that the proposed recommendations not be finalized. Before addressing the individual findings, this letter describes the two distinct hospitals that were sampled and explains why the "one-size-fits-all" extrapolation method recommended is invalid. In addition, we highlight particular concerns related to the OIG's recommended downcodes for certain claims. For these denials, auditors could not explain the bases

¹Such pre-review and determination not to audit a particular risk area after examining our 100% accuracy appears inconsistent with conducting a valid "random" sample to characterize a provider's compliance with Medicare billing standards, as purportedly was done here. Rather, it appears that the removal of this category after a determination that there were no errors results in a clear bias that voids the extrapolation.

for their downcodes and, in fact, suggested methods that contradict CMS' standards. Finally, we respond to the OIG auditors' individual findings.

I. The OIG's Design Is Invalid, Unapproved, And In Violation of Recognized Statistical Methods And CMS' Standards

Importantly, prior to meeting with CMC Hospital's leadership at the start of the claims review process for this audit, the OIG had already met with a statistician who "approved" a sampling plan to review 240 Medicare inpatient claims paid between January 1, 2014 through December 31, 2015 at one hospital -- the Carolinas Medical Center. Even after we informed the auditors that they had erroneously identified claims from two very different hospitals, the OIG refused to modify its process or even consider the importance of knowing what its review was sampling.² Contrary to the description in its sampling plan, this audit actually involves a random sample of claims paid to two hospitals: "CMC Hospital" and "CMC CMC Mercy" Hospital (collectively, the "Providers" or the "Hospitals").

Because the differences between the Hospitals are significant, a rote sampling method without appropriate weighting or correction for the clear bias here is invalid. CMC Hospital is a level one trauma center with 874 beds, with typically higher acuity patients and greater lengths of stay than other hospitals. It serves as a regional referral center for the sickest of patients and is an approved transplant center for heart, kidney, pancreas and liver. CMC Hospital also includes a cancer institute, a rehabilitation center as well as a children's hospital. In contrast, CMC Mercy is an acute care hospital located over one mile from CMC Hospital, and specializes in the care of seniors, complex foot and ankle surgery, bariatric surgery, and women's pelvic health. In addition, CMC Mercy has a substance abuse and detoxification services unit. Clearly, these differences in patient populations and treatments impact reimbursement for billed claims that were sampled from each provider.

The OIG made no adjustments to account for the differences in acuity and payment, nor applied appropriate weighting to ensure accuracy in its projections. Rather, the OIG used its pre-

² Although the Draft Report states that the examined "Hospital" is, in fact, two different acute care facilities, OIG failed to recognize the important differences in the types of claims (and reimbursement) in designing its sampling methods and getting approval from a qualified statistician, all of which the OIG did before learning of its mistake.

determined rote formula as a "rule" to calculate an alleged overpayment. The OIG's extrapolation method here is improper. Indeed, the unreliability of the OIG methods is evident in the objective calculations in the Draft Report. For example, for Stratum 6, the reported kurtosis of the data is very high, suggesting a skewed calculation to overstate a purported "overpayment." This outcome is not surprising, given that the differences in patient acuity, lengths of stay, and other factors influencing how a sample should be designed were never factored into the sample design.

The significant bias against the Hospitals is likely due to the fact that the statistician asked to "approve" the OIG methods was not informed about the population of claims being sampled from two different hospitals. Thus, the methods used by the OIG were not actually "approved" by a statistician in violation of CMS Program standards. Moreover, the resulting projected overpayment is invalid and should not be finalized.

2. **The OIG Auditors Arbitrarily Denied Claims, In Violation Of The Law And CMS Standards.**

The Hospitals dispute several of the findings in individual claims that result in alleged overpayments. Many of the purported "overpayments" are the direct result of the OIG's application of a new, unpublished rule governing the discharge of patients who resume home health services. Applying its new, unpublished standard that contradicts the law and CMS' guidance, the OIG denied payments even where there was no indication of a "transfer" of care to the home health setting. We strongly object to the OIG's creation of this new rule that contradicts CMS' longstanding policy under the Post-Acute Transfer rule (the "Transfer Rule").

Specifically, the OIG created one strata to review coding for patients who were discharged from the hospital and ultimately received home health care. In performing this analysis, the OIG auditors explained that if home health care was "related to" the reason for hospital admission, claims associated with such patients' hospitalization would be down-coded under the Transfer Rule. In its Draft Report, the OIG states:

For example, if a patient was already receiving home health services for chronic heart failure, was admitted to the Hospital for an acute exacerbation of the heart failure, the Hospital did not consider [discharge home to resume home health services] to be a related transfer. **However, Medicare guidance does not make a distinction between new home health services and the continuation of services with regard to relatedness.**

(Draft Report, p. 5) (emphasis added). This is a mischaracterization of both the Transfer Rule and our position, as we discussed at the exit conference.

Based on CMS guidance and longstanding practice, we understand that claims are subject to the Transfer Rule when an inpatient whose claim is coded under certain MS-DRGs is discharged from a hospital **and there is a transfer of care to the home health outpatient setting**. This is consistent with CMS' explanation in issuing the final Transfer Rule:

[H]ome health services would be considered related to the hospital discharge **if the patient is discharged from the hospital with a written plan of care for the provision of home health care services from a home health agency**.

(63 Fed. Reg. 40954, 40976 (July 31, 1998) (emphasis added)). Importantly, in response to comments regarding this Rule when it was first implemented, CMS specifically rejected a suggestion that *any* home care beginning within 3 days of a hospital discharge constitutes a "transfer." (*Id.*). **Instead, only those discharges that are actual transfers of acute care treatments to the HHA are subject to the Rule. There can be no "transfer" of care if the inpatient physician does not order a specific home health intervention.** (See CMS Provider Inquiry Assistance, Related MedLearn Article # SE 801).

At the exit conference, we asked the OIG to explain how it determined that the Transfer Rule was triggered to downcode claims reviewed in this audit. We emphasized our understanding that if a discharging physician orders home healthcare placement with new treatments to be carried out in that setting, the discharge could be considered a "transfer" of care under the rule. Conversely, if a patient has a chronic condition for which she receives home health care and she requires admission for an acute crisis, then returns to have the services in the home health setting *without new interventions (or a transfer of care)*, no downcode is appropriate.

In response, the OIG auditors stated that they directed medical reviewers to apply the Transfer Rule in any circumstance in which home health care was "related" to the cause of admission, *a much broader standard than what the law requires*. We probed the OIG regarding how such a broad standard applied to patients with chronic conditions and longstanding home health care services. The OIG auditors, however could not provide a clear answer. Because we

believe the auditors applied the wrong standards to arbitrarily downcode claims, the recommended denials should not be finalized.³

3. The Hospitals' Specific Responses To The Findings In The Draft Report

For the remainder of our response, we refer to the findings regarding claims for each of the Hospitals individually, as appropriate.

a. Billing Errors Associated With Inpatient Claims

i. OIG Finding: Incorrectly Billed Diagnosis-Related-Group Codes

For CMC Hospital, the OIG asserted that 31 claims were coded inaccurately, so the payment for care delivered should be reduced. For CMC Mercy, auditors identified 15 claims as being miscoded for higher payments than were supported. In total, the OIG alleges that the Hospitals were overpaid a net of \$144,179.

We respectfully disagree with the findings in the sampled claims and plan to appeal adverse determinations. Although we plan to challenge certain denials, we recognize that human error can lead to isolated mistakes in DRG coding. As noted in the Draft Report, since the time of the audit period, we have adopted additional measures, including additional education and focus to improve our coding accuracy in all aspects of our operations.

ii. OIG Finding: Incorrectly Billed Discharge Status Codes

The OIG asserts that for 29 of the 240 inpatient claims reviewed in its sample, CMC Hospital incorrectly billed the patient's discharge disposition. Of that total, the OIG asserted that for CMC Hospital, 21 discharges should have been billed as "transfers" for care "related" to the patient's inpatient admission, with a resulting reduction in reimbursement. For CMC Mercy, the OIG claims that 3 should have been coded as transfers related to the patient's admission, identifying an overpayment for each claim.

³ We appreciate the auditors' discussions at the exit conference; however, when it became clear that we had different understandings of the standards to be applied, we requested an opportunity to discuss the issues with CMS. We have contacted CMS to receive the necessary guidance in order to determine whether we should modify our processes or conduct additional reviews or disclosures as suggested in the Draft Report.

In some instances, the Hospitals acknowledge that there could have been an error in designating discharge locations for some sampled claims; however, as explained previously, we disagree with the OIG's findings related to the Transfer Rule and have contacted CMS for clarification. In addition, we intend to appeal denials made on this basis. Upon receipt of clarifying information, we will continue to review and refine our practices to support accurate billing.

iii. Incorrectly Billed as a Separate Inpatient Stay

In 8 out of 240 instances, the OIG asserts that the providers incorrectly billed for two separate acute care encounters when the admissions should have been combined.

In 4 instances, the Hospitals acknowledge that adhering to CMC's stringent policies to protect confidentiality of patient information for individuals receiving substance abuse treatments may have led to some mistaken billing. Specifically, in order to ensure the confidentiality of patient information for individuals treated in our substance abuse program, billing specialists may not have known that certain patients were being transferred to or from that particular unit. In other words, if a beneficiary was admitted for inpatient care for CMC Mercy's substance abuse program but was "discharged" to CMC Hospital for an acute medical crisis, billers may not have been made aware of an admission for substance abuse, given CMC's stringent policies to protect those patients' information. Unfortunately, in adopting privacy policies to satisfy federal law and protect these individuals, oversights within our billing department occurred.

Upon identifying the root cause of this processing error, we have reviewed accounts and claims that predate as well as those that were filed after the end of the audit period and identified 26 cases that were erroneously billed. Accordingly, we are in the process of refunding \$48,512.73 to Palmetto, our MAC, in accordance with the 60-day rule and recommendations in the Draft Report. To ensure ongoing compliance, we have modified our practices to ensure that the billing department has information needed to correctly code similar same-day readmissions.

With regard to the remaining instances in which the OIG asserts separate admissions should have been billed as one, we disagree with the audit findings. In several instances, based on clinical review of our physicians, a second admission was appropriate after patients were discharged. In other instances, we pointed out to the OIG auditors that we were following the posted guidance of

our MAC to code two separate admissions for patients who left against medical advice ("AMA"). Upon reviewing those published documents, the auditors contacted our MAC, resulting in the document's being modified to "correct" any confusion. Because correcting the published information confirms that the posted guidance was confusing, our reliance on that guidance was reasonable for the periods reviewed. We intend to appeal these denials.

We have re-educated staff with our MAC's corrected guidance to ensure appropriate billing and coding for patients who leave the Hospitals AMA.

iv. Incorrectly Billed as Inpatient

Of the entire sample of 240 inpatient claims, the OIG only identified one instance (at CMC Mercy) in which clinical records accurately documented an outpatient stay that was erroneously billed as an inpatient admission. The OIG asserts that this isolated finding should be included in its extrapolated demand, despite recognizing that the provider should be compensated under Part B for the medically necessary services provided, with the \$7,742 "overpayment" reduced.

Because this error occurred in only one instance of 240 cases reviewed (with an error "rate" far less than 1%), any revised overpayment amount related to this finding should not be included to extrapolate any refund demand. In the event it remains part of any extrapolated demand, we concur with the OIG that the alleged overpayment is inflated and needs to be revised.

b. The Extrapolation Method And Calculations Are Invalid

Although statistical sampling to extrapolate overpayments may be acceptable where universal review is not possible, samples must be valid to satisfy due process standards. (*See Chaves County Home Health Services Inc. v. Sullivan*, 931 F.2d 914 (D.C. Cir. 1991) *cert. denied*, 502 U.S. 1091 (1992)). That did not occur here.

A fundamental principle in such statistical sampling is that a qualified statistician must review and approve sampling methods prior to beginning a review. (PIM Ch. 8, Sec. 8.4.1.5). In this audit, the statistician "approved" a plan that failed to account for the fact that claims from multiple hospitals were being included. The OIG auditors decided the sample claims that would be reviewed, *without even knowing that they were pulling claims from two different hospitals*. Had

the auditors informed the supervising statistician about what they were, in fact reviewing, there could have been appropriate adjustments to the study design and calculations to account for bias. Instead, the OIG applied as a "rule" its determination that regardless of the outcome, any errors would be extrapolated using a rote formula, resulting in a biased (and inflated) overpayment estimate.

There are a host of additional reasons that the OIG's method is void, some of which we have alluded to previously. The objective data demonstrates the bias in the sampling methods used, resulting in estimates so imprecise that due process standards are not satisfied. Moreover, OIG's pre-assessment of one stratum and determination not to include its fully favorable outcome (a 0% error rate) evidences bias.

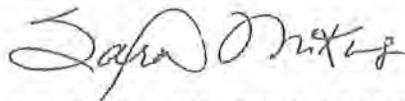
Ultimately, the extrapolation "rule" that OIG uses here is improper and should not be finalized.

4. **Conclusion**

We appreciate the opportunity to respond to the Draft Report and renew our request that the findings not be finalized. This audit was neither properly designed nor approved as required by government standards. Its results are biased. The sample and audit include review of an issue for which the OIG reviewers could not articulate the appropriate standard to be applied, leaving the Hospitals without any basis to conclude its coding erroneous for post-acute discharges.

We are committed to adopting appropriate measures to support compliance with Program requirements. We appreciate your consideration and trust that should you have any questions, you will contact us.

Sincerely,



Sara J. Mikus, RN, BSN, MPH, CHC
Senior Vice President, Chief Compliance Officer

cc: Mr. W. Spencer Lilly, President