

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE HOSPITAL PROVIDER  
COMPLIANCE AUDIT:  
LAKE HOSPITAL SYSTEM**

*Inquiries about this report may be addressed to the Office of Public Affairs at  
[Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov).*



**Amy J. Frontz  
Deputy Inspector General  
for Audit Services**

**June 2021  
A-05-19-00024**

# ***Office of Inspector General***

<https://oig.hhs.gov>

---

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

## ***Office of Audit Services***

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

## ***Office of Evaluation and Inspections***

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

## ***Office of Investigations***

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

## ***Office of Counsel to the Inspector General***

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

# *Notices*

---

**THIS REPORT IS AVAILABLE TO THE PUBLIC**  
at <https://oig.hhs.gov>

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

## **OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS**

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

## Report in Brief

Date: June 2021

Report No. A-05-19-00024

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



### Why OIG 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 2018, Medicare paid hospitals \$179 billion, which represents 47 percent of all fee-for-service payments for the year.

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

### How OIG Did This Audit

Our audit covered \$11.7 million in Medicare payments to the Hospital for 2,293 claims that were potentially at risk for billing errors. We selected for review a stratified sample of 90 inpatient and 10 outpatient claims with payments totaling \$1.4 million for our 2-year audit period (January 1, 2017, through December 31, 2018).

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: Lake Hospital System

### What OIG Found

The Hospital complied with Medicare billing requirements for 49 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 51 claims, resulting in overpayments of \$862,429 for calendar years 2017 and 2018.

On the basis of our sample results, we estimated that the Hospital received overpayments of approximately \$4.4 million for the audit period. As of the publication of this report, this amount included claims outside the Medicare 4-year claim reopening period.

### What OIG Recommends and Hospital Comments

We recommend that the Hospital refund to the Medicare contractor the portion of the \$4.4 million in estimated overpayments for the audit period for claims that it incorrectly billed that are within the reopening period; exercise reasonable diligence to identify, report, 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. The detailed recommendations are listed in the body of the report.

In written comments on our draft report, the Hospital disagreed with the “vast majority” of our findings and did not concur with our first recommendation to refund our estimated overpayments or our use of extrapolation; however, the Hospital agreed to voluntarily refund the overpayments of 14 claims with which it did agree. The Hospital concurred with the second recommendation to identify, report, and return and identify any returned overpayments and the third recommendation to strengthen internal controls. While the Hospital concurred with these recommendations, it contended that these recommendations are already integrated in its present Corporate Compliance Program.

After reviewing the Hospital’s comments, we maintain that our findings and recommendations are valid.

## TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objective .....	1
Background .....	1
The Medicare Program .....	1
Hospital Inpatient Prospective Payment System .....	1
Hospital Inpatient Rehabilitation Facility Prospective Payment System .....	1
Hospital Outpatient Prospective Payment System .....	2
Hospital Claims at Risk for Incorrect Billing .....	2
Medicare Requirements for Hospital Claims and Payments.....	2
Lake Hospital System.....	3
How We Conducted This Audit.....	4
FINDINGS .....	4
Billing Errors Associated With Claims Incorrectly Billed as Inpatient.....	5
Incorrectly Billed Inpatient Rehabilitation Facility Claims.....	5
Incorrectly Billed Diagnosis-Related Group Codes.....	7
Claims Incorrectly Billed as Inpatient.....	7
Overall Estimate of Overpayments.....	8
RECOMMENDATIONS.....	8
HOSPITAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE .....	9
HOSPITAL COMMENTS .....	9
Incorrectly Billed Inpatient Rehabilitation Facility Claims.....	9
Incorrectly Billed Diagnosis-Related Group Codes.....	10
Claims Incorrectly Billed as Inpatient.....	10
Extrapolation .....	10
OFFICE OF INSPECTOR GENERAL RESPONSE.....	10
Incorrectly Billed Inpatient Rehabilitation Facility Claims.....	11
Incorrectly Billed Diagnosis-Related Group Codes.....	11
Claims Incorrectly Billed as Inpatient.....	11
Extrapolation .....	12

APPENDICES

A: Audit Scope and Methodology .....13

B: Statistical Sampling Methodology .....15

C: Sample Results and Estimates .....17

D: Results of Audit by Risk Area .....18

E: Hospital Comments .....19

## **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 2018, Medicare paid hospitals \$179 billion, which represents 47 percent of all fee-for-service payments; accordingly, it is important to ensure that hospital payments comply with requirements.

### **OBJECTIVE**

Our objective was to determine whether Lake Hospital System (the Hospital) complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims from January 1, 2017, through December 31, 2018.

### **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 inpatient rehabilitation facilities. CMS implemented the payment system for cost-reporting periods

beginning on or after January 1, 2002. Under the payment system, CMS established a Federal prospective payment rate for each of the distinct case-mix groups (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 these types of hospital claims, among others, that were at risk for noncompliance:

- IRF claims,
- inpatient claims billed with high-severity-level DRG codes,
- inpatient claims billed for mechanical ventilation,
- inpatient claims billed as elective procedures, and
- outpatient claims with payments greater than \$25,000.

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

---

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

<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*, chapter 6, § 6.5.2). We are not constrained by the two-midnight presumption in selecting claims for medical review.



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)).

Claims must be filed on forms prescribed by CMS in accordance with CMS instructions (42 CFR § 424.32(a)(1)). The *Medicare Claims Processing Manual* (the Manual) requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly (Pub. No. 100-04, chapter 1, § 80.3.2.2). The Manual states that providers must use HCPCS codes for most outpatient services (chapter 23, § 20.3).<sup>3</sup>

OIG believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers must report and return any identified overpayments by the later of (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.<sup>4</sup>

The 6-year lookback period is not limited by OIG’s audit period or restrictions on the Government’s ability to reopen claims or cost reports. To report and return overpayments under the 60-day rule, providers can request the reopening of initial claim determinations, submit amended cost reports, or use any other appropriate reporting process.<sup>5</sup>

## **Lake Hospital System**

The Hospital is a 413-bed hospital system located in Concord, Ohio. According to CMS’s National Claims History (NCH) data, Medicare paid the Hospital approximately \$87 million for 5,738 inpatient and 51,872 outpatient claims from January 1, 2017, to December 31, 2018 (audit period).

---

<sup>3</sup> “Under the hospital outpatient prospective payment system, predetermined amounts are paid for designated services furnished to Medicare beneficiaries. These services are identified by codes established under the Centers for Medicare & Medicaid Services Common Procedure Coding System (HCPCS)” (42 CFR § 419.2(a)).

<sup>4</sup> The Act § 1128J(d); 42 CFR §§ 401.301–401.305; and 81 Fed. Reg. 7654 (Feb. 12, 2016).

<sup>5</sup> 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, Provider Reimbursement Manual—Part 1, Pub. No. 15-1, § 2931.2; and 81 Fed. Reg. at 7670.

## HOW WE CONDUCTED THIS AUDIT

Our audit covered \$11,666,797 in Medicare payments to the Hospital for 2,293 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 claims (90 inpatient and 10 outpatient) with payments totaling \$1,409,242. Medicare paid these 100 claims during our audit period.

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 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 49 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 51 claims (all of which were inpatient claims), resulting in overpayments of \$862,429 for the audit period. Specifically, 50 inpatient claims had overpayments of \$864,449; 1 inpatient claim had an underpayment of \$2,019. 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 \$4,385,974 for the audit period.<sup>6</sup> As of the publication of this report, this amount included claims outside of the 4-year claim reopening period.

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

---

<sup>6</sup> To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

## **BILLING ERRORS ASSOCIATED WITH CLAIMS INCORRECTLY BILLED AS INPATIENT**

The Hospital incorrectly billed Medicare for 51 of the 90 inpatient claims that we audited. These errors resulted in net overpayments of \$862,429.

### **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)).

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 who must conduct face-to-face visits with the patient at least 3 days per week throughout the patient’s stay (42 CFR § 412.622(a)(3)(i–iv)).<sup>7</sup>

Federal regulations require that the patient’s medical record contain certain documentation to ensure that the IRF coverage requirements are met. The record must include: (1) a comprehensive preadmission screening that is completed within the 48 hours preceding the admission; (2) a post-admission physician evaluation that is completed within 24 hours of admission and documents the patient’s status on admission to the IRF, and includes a comparison with the information in the preadmission screening; and (3) an individualized overall plan of care that is completed within 4 days of admission to the IRF (42 CFR § 412.622(a)(4)(i–iii)).

According to Federal regulations, the patient must require an interdisciplinary team approach to care, as evidenced by documentation in the medical record of weekly interdisciplinary team meetings. The meetings must be led by a rehabilitation physician and further consist of a registered nurse, a social worker or case manager, and a licensed or certified therapist from each therapy discipline involved in treating the patient (42 CFR § 412.622(a)(5)(A)).<sup>8</sup>

---

<sup>7</sup> 42 CFR § 412.622(a)(3)(iv) was amended effective October 1, 2018, to provide that the post-admission physician evaluation described in 42 CFR § 412.622(a)(4)(ii) may count as one of the face-to-face visits (83 Fed. Reg. 38514, 38573 (Aug. 6, 2018)).

<sup>8</sup> 42 CFR § 412.622(a)(5)(A) was redesignated as § 412.622(a)(5)(i) and amended effective October 1, 2018, to provide that the rehabilitation physician may lead the interdisciplinary team meeting remotely (83 Fed. Reg. 38514, 38573 (Aug. 6, 2018)).

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)).

For 38 of the 90 selected inpatient claims, the Hospital incorrectly billed IRF services. Specifically, for 12 of these 38 claims, the Hospital incorrectly billed IRF claims that did not comply with Medicare documentation requirements. The 12 claims consisted of 1 or more of the following errors:

- for 2 claims, the documentation did not show close supervision of care by the rehabilitation physician as demonstrated by at least 3 face-to-face visits per week that met Medicare requirements (i.e., medical and functional assessments and needed modifications of treatment);
- for 3 claims, the documentation did not show that all required team members were present at the interdisciplinary team meetings;
- for 1 claim, the medical record did not contain an admission order;
- for 2 claims, the pre-admission screening was not completed within the 48 hours preceding the patient's admission to the IRF;
- for 1 claim, the post-admission physician evaluation was not completed within 24 hours of the patient's admission to the IRF;
- for 7 claims, the individualized overall plan of care was not completed within 4 days of the patient's admission to the IRF; and
- for 1 claim, the patient was not grouped into the correct case-mix group pursuant to Medicare requirements.

For 35 of the 38 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 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. In addition, 9 of the 35 claims did not comply with Medicare documentation requirements.<sup>9</sup>

---

<sup>9</sup> These claims were only counted as one error each for purposes of our statistical estimates.

The Hospital did not provide a cause for these errors because officials generally contended that these claims met Medicare requirements. The Hospital disputed the preliminary audit findings prior to issuance of our draft report; however, the Hospital had identified opportunities for improvement when its Medical Director is not present, and the Hospital stated it had sufficient key controls in place and followed its key controls.

As a result of these errors, the Hospital received overpayments of \$798,533.

### **Incorrectly Billed Diagnosis-Related Group Codes**

The Act precludes payment to any provider without information necessary to determine the amount due the provider (§ 1815(a)). DRG codes are assigned to specific hospital discharges based on claim data submitted by hospitals (42 CFR § 412.60(c)), so claim data must be accurate. Consequently, 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 90 selected inpatient claims, the Hospital submitted claims to Medicare that were incorrectly coded. Specifically, certain procedure or diagnosis codes were not supported by the medical records. Three of the four incorrect claims resulted in overpayments, while one claim was an underpayment. The Hospital did not provide a cause for these errors because officials generally contended that these claims met Medicare requirements. Prior to issuance of our draft report, the Hospital stated that it had sufficient key controls in place and followed its key controls.

As a result of these errors, the Hospital received net overpayments of \$2,373.

### **Claims 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 regulations provide that the 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” (42 CFR § 412.3(d)(1)(i)).

For 9 of the 90 selected inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for inpatient status that should have been billed as outpatient or outpatient with observation services. The medical records did not support the necessity for inpatient hospital services. The Hospital did not provide a cause for these errors because officials generally contended that the claims met Medicare requirements. During the period of review, the Hospital stated that it had sufficient key controls in place and followed its key controls.

As a result of this error, the Hospital received overpayments of \$61,523.

## **OVERALL ESTIMATE OF OVERPAYMENTS**

The combined net overpayments on our sampled claims totaled \$862,429. On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$4,385,974 for the audit period. As of the publication of this report, this amount included claims outside of the Medicare 4-year claim-reopening period.

## **RECOMMENDATIONS**

We recommend that Lake Hospital System:

- refund to the Medicare contractor the portion of the \$4,385,974 in estimated overpayments for the audit period for claims that it incorrectly billed that are within the 4-year reopening period;<sup>10</sup>
- based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule,<sup>11</sup> and identify any of those

---

<sup>10</sup> OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a Medicare administrative contractor or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

<sup>11</sup> This recommendation does not apply to any overpayments that are both within our sampling frame (i.e., the population from which we selected our statistical sample) and refunded based on the extrapolated overpayment amount. Those overpayments are already covered in the previous recommendation.

returned overpayments as having been made in accordance with this recommendation;  
and

- strengthen controls to ensure full compliance with Medicare requirements.

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

In written comments on our draft report, the Hospital disagreed with the “vast majority” of our findings, the recommendation to refund \$4,385,974, and our use of extrapolation. The Hospital agreed to voluntarily refund 14 claims with which it did agree. The Hospital concurred with the second recommendation to identify, report, and return and identify any returned overpayments and the third recommendation to strengthen internal controls.<sup>12</sup> While the Hospital concurred with these recommendations, it contended that these recommendations are already integrated in its present Corporate Compliance Program.

We summarized the Hospital’s response by categories outlined in the report and by the Hospital’s comments regarding the extrapolation below. After review and consideration of the Hospital’s comments, we maintain that our findings and recommendations are correct.

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

### **HOSPITAL COMMENTS**

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

The Hospital disagreed with 26 of the 38 claims that were identified as incorrectly billed as IRF claims. They contended that OIG’s contracted reviewer clearly used subjective factors that are not in accordance with the Medicare IRF coverage criteria in making determinations as to whether the patient evidenced the ability to improve with inpatient rehabilitation services or whether the patient required physician supervision. Further, the Hospital believed that the reviewer “scaled” or applied a rubric to assess the patient at admission, which is not consistent with the Medicare coverage criteria.

The Hospital stated that in addition to subjectively or inaccurately applying the Medicare IRF coverage criteria, the contracted reviewer also failed to give deference to the treating physician.

---

<sup>12</sup> The Hospital stated that it concurs with our second recommendation and that it will refund any overpayments identified by the OIG with which the Hospital concurs, but it is unclear whether the Hospital intends to exercise reasonable diligence to identify overpayments (*i.e.*, determine receipt of and quantify any overpayments) during the 6-year lookback period. In contrast with its statement about repaying overpayments, the Hospital did not expressly state whether it would or would not exercise reasonable diligence to identify overpayments during the 6-year lookback period. We continue to recommend that it do so.

The Hospital agreed to voluntarily refund the 12 remaining claims. It noted that these claims failed to meet Medicare documentation requirements, which it considered technical errors. The Hospital proactively reviewed and made appropriate updated and operational improvements as part of its ongoing Corporate Compliance Program.

### **Incorrectly Billed Diagnosis-Related Group Codes**

The Hospital disagreed that the four claims we identified as incorrectly billed were incorrectly coded. It stated that we failed to review specific documentation contained within the medical record that supported the original diagnosis codes. The Hospital engaged independent certified coders who confirmed that the original coding of these claims was correct. The Hospital further contended that it had sufficient internal controls in place and followed its key controls, and it maintained that there were no additional controls that it needed to implement in this area.

### **Claims Incorrectly Billed as Inpatient**

The Hospital disagreed with seven of the nine claims that were identified as being incorrectly billed as inpatient admissions. For these seven claims, the Hospital contended that it had internal controls to perform utilization review of patient status at the time of admission and that the medical record documentation for inpatient admission met the Medicare two-midnight rule found in 42 CFR § 412.3(d)(1).

The Hospital agreed to voluntarily refund the two remaining claims. Again, it asserted that it had sufficient internal controls in place and followed its key controls and submitted that there were no additional controls that it needed to implement in this area.

### **Extrapolation**

The Hospital disputed our sampling and extrapolation approach, stating that extrapolation was not appropriate for this audit pursuant to section 1893(f)(3) of the Social Security Act and chapter 8, section 8.4.1.4 of the *Medicare Program Integrity Manual* (MPIM) and that the report did not contain sufficient information to replicate the audit even if extrapolation were appropriate. In addition, the limited information in the report shows that the extrapolation is not statistically valid.

### **OFFICE OF INSPECTOR GENERAL RESPONSE**

After review and consideration of the Hospital's comments, we maintain that our findings and the associated recommendations are valid.



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

We disagree with the Hospital's claim that we: (1) subjectively or inaccurately applied the Medicare IRF coverage criteria, (2) used a scale or applied a rubric to assess the patient's status at admission, or (3) applied additional elements that were not part of the Medicare criteria. We obtained an independent medical review for all claims in our sample. We submitted the claims to a medical review contractor that reviewed the medical records in their entirety to determine whether the services were medically necessary and provided in accordance with Medicare requirements. We worked with the medical reviewers to ensure that they applied the correct Medicare criteria and that they used professionals with appropriate medical expertise, including physicians with training and expertise in rehabilitation.

We appropriately assessed the medical record documentation to determine whether it supported the Medicare payments. The medical reviewer considered the patient's entire clinical picture, including other medical needs and comorbid conditions, and found that these beneficiaries: (1) did not require the active and ongoing therapeutic intervention of multiple therapy disciplines; (2) generally did not require and could not reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program; (3) were not sufficiently stable at the time of admission to the IRF to actively participate in the intensive rehabilitation program; or (4) did not require supervision by a rehabilitation physician. In addition, contrary to the Hospital's unsupported contention, our medical reviewers were not required to give deference to the decisions made by the treating physicians.

## **Incorrectly Billed Diagnosis-Related Group Codes**

For the claims we found were incorrectly coded, the independent medical reviewer who reviewed the claims was a certified coding specialist and a registered health information technician skilled in classifying clinical data from medical records and assigning number codes for each diagnosis and procedure. The reviewer had expertise in ICD-9, ICD-10, and CPT coding systems and was knowledgeable in medical terminology, disease processes, and pharmacology. The reviewer used this expertise and knowledge to analyze the claims and determine whether they were incorrectly coded. In addition, the Hospital states that they conducted their own coding review, however the results of this review were not provided to OIG for consideration.

## **Claims Incorrectly Billed as Inpatient**

For the claims we found were incorrectly billed as inpatient, the independent medical reviewer who reviewed the claim applied Medicare regulations or policies established by CMS, including regulations regarding medical necessity and the Two-Midnight Rule. Federal regulations (42 CFR § 412.3(d)(1)) states that an inpatient admission is generally appropriate if the ordering physician expected the patient to require hospital care for a period of time that crossed two midnights.

## Extrapolation

We carefully considered the Hospital's comments on our sampling and estimation methods, and we maintain that our statistical approach resulted in a statistically valid and reasonably conservative estimate of the amount overpaid by Medicare to the Hospital.

The requirement that a determination of a sustained or high level of payment error must be made before extrapolation applies only to Medicare contractors.<sup>13</sup> Further, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.<sup>14</sup> Moreover, the legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.<sup>15</sup> We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

We acknowledge that the hospital requested the sampling methodology and extrapolation information. The request included a statement that it would be sufficient if we included the information in the draft report in lieu of a separate response. We described our statistical sampling methodology, the validity of the extrapolation, and our sample results in Appendices B and C. As described in Appendix B, we used the OIG, Office of Audit Services (OAS), statistical software to calculate our estimates. This software, named RAT-STATS, is a free software package that providers can download to assist in calculating statistical estimates. Both the software and the instructions are available on the OIG website. The request did not ask for the detail to allow it to replicate the results of the audit, however this information can be provided.

---

<sup>13</sup> The Act § 1893(f)(3) and CMS, Medicare Program Integrity Manual, Pub. No. 100-08, chapter 8, § 8.4 (effective January 2, 2019).

<sup>14</sup> See *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).

<sup>15</sup> See *John Balko & Assoc. v. Sebelius*, 2012 WL 6738246 at \*12 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at \*13 (S.D. Tex. 2012).

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered \$11,666,797 in Medicare payments to the Hospital for 2,293 claims that were potentially at risk for billing errors. We selected for audit a stratified random sample of 100 claims (90 inpatient and 10 outpatient) with payments totaling \$1,409,242. Medicare paid these 100 claims from January 1, 2017, through December 31, 2018 (audit period).

We focused our audit on the risk areas identified as a result 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 claims were supported by the medical records.<sup>16</sup>

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 audit work from June 2019 through January 2021.

### METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Hospital's inpatient and outpatient paid claim data from CMS's 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 90 inpatient claims and 10 outpatient claims totaling \$1,409,242 for detailed review (Appendix B);

---

<sup>16</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*, chapter 6, § 6.5.2). We are not constrained by the two-midnight presumption in selecting claims for medical review.

- obtained and reviewed billing and medical record documentation provided by the Hospital to support the selected claims;
- used an independent medical review contractor to determine whether the 100 claims contained in the sample 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);
- discussed the results of our audit with Hospital officials on November 3, 2020; and
- reviewed and considered additional documentation from the hospital after discussing the results.

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

### SAMPLING FRAME

We constructed a sampling frame containing select inpatient and outpatient claims paid to the Hospital during the audit period for selected services provided to Medicare beneficiaries. The sampling frame consisted of a database of 2,293 claims (1,106 inpatient and 1,187 outpatient), valued at \$11,666,797, from CMS's NCH file.<sup>17</sup>

### 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 four strata on the basis of claim dollar value. Stratum 1 includes low-dollar inpatient claims (payment amounts of less than \$8,118), stratum 2 includes moderate-dollar inpatient claims (payment amounts greater than or equal to \$8,118 and less than \$17,731), stratum 3 includes high-dollar inpatient claims (greater than or equal to \$17,731), and stratum 4 includes all outpatient claims. All claims were unduplicated, appearing in only one risk area and only once in the entire sampling frame.

We selected 100 claims for review, as shown in Table 1.

**Table 1: Frame Description and Sample Size**

<b>Stratum</b>	<b>Medicare Type of Claim</b>	<b>Number of Claims in Frame</b>	<b>Amount of Payments in Frame</b>	<b>Sample Size</b>
1	Inpatient risk area, low-dollar claims	675	\$3,356,873	20
2	Inpatient risk area, moderate-dollar claims	286	3,484,773	33
3	Inpatient risk area, high-dollar claims	145	3,508,963	37
4	Outpatient risk area (risk areas 7–9)	1,187	1,316,189	10
	<b>Totals</b>	<b>2,293</b>	<b>\$11,666,797<sup>18</sup></b>	<b>100</b>

<sup>17</sup> Our sampling frame excluded claims associated with (1) claims with certain discharge status and diagnosis codes, (2) all \$0 paid claims, (3) claims spanning less than two midnights, and (4) claims under review by the Recovery Audit Contractor.

<sup>18</sup> The stratum amounts do not sum to the total amount due to rounding.

## **SOURCE OF RANDOM NUMBERS**

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

## **METHOD OF SELECTING SAMPLE ITEMS**

We consecutively numbered the claims within strata 1 through 4. After generating 20 random numbers for stratum 1, 33 random numbers for stratum 2, 37 random numbers for stratum 3, and 10 random numbers for stratum 4, we selected the corresponding claims in each stratum.

## **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). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

**APPENDIX C: SAMPLE RESULTS AND ESTIMATES**

**SAMPLE RESULTS**

**Table 2: 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	675	\$3,356,873	20	\$94,685	8	\$24,042
2	286	3,484,773	33	404,894	19	246,579
3	145	3,508,963	37	902,068	24	591,808
4	1,187	1,316,189	10	7,594	0	0
<b>Total</b>	<b>2,293</b>	<b>\$11,666,797<sup>19</sup></b>	<b>100</b>	<b>\$1,409,242<sup>20</sup></b>	<b>51</b>	<b>\$862,429</b>

Notice: The table includes rounded totals.

**ESTIMATES**

**Table 3: Estimates of Overpayments in the Sampling Frame for the Audit Period**  
*(Limits Calculated for a 90-Percent Confidence Interval)*

Point estimate	\$5,267,680
Lower limit	4,385,974
Upper limit	6,149,387

<sup>19</sup> The stratum amounts do not sum to the total amount due to rounding.

<sup>20</sup> *Id.*

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

**Table 3: Sample Results by Risk Area**

<b>Risk Area</b>	<b>Selected Claims</b>	<b>Value of Selected Claims</b>	<b>Claims with Over/Under-payments</b>	<b>Value of Over/Under-payments</b>
Inpatient rehabilitation facility	42	\$886,949	38	\$798,533
Inpatient claims billed with high-severity-level DRG codes	47	481,742	13	63,896
Inpatient mechanical ventilation codes	1	32,957	0	0
<b>Inpatient Totals</b>	<b>90</b>	<b>\$1,401,648</b>	<b>51</b>	<b>\$862,429</b>
Outpatient claims with bypass modifiers	10	\$7,594	0	0
<b>Outpatient Total</b>	<b>10</b>	<b>\$7,594</b>	<b>0</b>	<b>0</b>
<b>Inpatient and Outpatient Totals</b>	<b>100</b>	<b>\$1,409,242</b>	<b>51</b>	<b>\$862,429</b>

Note: 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.



## APPENDIX E: HOSPITAL COMMENTS



7590 Auburn Road  
Concord Township, OH 44077  
440-375-8100  
440-354-2400  
440-953-9600  
lakehealth.org

April 23, 2021

**VIA CERTIFIED MAIL; RETURN RECEIPT REQUESTED AND ELECTRONIC SUBMISSION**

Ms. Sheri L. Fulcher  
Regional Inspector General for Audit Services  
Department of Health and Human Services  
Office of Inspector General  
Office of Audit Services, Region V  
233 North Michigan, Suite 1360  
Chicago, IL 60601

**RE: Written Comments to Draft Report Medicare Hospital Provider Compliance Audit: Lake Hospital System Report A-05-19-00024**

Dear Ms. Fulcher,

The purpose of this letter is to provide written comments on behalf of Lake Hospital System, Inc. dba Lake Health ("Lake Health") in response to the draft audit report *Medicare Hospital Provider Compliance Audit: Lake Hospital System* dated March 26, 2021 ("Draft Report") resulting from an audit of selected inpatient and outpatient claims from January 1, 2017 through December 31, 2018 (the "Audit").

Lake Health has a long-standing Corporate Compliance Program that, on paper and in practice, evidences Lake Health's commitment to ensuring the highest level of ethics and compliance. To be clear, for any claim where Lake Health concurs with the findings set forth in the Draft Report, Lake Health has committed to voluntarily refunding such claims upon the conclusion of the Audit. Also, Lake Health appreciates the opportunity to provide written comments to address the findings and recommendations set forth in the Draft Report, including those findings and recommendations with which Lake Health disagrees.

The Draft Report contains 3 recommendations. In its cover letter to the Draft Report, the OIG requested that Lake Health indicate its concurrence or nonconcurrence with each recommendation. We address these below. Additionally, this letter also addresses the specific categories of denials as well as the extrapolation of damages performed by the OIG.

**Lake Health Written Response to Draft Report Recommendations**

1. Refund \$4,385,974 to the Medicare contractor.

Lake Health states its nonconurrence with the Draft Report's recommendation that Lake Health refund \$4,385,974 to the Medicare contractor. For the reasons set forth herein, Lake Health does not agree with the Draft Report's overpayment findings for the inpatient claims at issue in this Audit. Further, Lake Health does not agree that extrapolation was appropriate in this case in accordance with the Chapter 8 of the Medicare Program Integrity Manual (CMS Pub. #100-08) ("MPIM"). Lake Health reserves the right to submit additional arguments regarding the selection of the statistical sampling as well as the statistical methodologies as the Draft Report does not provide sufficient information to allow the extrapolation to be replicated.

*2. Identify, report, and return any overpayments and identify any returned overpayments made in accordance with the Audit.*

Lake Health states its concurrence with the Draft Report's recommendation that Lake Health identify, report, and return any overpayments discovered by it. Further, Lake Health states its concurrence to specifically identify any returned overpayments made in accordance with this Audit. Lake Health acknowledges the affirmative duty set forth in its Corporate Compliance Program to identify, report, and return any overpayments identified by Lake Health. This duty is in accordance with Section 1128J(d) of the Social Security Act. With respect to this Audit, Lake Health has declared, and continues to declare, its intent to voluntarily refund any overpayments identified in the Draft Report, *and with which it concurs*, at the conclusion of this Audit. However, this commitment should not be construed as Lake Health's concurrence as to all of the purported overpayments stated by the OIG in its Draft Report. To be clear, Lake Health disagrees with a vast majority of the OIG's findings in its Draft Report. Lake Health will provide courtesy notice to the OIG of all claims voluntarily refunded by Lake Health in instances where Lake Health agrees with the OIG's findings in this Audit.

*3. Strengthen internal controls.*

Lake Health states its concurrence with the Draft Report's recommendations that Lake Health take appropriate action to strengthen internal controls. Lake Health has a commitment to an effective culture of compliance. Prior to the Audit, Lake Health has evidenced its commitment to identifying opportunities for improvement as this has been a long-standing practice of Lake Health's Corporate Compliance Program. On August 30, 2019, Lake Health provided the OIG with information regarding its existing Corporate Compliance Program and its historical operations. Importantly, Lake Health did have internal controls in place concerning the inpatient claim categories at issue in this Audit. Lake Health, in accordance with its Corporate Compliance Program, proactively took appropriate steps to strengthen existing internal controls, policies, and procedures prior to and during the Audit process. Lake Health will continue to identify areas of opportunity and improvement in furtherance of its commitment to an effective Corporate Compliance Program. To be clear, Lake Health's concurrence with this recommendation is a commitment to continue its robust compliance operations.

**Lake Health Written Response to Alleged Overpayments by Category**

The Audit reviewed 100 claims consisting of 90 inpatient claims and 10 outpatient claims. Notably, OIG stated in its Draft Report that no errors were found with respect to the 10 outpatient claims. Out of the 90 inpatient claims audited, the OIG alleged 51 claims had errors. The Draft Report extrapolated the alleged overpayment amount of \$862,429 from the sampled claims to a total alleged overpayment amount of \$4,385,974.

The 51 inpatient claims with alleged errors are broken down into the following categories:

1. Inpatient Rehabilitation Claims: 38 alleged overpayments
2. Incorrectly Billed DRG Codes: 3 alleged overpayments and 1 alleged underpayment
3. Incorrectly Billed Inpatient Claims: 9 alleged overpayments

We will address the alleged errors by category in further detail below.

The OIG was willing to engage in ongoing dialogue following the Exit Conference held on January 6, 2021. Lake Health appreciated the opportunity to engage in continued dialogue with the OIG concerning this Audit and the additional information provided by the OIG to Lake Health. Lake Health submitted oral and written statements regarding its position on the denied claims that included both substantive and legal arguments. We will address the substantive arguments below with respect to the alleged errors by category in further detail below. We will also address the extrapolation separately.

#### *1. Inpatient Rehabilitation Claims*

The Draft Report alleges 38 claims were incorrectly billed as inpatient rehabilitation (“IRF”) claims. Lake Health disagrees with 26 of the OIG claim denials. The OIG’s contracted reviewer clearly used subjective factors that are not in accordance with the Medicare IRF coverage criteria in making determinations as to whether the patient evidenced the ability to improve with inpatient rehabilitation services or whether the patient required physician supervision. The OIG contracted reviewer did not reference the Medicare coverage criteria specifically in his/her denial reasons for these claims. Rather, the contracted reviewer scaled or applied a rubric to assess the patient’s status at admission. This scaling system or rubric is not consistent with the Medicare coverage criteria. The scaling system is analogous to the scaling system that is used for Functional Independence Measurement, which is not applicable in this case.

Lake Health is concerned by this subjective scaling system. On January 27, 2021, Lake Health issued a request for any materials provided by the OIG to its contracted reviewers to assist with their review. On March 24, 2021, the OIG provided Lake Health with a copy of the *Hospital Compliance Error Matrix*. The OIG confirmed that this is a document the OIG provides to its reviewers, which contains the Medicare regulations and coverage criteria in effect at the time the services were rendered. Lake Health reviewed the *Hospital Compliance Error Matrix* and confirmed its consistency with the Medicare coverage criteria for IRF claims. However, the OIG’s contracted reviewer clearly utilized a subject “scaling system” and subjective criteria that is inconsistent with the Medicare coverage guidelines and the *Hospital Compliance Error Matrix*. The denial reasons can be summarized as follows:

1. Denial Reason #1 – patient has “minimal impairment,” requires “minimum assistance,” requires “moderate assistance,” or requires “maximum assistance”

The contracted reviewer categorized patients according to rubric or “scaling” system that is not consistent with the Medicare coverage guidelines. The patients in this category were denied by the contracted reviewer because these patients were characterized as (1) only requiring “moderate assistance,” meaning, the patient was not “sick enough” for inpatient rehabilitation; or (2) requiring “maximum assistance,” meaning, the patient was “too sick” for inpatient rehabilitation. This scaling system is analogous to the rubric used for Functional Independence Measurement, but it is not included in the Medicare guidelines as part of the preadmission decision-making. To be clear, the Medicare preadmission criteria do not dictate any specific functional level for admission to an IRF. Upon further review, these characterizations were not included in the Hospital Compliance Error Matrix provided by the OIG. It is clear that the contracted reviewer in this Audit inserted a subjective set of admission criteria.

2. Denial Reason #2 – the patient was “stable at the time of discharge” from the acute inpatient setting and admission to the IRF

One of the key elements set forth in the Medicare IRF coverage criteria is that the patient “is sufficiently stable and can reasonably be expected to actively participate in...an intensive rehabilitation therapy program.” This is also a required element as set forth in the *Hospital Compliance Error Matrix*. Effectively, the reviewer used the required element for admission to the IRF – that the patient be medically stable – as a denial for admission to the IRF. In all of these cases, the patients had chronic illnesses, but were medically stable. The patient must be medically stable for appropriate discharge from the acute inpatient setting. And the patient must be medically stable for admission to the IRF in order to actively participate in the rehabilitation program. Again, the contracted reviewer blatantly disregarded the IRF Medicare coverage criteria. And subjectively used the require element, which was met, to deny the admission.

3. Denial Reason #3 – the use of the phrase “physician supervision by rehabilitation physician is not required” and “physician supervision guidelines not met”

Lastly, the contracted reviewer stated that the patient does not require physician supervision or that the physician supervision is not met due to the lack of active medical management by the physician. The Medicare coverage criteria requires physician supervision of the patient’s care while in the IRF, which includes a face-to-face visit with the patient at least 3 days per week to assess the patient both medically and functionally and to modify the course of treatment *as necessary*. Again, this is included in the OIG’s *Hospital Compliance Error Matrix*. The guidelines do not require active decline or continued impairment from the patient’s underlying comorbidities. The guidelines also do not require medical intervention to support the medical necessity of the intensive rehabilitation services.

Again, the contracted reviewer applied additional elements that are simply not set forth in the Medicare criteria for IRF coverage. The contracted reviewer denied claims where there was no active medical management by the physician. However, the medical record documentation clearly evidences that the physician periodically assessed the patient both medically and functionally and

modified the treatment plan, where needed. The contracted reviewer inappropriately added an additional element that there be active medical management of the patient.

In addition to subjectively or inaccurately applying the Medicare IRF coverage criteria, the contracted reviewer also failed to give deference to the treating physician in this case who was the best position to assess the patient and make clinical determinations. Following receipt of the OIG's preliminary findings, Lake Health's IRF Medical Director, Dr. Nicholas Detore, and Lake Health's Chief Medical Officer, Dr. John Baniewicz, reviewed the medical records. Dr. Detore is also the treating physician in all of these cases. Lake Health also engaged independent certified coders, Sean Weiss<sup>1</sup> and Stephanie Allard<sup>2</sup> with DoctorsManagement, LLC, to review the claims. Dr. Detore, Dr. Baniewicz, Mr. Weiss, and Ms. Allard all disagree with the OIG's findings in 26 cases.

Additionally, these patients had documented chronic conditions that required ongoing medical management in an inpatient setting. Without the IRF, these patients would not have made the functional improvements evidenced within the medical record documentation. This, in and of itself, evidences the medical necessity and appropriateness of the admission. Notably, the AHA/ASA Guidelines for Adult Stroke Rehabilitation and Recovery also state that an IRF place of service is preferred to a skilled nursing facility ("SNF") level of care – especially given the drastic difference in the level of care and services provided by each institutional setting.

In an IRF, patients receive at least 3 hours of therapy per day for at least 5 days per week. Patients are also seen and evaluated by a physician every 3 days. In a SNF, patients are only seen every 30 days by a physician and receive only 1 hour of therapy per day, which is not delivered by an interdisciplinary team. It is clear that the contracted reviewers in this case are not familiar with the Medicare coverage criteria, the AHA/ASA Guidelines for Adult Stroke Rehabilitation and Recovery, or the vast difference in the level of care provided in an IRF as compared to a SNF. Most of these cases involve patients who have experienced a stroke. The recommended level of care, which is the community standard of care, is admission to an IRF and not a SNF as the level of care provided in a SNF does not allow the patient to reach his/her full recovery potential.

While the *Jimeno* guidelines state that outcomes cannot be used in determining whether the admission is appropriate, the fact that the patients in each of these cases achieved measurable, functional improvement (that could not have been achieved in a SNF setting) further supports the treating physician's clinical decision-making. Again, the treating physician makes the clinical judgment whether to admit the patient using the Medicare criteria and the treating physician's physical examination of the patient at the time of admission and without the foresight into whether the patient will, in fact, make measurable functional improvements. However, in these cases, the patients did make measurable functional improvements.

Lake Health agrees to voluntarily refund the 12 claims with which it agrees. Notably, these claims failed to meet Medicare documentation requirements, which are technical errors. As noted in the Draft Report, Lake Health did have internal controls in place to prevent these technical errors, including, but not limited to, a comprehensive checklist incorporating the Medicare guidelines for

---

<sup>1</sup> Sean Weiss, CHC, CEMA, CMCO, CPMA, CPC-P, CMPE, CPC, Vice President of Compliance, DoctorsManagement, LLC.

<sup>2</sup> Stephanie Allard, CPC, CEMA, RHIT, Senior Compliance Specialist, DoctorsManagement, LLC.

medical record documentation. The claims at issue are from CY 2017 and 2018 and Lake Health's IRF Department did have a checklist and utilized the checklist during this time period. As part of its Corporate Compliance Program, Lake Health regularly reviews and updates its key internal controls to prevent such technical errors, including the checklist. In this case, Lake Health proactively reviewed and made appropriate updates and improvements to its checklist. Lake Health submits that there are no additional controls that it needs to implement in this area as Lake Health has already proactively implemented operational improvements as part of its ongoing Corporate Compliance Program.

### *2. Incorrectly Billed DRG Codes*

The Draft Report alleges 4 claims were incorrectly coded, with 3 claims containing overpayments and 1 claim containing an underpayment. Lake Health disagrees that the 4 claims were incorrectly coded. Following receipt of the OIG's preliminary findings, Lake Health's Lead Senior Coder, Beth Ayers, reviewed the medical records. Lake Health confirmed that its original coding was correct in each of the 4 claims. Specifically, the OIG failed to review specific documentation contained within the medical record, which supported the original diagnosis codes. Further, Lake Health engaged independent certified coders, Sean Weiss and Stephanie Allard with DoctorsManagement, LLC, to review the claims. Mr. Weiss and Ms. Allard confirmed that the original coding of each of the 4 claims was correct.

As confirmed by the OIG in its Draft Report, Lake Health had sufficient internal controls in place and followed its key controls. As part of its Corporate Compliance Plan, Lake Health regularly reviews these controls to identify areas for improvement opportunities. Lake Health will continue to follow its key internal controls, which ensure accurate claims submission. Lake Health submits that there are no additional controls that it needs to implement in this area.

### *3. Incorrectly Billed Inpatient Claims*

The Draft Report alleges 9 claims were incorrectly billed as inpatient admissions and should have been billed as outpatient or observation. Lake Health disagrees with these findings. Following receipt of the OIG's preliminary findings, Valerie Williamson, MSN, BSN, RN, who serves as Lake Health's Director of Care Coordination, Director UR Management, and Director of Population/Community Health Team, reviewed the medical records. Lake Health disagrees with 7 of the alleged overpayments. Specifically, Lake Health has internal controls to perform utilization review of patient status at the time of admission. In the 7 cases disputed by Lake Health, the medical record documentation for inpatient admission meets either InterQual or Milliman criteria for inpatient admission as well as the Medicare two-midnight rule found at 42 C.F.R. §412.3(d)(1). Further, Lake Health engaged, Sean Weiss and Stephanie Allard with DoctorsManagement, LLC, to review the claims. Mr. Weiss and Ms. Allard also disagreed with the OIG's findings in 7 of the claims.

Lake Health agrees to voluntarily refund the 2 claims with which it agrees.

As confirmed by the OIG in its Draft Report, Lake Health had sufficient internal controls in place and followed its key controls. As part of its Corporate Compliance Plan, Lake Health regularly

reviews these controls to identify areas for improvement opportunities. Lake Health will continue to follow its key internal controls, to ensure accuracy in determination of patient status at admission. Lake Health submits that there are no additional controls that it needs to implement in this area.

### **Lake Health Written Response to Extrapolation**

1. *Extrapolation is not appropriate in this case.*

The OIG conducted this Audit as part of a series of hospital compliance audits focused on certain risk areas for noncompliance applicable to all hospitals and not due to any perceived improper billing or compliance practice on the part of Lake Health. The MPIM states that “[t]he Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), mandates that before using extrapolation...to determine overpayment amounts to be recovered by recoupment, offset, or otherwise, there must be a determination of sustained or high level of payment error, or documentation that educational intervention has failed to correct the payment error.”<sup>3</sup>

In this Audit, there is no allegation that a sustained or high level of payment error exists. In fact, the Draft Report makes a general speculative statement that these alleged errors primarily occurred because Lake Health did not have adequate controls in place. The Draft Report did not make any specific findings with respect to the lack of internal controls. The Draft Report did not identify any systemic issue contributing to a problematic or concerning error rate. The Draft Report also confirms in several paragraphs that Lake Health did, in fact, have sufficient key controls in place that were followed with respect to the claims at issue. Furthermore, the Draft Report does not specifically identify any additional action other than a general strengthening of internal controls. The OIG is not exercising any additional oversight of Lake Health or taking further action as a result of this Audit.

Section 8.4.1.4 of the MPIM lists specific ways that a contractor can demonstrate that a sustained or high level of payment error exists:

- A high error rate of greater than or equal to 50% from a previous payment review;
- Historical pattern of noncompliant billing practices of the particular provider;
- CMS approval that is provided in connection to a payment suspension;
- Information received from law enforcement investigations;
- Allegations of wrongdoing by a current or former employee of the provider; and/or
- Audits or evaluations conducted by the OIG.

This Audit is not connected, in any way, to any other investigation or payment review by the OIG or any other contractor. There was no probe audit conducted prior to this Audit that yielded a high error rate. In fact, Lake Health provided evidence of its ongoing auditing and monitoring activities as part of its Corporate Compliance Program which included the categories of claims at issue in this Audit. To be clear, the OIG has issued no adverse findings with respect to Lake Health’s ongoing activities under its Corporate Compliance Program.

---

<sup>3</sup> MPIM, Chapter 8, Section 8.4.1.2 and 8.4.1.4.

The Draft Report makes no statement and contains no evidence of a sustained or high level of payment error to support that extrapolation in this Audit would be appropriate. The OIG does not identify any of the elements set forth above in the Draft Audit to support its decision to extrapolate. Further, there is no evidence that Lake Health received educational intervention by the OIG or any Medicare contractor for the categories of inpatient claims at issue in this Audit. As such, there is no sufficient basis set forth in the Draft Report that supports a determination that extrapolation may be used in this Audit.

2. *The Draft Report does not contain sufficient information to allow Lake Health to appropriately respond and the extrapolation should be disregarded as it is not statistically valid.*

First, assuming, *arguendo*, that extrapolation was appropriate in this Audit, the Draft Report does not provide sufficient information to allow Lake Health to replicate the audit. Anticipating that this will likely be an issue, on March 25, 2021, Lake Health requested this detailed information and data from the OIG. The Draft Report did not honor this request. The Draft Report states that the sampling frame was constructed from “select inpatient and outpatient claims paid to the Hospital during the audit period for selected services provided to Medicare beneficiaries.” Lake Health received a total of \$87 million in Medicare payments from January 1, 2017 through December 31, 2018. However, the sampling frame was valued at \$11,66,797. The OIG constructed this sample frame by identifying low-dollar, moderate-dollar, and high-dollar “inpatient risk” claims. It is completely unclear how “inpatient risk” claims are defined. Lake Health is unable to identify those claims and it is impossible to replicate the audit to verify its accuracy.

Second, the limited information in the Draft Report shows that the extrapolation is not statistically valid. Section 8.4.2 of the MPIM states, “If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimate, then assertions that the sample and its resulting estimates are ‘not statistically valid’ cannot be legitimately made.” The MPIM makes clear that all six of the criteria must be met in order for the extrapolation to be considered an appropriate action. The Draft Report does not support that all six criteria are met in this Audit; as such, all damage estimates using extrapolation should be disregarded.

The Draft Report does not contain sufficient information and data to evidence how the sample size was determined or the sample size distribution across the strata. Examples of such data include electronic workbooks containing data for the universe of data and the specific sampling frame. The Draft Report makes clear that the paid amount is simply not the estimate sample size. Lake Health is unable to analyze the OIG’s strategy, scheme, or methodology due to this lack of information.

Further, it is not enough to simply state that the sample is random as set forth in the Draft Report. The random sample must come from a homogenous universe. The Draft Report states that the stratification was based upon (1) claims identified for risk by the OIG (which is undefined), and



(2) the paid amount of the claim. This is not proper. Paid amounts for the same procedure code performed by the same provider may vary considerably due to patient copayment obligations, deductible amounts, secondary payment rules, primary payor edicts, contractual exclusions, modifier policies, bundling rules, and other payment rules. It is clear that the stratification was not performed in a manner to ensure a homogenous universe. Therefore, the random sample appears to be a heterogenous sampling, which would not produce accurate extrapolation results.

Because the information in the Draft Report is limited, Lake Health is unable to perform a full analysis of the extrapolation. As such, Lake Health reserves the right to supplement its position should the OIG agree to provide the detailed information. However, the Draft Report provides enough information to evidence that the six criteria set forth in the MPIM are not met in this instance.

### **Conclusion**

Lake Health appreciates the opportunity to present this written response to the Draft Report. Lake Health is appreciative of the ongoing discussions and dialogue that occurred between the parties throughout this Audit process. However, Lake Health respectfully disagrees with the vast majority of the OIG's conclusions set forth in the Audit Report. Lake Health takes its commitment to compliance and the patients it serves very seriously. We hope that this written response is evidence of Lake Health's knowledge of its legal obligations, but also the high quality and effectiveness of its Corporate Compliance Program.

Very truly yours,

*/Robert B. Tracz/*

Robert B. Tracz  
Senior Vice President  
Finance & Chief Financial Officer  
Lake Health

*/Joyce Taylor/*

Joyce Taylor, RN, MBA, CPHQ  
Vice President, Quality  
Chief Quality Officer  
Lake Health