

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE HOSPITAL PROVIDER  
COMPLIANCE AUDIT: CAROLINAS  
HOSPITAL**

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# ***Office of Inspector General***

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## Report in Brief

Date: November 2019

Report No. A-04-18-08063



### Why OIG Did This Audit

This audit is part of a series of hospital compliance audits. 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 2017, Medicare paid hospitals \$206 billion, which represents 55 percent of all fee-for-service payments for the year.

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

### How OIG Did This Audit

We selected for review a stratified random sample of 80 inpatient and 20 outpatient claims with payments totaling \$1.5 million for our 2-year audit period (January 1, 2016, through December 31, 2017).

We focused our audit on the risk areas that we identified as a result of prior OIG audits at other hospitals. We evaluated compliance with selected billing requirements.

## Medicare Hospital Provider Compliance Audit: Carolinas Hospital

### What OIG Found

Carolinas Hospital complied with Medicare billing requirements for 55 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 45 claims, resulting in overpayments of \$431,757 for the audit period. The 41 inpatient claims had billing errors, resulting in overpayments of \$431,431, and 4 outpatient claims had billing errors, resulting in overpayments of \$326.

Specifically, the Hospital incorrectly billed:

- 22 inpatient rehabilitation claims that did not meet coverage requirements,
- 15 inpatient Medicare Part A claims that should have been billed as outpatient or outpatient with observation,
- 4 inpatient claims and 1 outpatient claim that were incorrectly coded, and
- 3 outpatient claims that were subject to the consolidated billing requirements.

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$3.4 million for the audit period.

### What OIG Recommends and Carolinas Hospital Comments

We recommend that Carolinas Hospital refund to the Medicare contractor at least \$3.4 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 rule; and strengthen controls to ensure full compliance with Medicare requirements.

Carolinas Hospital disagreed that it incorrectly billed inpatient rehabilitation claims and beneficiary stays that should have been billed as outpatient. In addition, the Hospital disagreed with our use of extrapolation, our inclusion of inpatient claims spanning two or more midnights, and our recommendation that it refund the extrapolated overpayment and identify and return any additional similar overpayments received outside of the audit period.

We obtained independent medical review for all inpatient claims in our sample. We provided the independent medical reviewer with all documentation necessary to sufficiently determine medical necessity for all inpatient claims, and our report reflects the results of that review. Our statistical methods have been fully explained and repeatedly validated. Therefore, we maintain that all of our findings and recommendations are correct.

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## **INTRODUCTION**

### **WHY WE DID THIS AUDIT**

This audit is part of a series of hospital compliance audits. 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 2017, Medicare paid hospitals \$206 billion, which represents 55 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 Hospital (the Hospital) complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims from January 1, 2016, through December 31, 2017.

### **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 uses Medicare contractors to, among other things, process and pay claims submitted by hospitals.

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

Under the inpatient prospective payment system, CMS pays hospital costs at predetermined rates for patient discharges. The rates vary according to the diagnosis-related group (DRG) to which a beneficiary's stay is assigned and the severity level of the patient's diagnosis. The DRG payment is, with certain exceptions, intended to be payment in full to the hospital for all inpatient costs associated with the beneficiary's stay. In addition to the basic prospective payment, hospitals may be eligible for an additional payment, called an outlier payment, when the hospital's costs exceed certain thresholds.

#### **Hospital Inpatient Rehabilitation Facility Prospective Payment System**

Inpatient rehabilitation facilities (IRFs) provide rehabilitation for patients who require a hospital level of care, including a relatively intense rehabilitation program and an interdisciplinary, coordinated team approach to improve their ability to function. Section 1886(j) of the Social Security Act (the Act) established a Medicare prospective payment system for rehabilitation facilities. CMS implemented the payment system for cost-reporting periods beginning on or

after January 1, 2002. Under the payment system, CMS established a Federal prospective payment rate for each of the distinct case-mix groups (CMGs). The assignment to a CMG is based on the beneficiary's clinical characteristics and expected resource needs.

### **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.<sup>1</sup> All services and items within an APC group are comparable clinically and require comparable resources.

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

Previous Office of Inspector General (OIG) audits at other hospitals identified types of claims at risk for noncompliance. Out of the areas identified as being at risk, we focused our audit on the following:

- inpatient rehabilitation facility (IRF) claims,
- inpatient mechanical ventilation,
- inpatient same day discharge and readmit,
- inpatient high-severity level DRG codes,
- inpatient elective procedures,
- inpatient comprehensive error rate testing (CERT) DRG codes,
- outpatient bypass modifiers,
- outpatient skilled nursing facility (SNF) consolidated billing, and
- outpatient claims paid in excess of \$25,000.

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



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 audit.<sup>2</sup>

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

Medicare payments may not be made for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Act § 1862(a)(1)(A)). In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§§ 1815(a) and 1833(e)).

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

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

The OIG believes that this audit report constitutes credible information of potential overpayments. Providers who receive notification of these potential overpayments must (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify any overpayment amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (60-day rule).<sup>3</sup>

## **Carolinas Hospital**

The Hospital is part of Community Health Systems, Inc., and is a 396-bed acute care for profit hospital, located in Florence, SC. According to CMS’s National Claims History (NCH) data, Medicare paid the Hospital approximately \$96 million for 8,381 inpatient and 62,327 outpatient claims between January 1, 2016, and December 31, 2017 (audit period).

## **HOW WE CONDUCTED THIS AUDIT**

Our audit covered \$12,170,094 in Medicare payments to the Hospital for 1,054 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of

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<sup>2</sup> For purposes of selecting claims for medical review, CMS instructs its Medicare contractors to follow the “two-midnight presumption” in order not to focus their medical review efforts on stays spanning two or more midnights after formal inpatient admission in the absence of evidence of systemic gaming, abuse, or delays in the provision of care (*Medicare Program Integrity Manual*, ch. 6, § 6.5.2). We are not constrained by the two-midnight presumption in selecting claims for medical review.

<sup>3</sup> The Act § 1128J(d); 42 CFR part 401 subpart D; 42 CFR §§ 401.305(a)(2) and (f); and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016).

100 claims (80 inpatient and 20 outpatient) with payments totaling \$1,464,436. Medicare paid these 100 claims during our audit period.

We focused our audit on the risk areas identified because of prior OIG audits at other hospitals. We evaluated compliance with selected billing requirements and submitted all claims to an independent medical review contractor to determine whether the claim was supported by the medical record. 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**

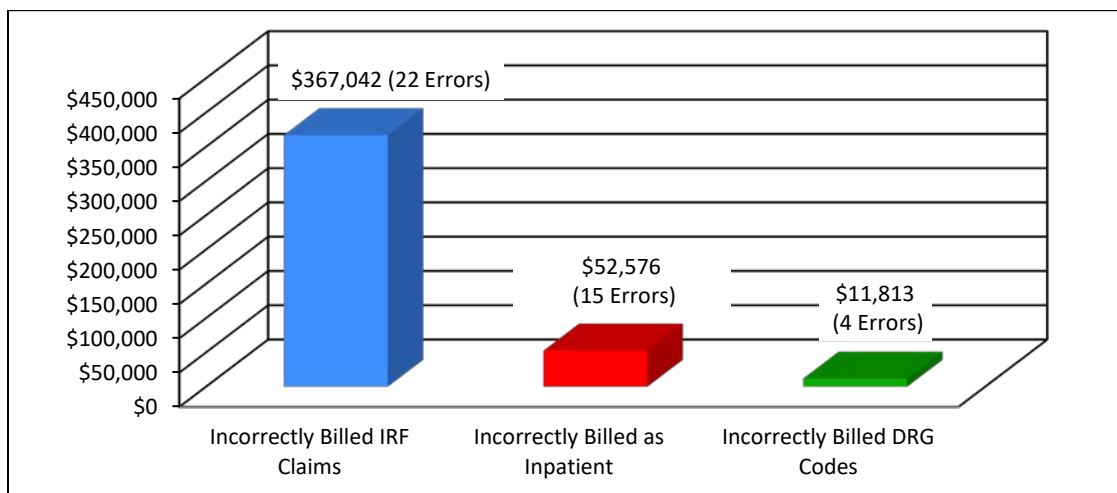
The Hospital complied with Medicare billing requirements for 55 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 45 claims, resulting in overpayments of \$431,757 for the audit period. Specifically, 41 inpatient claims had billing errors, resulting in overpayments of \$431,431, and 4 outpatient claims had billing errors, resulting in overpayments of \$326. 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 \$3,461,376 for the audit period. See Appendix B for statistical sampling methodology, Appendix C for sample results and estimates, and Appendix D for results of audit by risk area.

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

The Hospital incorrectly billed Medicare for 41 of the 80 inpatient claims that we reviewed. These errors resulted in overpayments of \$431,431, as shown in Figure 1.

**Figure 1: Inpatient Billing Errors**



### **Incorrectly Billed Inpatient Rehabilitation Facility Claims**

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

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

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

For an IRF claim to be considered reasonable and necessary, Federal regulations require that there be a reasonable expectation that, at the time of admission, the patient (1) requires the active and ongoing therapeutic intervention of multiple therapy disciplines; (2) generally requires and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program; (3) is sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation program; and (4) requires physician supervision by a rehabilitation physician (42 CFR § 412.622(a)(3)(i-iv)).

For 22 of the 80 selected inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for acute inpatient rehabilitation. IRF services for these beneficiaries were not considered reasonable and necessary because these beneficiaries did not require the active and ongoing therapeutic intervention of multiple therapy disciplines; generally did not require and could not reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program; were not sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation program; or did not require supervision by a rehabilitation physician. The Hospital did not provide a cause for these errors because officials contended that these claims met Medicare requirements.

As a result of these errors, the Hospital received overpayments of \$367,042.

### **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)). 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)).

A payment for services furnished to an individual may be made only to providers of services that are eligible and only if, “with respect to inpatient hospital services . . . , which are furnished over a period of time, a physician certifies that such services are required to be given on an inpatient basis for such individual’s medical treatment . . .” (the Act, § 1814(a)(3)). Federal regulations require an order for inpatient admission by a physician or other qualified provider at or before the time of the inpatient admission (42 CFR § 412.3(a)-(c)).

In addition, the regulations provide that an inpatient admission, and subsequent payment under Medicare Part A, is generally appropriate if the ordering physician expects the patient to require care for a period of time that crosses two midnights (42 CFR § 412.3(d)(1)). Furthermore, the *Medicare Benefit Policy Manual* states that physicians “should use the expectation of the patient to require hospital care that spans at least two midnights period as a benchmark, i.e., they should order admission for patients who are expected to require a hospital stay that crosses two midnights and the medical record supports that reasonable expectation” (Pub. No. 100-02, chapter 1 § 10). The *Medicare Benefit Policy Manual* further states that:

the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient’s medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital’s by-laws and admissions policies, and the relative appropriateness of treatment in each setting. Factors to be considered when making the decision to admit include such things as:

- The severity of the signs and symptoms exhibited by the patient;
- The medical predictability of something adverse happening to the patient;
- The need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and
- The availability of diagnostic procedures at the time when and at the location where the patient presents.

Admissions of particular patients are not covered or noncovered on the basis of the length of time the patient actually spends in the hospital (Pub. No. 100-02, chapter 1 § 10).

For 15 of the 80 selected inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for inpatient status and should have billed as outpatient or outpatient with observation. Because the medical records did not support the necessity for inpatient hospital services, the services should have been provided at a lower level of care. The Hospital did not provide a cause for these errors because officials contended that these claims met Medicare requirements.

As a result of these errors, the Hospital received overpayments of \$52,576.

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

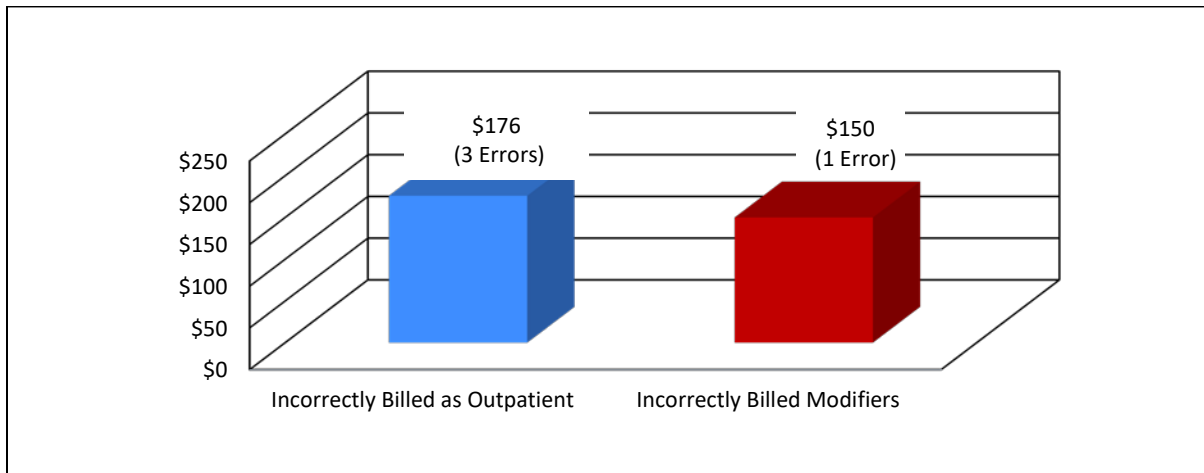
For 4 of the 80 selected inpatient claims, the Hospital submitted claims to Medicare that were incorrectly coded, resulting in incorrect DRG payments to the Hospital. Specifically, certain procedure or diagnosis codes were not supported by the medical records. Hospital officials stated that these errors occurred because of human error by a staff member who was subsequently terminated for failure to meet accuracy standards.

As a result of these errors, the Hospital received overpayments of \$11,813.

## BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 4 of the 20 outpatient claims that we reviewed. These errors resulted in overpayments of \$326, as shown in Figure 2.

**Figure 2: Outpatient Billing Errors**



### Incorrectly Billed as Outpatient

Under the consolidated billing provisions of sections 1862(a)(18) and 1842(b)(6)(E) of the Act, SNFs are responsible for billing Medicare for most services, including outpatient hospital services, provided to a SNF resident during a stay covered by Part A. Pursuant to Medicare regulations (42 CFR § 411.15(p)) and manual provisions implementing the SNF consolidated billing requirement,<sup>4</sup> outside suppliers, including outpatient hospitals, must bill according to the consolidated billing provisions for services furnished to SNF residents and must be paid by the SNF rather than by Medicare Part B.

For 3 of the 20 selected outpatient claims, the Hospital incorrectly billed Medicare Part B rather than the appropriate SNFs for services that were subject to the consolidated billing requirements. Hospital officials stated that these errors occurred because a reconciliation process was not in place between the lab and billing departments prior to the processing of patient bills, resulting in the Hospital billing for SNF covered services.

As a result of these errors, the Hospital received overpayments totaling \$176. For two of these claims, the Hospital refunded \$97 of the overpayments after the start of our review.

<sup>4</sup> The Manual, chapter 6, §§ 10 and 20.

## **Incorrectly Billed Modifiers**

The Manual, chapter 1, § 80.3.2.2, requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly.

“The ‘59’ modifier is used to indicate a distinct procedural service . . . . [T]his 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)” (the Manual, chapter 23, § 20.9.1.1(B)).

Effective January 1, 2015, CMS established four new HCPCS modifiers to define subsets of modifier 59. The four new HCPCS modifiers to selectively identify subsets of Distinct Procedural Services are: Modifier XE-Separate Encounter, Modifier XS-Separate Structure, Modifier XP-Separate Practitioner, and Modifier XU-Unusual Non-Overlapping Service. CMS will continue to recognize modifier 59, but providers should use one of the more descriptive modifiers when it is appropriate (Pub 100-20, “One Time Notification,” Transmittal 1422 Aug. 15, 2014).

For 1 of 20 selected outpatient claims, the Hospital incorrectly billed Medicare Part B for 2 HCPCS codes, both appended with an XE modifier, that were not separate from other services or procedures billed on the same claim. Hospital officials stated that the incorrect billing occurred because of human error.

As a result of this error, the Hospital received an overpayment of \$150.

## **OVERALL ESTIMATE OF OVERPAYMENTS**

The combined overpayments for the 45 sampled claims that did not fully comply with Medicare billing requirements totaled \$431,757. On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$3,461,376 for the audit period. During the course of our audit, the Hospital submitted two of these claims for reprocessing, and we verified those claims as correctly reprocessed. Accordingly, we have reduced the recommended refund by \$97.

## RECOMMENDATIONS

We recommend that Carolinas Hospital:

- refund to the Medicare contractor \$3,461,279 (\$3,461,376 less \$97 that the Hospital has already repaid) in estimated overpayments for the audit period for claims that it incorrectly billed;<sup>5</sup>
- 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
- strengthen controls to ensure full compliance with Medicare requirements so that:
  - all IRF beneficiaries meet Medicare criteria for acute inpatient rehabilitation;
  - all inpatient beneficiaries meet Medicare criteria for inpatient hospital services;
  - procedure and diagnosis codes are supported in the medical records and staff are properly trained;
  - procedures are in place to properly bill claims subject to SNF consolidated billing requirements; and
  - medical records accurately document distinct procedural services and staff are properly trained.

## OTHER MATTERS

Of the 80 inpatient claims in our sample, the Hospital incorrectly billed Medicare Part A for 9 beneficiary stays of less than two midnights (known as “inpatient short stays”), which it should have billed as outpatient or outpatient with observation. Because the medical records did not support the necessity for inpatient hospital services, the services should have been provided at a lower level of care. As a result of these errors, the Hospital received overpayments totaling \$66,587.

We did not review any of the claims in our sample because they were inpatient short stays; instead, we reviewed them because they fell into one of the high-risk categories discussed in the background section of this report. We voluntarily suspended reviews of inpatient short stay

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<sup>5</sup> 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 Medicare Administrative Contractor 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 Parts A and B appeals process has five levels, including a contractor redetermination, a reconsideration by a Qualified Independent Contractor, and a decision by the Office of Hearings and Appeals. 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.



claims after October 1, 2013. Therefore, we are not including the number and estimated dollar amount of these errors in our overall estimate of overpayments or in our repayment recommendation.

## **HOSPITAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

### **HOSPITAL COMMENTS**

In written comments on our draft report, the Hospital agreed with the errors identified for four incorrectly billed DRG codes and for all four incorrectly billed outpatient claims. However, the Hospital:

- disagreed that it incorrectly billed Medicare for 22 IRF claims that we identified as not meeting Medicare requirements for acute inpatient rehabilitation;
- stated that, for the IRF claims, we did not use a physician reviewer who was board certified in physical medicine and rehabilitation and that it was unclear whether our physician reviewer had the knowledge and experience necessary to reliably evaluate:
  - the clinical decision-making process,
  - the physician's decision to admit the patient, or
  - the appropriateness of the claims at issue;
- disagreed that it incorrectly billed Medicare for 15 inpatient claims that did not meet Medicare criteria for inpatient status and should have billed as outpatient or outpatient with observation;
- disagreed with our use of extrapolation; and
- disagreed with the inclusion of any findings related to inpatient short stays.

The Hospital stated that it intends to pursue appeals of the claims with which it disagrees and to evaluate any obligations under the 60-day rule once its Medicare administrative appeals have concluded.

For IRF claim denials, the Hospital stated that our draft report concluded that 22 IRF claims were billed incorrectly because our medical reviewer applied the wrong standard in determining whether Medicare medical necessity requirements were met, namely that a lower level of care was more appropriate. In addition, the Hospital stated that we appeared to justify the denial of certain claims, at least in part, because the patient's medical conditions were stable at the time of admission. The Hospital also stated that we appeared to deny other claims because the patient's primary diagnosis does not support the medical necessity of acute-level rehabilitation without considering the patient's other medical needs or co-morbid conditions that made the IRF admission appropriate. Furthermore, the Hospital stated that, for many claims, we determined that there was no reason to think that an intensive rehabilitation

therapy program would significantly impact the patient's condition compared to therapy provided at a less intense level, even though the discharge summary notes document improvement upon discharge. Finally, the Hospital stated that, based on its review of each account, all documentation supported the IRF admission as reasonable and necessary and met Medicare requirements for an IRF stay, as evidenced by the comprehensive pre-admission screens, the post admission physical evaluation, the individualized overall plan of care, and documentation of weekly team conferences with all required personnel.

For claims that were incorrectly billed as inpatient that spanned more than two midnights, the Hospital stated that our medical reviewer appeared to misunderstand the applicable Medicare standards by failing to frame his analysis in the context of the two-midnight rule and failing to address why the two-midnight "presumption" has been rebutted. In addition, the Hospital stated that we erred in calculating the estimated overpayments because we did not account for the reimbursement the Hospital would have been eligible to receive under Medicare Part B.

The Hospital objected to the inclusion in our report of claims that did not span more than two midnights because they were out of scope for the audit. In addition, the Hospital stated the estimated overpayment for these claims failed to account for an offset for Part B reimbursement.

The Hospital objected to our use of extrapolation because we did not first demonstrate either a sustained or high level of payment error or that documented educational intervention has failed to correct the payment error (42 U.S.C. § 1395dd(f)(3)). The Hospital does not believe the errors that we alleged satisfy the undefined threshold of a high level of payment error. In addition, the Hospital disputes the majority of our findings, which will further reduce any error rate. Furthermore, the Hospital stated that our use of extrapolation in the sample of IRF claims to the entirety of IRF claims the Hospital submitted for reimbursement is inappropriate because of the highly fact-dependent nature of medical necessity determinations, such as the findings made with respect to the IRF claims. The Hospital further indicated that it has been unable to validate our extrapolation methodology.

Hospital officials concluded that, to the extent these errors are included in the final report, the Hospital intends to appeal these decisions. The Hospital has already begun the process for refunding the 8 claims associated with the uncontested errors.

The Hospital partially agreed with our third recommendation and provided information regarding its controls over DRG findings and outpatient claims. See Appendix E for the Hospital's comments on our draft report in their entirety.

## **OFFICE OF INSPECTOR GENERAL RESPONSE**

After review and consideration of the Hospital's comments, we maintain that our findings and recommendations are correct. We obtained an independent medical review to determine the medical necessity for all inpatient claims in our sample, including the 22 incorrectly billed IRF

claims. The physician who reviewed the IRF claims is Board certified in Physical Medicine and Rehabilitation, Pain Management, and Spinal Cord Injury Medicine. This physician has been Board certified in Physical Medicine and Rehabilitation since 1996. The Hospital's assertion that the physician who reviewed the IRF claims was not Board certified, and was not knowledgeable and experienced, is without merit.

Our medical reviewer did not determine the Medicare medical necessity of IRF claims based on whether a lower level of care was more appropriate. Our medical reviewer prepared detailed medical review determination letters that documented relevant facts and the results of his analysis. These were provided to the Hospital before we issued our draft report. Although our medical reviewer included the comment "lower level of care more appropriate" in his determination letters, this was not the standard applied in making a medical necessity determination for IRF admissions. Noting that a lower level of care could have been more appropriate was a comment by the physician reviewer, based on his review of the claims in which the medical record demonstrated that the IRF admission was not medically necessary. It is not, as the Hospital alleges, a basis for the medical necessity determination. As reflected in the rationale section of the determination letters, the medical reviewer never stated that the IRF admission was not medically necessary *because* a less intense level of care was medically indicated. Instead, it was an observation based on the lack of support for the IRF admission in the medical records. The Hospital's assertion that the medical reviewer denied IRF claims on the basis that a lower level of care was more appropriate is without merit.

None of the IRF claims were denied based on the patient being stable at the time of admission. For an IRF claim to be considered reasonable and necessary, Federal regulations require that there be a reasonable expectation that, at the time of admission, the patient (1) requires the active and ongoing therapeutic intervention of multiple therapy disciplines; (2) generally requires and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program; (3) is sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation program; and (4) requires physician supervision by a rehabilitation physician (42 CFR § 412.622(a)(3)(i-iv)). In making medical necessity determinations, the medical reviewer applied the applicable Federal regulations and guidance, which require consideration of stability as part of the overall determination of medical necessity. The medical reviewer did not err in noting that patients had stable medical conditions at the time of an IRF admission. Claims in which stability were noted in the determination letters were denied based on the patients' full medical and clinical picture.

Our medical reviewer also did not deny claims solely because the patient's primary diagnosis did not support the medical necessity of acute-level rehabilitation without considering the patient's other medical needs or co-morbid conditions. Although a primary diagnosis of debility was noted in some cases, the documentation included other evidence that these patients had a clinical picture that, at the time of admission, did not support a reasonable expectation that these patients required the level of physician and nursing oversight present in an IRF. Likewise, the documentation in some cases demonstrated that, at the time of admission, the patient

could not reasonably be expected to participate in and benefit from an IRF admission. The comorbidities and medical issues for these patients was noted in the “Facts” section and summarized or referenced as relevant in the “Rationale” section of the determination letters. Any notation of a debility diagnosis was not the sole basis for our physician reviewer’s findings.

The Hospital’s argument that all 22 IRF admissions are supported by evidence of post-admission improvement in the discharge summary notes is flawed. The medical necessity of an IRF admission, as acknowledged by the Hospital, is not based on the course of the stay, but on whether the documentation supported a reasonable expectation, *at the time of admission*, that the patient met Medicare criteria for an IRF admission. There is no basis under Medicare rules or CMS guidance for relying on progress during, or the outcome from, an IRF admission to justify the decision to admit the patient in the first instance. Accordingly, the Hospital’s argument that patients’ improved conditions pursuant to an IRF admission support the appropriateness of the decision to admit the patient to the IRF is without merit.

We acknowledge that the medical records include the requisite documentation that CMS guidance and Medicare rules require. However, the mere presence of this documentation in the record does not necessarily mean that the IRF admission was medically necessary. Instead, the documentation may be used to support the findings of medical necessity, and the information contained in the documents must meet the criteria for an IRF admission.

Our medical reviewer did not, as the Hospital asserts, misunderstand the applicable Medicare standards by failing to frame his analysis in the context of the two-midnight rule and failing to address why the two-midnight presumption has been rebutted. Federal regulations (42 CFR § 412.3(d)(1)) state that an inpatient admission is generally appropriate if the ordering physician expects the patient to require hospital care for a period of time that crosses two midnights. This regulation (42 CFR § 412.3(d)(1)(i)) also states that “[t]he expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration”. Accordingly, our medical reviewer framed his inpatient admission analysis “in the context of” the regulatory text; he explicitly based his medical necessity determinations on medical factors documented in medical records. That he did not use the terms “two-midnight rule,” “two-midnight benchmark,” or “two-midnight presumption” in his determination letters is of no consequence.

In our audits, we cannot offset Medicare Part A overpayments with amounts that may be payable under Medicare Part B. We cannot judge the value of Part B claims that have yet to be submitted. We note that, historically, CMS has not allowed rebilling as an exception to the timely filing requirements if a claim is denied. CMS has stated that hospitals are responsible for determining whether submission of a Part A or Part B claim is appropriate within the applicable timeframe and that adopting an exception to the timely filing requirements would allow hospitals to avoid the responsibility of correctly submitting claims to Medicare.

The inclusion of claims that did not span two midnights in this report is limited to the Other Matters section and is not reflected in our extrapolated overpayment. These claims were subjected to the same medical review process as all other claims in this report and are included in the Other Matters section for informative purposes only.

With respect to extrapolation, the requirement that a determination of a sustained or high level of payment error or documented failed educational intervention must be made before extrapolation applies only to Medicare contractors. See Social Security Act § 1893(f)(3) and CMS Medicare Program Integrity Manual, Pub. No. 100-08, ch. 8.4, § (effective January 2, 2019). Although the Hospital indicated that it has been unable to validate our extrapolation methodology, it has provided no specifics regarding its concerns. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.<sup>6</sup> The statistical lower limit that we use for our recommended recovery represents a conservative estimate of the overpayment that we would have identified if we had reviewed each and every claim in the sampling frame. The conservative nature of our estimate is not changed by the nature of the errors identified in this audit.

Our statistical sampling methodology and our sample results are described in Appendices B and C. As described in Appendix B, we used the OIG/OAS statistical software to calculate our estimates. This software, named RAT-STATS, is a free statistical software package that providers can download to assist in claims review. Both the software and the instructions are available on the OIG website. Furthermore, we provided the Hospital with our sampling methodology including our sample plan, sample frame, sample items, and random number output files from RAT-STATS that the Hospital can use to recreate our sample.

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<sup>6</sup> Yorktown Med. Lab., Inc. v. Perales, 948 F.2d 84 (2d Cir. 1991); Illinois Physicians Union v. Miller, 675 F.2d 151 (7th Cir. 1982); Momentum EMS, Inc. v. Sebelius, 2013 U.S. Dist. LEXIS 183591 at \*26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (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).

## **APPENDIX A: AUDIT SCOPE AND METHODOLOGY**

### **SCOPE**

Our audit covered \$12,170,094 in Medicare payments to the Hospital for 1,054 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 claims (80 inpatient and 20 outpatient) with payments totaling \$1,464,436. Medicare paid these 100 claims from January 1, 2016, through December 31, 2017 (audit period).

We focused our audit on the risk areas identified in prior OIG audits at other hospitals. We evaluated compliance with selected billing requirements and submitted all claims to an independent medical review contractor to determine whether the claims were supported by the medical records.

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 NCH data, but we did not assess the completeness of the file.

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

We conducted our fieldwork from February 2018 through September 2018.

### **METHODOLOGY**

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Hospital's inpatient and outpatient paid claims data from CMS's NCH database 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 80 inpatient claims and 20 outpatient claims totaling \$1,464,436 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 all claims complied with selected billing 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 audit with Hospital officials.

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

## APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

### TARGET POPULATION

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

### SAMPLING FRAME

According to CMS's NCH database, Medicare paid the Hospital \$96 million for 8,381 inpatient and 62,327 outpatient claims during the audit period.

We obtained a database of claims from the NCH data totaling \$62 million for 4,275 inpatient and 17,957 outpatient claims in 28 risk areas. From these 28 areas, we selected 9 consisting of 9,512 claims totaling \$16,240,285 for further review.

We performed data filtering and analysis of the claims within each of the nine high-risk areas. The specific filtering and analysis steps performed varied depending on the Medicare issue but included such procedures as removing:

- claims with certain discharge status and diagnosis codes,
- paid claims less than \$0, and
- claims under review by the Recovery Audit Contractor as of February 1, 2018.

We assigned each claim that appeared in multiple risk areas to just one area on the basis of the following hierarchy: IRF Claims, Inpatient Mechanical Ventilation Claims, Inpatient Claims Billed with Same Day Discharge and Readmit, Inpatient Claims Billed with High Severity Level DRGs, Inpatient Elective Procedures Claims, Inpatient Claims Billed with CERT DRG Codes, Outpatient Claims with Bypass Modifiers, Outpatient SNF Consolidated Billing Claims, and Outpatient Claims Paid in Excess of \$25,000. In addition, we grouped inpatient claims by high risk or moderate risk based on previous hospital compliance audits. This resulted in a sample frame of 1,054 Medicare paid claims in 9 high-risk areas totaling \$12,170,094 from which we drew our sample (Table 1).



**Table 1: Risk Areas**

<b>Medicare Risk Area</b>	<b>Frame Size</b>	<b>Value of Frame</b>
IRF Claims	361	\$6,437,750
Inpatient Mechanical Ventilation Claims	8	240,520
Inpatient Claims Billed With Same Day Discharge and Readmit	6	37,349
Inpatient Claims Billed With High Severity Level DRGs	135	936,055
Inpatient Elective Procedures Claims	217	1,751,620
Inpatient Claims Billed With CERT DRG Codes	249	940,069
Outpatient Claims With Bypass Modifiers	9	13,037
Outpatient SNF Consolidated Billing Claims	12	1,183
Outpatient Claims Paid in Excess of \$25,000	57	1,812,511
<b>Total</b>	<b>1,054</b>	<b>\$12,170,094</b>

**SAMPLE UNIT**

The sample unit was a Medicare paid claim.

**SAMPLE DESIGN AND SAMPLE SIZE**

We used a stratified random sample. We stratified the sampling frame into three strata on the basis of claim type and relative risk of improper payment based on previous OIG audit work. Stratum 1 includes inpatient claims considered to be high risk (IRF and inpatient mechanical ventilation claims); stratum 2 includes claims considered to be moderate risk (all remaining inpatient claims); and stratum 3 includes all outpatient claims. All claims were unduplicated, appearing in only one area and only once in the entire sampling frame.

We selected 100 claims for review as shown in Table 2.

**Table 2: Claims by Stratum**

<b>Stratum</b>	<b>Claims Type</b>	<b>Frame Size (Claims)</b>	<b>Value of Frame</b>	<b>Sample Size</b>
1	Inpatient High-Risk Claims	369	\$6,678,270	40
2	Inpatient Moderate-Risk Claims	607	3,665,093	40
3	Outpatient Claims	78	1,826,731	20
	<b>Total</b>	<b>1,054</b>	<b>\$12,170,094</b>	<b>100</b>

## **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 strata 1 through 3. After generating the random numbers, we selected the corresponding claims in each stratum.

## **ESTIMATION METHODOLOGY**

We used the OIG/OAS statistical software to calculate our estimates. To be conservative, we used the lower-limit of the two-sided 90-percent confidence interval to estimate the amount of improper Medicare payments in our sampling frame during the audit period. Lower limits calculated in this manner as designed to be less than the actual overpayment total 95 percent of the time.

**APPENDIX C: SAMPLE RESULTS AND ESTIMATES**

**Table 3: Sample Results**

<b>Stratum</b>	<b>Frame Size (Claims)</b>	<b>Value of Frame</b>	<b>Sample Size</b>	<b>Value of Sample</b>	<b>Number of Incorrectly Billed Claims in Sample</b>	<b>Value of Overpayments in Sample</b>
1	369	\$6,678,270	40	\$753,210	22	\$367,042
2	607	3,665,093	40	261,909	19	64,389
3	78	1,826,731	20	449,317	4	326
<b>Total</b>	<b>1,054</b>	<b>\$12,170,094</b>	<b>100</b>	<b>\$1,464,436</b>	<b>45</b>	<b>\$431,757</b>

**ESTIMATES**

**Table 4: Estimates of Overpayments for the Audit Period**

*Limits Calculated for a 90-Percent Confidence Interval*

Point estimate	\$4,364,334
Lower limit	3,461,376
Upper limit	5,267,292

**APPENDIX D: RESULTS OF AUDIT BY RISK AREA**

**Table 5: Sample Results by Risk Area**

<b>Risk Area</b>	<b>Selected Claims</b>	<b>Value of Selected Claims</b>	<b>Claims With Overpayments</b>	<b>Value of Overpayments</b>
IRF Claims	39	\$724,342	22	\$367,042
Inpatient Mechanical Ventilation Claims	1	28,868	-	-
Inpatient Claims Billed With Same Day Discharge and Readmit	1	5,452	-	-
Inpatient Claims Billed With High Severity Level DRGs	7	50,158	5	17,723
Inpatient Elective Procedures Claims	16	152,720	1	3,117
Inpatient Claims Billed With CERT DRG Codes	16	53,579	13	43,549
<b>Inpatient Totals</b>	<b>80</b>	<b>1,015,119</b>	<b>41</b>	<b>431,431</b>
Outpatient Claims With Bypass Modifiers	2	3,611	1	150
Outpatient SNF Consolidated Billing Claims	4	379	3	176
Outpatient Claims Paid in Excess of \$25,000	14	445,327	-	-
<b>Outpatient Totals</b>	<b>20</b>	<b>449,317</b>	<b>4</b>	<b>326</b>
<b>Inpatient and Outpatient Totals</b>	<b>100</b>	<b>\$1,464,436</b>	<b>45</b>	<b>\$431,757</b>

Notice: The table above illustrates the results of our audit by risk area. In it, we have organized inpatient and outpatient claims by the risk areas we reviewed. However, we have organized this report's findings by the types of billing errors we found at 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.

April 4, 2019

VIA UPS OVERNIGHT DELIVERY

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

**Re: Carolinas Hospital's Response to the OIG Draft Report A-04-18-08063**

Dear Ms. Pilcher:

Carolinas Hospital ("Carolinas" or "Hospital")<sup>1</sup> appreciates the opportunity to provide a written response to the U.S. Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG") draft report A-04-18-08063 titled *Medicare Compliance Review of Carolinas Hospital* ("OIG Draft Report"). As requested, we are submitting responses to the proposed findings, including reasons for concurrence or nonconcurrence with each recommendation. For the reasons outlined in this response, the OIG Draft Report should be substantially revised prior to being finalized because the alleged claims errors are greatly overstated due to the review contractor's erroneous interpretation and application of applicable Medicare coverage and documentation requirements. We respectfully request that the errors outlined in this response be corrected prior to finalizing the report.

**I. EXECUTIVE SUMMARY**

As detailed below, Carolinas acknowledges the importance of continuous improvements to compliance efforts and pursued various proactive compliance efforts to promote compliant billing processes before, during, and after the audit period of calendar years 2016 and 2017. However, Carolinas strongly disagrees with the vast majority of the alleged claim errors included in the OIG Draft Report and requests that the report not be finalized without being revised to address Carolinas's concerns.

The OIG Draft Report alleges that 45 of the 100 inpatient and outpatient claims reviewed did not fully meet applicable requirements. Specifically, the OIG Draft Report identifies 22 errors associated with inpatient rehabilitation facility ("IRF") claims, 15 errors associated with inappropriate inpatient admissions, 4 errors associated with Diagnosis Related Group ("DRG") codes, and 4 errors associated with outpatient claims.

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<sup>1</sup> Until February 28, 2019, Carolinas was part of Community Health Systems Professional Services Corporation ("CHSPSC"). Although Carolinas has now been acquired by the Medical University of South Carolina, this response was prepared by CHSPSC because the OIG audit involved dates of service during CHSPSC's ownership and any representations made in this response are limited to the time period of CHSPSC's ownership.

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Carolinas carefully reviewed the preliminary findings included in the OIG Draft Report and concurred with 8 of the findings, specifically the 4 outpatient findings (Samples # 85, 87, 89, and 96) and the 4 DRG coding findings (Samples # 60, 63, 69, and 72). However, Carolinas disputes the vast majority of the alleged claim errors, including:

- All 22 of the IRF claim denials.
- All 15 of the patient status claim denials.

Carolinas also disputes the use of extrapolation to derive the alleged overpayments and the inclusion of any findings related to inpatient stays of less than two-midnights (“Short-Stays”).<sup>2</sup>

## II. CAROLINAS’S RESPONSE TO THE OIG REVIEW METHODOLOGY AND DRAFT FINDINGS

### a. BACKGROUND OF AUDIT

The OIG performed a review of 100 inpatient and outpatient claims for calendar years 2016 and 2017. As noted, the OIG Draft Report alleged that 45 of the 100 claims failed to comply with applicable Medicare requirements. Carolinas worked collaboratively with OIG throughout the review process and provided the requested claim information. We understand that OIG engaged a subcontractor, MAXIMUS, to perform the clinical review.

As detailed in this response, Carolinas disputes MAXIMUS’ review approach and findings for 37 of the 45 alleged claim errors.

### b. IRF FINDINGS

Carolinas disagrees with OIG’s assertion that for 22 of the 80 inpatient claims, Carolinas incorrectly billed Medicare Part A for beneficiary stays that allegedly did not fully meet Medicare criteria for acute inpatient rehabilitation. OIG generally contends that IRF services for these beneficiaries were not “reasonable and necessary” and that the services could have been provided at a lower level of care (“LOC”). Specifically, for each of the 22 IRF claim denials, OIG asserts that:

1. It was not medically necessary for the patient to receive IRF services,
2. There was not a reasonable expectation that the patient, at the time of admission, met all of the coverage requirements for an IRF LOC, and
3. The overall plan of care clinical content was not medically necessary.

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<sup>2</sup> Carolinas understands that OIG’s audit recommendations do not represent final determinations by the Medicare program and that Carolinas will have the opportunity to appeal any claims denials by HHS and its contactors through the Medicare appeals process. Nothing in this response should be interpreted as limiting Carolinas’s bases for appeal.

Notably, however, OIG found that each account met all Medicare documentation requirements. OIG’s Draft Report alleges that as a result of the alleged IRF claim errors, Carolinas received overpayments of \$367,042 for the audit period. As further explained below, each of the 22 IRF claims was appropriately billed and, as documented in the medical record, each of the IRF admissions was medically necessary based on the treating physicians’ clinical judgment.

As a preliminary matter, the physician who reviewed the claims was described in OIG’s Draft Report as “duly licensed to practice medicine,” but OIG did not provide the physician reviewer’s specialty or board certification. Based on the reviewer’s demonstrated lack of understanding of rehabilitation medicine, it does not appear that OIG used a physician reviewer that is board certified in physical medicine and rehabilitation. As provided by the Centers for Medicare & Medicaid Services (“CMS”), the focus of a review of IRF services is “**on the rehabilitation physician’s decision-making process in the decision to admit the patient.**”<sup>3</sup> Without the necessary training and experience in IRF care and IRF coverage regulations, it is unclear whether the OIG physician reviewer had the knowledge and experience necessary to evaluate the clinical decision-making process, the physician’s decision to admit the patient and the appropriateness of the claims at issue with reliability.

In addition, OIG’s Draft Report provides that 22 IRF claims were billed incorrectly because OIG determined that a “lower LOC [was] more appropriate.” This denial reason is inappropriate and demonstrates that the IRF coverage regulations were applied incorrectly by the physician reviewer. As CMS has stated, the relevant inquiry is **not** whether the patient could have been treated in a “lower” setting of care, such as a skilled nursing facility (“SNF”). Instead, the inquiry is whether the patient has met all of the required criteria for admission to an IRF—regardless of whether the patient could have been treated in another setting.<sup>4</sup> In other words, the IRF regulations do not require providers to “prove” patients meet the IRF LOC versus a lower LOC. In addition, as noted above, CMS recognizes that information that the rehabilitation physician has **at the time of admission** determines whether the IRF services are reasonable and necessary.<sup>5</sup> Accordingly, for each account, the OIG reviewer applied the wrong standard in determining that a “lower LOC [was] more appropriate.”

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<sup>3</sup> See CMS Presentation Materials for November 2009 Call, available at

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Coverage.html>.

<sup>4</sup> See CMS IRF Training Call Transcript November 2009 (explaining that “nowhere on the slide and nowhere in this presentation are we going to talk about whether the patient could have been treated in a skilled nursing facility or another setting of care. Under the new requirements, a patient meeting all of their required criteria for admission to an IRF would be appropriate for IRF care whether or not he or she could have been treated in a skilled nursing facility”).

<sup>5</sup> See CMS IRF Training Call Transcript November 2009 (“For example, suppose that on admission to the IRF, a patient has a risk for a clinical complication that would complicate the patient’s participation in the rehabilitation therapy program. This is information that the rehabilitation physician has at the time the patient is admitted, and would be a reason for the IRF stay to be reasonable and necessary even if the patient’s clinical complication is well managed by the IRF and does not actually cause any difficulties during the patient’s rehabilitation therapy program.”).

Moreover, for certain claims, such as Samples # 7, 12, 15, and 19, OIG appears to justify its denial, at least in part, because the OIG contends that the patient’s medical conditions were stable at the time of admission. This assertion, however, contradicts clear CMS guidance that requires the patient to be stable at the time of admission to an IRF. Per the Medicare Benefit Policy Manual, “A patient who has not yet completed the full course of treatment in the referring hospital is expected to remain in the referring hospital, with appropriate rehabilitative treatments provided, until such time as the patient has completed the full course of treatment. Though medical management can be performed in an IRF, patients must be able to fully participate in and benefit from the intensive rehabilitation therapy program provided in IRFs in order to be transferred to an IRF.”<sup>6</sup> Thus, a patient must be clinically stable in order to participate in the rehabilitation program, and CMS’s expectation is that the patient’s medical condition would be stable upon admission to the IRF.

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Likewise, OIG found that for many of the alleged IRF claim errors, such as Sample #39 and Sample #40, the patient “had a primary rehabilitation diagnosis of debility which does not support the medical necessity of acute level rehabilitation.” Similarly, OIG notes that Sample #3 was medically stable at the time of admission, but that the patient was limited by severe debility and the severity of her co-morbid conditions. For these examples, OIG’s denials appear to be based on the patient’s *primary diagnosis* without considering the patient’s other medical needs that made the IRF admission appropriate. But the reason for IRF admission is not driven solely by the primary diagnosis. The IRF admission is based on the patient’s medical and functional impairment and needs, which are clearly documented in the medical records.

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In addition, OIG’s determination ignores the fact that the patients with debility also suffered from various co-morbid conditions. For example, OIG Sample #7 had comorbid conditions that included diabetes, hypertension, atrial fibrillation, and coronary artery disease. Similarly, OIG Sample #6 had suffered from comorbid conditions including a periprosthetic femoral shaft fracture and cholangiocarcinoma. In addition, for Samples #6 and #7, the fact that the patients were at risk for complications supports the medical necessity of an IRF admission, even if the patients’ conditions did not necessarily require any intervention by the IRF staff. Whether a patient’s medical condition is acute or chronic does not factor in the question of medical necessity. OIG’s reviewer failed to consider the medical and functional patient needs qualifying these patients for IRF admissions.

Additionally, for many claims, OIG determined that “[t]here was no reason to think that an intensive rehabilitation therapy program would significantly impact the patient’s condition differently compared with therapy provided at a less intense level.” But the discharge summary notes for the 22 accounts in fact document improvement upon discharge. The fact that the patient’s condition improved with IRF therapy supports and validates that the IRF services provided to the patient benefited the patient and that IRF therapy was appropriate.

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<sup>6</sup> Medicare Benefit Policy Manual, Ch. 1, § 110.



Based upon Carolinas's audit of the accounts, each account contains the documentation to support the IRF admission as reasonable and necessary. In addition, the records reflect that the services provided met the Medicare requirements for an IRF stay, as evidenced by:

- The comprehensive Pre-Admission Screens ("PAS") were completed within the 48-hour period immediately preceding admission. The PAS was completed by a licensed Registered Nurse ("RN") and reviewed by the Rehabilitation Medical Director and, in each instance, met the IRF criteria prior to admission.
- The PAS demonstrated that the patient required active and ongoing therapeutic intervention of a multidisciplinary team.
- The PAS also outlined that at the time of admission, the patient had the ability to actively participate in and benefit from an intensive rehabilitation therapy program consisting of at least two therapy disciplines.
- The Post Admission Physical Evaluation ("PAPE"), authored by the rehabilitation physician, was completed within 24 hours of admission and documents the patient's status upon admission to the IRF. In addition, the PAPE included a comparison of the information in the PAS.
- The PAPE concludes that the patient was sufficiently medically stable at the time of admission to the IRF in order to be able to actively participate in the intensive rehabilitation therapy program.
- The Individualized Overall Plan of Care ("IOPOC"), which was synthesized by the physician, was completed by the fourth day of admission to the IRF.
- The IOPOC reflects that the patient required an interdisciplinary team approach for care with individualized patient goals.
- For each account, the record contains documentation of the weekly team conferences led by the physician and attended by the RN, social worker and/or case manager, licensed therapists from each discipline involved in treating the patient, and the rehabilitation physician.
- The record contained documentation of at least three face to face visits weekly by the rehabilitation physician within physician progress notes indicating the patient received direct ongoing active treatment and supervision by a rehabilitation physician.

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Again, OIG acknowledges that all 22 of the alleged IRF errors satisfied the documentation requirements. Yet the OIG reviewer nonetheless denied these 22 IRF claims as a result of the misapplication of the IRF coverage requirements.

### c. PATIENT STATUS FINDINGS

OIG's Draft Report includes findings involving both non-Short-Stay and Short-Stay inpatient admissions. Specifically, for 15 non-Short-Stay claims and for 9 Short-Stay claims, the OIG draft report contends that Carolinas incorrectly billed Medicare Part A for inpatient stays that could have been billed as outpatient or outpatient with observation. OIG calculates the estimated overpayments for the errors attributed to the non-Short Stay Claims as \$52,576. For the Short-Stay claims, OIG calculates an overpayment of \$66,587, but, as further detailed below, OIG does not include this amount in its overall overpayment estimate and repayment recommendation.

#### i. Non-Short-Stay Claims

Pursuant to 42 C.F.R. § 412.3(d)(1) and what is commonly referred to as the Two Midnight Rule, the appropriateness of an inpatient admission turns on whether the admitting physician expects the patient to require medically necessary hospital services that cross two midnights. Under CMS policy, hospital claims with lengths of stay of greater than two midnights after formal admission are **presumed** to be reasonable and necessary for Medicare Part A payment.<sup>7</sup> This is referred to as the Two Midnight Presumption. Importantly, all 15 of the non-Short-Stay claims involved stays of *two or more* midnights after admission and thus would be entitled to the Two Midnight Presumption. In fact, many of the non-Short-Stay claims spanned multiple days.

OIG's physician reviewer appears to misunderstand the applicable Medicare standards by failing to frame the analysis in the context of the Two Midnight Rule or the Two Midnight Presumption. Rather than identifying the applicable standard as the Two Midnight Rule, OIG's physician reviewer states that "inpatient care is necessary when the patient's signs and symptoms and general medical condition can only be managed safely in an acute inpatient setting, when the patient requires diagnostic studies in an inpatient setting, or if it is medically necessary for the patient to remain in the acute inpatient setting." That interpretation by the physician reviewer is decidedly *not* the applicable Two-Midnight Rule promulgated by CMS. Further, although there are conclusory statements as to the absence of documentation relating to the expected length of stay for certain claims, the physician reviewer fails to address why the Two Midnight Presumption has been rebutted. Carolinas has significant concerns regarding the reliability of the findings in the OIG Draft Report in light of the apparent failure to apply to correct CMS inpatient admission standards.<sup>8</sup>

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<sup>7</sup> See CMS, Medicare Learning Network Matter Number SE19002 (Jan. 24, 2019), available at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19002.pdf>.

<sup>8</sup> Carolinas also notes that, citing 42 C.F.R. § 424.13(a), OIG's Draft Report states that "Federal regulations state that Medicare Part A pays for inpatient hospital services only if a physician certifies or recertifies, among other things, the reasons for continued hospitalization." That is an incorrect statement with respect to the applicable Medicare requirements. 42 C.F.R. § 424.13(a) only requires a physician certification for specific cases, such as cases involving 20 inpatient days or more or outlier cases, which further supports Carolinas's conclusion that OIG's findings are not based on the correct CMS standards.

Further, even if OIG's claims findings were accurate, which they are not, OIG erred in calculating the estimated overpayments in that it failed to account for the reimbursement Carolinas would have been eligible to receive under Medicare Part B. OIG does not contest the fact that Carolinas provided legitimate hospital services for which Carolinas could have sought reimbursement under Medicare Part B. Thus, OIG's overpayment estimates—which are based on the flawed assumption that Carolinas would have received *no* reimbursement at all for the claims at issue—is overstated. This issue is magnified by the fact that OIG is proposing to extrapolate its overpayment estimate to a broader universe of claims.

### **ii. Short-Stay Claims**

Despite acknowledging that an evaluation of patient status with respect to the Short-Stay claims is out of scope for the audit and not appropriate to include in its repayment recommendation, OIG's Draft Report states that, for 9 out of the 80 selected inpatient claims in the sample, Carolinas incorrectly billed Medicare Part A for claims that should have been billed as outpatient or observation. Carolinas objects to the inclusion of this finding in OIG's Draft Report given that, as clearly recognized by OIG, it is out of scope for this audit.

OIG suspended reviews of Short-Stays after October 1, 2013 and CMS has limited the review of such claims to specific reviews conducted by Beneficiary and Family Centered Care Quality Improvement Organizations. These limitations were enacted for good reason; there has been significant confusion and inconsistency among review contractors with respect to the application of the Two-Midnight Rule. Thus, including any reference to findings involving Short-Stays in the OIG Draft Report is inappropriate.

OIG's estimated overpayment for these claims also suffers from the same defect as the estimated overpayment for the non-Short-Stay claims in that OIG failed to account for an offset for Part B reimbursement. Again, OIG does not contest the legitimacy of the services provided to the patients, only the LOC.

### **d. DRG FINDINGS**

OIG's Draft Report provides that for 4 of 80 selected inpatient claims, Carolinas submitted claims to Medicare that were incorrectly coded, resulting in incorrect DRG payments to Carolinas. Specifically, OIG asserts that the procedure or diagnosis codes were unsupported by the medical records. OIG calculates overpayments in the amount of \$11,813 as a result of the alleged errors. Carolinas concurs with OIG's DRG findings with respect to these 4 claims.

### **e. OUTPATIENT CLAIMS FINDINGS**

Carolinas concurs with the outpatient claim findings. The OIG Draft Report states that, for 4 of the 20 outpatient claims reviewed, OIG identified billing errors, resulting in a total overpayment of

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\$326. Three of the 4 errors were attributed to Carolinas billing Medicare Part B rather than the applicable SNF for services that were subject to consolidated billing requirements. The one remaining error was related to an issue with an XE modifier.

Carolinas generally concurs with OIG’s findings with respect to the outpatient claims. However, for the 3 claims involving SNF consolidated billing, Carolinas notes that it billed Medicare Part B rather than the SNF based on documentation provided by the SNF. Said differently, Carolinas attributes this error to misinformation provided by the SNF, rather than deficiencies in Carolinas’s processes. With respect to the one XE modifier error, Carolinas believes this issue was caused by human error and does not necessarily reflect issues with applicable processes.

**f. EXTRAPOLATION**

As part of its review, OIG only reviewed 100 claims. For those 100 claims, OIG estimated total overpayments of \$431,757. However, the OIG Draft Report seeks to extrapolate that estimated overpayment to a much broader universe of claims, resulting in an estimated overpayment of **\$3,461,376** for the audit period. As detailed below, extrapolation is improper in this review.

Congress has placed statutory limits on Medicare contractors’ use of extrapolation. 42 U.S.C. § 1395dd(f)(3) prohibits the use of extrapolation by a Medicare contractor to determine overpayment amounts absent either **“a sustained or high level of payment error”** or **“documented educational intervention has failed to correct the payment error.”** In its Draft Report, OIG does not allege that educational intervention has failed. Although what constitutes a “high level of payment error” is not further defined, Carolinas does not believe the errors as alleged by OIG satisfy that undefined threshold. Further, Carolinas disputes the vast majority of OIG’s findings and anticipates succeeding in overturning a number of these claim denials on appeal, which will further reduce any error rate. Also, as noted, OIG’s overpayment estimate fails to account for the reimbursement Carolinas would have received under Part B for the alleged inpatient patient status errors. OIG has not demonstrated that there is a basis for extrapolating the alleged overpayment.

Extrapolation is also inappropriate due to the highly fact-dependent nature of medical necessity determinations, such as the findings made with respect to the IRF claims. “[T]he essence of inferential statistics is that one may confidently draw inferences about the whole from a representative sample of the whole.”<sup>9</sup> The appropriateness of statistical sampling turns on “the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action.”<sup>10</sup> Here, a number of the alleged errors by OIG are based on highly fact-specific and individualized determinations of medical necessity with respect to a specific patient’s clinical background and comorbid conditions. Thus, OIG’s use of extrapolation in the sample of IRF claims to the entirety of IRF claims submitted for reimbursement by Carolinas is inappropriate.

<sup>9</sup> *United States v. Pena*, 532 F. App’x 517, 520 (5th Cir. 2013).

<sup>10</sup> *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016); see *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1020 (5th Cir. 1997).

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Finally, based on the information that was provided regarding the sampling approach, Carolinas has been unable to validate the extrapolation methodology that was used by OIG. For these reasons, Carolinas does not concur with the use of extrapolation to determine the alleged overpayment in this review.

### III. RESPONSE TO OIG’S RECOMMENDATIONS

Carolinas is committed to complying with all statutes, regulations, and other standards governing participation in federal healthcare programs, including Medicare, and continuously strives to maintain and improve its internal controls and monitoring process to minimize the risk of errors. To that end, as part of its Compliance Program, among other things, Carolinas has developed comprehensive policies, procedures, education, auditing, and other initiatives. In the event potential opportunities for enhancement are identified, Carolinas focuses needed resources to investigate the issue and appropriately remediate issues in a timely manner. Below we respond to OIG’s recommendations outlined in the OIG Draft Report.

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#### a. OVERPAYMENT REFUNDS

OIG recommends that Carolinas refund an extrapolated alleged overpayment of \$3,461,279. However, Carolinas does not concur with this recommendation because, as outlined in this response, Carolinas disputes the vast majority of the alleged claim errors and the extrapolation. Accordingly, to the extent these errors are included in the final OIG report Carolinas intends to appeal these decisions.

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Carolinas has already begun the process for refunding the 8 claim overpayments associated with the errors that are not contested—the four outpatient samples, Samples # 85, 87, 89, and 96, and the 4 DRG coding findings, Samples # 60, 63, 69, and 72.

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#### b. 60-DAY OVERPAYMENT RULE ADDITIONAL DILIGENCE

OIG further recommends that Carolinas “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.” Carolinas believes that any additional review outside the time period of the OIG audit is premature and, therefore, does not concur with this recommendation.

Carolinas takes compliance with the 60-day overpayment law and rule very seriously. However, Carolinas disputes the *vast majority* of the alleged overpayments in this review.<sup>11</sup> As such, to the extent OIG finalizes the report and does not revise the alleged claim errors, Carolinas will be required to appeal the adverse findings. Importantly, the CMS overpayment final rule for Medicare Part A and B provides:

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<sup>11</sup> Specifically, Carolinas disputes all 22 of the IRF claim denials and all 15 of the patient status claim denials, which amount to \$419,618 of the \$431,757 in alleged overpayments.

If the provider appeals the contractor identified overpayment, ***the provider may reasonably assess that it is premature to initiate a reasonably diligent investigation into the nearly identical conduct in an additional time period until such time as the contractor identified overpayment has worked its way through the administrative appeals process.***<sup>12</sup>

Accordingly, to the extent the adverse findings are finalized, Carolinas intends to pursue appeals of the claims in which it disagrees with the OIG’s findings and, consistent with its overpayment rule obligations, will evaluate any obligations under the 60-day rule once its Medicare administrative appeals have concluded.

**c. STRENGTHENING OF CONTROLS<sup>13</sup>**

As noted, CHSPSC recently divested Carolinas but, during the time period of CHSPSC’s ownership, Carolinas maintained various controls to ensure compliance with applicable Medicare requirements.

***i. IRF Findings***

The OIG Draft Report recommends that Carolinas strengthen controls to ensure full compliance with Medicare requirements, including ensuring all IRF beneficiaries meet Medicare criteria for acute inpatient rehabilitation.

We do not concur with the OIG findings for the IRF records; therefore no additional corrective actions are being taken or planned. Carolinas’s process for admitting IRF patients is rigorous and attempts to ensure that all patients meet Medicare coverage requirements.

***ii. Patient Status Findings***

The OIG Draft Report recommends that Carolinas ensure documentation supporting the medical necessity for inpatient hospital services is contained in the medical record. We do not concur with the patient status findings; therefore no additional corrective actions are being taken or planned.

That said, Carolinas has already devoted substantial resources to ensuring compliance with patient status requirements. For example, Carolinas has adopted multiple practices to improve controls relating to patient admissions, including the placement of case managers in the Emergency

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<sup>12</sup> Medicare Program; Reporting and Returning of Overpayments, 81 Fed. Reg. 7654, 7667 (Feb. 12, 2016) (emphasis added).

<sup>13</sup> CHSPSC divested Carolinas on February 28, 2019. As such, CHSPSC’s response to the recommendations to strengthen controls is limited to the time period of CHSPSC’s ownership.

Department throughout the week and making an on-site physician advisor accessible on a daily basis. Carolinas has also worked to ensure medical records contain documentation supporting medical necessity through ongoing audits and by engaging Clinical Documentation Specialists to perform concurrent reviews of medical record documentation and provide feedback and education to medical and clinical services staff. Additionally, beginning in late 2018, Carolinas worked to enhance practices relating to case management and discharge rounding to ensure patients are discharged in a timely and efficient manner.

### **iii. DRG Findings**

OIG recommends that Carolinas ensure that procedure and diagnosis codes are supported in the medical records and staff are properly trained.

Carolinas concurs with these recommendations and has various controls in this area. For example, Carolinas has conducted various coding audits that include a thorough review of medical record documentation in support of the claim. The primary focus of these coding audits is on the following types of claims: high risk (*e.g.*, items on the OIG Work Plan and claims involving a single complication or comorbidity or a single major complication or comorbidity), high frequency claims, error-prone claims (as identified by prior audit or benchmark data), claims that are representative of a new service line or technology, or representative of a specialty service. In addition, as noted, Carolinas engaged Clinical Documentation Specialists to perform concurrent reviews of medical record documentation and provide feedback and education to medical and clinical services staff.

With respect to training, coding education and training activities are conducted regularly, with content made available in a variety of methods, including live webinars, study modules, newsletters, and job aides. Education and training topics have included trends identified through audit activities, as well as updates to the ICD-10-CM/PCS and CPT/HCPCS code sets, and relevant regulatory guidance related to coding. In addition, audit results are regularly summarized and feedback is provided directly to Coding leadership. Coders have the opportunity to review and correct identified errors, and the claims are subsequently submitted for re-billing.

Finally, outpatient coding audits have been conducted which include claims samples representing distinct procedural services as defined by the American Medical Association CPT code set and regulatory guidance such as National Correct Coding Initiative Edit Policy. Distinct procedural services, modifier application, and bundling concepts will continue to be areas of emphasis in education and training for Coding and Billing staff.

### **iv. Outpatient Claims**

OIG recommends that Carolinas (i) ensure that procedures are in place to properly bill claims subject to the SNF consolidated billing requirements and (ii) ensure medical records accurately document distinct procedures services and staff are properly trained.

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Carolinas concurs with these recommendations and has provided applicable training to coding and billing staff and conducted outpatient coding audits. However, Carolinas does not believe the claim errors identified by OIG necessarily reflect deficiencies in Carolinas's existing processes. The SNF consolidated errors were caused by misinformation provided by the applicable SNF which instructed Carolinas to bill Medicare Part B. Further, the XE modifier error was due to human error and thus would not have necessarily been prevented by additional compliance efforts.

#### IV. CONCLUSION

We appreciate the opportunity to respond to OIG's Draft Report and respectfully request that OIG modify its findings and report based on the issues raised in this response. Please do not hesitate to contact me if you would like to further discuss this matter further at 615-465-7150 or [andi\\_bosshart@chs.net](mailto:andi_bosshart@chs.net).

Sincerely,

/Andi Bosshart/

Andi Bosshart, RHIA, CHC  
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