Department of Health and Human Services
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Office of Audit Services

February 2026 | A-04-23-08098

Sarasota Memorial Hospital Received At Least $12.1 Million in Medicare Overpayments

REPORT HIGHLIGHTS

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Why OIG Did This Audit

- For calendar year 2021, Medicare paid hospitals $182 billion, which represents 46 percent of all fee-for-service payments; accordingly, it is important that hospital payments comply with requirements.
- This audit is part of a series of audits examining hospitals with a high volume of claims previously identified as high-risk for noncompliance.
- Sarasota Memorial Hospital (the Hospital) was selected because it submitted a substantial number of potentially high-risk claims to Medicare.

What OIG Found

- The Hospital complied with Medicare billing requirements for 74 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 26 claims, resulting in net overpayments of $272,364 from January 1, 2020, through December 31, 2021 (audit period).
- On the basis of our sample results, we estimated that the Hospital received net overpayments of at least $12.1 million for the audit period.
- These errors occurred primarily because the Hospital did not always follow its written policies and procedures to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

What OIG Recommends

We recommend that the Hospital refund to the Federal government the $12.1 million in estimated net overpayments, consider conducting internal audits for claims after our audit period based on the risks identified by this audit, and provide additional training regarding Medicare billing requirements. Our complete recommendations are found in the audit report.

The Hospital disagreed with most of our findings and all our recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

For calendar year 2021, Medicare paid hospitals $182 billion, which represented 46 percent of all fee-for-service payments. This audit is part of a series of hospital compliance audits. Previous Office of Inspector General (OIG) audits at other hospitals identified certain types of inpatient and outpatient hospital claims as being at risk for noncompliance.[1] Using computer matching, data mining, and other data analysis techniques, we identified hospitals with a disproportionate number of these claims. We selected Sarasota Memorial Hospital (the Hospital) for this audit because it was one of those hospitals that had a substantial number of claims submitted to Medicare in areas OIG designated as high-risk.[2]

OBJECTIVE

Our objective was to determine whether the Hospital complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims from January 1, 2020, through December 31, 2021 (audit period).[3]

BACKGROUND

The Medicare Program

Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for enrollees 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 Administrative Contractors (MACs) to, among other things, process and pay claims submitted by hospitals.

[1] Hospital compliance audit reports issued by OIG are published on the OIG website.

[2] Submitting claims at risk for noncompliance does not by itself mean the claims were noncompliant. Determinations of noncompliance are completed by independent medical review.

[3] This was the most recent data available at the time we started this audit.

Hospital Inpatient Prospective Payment System

Under the inpatient prospective payment system (PPS), CMS pays hospital costs at predetermined rates for enrollee discharges.[4] The rates vary according to the diagnosis-related group (DRG) to which an enrollee's stay is assigned and the severity level of the enrollee'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 enrollee'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 enrollees who require a hospital level of care, including an 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 PPS for IRFs. Under the payment system, CMS established Federal prospective payment rates for distinct case-mix groups (CMGs). The assignment to a CMG is based on the enrollee's clinical characteristics and expected resource needs.

Hospital Outpatient Prospective Payment System

Under the hospital outpatient PPS, Medicare pays for hospital outpatient services on a 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.[5] All services and items within an APC group are comparable clinically and require similar resources. The HCPCS includes the

[4] The inpatient PPS pays the costs of inpatient stays at acute care hospitals, also known as "subsection (d) hospitals" because they are defined at section 1886(d)(1)(B) of the Act. Inpatient Rehabilitation Facilities (IRFs) are excluded from this definition and are not paid under the inpatient PPS. We discuss and treat IRF claims separately.

[5] The healthcare industry uses HCPCS codes to standardize coding for medical procedures, services, products, and supplies.

American Medical Association's (AMA's) Current Procedural Terminology (CPT®)[6, 7] codes for physician services and CMS-developed codes for certain nonphysician services.[8]

Hospital Claims at Risk for Incorrect Billing

We reviewed the following OIG-designated high-risk areas as part of this audit:

- IRF and psychiatric facility claims
- Inpatient claims with the following:
    - High-severity level DRG codes
    - Comprehensive error rate testing (CERT) error prone DRG codes[9]
    - DRGs for severe malnutrition
    - Resumption of home health services[10]
    - Claims paid in excess of charges
    - Mechanical ventilation
    - Same day discharge and readmission

[6] *CPT copyright 2020 American Medical Association. All rights reserved.*

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

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[7] **U.S. Government End Users**. CPT is commercial technical data, which was developed exclusively at private expense by the AMA, 330 North Wabash Avenue, Chicago, Illinois 60611. Use of CPT in connection with this product shall not be construed to grant the Federal Government a direct license to use CPT based on FAR 52.227-14 (Data Rights - General) and DFARS 252.227-7015 (Technical Data - Commercial Items).

[8] 45 CFR § 162.1002(c)(1); The Medicare Claims Processing Manual, Publication No. 100-04 (the Manual), chapter 4, § 20.1.

[9] CMS calculates the Medicare Fee-for-Service improper payment rate through the CERT program. Each year, CERT evaluates a statistically valid stratified random sample of claims to determine whether they were paid properly under Medicare coverage, coding, and billing rules. As a result of our analysis of CERT data, we identified 10 DRGs that are most at risk for billing errors: 149, 312, 313, 518, 519, 520, 742, 743, 947, and 948.

[10] Resuming home health services means that an enrollee who previously received home health services is starting to receive the services again after a period of hospitalization.

- Outpatient claims with bypass modifiers[11]

- Outpatient skilled nursing facility (SNF) consolidated billed claims

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

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)).

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) (chapter 1, section 80.3.2.2) requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly.

Limitation on Recovery of Overpayments

MACs may reopen a claim for good cause within 4 years from the date of the initial determination or redetermination.[12] First Coast Service Options, Inc., the Hospital's MAC, reopened all claims in our audit sample frame within 4 years from the date of the initial determination of each of those claims.

Section 1870 of the Act prohibits the recovery of Medicare fee-for-service overpayments if the provider was without fault with respect to the overpayment.[13] A provider is presumed to be without fault for Medicare fee-for-service overpayments if the overpayment determination is made by the Medicare program after the fifth year following the year in which notice of such

[11] A bypass modifier refers to a two-digit code appended to a medical procedure code (CPT or HCPCS) on a claim submitted for reimbursement by Medicare. The modifier serves to override edits that otherwise prevent payment for two or more services billed together.

[12] 42 CFR § 405.980(b)(2).

[13] Section 1870; 78 Fed. Reg. 74230, 74445 (Dec. 10, 2013); Medicare Financial Management Manual, chapter 3, §§ 70.3 and 80.

payment was sent to the provider.[14] MACs typically waive recovery in accordance with this presumption but have the authority to determine whether there is sufficient evidence to rebut the presumption.

Sarasota Memorial Hospital

The Hospital is a 904-bed short-term, acute-care hospital, located in Sarasota, Florida. According to CMS's National Claims History (NCH) data, Medicare paid the Hospital approximately $609 million for 35,237 inpatient and 441,606 outpatient claims during the audit period.

HOW WE CONDUCTED THIS AUDIT

Our audit covered roughly $80 million in Medicare payments made to the Hospital for 5,654 claims in the risk areas identified above.[15] We selected for review a stratified random sample of 100 claims (65 inpatient, 20 IRF, and 15 outpatient) with Medicare payments totaling about $1.7 million made during our audit period.[16]

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 audit scope and methodology.

FINDINGS

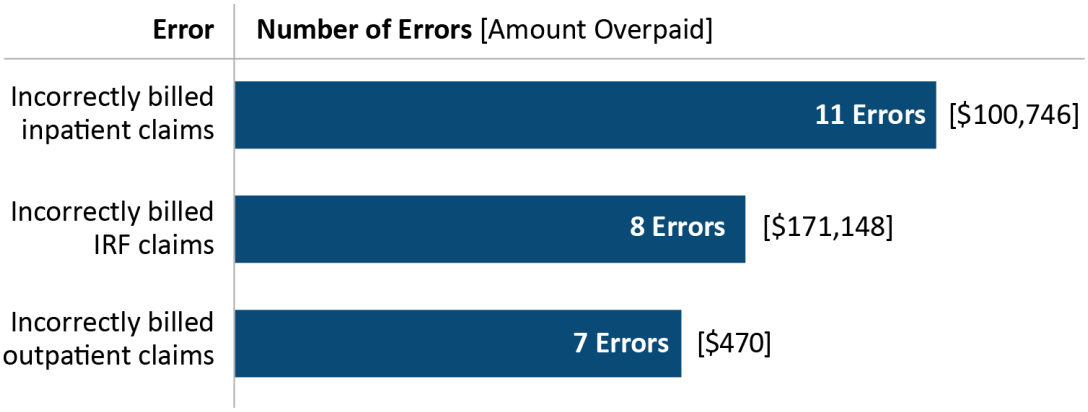
The Hospital complied with Medicare billing requirements for 74 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 26 claims, resulting in net overpayments of $272,364. Figure 1, on the next page, provides a breakdown of the error types, number of claims in error and the associated overpayments.

[14] Section 1870; 78 Fed. Reg. 74230, 74445 (Dec. 10, 2013); Medicare Financial Management Manual, chapter 3, §§ 70.3 and 80.

[15] The total Medicare payments were $79,527,488.

[16] The total Medicare payments were $1,652,684.

Figure 1: Inpatient and Outpatient Billing Errors



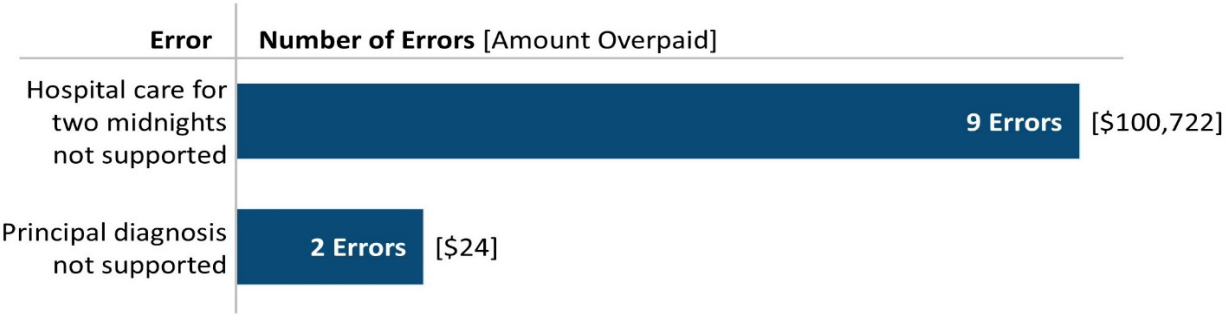
These errors occurred primarily because the Hospital did not always follow its policies and procedures to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

On the basis of our sample results, we estimate that the Hospital received net overpayments of at least $12.1 million for the audit period.[17] See Appendix B for the statistical sampling methodology, Appendix C for sample results and estimates, and Appendix D for the results of our audit by risk area.

INCORRECTLY BILLED INPATIENT CLAIMS

For 11 of the 65 selected inpatient claims, our independent medical review contractor determined that the Hospital incorrectly billed Medicare Part A for enrollee stays that did not meet Medicare criteria for inpatient services at acute care hospitals. These errors resulted in net overpayments totaling $100,746. Figure 2 provides a breakdown of the error types, number of claims in error, and the associated overpayments.

Figure 2: Inpatient Billing Errors



[17] Our actual estimate is $12,199,717. 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.

Hospital Care for Two Midnights Not Supported

No payment may be made under Medicare Part A for any expenses incurred 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)).

Federal regulations provide that an inpatient admission, and subsequent payment under Medicare Part A, is appropriate if the ordering physician expects the enrollee to require care for a period that crosses 2 midnights (42 CFR § 412.3(d)(1)).

For 9 of the 65 selected inpatient claims, the medical records did not support that it was reasonable for the admitting physician, at the time the inpatient order was written, to have expected that hospital care was required for a period that crosses 2 or more midnights.[18] Overpayments associated with these 9 claims totaled $100,722.

Principal Diagnosis Not Supported

DRG codes are assigned to specific hospital discharges based on claims data submitted by hospitals (42 CFR § 412.60(c)), so claims data must be accurate.

For 2 of the 65 selected inpatient claims, the Hospital submitted claims to Medicare that had principal diagnosis codes that were not supported by the medical records. The incorrectly coded claims resulted in incorrect DRG payments to the Hospital. Incorrect DRG payments made to the Hospital associated with these two claims totaled $24.

Principal Diagnosis Code Not Supported

One enrollee was admitted to the Hospital with an incorrect principal diagnosis code used for pain caused by internal prosthetic devices, implants, and grafts. The actual cause of admission was a complication related to breast implants. The change in the principal diagnosis code caused a change in the DRG code, which should be reimbursed at a lower payment rate.

INCORRECTLY BILLED INPATIENT REHABILITATION FACILITY CLAIMS

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 enrollee (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 to be able to actively

[18] Our medical review contractor also determined that these 9 claims did not meet InterQual® Level of Care Criteria for inpatient hospital admission. These criteria are evidence-based clinical decision support tools that many hospitals use to help assess clinical appropriateness and strengthen patient outcomes. Failure to meet InterQual Level of Care Criteria does not equate with failure to meet Medicare requirements, but we believe this is useful information for the Hospital for their quality assurance efforts. See the first item in Other Matters for additional information.

participate in the intensive rehabilitation program; and (4) requires supervision by a rehabilitation physician (42 CFR § 412.622(a)(3)(i-iv)). During the COVID-19 Public Health Emergency (PHE), the second requirement and the "intensive" nature of rehabilitation therapy in the third requirement were waived (42 CFR § 412.622(a)(3)(ii-iii)).

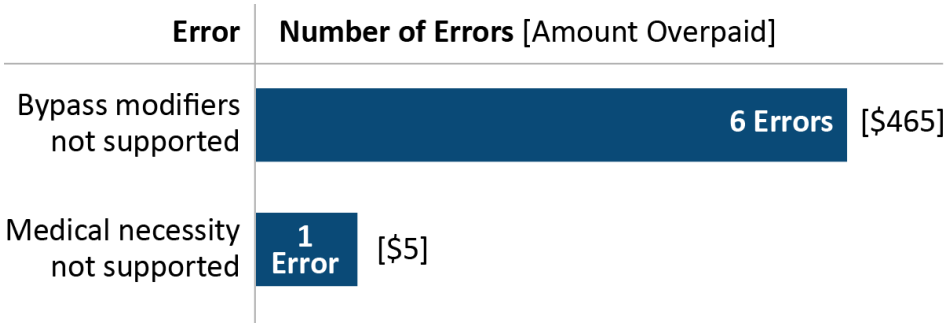
For 8 of the 20 selected IRF claims, our independent medical review contractor determined that the Hospital incorrectly billed Medicare Part A for enrollee stays that did not meet Medicare criteria for acute inpatient rehabilitation. For seven of the eight claims, there was not a reasonable expectation that the enrollee required supervision by a rehabilitation physician. The remaining claim's documentation did not support a reasonable expectation that the enrollee was sufficiently stable to be able to actively participate in a rehabilitative program at the time of admission. Overpayments associated with these 8 claims totaled $171,148.

IRF Claim Did Not Meet Criteria
One enrollee was admitted for inpatient rehabilitation services with active and ongoing medical issues, such as pain and lethargy, which would reasonably be expected to interfere with their active participation in therapy. The initial physical therapy evaluation noted poor tolerance because of pain, and additional assessments were not performed for the same reason. The enrollee was discharged to the acute-care unit of the Hospital because the enrollee could not tolerate a rehabilitation program.

INCORRECTLY BILLED OUTPATIENT CLAIMS

For 7 of the 15 selected outpatient claims, our independent medical review contractor determined that the Hospital incorrectly billed Medicare Part B for claims that did not meet Medicare criteria for outpatient services. These errors resulted in overpayments totaling $470. Figure 3 provides a breakdown of the error types, number of claims in error, and the associated overpayments.

Figure 3: Outpatient Billing Errors



Bypass Modifiers Not Supported

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)). Claims must be

filed on forms prescribed by CMS in accordance with CMS instructions (42 CFR § 424.32(a)(1)). Acute care hospitals are required to report HCPCS codes, of which CPT codes are a subset, on outpatient claims (the Manual, chapter 4, § 20.1), and providers are required to complete claims accurately so that Medicare contractors may process them correctly and promptly (the Manual, chapter 1, § 80.3.2.2).

Modifier 59 is used to identify procedures/services, other than evaluation and management services, that are not normally reported together but are appropriate to report separately under certain circumstances. Documentation must support a different session, different procedure or surgery, different site or organ system, separate incision/excision, separate lesion, or separate injury (or area of injury in extensive injuries) not ordinarily encountered or performed on the same day by the same individual (Medicare National Correct Coding Initiative (NCCI) Policy Manual, chapter 1, section E).[19]

Modifiers XE, XS, XP, XU became effective January 1, 2015. These modifiers were developed to provide greater reporting specificity in situations where modifier 59 was previously reported and may be used in lieu of modifier 59 whenever possible. The modifiers are defined in the NCCI Policy Manual as follows:

- **XE—**Separate Encounter: A service that is distinct because it occurred during a separate encounter. This modifier shall only be used to describe separate encounters on the same date of service.
- **XS—**Separate Structure: A service that is distinct because it was performed on a separate organ/structure.
- **XP—**Separate Practitioner: A service that is distinct because it was performed by a different practitioner.
- **XU—**Unusual Non-Overlapping Service: the use of a service that is distinct because it does not overlap usual components of the main service.

For 6 of 15 selected outpatient claims, the Hospital incorrectly billed Medicare Part B using HCPCS codes with bypass modifier XU, even though the services were not separate from other procedures on the same claim. Overpayments associated with these six claims totaled $465.

Unsupported Modifier
One claim was incorrectly coded with modifier XU, which improperly unbundled the billing for a compression wrap that should not have been separately billed from a skin graft procedure.

[19] *The responsibility for the content of any "National Correct Coding Policy" included in this product is with the Centers for Medicare and Medicaid Services and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable to or related to any use, nonuse or interpretation of information contained in this product.*

Medical Necessity Not Supported

No payment may be made under Medicare Part B for any expenses incurred 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 1 of the 15 selected outpatient claims, the medical record did not include any clinical information supporting the medical necessity of a billed laboratory test. The overpayment associated with that claim was $5.

HOSPITAL STAFF DID NOT ALWAYS FOLLOW PROCEDURES TO PROPERLY BILL HOSPITAL SERVICES

The 26 incorrectly billed claims did not comply with Medicare requirements because staff did not consistently follow the Hospital's written policies designed to prevent noncompliance with the Two-Midnight Rule, medical necessity, IRF admissions, documentation, billing, and coding. Although Hospital officials contend that the claims met Medicare requirements, they did not provide any additional information that would affect our finding.

RECOMMENDATIONS

- We recommend that the Hospital refund to the Federal government the estimated $12,199,717 in net overpayments for incorrectly billed claims, excluding amounts presumed to be unrecoverable under the Section 1870 waiver of liability provision.[20, 21]

- We recommend that the Hospital consider conducting one or more internal audits or investigations for claims beyond our audit period, based on the risks identified by this audit, to identify any similar overpayments and return any identified overpayments to the Medicare program.

- We recommend that the Hospital provide additional training to clinical and billing personnel on its policies and procedures related to the following:

[20] OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC 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.

[21] First Coast Service Options, Inc. retains the authority to determine whether there is sufficient evidence to rebut the Section 1870 "fifth year following" "without fault" presumption that might limit the recovery of any of these overpayments.

- The Two-Midnight Rule
- The medical necessity of inpatient and outpatient services
- IRF admissions
- The billing of services provided
- Inpatient and outpatient coding

HOSPITAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Hospital disagreed with most of our findings and all our recommendations. The Hospital stated that the audit conclusions are flawed due to OIG's failure to adequately consider the clinical judgment of treating physicians and the effect of the COVID-19 PHE, as well as OIG's misapplication of Medicare legal requirements, such as the Two-Midnight Rule. In addition, the Hospital disagreed with OIG's use of statistical extrapolation, asserting it lacks the required threshold findings and is inappropriate for subjective medical necessity determinations. The Hospital also stated that our audit is inconsistent with Generally Accepted Government Auditing Standards (GAGAS). Furthermore, the Hospital provided clinical rebuttals to sampled claims presented in the report. Finally, the Hospital defended its compliance processes, including utilization review, physician training, and internal audits.

We summarized the Hospital's agreements, disagreements, and objections below.[22]

After reviewing the Hospital's comments, we removed four errors based on additional documentation provided by the Hospital related to IRF documentation for an Interdisciplinary Team (IDT) meeting, a preadmission screening, a missing admission order, and the Two-Midnight Rule. In addition, we revised two overpayment amounts based on the additional information provided. As a result, we updated our findings, estimated overpayment amount, and recommendations. We also maintain that our findings and recommendations, as revised, are correct.

[22] We list the Hospital's agreements, disagreements, and objections by subject matter because the Hospital touched on a number of topics across several headings. We have responded to the Hospital's comments within each topic area.

The Hospital's comments, excluding its exhibits, are included as Appendix E.[23]

AUDIT RECOMMENDATIONS

Hospital Comments

The Hospital did not concur with any of our recommendations. Regarding our first recommendation, the Hospital asserted that our findings are both clinically and legally erroneous. For the few claims where the Hospital agreed with us, it stated it will issue refunds. For the rest, it stated it will challenge any adverse determinations by its MAC through the Medicare appeals process.

Regarding our second recommendation, the Hospital argued that the issues identified are isolated and do not justify further audits. In addition, it said the claims in question occurred during the PHE, and there is no indication that similar issues exist outside this period. Regarding our third recommendation, the Hospital maintained that its existing compliance and training programs are robust and that the audit findings do not reveal systemic deficiencies requiring additional training and education.

Office of Inspector General Response

We disagree with the Hospital's assertion that our findings are erroneous. We submitted the selected claims to an independent medical review contractor who 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 our medical reviewer to ensure that their review was conducted by professionals, including physicians and coders, with relevant expertise, and that the appropriate Medicare criteria were applied. In response to the Hospital's draft report comments and the additional information provided, we removed four errors and revised the calculated overpayment for two errors. As a result, we also revised our estimated overpayment and recommendation. The Hospital has the right to appeal any action taken by CMS or MAC based on our findings, as previously stated in the report.

For our second recommendation, we disagree that the errors are isolated, that they do not justify further audits, and that there is no indication that similar issues exist. We identified multiple findings in error categories, such as the Two-Midnight Rule and incorrectly coded

[23] Exhibit A to the Hospital's comments is a copy of our draft report. Exhibit B contains the Hospital's internal rebuttal statements for the findings the Hospital did not agree with. In addition, the Hospital hired an expert health care consulting firm and included the expert's opinion related to the medical necessity and appropriateness of billing as Exhibit C. Exhibits D–F contain the recalculated payment amount for two claims and documentation supporting one IRF claim related to an enrollee being sufficiently stable to be able to actively participate in a rehabilitation therapy program. Although we did not include Exhibits A–F in our final report, they were considered in their entirety in preparing our final report and will be provided to CMS.

claims, indicating that these errors are not isolated and similar issues may exist.[24] We continue to believe the hospital should consider performing internal audits or investigations for claims beyond our audit period

For our third recommendation, we do not agree with the Hospital that additional training is not needed, despite acknowledging the Hospital's existing compliance and training programs. We continue to believe that additional training can be provided to increase compliance with Medicare requirements. In response to the Hospital's comments, we revised this recommendation by removing the reference to IRF documentation.

MEDICAL REASONABLENESS AND NECESSITY OF INPATIENT ADMISSION

Hospital Comments

The Hospital disagreed with the 11 claims we identified as errors, stating that the documentation supported the admitting physician's expectation that hospital care would span 2 or more midnights.

For each of these claims, the Hospital indicated that the medical records and the report provided by their medical consultants support the physician's expectation that the patient required hospital care that would span 2 or more midnights. The Hospital further asserted that our medical reviewer failed to consider post-admission information when determining whether the Hospital complied with the Two-Midnight Rule, did not consider the time spent in the hospital before inpatient admission (e.g., observation status) toward satisfying the Two-Midnight Rule, failed to apply the Two-Midnight Presumption, and failed to consider unforeseen circumstances that resulted in the patient's discharge before staying in the hospital across 2 midnights.

Post-Admission Information

The Hospital stated that our medical reviewer failed to consider post-admission information that would support a finding that an admission was medically reasonable and necessary. To support its position, the Hospital cited CMS guidance to Quality Improvement Organizations (QIOs) for reviews of hospital admissions.[25] In an example provided, the Hospital stated that

[24] We identified nine errors related to the Two-Midnight Rule and eight coding errors (two inpatient and six outpatient).

[25] Specifically, Chapter 1, Section 10 of the Medicare Benefits Policy Manual states that "Under original Medicare, the QIO for each hospital is responsible for deciding, during review of inpatient admissions on a case-by-case basis, whether the admission was medically necessary…. In making these judgements, however, QIOs consider only medical evidence which was available to the physician at the time an admission decision had to be made. They do not consider other information (e.g., test results) which became available only after admission, except in cases where considering the post-admission information would support a finding that an admission was medically necessary."

our medical reviewer ignored documentation showing the enrollee's instability and associated medical interventions after admission. In addition, the Hospital stated that our medical reviewer disregarded repeat laboratory studies.

Pre-Admission Hospitalization

The Hospital asserted that our medical reviewer improperly discounted the time the enrollee spent in the hospital before the inpatient admission decision. The Hospital stated that CMS guidance requires the admission decision to be based on the cumulative time spent at the hospital, beginning with the initial outpatient services.

The Hospital provided an example where it notes our reviewer improperly discounted the time the enrollee spent in observation status. The Hospital stated that our reviewer acknowledged that the enrollee was discharged a day after the inpatient order and had already crossed 2 midnights supported the admission decision.

Two-Midnight Presumption

The Hospital contended that our medical reviewers failed to account for the Two-Midnight Presumption when determining that some claims were noncompliant for enrollees admitted for longer than 2 midnights. The Hospital cited CMS guidance instructing Medicare contractors that, pursuant to the Two-Midnight Presumption, post-payment medical reviews should not focus on stays spanning 2 or more midnights after a formal admission, unless there is evidence of systemic gaming, abuse, or care delays used to qualify for the rule.[26]

The Hospital also contended that although our audit report states that we are not constrained by the Two-Midnight Presumption for the purpose of selecting claims for review (Appendix A, footnote 47), we do not state whether our medical reviewers were obligated to account for the rule, nor did we identify any evidence of systematic gaming, abuse, or delays in the provision of care that might rebut it. The Hospital acknowledges that the presumption is directed at Medicare contractors—and presumably not the OIG—but appears to be asserting that the Hospital still gets the benefit of the presumption because a Medicare contractor will be determining whether overpayments exist and recovering any overpayments.

Short-Stay Claims

The Hospital stated that our medical reviewers found several claims to be in error because the enrollee was discharged before 2 midnights had passed. It said that an enrollee may still have been appropriately admitted as an inpatient when the enrollee's stay does not cross 2 midnights because of subsequent "unforeseen circumstances that result in a shorter stay than the physician's reasonable expectation based on the information available at the time."

[26] *Medicare Program Integrity Model* (*MPIM*), chapter 6, § 6.5.2.

In one example it provides, the Hospital said that our medical reviewer overlooked the seriousness of the enrollee's condition on admission. The Hospital stated that the enrollee had an unexpected and rapid recovery and was discharged at their insistence the day after admittance. However, the Hospital stated that because of the high risk of an adverse event, it was reasonable for the admitting physician to have expected the enrollee to require hospital care that crossed 2 midnights.

Office of Inspector General Response

With respect to the Hospital's contention that we erred in finding 11 inpatient admissions did not meet the Two-Midnight Rule, we maintain that 9 inpatient admissions did not meet this requirement. However, based on additional information provided by the Hospital, we agree with the Hospital on two of the disputed claims. For one of those claims, our review did not account for the entire time of the hospital stay. The second claim showed that the intent, decision, and recommendation of the physician to admit the enrollee as an inpatient can clearly be derived from the medical record.[27] Accordingly, we have removed these errors.

We generally disagree with the Hospital's argument that our medical reviewer did not apply the relevant legal standards related to the use of post-admission information, pre-admission hospitalization, the Two-Midnight Presumption, and unforeseen circumstances, as discussed below.

Post-Admission Information

We disagree with the Hospital's contention that our medical reviewer should have considered post-admission information that would support a finding that an admission was medically reasonable and necessary. CMS guidance to QIOs for reviews of hospital admissions is not relevant criteria, as QIOs do not perform post-payment medical reviews for payment purposes. In addition, guidance in the Medicare Benefit Policy Manual cannot alter Medicare regulations, such as the Two-Midnight Rule. The Two-Midnight Rule requires the admitting physician, at the time the inpatient order was written, to have expected that hospital care was required for a period that crosses 2 or more midnights. In guidance to Medicare contractors who perform post-payment medical review, CMS has said that "Medicare review contractor reviews shall assess the information available at the time of the original physician/practitioners' decision" (*Medicare Program Integrity Manual* (*MPIM*), chapter 6, § 6.5.2.B). CMS recently clarified this guidance with the following: "The entire medical record shall be reviewed to support or refute the reasonableness of the practitioner's expectation, but entries after the point of the admissions order are only used in the context of interpreting what the practitioner knew and expected at the time of admission." Our medical review contractor examined the medical records in their entirety to determine whether they supported that it was reasonable for the admitting physician, *at the time the inpatient order was written*, to have expected that hospital

[27] This claim had two errors associated with it. There was one error for the Two-Midnight Rule and the other for a missing inpatient order.

care was required for a period that crosses 2 or more midnights. Our medical reviewers determined that the medical records did not.

Pre-Admission Hospitalization

We agree with the Hospital's assertion that our medical reviewer found that one specific enrollee had already been hospitalized for one or more midnights at the time of inpatient admission. We agree that the decision to admit this enrollee should have been based on the cumulative time spent at the hospital, beginning with the initial outpatient service, and have removed this error. However, this argument applies to just this one claim we found to be in error.

Two-Midnight Presumption

The Two-Midnight Presumption is the name given for CMS's instruction to Medicare contractors to presume hospital stays spanning 2 or more midnights after an enrollee is formally admitted as an inpatient are reasonable and necessary for Part A payment. CMS directs Medicare contractors to not focus their medical review efforts on stays spanning 2 midnights after formal inpatient admission absent evidence of systemic gaming, abuse, or delays in the provision of care in an attempt to qualify for the Two-Midnight Presumption.[28] The Two-Midnight Presumption is limited in scope to Medicare contractors' selection of claims for review.[29] It cannot override the Two-Midnight Rule, a regulation properly established through notice and comment rulemaking. Moreover, the Two-Midnight Presumption does not limit what claims OIG can review, as that is governed by the Inspector General Act. It also has no bearing on a MAC's post-OIG audit determination whether overpayments exist and whether to recoup any overpayments since the medical review was undertaken by the OIG, and not the MAC.

For the specific example cited by the Hospital, our medical reviewers did not have to document any systematic gaming, abuse, or delays in the provision of care, or provide any evidence to rebut the Two-Midnight Presumption because the presumption does not apply to the OIG.

We also disagree with the Hospital's assertion that the medical record supports the admitting physician's reasonable expectation that the hospital stay would cross 2 midnights. The enrollee's symptoms had been resolved in the emergency department, negating the need for a two-midnight stay. Therefore, it was not reasonable for the admitting physician to expect that the hospital stay would cross 2 midnights.

[28] *MPIM*, chapter 6, § 6.5.2.

[29] 78 Fed. Reg. 50496, 50952 (Aug. 19, 2013).

Short-Stay Claims

The Hospital asserted that our medical reviewer erroneously found that several claims were not compliant because the enrollee was discharged before 2 midnights had passed. The Hospital asserted that the enrollees were appropriately admitted, but their stays did not cross 2 midnights due to unforeseen circumstances. We disagree. For each of these claims, the medical records do not support that it was reasonable for the admitting physician to have expected the enrollee to require hospital care crossing 2 midnights. These enrollees staying in the Hospital for less than 2 midnights had no bearing on our medical reviewer's determinations.

For the example provided by the Hospital, our independent medical reviewer determined that it was not reasonable for the admitting physician to have expected the enrollee to require hospital care crossing 2 midnights. This determination was based on the information available to the admitting physician at the time the inpatient order was written and had nothing to do with the enrollee's unexpected and rapid recovery.

INPATIENT CODING ISSUES

Hospital Comments

The Hospital disagreed with one of the overpayment calculations for a coding error because we miscalculated the overpayment amount. The Hospital stated that we used this error as an example in a text box in our draft report and that the description of the principal diagnosis code was incorrect.

Office of Inspector General Response

We agree with the Hospital that the overpayment for this error was miscalculated, and the description of the principal diagnosis code was incorrect.[30] As a result, we confirmed with the Hospital the correct overpayment amount, revised the overpayment amount in the report, and revised the example to correct the description of the principal diagnosis.

INPATIENT ORDER

Hospital Comments

The Hospital agreed with the finding by our medical review contractor that an admission order was missing from one enrollee's medical record, but disputes that the claim was noncompliant. The Hospital stated that in 2018, CMS removed regulatory language requiring the physician

[30] We used an online inpatient PPS calculator to determine the payment amount for the correct DRG code. Because of an unknown issue, the calculator provided an incorrect payment amount that was identified by the Hospital. The calculator has since been updated and provided the correct payment amount that matched the hospitals recalculation.

order to be present in the medical record as a condition of payment. The Hospital also said that the medical record supports the attending physician's intent to admit the enrollee as an inpatient and the reasonable expectation that the enrollee would require treatment for 2 midnights. The Hospital concluded that finding the claim in error based on the absence of an admission order is inappropriate.

Office of Inspector General Response

We concur with the Hospital that the medical record supports the attending physician's intent to admit the enrollee as an inpatient for this one claim. Federal regulations require that documentation include an inpatient admission order by a physician or other qualified practitioner at or before the time of the inpatient admission.[31] However, CMS has stated, "In very rare circumstances, the order to admit may be missing or defective (that is, illegible or incomplete), yet the intent, decision, and recommendation of the physician (or other practitioner who can order inpatient services) to admit the beneficiary as an inpatient can clearly be derived from the medical record. In these rare situations, CMS has provided contractors with discretion to determine that this information constructively satisfies the requirement that the hospital inpatient admission order be present in the medical record."[32] Therefore, we have removed this error.

REASONABLE EXPECTATION OF NEED FOR SUPERVISION BY A REHABILITATION PHYSICIAN

Hospital Comments

The Hospital disagreed with our finding that in seven instances there was not a reasonable expectation at the time of admission that the enrollees required supervision by a rehabilitation physician. It contended that our medical reviewer misapplied the regulatory standard by treating the requirement for physician supervision as separate from the requirement for face-to-face visits. The Hospital asserted that according to 42 CFR § 412.622(a)(3)(iv), the reasonable expectation of the need for supervision is demonstrated by the rehabilitation physician's face-to-face visits at least three times per week. It emphasizes that this is not a separate or additional requirement but the mechanism by which the supervision standard is fulfilled. The Hospital stated that all seven errors we identified included documentation showing that the rehabilitation physician conducted the required face-to-face visits. The Hospital also contended that our medical reviewer failed to defer to the professional judgment of its rehabilitation physicians and disregarded the opinions of the Hospital's reviewers and outside medical reviewers retained by the Hospital.

[31] 42 CFR § 412.3.

[32] 78 Fed. Reg. 50496, 50941 (Aug. 19, 2013).

Office of Inspector General Response

We disagree with the Hospital's assertion that our medial reviewer misapplied the regulatory standard. Two separate requirements exist, and they are not synonymous with each other. For an IRF claim to be considered reasonable and necessary, four requirements must be met, including that there must be a reasonable expectation at the time of the enrollee's admission that the enrollee requires physician supervision by a rehabilitation physician.[33] If it is determined that an enrollee meets this requirement, then the rehabilitation physician must conduct at least three face-to-face visits with the enrollee per week (42 CFR § 412.622(a)(3)(iv)). The fact that a rehabilitation physician performs at least three face-to-face visits per week after admission does not prove that, *at the time of the enrollee's admission to the IRF*, there was a reasonable expectation that the enrollee would need ongoing supervision by a rehabilitation physician.

We also disagree with the Hospital's contention that our medical reviewer must defer to the professional judgment of the Hospital's rehabilitation physician and that we disregarded the opinions of the Hospital's reviewers and outside medical reviewers retained by the Hospital. Our medical reviewer is not required to defer to the professional judgment of the Hospital's rehabilitation physician. In addition, our medical reviewer considered the original documentation (i.e., the medical records) in determining whether the enrollee met the requirement for supervision by a rehabilitation physician in accordance with CMS's documentation requirements.[34] We did not submit the Hospital's after-the-fact opinions to our medical reviewers.

STABILITY TO ACTIVELY PARTICIPATE IN REHABILITATION

Hospital Comments

The Hospital disagreed with one error related to documentation that did not support a reasonable expectation that, at the time of the enrollee's admission to the IRF, the enrollee was stable enough to actively participate in an intensive rehabilitation program. The Hospital argued that our medical necessity criteria imposed too fine a line between being ill enough to require rehabilitation services and being too ill to participate in therapy. The Hospital further asserted that the dates of service for this claim were during the PHE, so the waiver of the "intensive" nature of the rehabilitation program was in effect. The Hospital also stated that our findings neglect the role of a rehabilitation physician, which is to monitor the enrollee's medical and functional status and revise the plan of care (POC) as needed.

[33] See page 7 "Incorrectly Billed Inpatient Rehabilitation Facility Claims" of this report for the four requirements for an IRF admission.

[34] 42 CFR § 412.622(a)(4).

Office of Inspector General Response

We disagree with the Hospital's assertions regarding this claim. Our draft report inadvertently said that the admission of the enrollee came after the PHE and the enrollee was discharged from the IRF because the enrollee could not tolerate an "intensive" rehabilitation program. The report has been corrected to reflect that this admission took place during the PHE and our medical reviewer applied the relevant criteria, 42 CFR § 412.622(a)(3)(iii), with the waiver of the "intensive" nature of the rehabilitation therapy in mind. As we told the Hospital before issuing the draft report, our medical reviewer found that documentation did not support a reasonable expectation at the time of admission that the patient was sufficiently stable "to actively participate in a rehabilitation program." Our medical reviewer carefully weighed two requirements: first, that the enrollee generally needs and can reasonably be expected to actively participate in and benefit from a rehabilitation therapy program; and second, that the enrollee is sufficiently stable at the time of admission to the IRF to do so. Our medical reviewer did not narrow these requirements to question this claim. Lastly, in performing post-payment medical review, we are under no obligation to defer to the clinical decision-making of a treating physician. The OIG is obligated to audit the Medicare program to fight fraud, waste, and abuse, which necessarily involves finding some payments that failed to comply with Medicare requirements despite the best judgment of treating physicians.

INTERDISCIPLINARY TEAM DOCUMENTATION AND PREADMISSION SCREENING

Hospital Comments

The Hospital agreed that documentation for one finding did not indicate that a speech therapist attended an IDT meeting for one enrollee, as required. However, the Hospital stated that the speech therapist had a visit with the enrollee shortly after the IDT meeting where the therapist completed discharge from speech therapy services and the enrollee was discharged from the IRF the next day. The Hospital stated that as of the time of the IDT meeting, speech therapy was no longer an active discipline involved in the enrollee's care, and the therapist's attendance was not required.

The Hospital disputed our finding that preadmission screening for one enrollee did not explicitly include the expected length of time to achieve the enrollee's improvement goals, as required by 42 CFR § 412.622(a)(4)(i)(B). The Hospital stated that although the preadmission screening document lacked this detail, the POC, which was completed within hours of the screening, did include an expected therapy duration of three weeks.

Office of Inspector General Response

We agree with the Hospital that the claim related to the speech therapist's attendance met IDT requirements. The documentation supports that the speech therapist had conducted a discharge visit before the team meeting. Therefore, we have removed this error.

In addition, we agree with the Hospital that although the preadmission screening for one claim did not include the expected length of stay, other documents prepared within hours of the screening stated the expected length of stay would be three weeks. Therefore, we have removed this error.

OUTPATIENT CODING ISSUES

Hospital Comments

The Hospital stated that it does not dispute our findings on six outpatient coding errors and one error related to medical necessity of a billed laboratory test. It affirmed that it will issue a refund. However, the Hospital stated that we miscalculated the overpayment for one coding error.

Office of Inspector General Response

We appreciate that the Hospital will take the necessary steps to refund the seven claims. We also agree with the Hospital that the overpayment for one error was miscalculated because we inadvertently pulled the incorrect payment amount for a different HCPCS that was provided on the same day. We have revised the amount for this error.

STATISTICAL SAMPLING AND EXTRAPOLATION

Hospital Comments

The Hospital stated that, pursuant to 42 U.S.C. § 1395ddd(f)(3) [the Act, § 1893(f)(2)] and chapter 8, section 8.4.1.4 of the *MPIM*, we lacked evidence to justify the use of extrapolation. The Act and *MPIM* state that a Medicare contractor cannot use extrapolation to determine overpayment amounts unless (1) there has been a sustained or high level of payment error, or (2) a documented educational intervention has failed to correct the payment error. It contended that the audit notification letter stated that statistical sampling would be used but did not say that we would be examining any history of payment errors or failed interventions. Furthermore, the Hospital noted that even our own calculated error rates—30 percent for claims and 21.7 percent for financial—each fall below the 50 percent threshold defined in Medicare guidance for a "high error rate." The Hospital acknowledged that the statutory threshold for using extrapolation applies specifically to Medicare contractors and is not binding on the OIG. However, the Hospital asserted that because any identified overpayment will ultimately be processed by a MAC, the audit should still align with CMS policies and procedures. In addition, the Hospital expressed concern that it was selected for review primarily due to its size and high volume of claims, rather than based on specific risk indicators.

The Hospital contended that statistical sampling is inappropriate in the context of medical necessity reviews, which are inherently subjective and require individualized, case-by-case assessments. The Hospital highlighted that many of the services in question were rendered

during the COVID-19 PHE, a period marked by evolving clinical guidance and heightened risks. The Hospital argued that extrapolating findings from a small sample to a broader universe of claims is unreliable and unjustified in such a context. Finally, the Hospital argued that we failed to explain our sampling methodology or how we determined the number of claims per stratum, which casts doubt on the reliability of the statistical analysis. As a result, the Hospital contended that we must redo our extrapolation.

Office of Inspector General Response

The requirement that a determination of a sustained or high level of payment error or documented failed educational intervention before extrapolation applies only to extrapolations by Medicare contractors.[35, 36] Moreover, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.[37] 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.[38] We properly executed our statistical sampling methodology because we defined our sampling frame and sample unit, selected a sample of claims at random from each stratum, applied relevant criteria in evaluating the sample, and used statistical sampling software to apply the correct formulas for the extrapolation. We provided the Hospital with the information necessary to replicate the sample from the sampling frame and to recalculate the estimated overpayment amount.[39] In addition, the Hospital has direct access to its own claims information, which it can use to validate the sampling frame.

[35] The Act § 1893(f)(3) and CMS' *MPIM*, Pub. No. 100-08, chapter 8, § 8.4.

[36] We also dispute the Hospital's assertion that the MAC charged with processing any associated overpayments connected to this audit is subject to the CMS policies it cited. These policies prohibit a MAC from using extrapolation in its own audits unless there is a sustained or high level of payment error or there is a failure of documented educational interventions. The MAC is not subject to such limitations in the adjudication of an OIG audit.

[37] *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 at *17 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

[38] See *John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at *34-35 (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); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D.

[39] We provided the Hospital with the sampling plan, the numbered sampling frame, the random seed, the output of software used to generate the random numbers, the sample results file, and the estimation input and output files.

The Hospital's assertion that it was targeted because it submits a high number of claims is inaccurate. The Hospital was selected using a risk-based approach that included a high number of claims in specific risk categories, high CERT error rates, and multiple Program for Evaluating Payment Patterns Electronic Report (PEPPER) outliers.[40]

The Hospital's contention that statistical sampling is inappropriate in the context of medical necessity reviews is incorrect. We submitted the claims selected for review to an independent medical review contractor who reviewed the medical record to determine whether the services were medically necessary and provided in accordance with Medicare requirements. We worked with our reviewer to ensure that it applied the correct Medicare criteria that was applicable during the audit period and that it used professionals with appropriate medical expertise, including physicians with appropriate training and expertise. Further, 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 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. Moreover, the court cases that the Hospital referenced in support of the proposition that extrapolation is inappropriate for the subjective determinations for medical necessity are limited to False Claims Act cases and therefore are inapplicable to OIG audit recommendations and CMS recoveries arising from OIG audits.[41] Furthermore, in *Chaves County Home Health Services v. Sullivan*, 732 F. Supp. 188 (D.C.D.C. 1990), a provider alleged that the use of statistical sampling and extrapolation without individual review of each claim was illegal. The District Court held otherwise, and the Court of Appeals affirmed finding that the provider had the opportunity to challenge the statistical validity of both the sample and the extrapolation on appeal (*Chaves County Home Health Services v. Sullivan*, 931 F.2d 914 (DC Cir. 1991)). The Hospital has five levels of appeal to challenge the statistical validity of both the sample and the extrapolation.

The Hospital's argument that we failed to explain our sampling frame or how we determined the number of claims per stratum is inaccurate. We used computer matching and data analysis techniques to focus our review on claims at risk for noncompliance to include in our sampling frame and exclude other claims we considered low risk. Our overpayment estimate does not extend beyond the specific claims listed in our sampling frame. As previously stated, we provided our approved sampling plan and all relevant documents the hospital needs to recreate our sample. In addition, the legal standard for choice of sample size is that it must be sufficient to be statistically valid, not that it be the most precise methodology.[42] As stated previously, we

[40] A PEPPER report is a tool developed by CMS to help hospitals ensure they are billing accurately and appropriately. An outlier is a hospital whose billing or coding practices fall outside of the norm when compared to other hospitals in the report.

[41] The Hospital referenced *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, 2015 WL 3903675, at *8 (D.S.C. June 25, 2015) and *United States v. Vista Hospice Care, Inc.*, 2016 WL 3449833, at *11 (N.D. Tex. June 20, 2016).

[42] See *John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at *34-35 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012).

properly executed a statistically valid sampling methodology, which included the choice of stratum sample sizes.

We have updated our findings and overpayments associated with any claims that had an incorrect overpayment amount. Accordingly, we have revised our estimated overpayment to reflect the recalculations and other errors that were overturned.

GENERALLY ACCEPTED GOVERNMENT AUDITING STANDARDS

Hospital Comments

The Hospital contended that because we did not provide our medical reviewers with the Hospital's claim-specific rebuttals prepared by its medical reviewers, our audit is inconsistent with GAGAS. The Hospital stated that if we decline to do so, we should qualify our statement about following GAGAS.

Office of Inspector General Response

We conduct our audits in accordance with GAGAS, which require that audits be planned and performed to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions. We disagree with the Hospital's contention that our audit did not follow GAGAS because we did not consider rebuttals provided by the Hospital or provide the rebuttals to our medical reviewer. The Hospital quoted sections 9.51 and 9.52 of the Government Auditing Standards 2024 Revision, which state that when auditors receive comments from an auditee, they should include a copy with their report, evaluate the validity of the comments, explain reasons for disagreement, and modify their report as necessary. We reviewed the rebuttals provided by the Hospital, and as a result, we agree with the Hospital in certain instances and revised our findings, recommendations, and estimated overpayment amount. A copy of the Hospital's comments is attached as Exhibit E, and the "Hospital Comments and Office of Inspector General Response" section of this report explains our reasons for disagreement. We did not share the rebuttals with our medical reviewer as there was no additional original documentation provided to us that our independent medical reviewers would need to consider. We confirmed with the Hospital that the complete medical record was originally provided to us and included all documentation to support the billing for each claim. Therefore, we have no reason to qualify our GAGAS statement in the report.

ADDITIONAL EVIDENCE

Hospital Comments

The Hospital indicated that our medical reviewer, in some instances, cherry-picked evidence from the medical record and failed to consider the overall condition of the enrollee that supported the treating physician's clinical judgment. In addition, the Hospital argued that our

medical reviewer's opinion amounts to second-guessing the treating physician's clinical judgment.

Office of Inspector General Response

We do not agree that our medical reviewers "cherry-picked" evidence from the medical records and did not consider the overall condition of the enrollees. We also disagree that our medical reviewer's opinions amounted to second-guessing the clinician's judgment. Our medical reviewers reviewed the medical records in their entirety to consider the overall condition of the enrollees. The medical reviewers used this evidence to render an independent, informed conclusion on each sampled claim with all the necessary context provided by thorough documentation. Our medical reviewers do not second-guess the clinical judgment of the treating physicians. Rather, they review the documentation of the treating physicians and other health care providers to make the distinctive determination of whether the claim complied with Medicare requirements. In addition, we ensured that our medical reviewers had the proper credentials and medical expertise (e.g., Rehabilitation Physician, Doctors in Internal Medicine, Registered Nurses and Certified Coders). Also, as previously stated, we reviewed and considered the Hospital's rebuttals and made changes to our findings in certain circumstances.

PUBLIC HEALTH EMERGENCY

Hospital Comments

The Hospital argued that our audit does not adequately account for the unique circumstances of the PHE, and in some cases unfairly re-evaluates physicians' admission decisions with the benefit of hindsight. These decisions were made in real time, often under pressure and uncertainty, based on the information available at that moment. A fair review must consider the broader context in which those clinical judgments were made, rather than applying retrospective standards years after the fact.

Office of Inspector General Response

We worked closely with our independent medical review contractor to ensure that it considered all relevant waiver provisions in place during our audit period due to the PHE. We instructed our medical review contractor to consider flexibilities outlined in CMS's "COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers," which included the "3-hour rule."[43] For all sample items where the enrollee received services during the PHE, our medical reviewers used the regulations for our audit period within the context of the waivers.

[43] The "3-hour Rule" waives the requirement under 42 CFR § 412.622(a)(3)(ii), which provides that payment generally requires that patients of an IRF receive at least 15 hours of therapy per week.

OTHER MATTERS

Claims Associated With InterQual Level of Care Criteria

During our audit period, CMS required its medical review contractors to use a screening tool as part of their medical review of acute inpatient PPS claims (*MPIM*, chapter 6, § 6.5.1). CMS did not require that the contractor use a specific tool, nor does CMS or the OIG endorse any specific tool.[44] During an earlier series of hospital compliance audits, in response to findings that claims did not meet Medicare inpatient admission requirements, several auditees noted that their documentation supported that the claims met the InterQual® or Milliman (the predecessor to MCG) Level of Care Criteria screening tools.[45]

As part of this audit, we asked our independent medical review contractor to apply clinical screening criteria to review the Hospital's inpatient PPS claims. This was done for informational purposes to provide the auditee with additional information that might assist them with their compliance and utilization review programs.

The contractor used InterQual® criteria to evaluate a sample of 65 claims. For 22 of those claims, our independent medical review contractor found that the admissions did not meet InterQual® criteria.[46] Although those claims do not constitute a failure to meet Medicare requirements, the results of our audit suggest that properly applying a screening tool in the Hospital's compliance or utilization review programs would reduce inappropriately billed claims.

Claims Associated With Rehabilitation Physician-Led Interdisciplinary Team Meetings

For an IRF claim to be considered reasonable and necessary, Federal regulations require an interdisciplinary team approach to care, as evidenced by documentation in the enrollee's 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 discipline involved in treating the enrollee (42 CFR § 412.622(a)(5)(i)).

For 14 of the 20 selected IRF claims, our independent medical review contractor found that the medical records documentation did not support that the rehabilitation physician led each interdisciplinary team meeting throughout the IRF stay, as required. Instead, the documentation indicated only that the physician attended the meetings and concurred with the

[44] Several commercially available screening tools exist, including InterQual® Level of Care Criteria, MCG Inpatient & Surgical Care Guidelines, and other proprietary systems.

[45] For example, see Medicare Hospital Provider Compliance Audit: Lake Hospital System (A-05-19-00024) and Medicare Hospital Provider Compliance Audit: St. Vincent Hospital (A-05-18-00040).

[46] Eleven of the 22 claims were reported as errors for not meeting two-midnight requirements.

findings. We did not find that the Hospital was non-compliant with this requirement, as the Medicare requirements are vaguely worded and subject to inconsistent interpretation. Because there was insufficient evidence to support such a finding, we did not report these errors as overpayments, based on our professional judgment. We believe CMS could provide clear guidance to hospitals regarding the requirement to document that a rehabilitation physician lead all interdisciplinary meetings.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $79,527,488 in Medicare payments to the Hospital for 5,654 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 claims (65 inpatient, 20 IRF, and 15 outpatient) with payments totaling $1,652,684.[47] Medicare paid these 100 claims from January 1, 2020, through December 31, 2021 (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.

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

During our audit, we did not assess the overall internal control structure of the Hospital. Rather, we limited our review to the Hospital's internal controls for compliance with Medicare billing requirements. To evaluate these internal controls, we:

- Interviewed Hospital officials regarding the Hospital's internal controls for compliance with Medicare billing requirements that related to the risk areas we identified

- Reviewed the Hospital's policies and procedures for the Two-Midnight Rule, medical necessity of inpatient and outpatient services, IRF admissions and documentation requirements, billing of services provided and inpatient and outpatient coding

- Reviewed a stratified random sample of 65 inpatient claims, 20 IRF claims, and 15 outpatient claims to determine if claims were properly billed and reimbursed

- Discussed with Hospital officials the cause of the identified errors

We performed our audit work from February 2023 to August 2025.

[47] For claim selection, CMS instructs Medicare review contractors to apply the Two-Midnight Presumption and avoid reviewing stays spanning 2 or more midnights, unless there is evidence of systemic abuse, gaming, or care delays (*MPIM*, chapter 6, § 6.5.2). However, OIG is not constrained by the Two-Midnight Presumption for the purpose of selecting claims for review.

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
- Created a sampling frame of paid Medicare claims from selected risk areas consisting of 5,654 claims with a total paid amount of $79,527,488
- Selected a stratified random sample of 100 claims (65 inpatient, 20 IRF, and 15 outpatient) with payments totaling $1,652,684
- Reviewed data from the Recovery Audit Contractor Data Warehouse for the claims included in the sample to determine whether the claims had been previously reviewed
- Reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been cancelled or adjusted
- Obtained from the Hospital all supporting documentation for the claims in our sample
- Used an independent medical review contractor to determine whether all claims complied with selected billing 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 in the sampling frame (Appendix C)
- Discussed the results 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

SAMPLING FRAME

Our sampling frame contained 5,654 Medicare paid claims in 11 risk areas totaling $79,527,488 from which we selected our sample (Table 1). The sampling frame included claims:

- With only certain discharge status and diagnosis codes
- With payments greater than $0
- Not under review by the Recovery Audit Contractor as of October 5, 2022

We assigned each claim that appeared in multiple risk areas to just one area on the basis of the following hierarchy: IRF Claims, Inpatient Psychiatric Facility Claims, Inpatient Claims Billed with High-Severity Level DRG Codes, Inpatient Claims Billed with High CERT Error DRG Codes, Inpatient Claims Billed with a DRG for Severe Malnutrition, Inpatient Claims Billed for Resuming Home Health, Inpatient Claims Paid in Excess of Billed Charges, Inpatient Claims Billed with Mechanical Ventilation, Inpatient Claims Billed with Same Day Discharge and Readmit , Outpatient Claims Billed with Bypass Modifiers, and Outpatient SNF Consolidated Billing Claims.[48]

Table 1: Risk Areas

Medicare Risk Area	Frame Size	Value of Frame
1. IRF Claims	1,529	$33,925,219
2. Inpatient Psychiatric Facility Claims	-	-
3. Inpatient Claims Billed with High-Severity Level DRG Codes	1,960	22,798,595
4. Inpatient Claims Billed with High CERT Error DRG Codes	1,538	15,016,997
5. Inpatient Claims Billed with Severe Malnutrition	175	4,893,331
6. Inpatient Claims Billed for Resuming Home Health	106	1,517,903
7. Inpatient Claims Paid in Excess of Billed Charges	12	258,755
8. Inpatient Claims Billed with Mechanical Ventilation	15	615,107
9. Inpatient Claims Billed with Same Day Discharge and Readmit	4	31,932
10. Outpatient Claims Billed with Bypass Modifiers	272	465,214
11. Outpatient SNF Consolidated Billing Claims	43	4,435
Total	**5,654**	**$79,527,488**

[48] After applying our filtering and analysis steps, no claims remained in our sampling frame from risk area 2, Inpatient Psychiatric Facility Claims.

SAMPLE UNIT

The sample unit was a Medicare paid claim.

SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified sample. We grouped the sampling frame into strata based on risk areas in Table 1 and claim paid amount, resulting in four strata. Stratum 1 includes all claims from risk area 1; strata 2 and 3 include claims from inpatient risk areas 3 through 9, separated by paid amount;[49] and stratum 4 includes all outpatient claims from risk areas 10 and 11. 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 2.

Table 2: Claims by Stratum

Stratum	Claims Type	Frame Size (Claims)	Value of Frame	Sample Size
1	Inpatient Risk Areas 1	1,529	$33,925,219	20
2	Inpatient Risk Areas 3–9, Low Dollar Claims	3,105	26,540,239	33
3	Inpatient Risk Areas 3–9, High Dollar Claims	705	18,592,381	32
4	All Outpatient Claim Risk Areas	315	469,649	15
	Total	**5,654**	**$79,527,488**	**100**

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE UNITS

We sorted the items in each stratum by a unique claim identifier, and then consecutively numbered the items in each stratum in the sampling frame. After generating the random numbers in accordance with our sample design, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the total amount of net overpayments in the sampling frame made to the Hospital at the lower limit of the two-sided 90-percent

[49] Paid claims less than or equal to $14,684 are in stratum 2 and paid claims greater than $14,684 are in stratum 3.

confidence interval (See 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

Table 3: Sample Details and Results

Stratum	Frame Size (Claims)	Value of Frame	Sample Size	Value of Sample	Number of Incorrectly Billed Claims in Sample	Value of Net Overpayments in Sample
1	1,529	$33,925,219	20	$431,758	8	$171,148
2	3,105	26,540,239	33	277,501	7	59,895
3	705	18,592,381	32	920,340	4	40,851
4	315	469,649	15	23,085	7	470
Total	**5,654**	**$79,527,488**	**100**	**$1,652,684**	**26**	**$272,364**

Table 4: Estimates of Net Overpayments in the Sampling Frame for the Audit Period (Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	$19,629,758
Lower limit	12,199,717
Upper limit	27,059,800

APPENDIX D: RESULTS OF AUDIT BY RISK AREA

Table 5: Sample Results by Risk Area*

Risk Area	Sample Size	Value of Sample	Number of Incorrectly Billed Claims in Sample	Value of Net Overpayments in Sample
Inpatient Billed with High-Severity Level DRG Codes	38	$628,270	6	$39,960
Inpatient Billed with High CERT Error DRG Codes	13	142,921	2	16,126
Inpatient for Resuming Home Health Services	7	119,982	2	23,053
Inpatient Severe Malnutrition	4	228,604	-	-
Inpatient Paid in Excess of Charges	2	38,101	1	21,607
Inpatient with Mechanical Ventilation	1	39,963	-	-
Inpatient Totals	**65**	**$1,197,841**	**11**	**$100,746**
IRF Claims	20	$431,758	8	$171,148
IRF Total	**20**	**$431,758**	**8**	**$171,148**
Outpatient With Bypass Modifiers	13	$22,818	6	$465
Outpatient SNF Consolidated Billing	2	267	1	5
Outpatient Totals	**15**	**$23,085**	**7**	**$470**
Inpatient and Outpatient Totals	**100**	**$1,652,684**	**26**	**$272,364**

* The table above illustrates the results of our audit by risk area. We organized inpatient and outpatient claims by the risk areas we reviewed. However, we organized this report's findings by the types of billing errors we found. Because the information is organized differently, the information in the individual risk areas in this table does not precisely match the information in the Findings section of this report.

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October 24, 2025

VIA KITEWORKS ONLY

Truman Mayfield
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Inspector General
Office of Audit Services
Region IV
61 Forsyth Street, SW, Suite 3T41
Atlanta, GA 30303

Re: Office of Audit Services Draft Report Number A-04-23-08098

Dear Mr. Mayfield:

I write on behalf of Sarasota Memorial Hospital ("SMH") to submit this response to the above-referenced draft report that the Office of Inspector General, Office of Audit Services ("OIG") provided to SMH on September 11, 2025 (the "Draft Report").[1] OIG's audit covered a sample of 100 claims for inpatient hospital, inpatient rehabilitation facility ("IRF"), and outpatient services from January 1, 2020 through December 31, 2021 (the "Audit Period"). OIG asserts that 30 of these 100 claims are noncompliant. From this small sample, and without giving meaningful consideration to the reports of qualified medical reviewers previously provided by SMH, OIG generalizes its findings to a universe of 5,654 claims during the Audit Period and asserts that SMH received an overpayment of at least $17,705,581.[2] Based on these findings, OIG makes several recommendations to SMH.

[1] A copy of the Draft Report is enclosed as **Exhibit A**. This response is timely. Although the Draft Report requested that SMH provide written comments in response to the Draft Report within 30 days of the date of the Draft Report, SMH requested, and OIG granted, an additional 15 days to respond. SMH later requested an additional 15-day extension to give it adequate time to engage with its third-party consultants who assisted with an independent review of the claims at issue. Despite it taking OIG more than two years to issue the Draft Report, OIG declined to grant the additional extension.

[2] The Draft Report is titled "Sarasota Memorial Hospital Received At Least $17.7 Million in Medicare Overpayments." The $17.7 million figure is an estimated amount, based on OIG's findings for 30 claims. The final report's title should make clear that the amount is an estimate. Alternatively, OIG should follow the convention used in other recently published reports and simply title this report, "Medicare Hospital Provider Compliance Audit: Sarasota Memorial Hospital."

SMH disagrees with most of OIG's findings, and it disagrees with all of OIG's recommendations, for four key reasons:

- Of the 23 claims SMH disputes, 18 are based in whole or in part on the OIG medical reviewer's disagreement with the treating physician's reasonable determinations. In some instances, the OIG medical reviewer cherry-picks evidence from the medical record, failing to consider the overall condition of the patient that supports the treating physician's clinical judgment. In others, the OIG medical reviewer's opinion amounts to nothing more than second-guessing the treating physician's clinical judgment (without demonstrating that the treating physician's clinical judgment was unreasonable). To support these disputed claims, SMH provided rebuttal statements prepared by its qualified physician reviewers. OIG has declined to consider those rebuttals.[3] To further bolster its position, SMH now provides an additional report for each claim from an independent, qualified medical reviewer explaining why the claim was compliant as billed (and disagreeing with the OIG medical reviewer).[4] Before finalizing its audit findings, SMH requests that OIG have its medical reviewers reconsider their findings based on these reports.[5] Where the heart of the issue is the reasonableness of the treating physician's judgment, it is simply unfair to ignore evidence from not one but two sets of qualified reviewers who stand behind the treating physician. It also is inconsistent with generally accepted government auditing standards.[6]

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[3] After receiving copies of the review results letters drafted by OIG's contracted medical reviewers, SMH submitted rebuttal statements prepared by its qualified physician reviewers on May 2, 2025. These rebuttals, enclosed as **Exhibit B**, contested the findings of OIG's medical reviewers. During the exit conference, on July 3, 2025, SMH requested that OIG consider these rebuttals, and, in particular, that it take the rebuttals to its contracted medical reviewers for reconsideration. OIG explained that, in general, it does not reengage its medical reviewers in cases where other physician reviewers reach different clinical opinions. Based on the materials SMH has received to date, including the Draft Report, it does not appear that OIG meaningfully considered (or had its medical reviewers meaningfully consider) the clinical opinions in the reports SMH previously provided.

[4] SMH engaged LW Consulting, Inc. ("LWCI"), a qualified, third-party consultant, to perform an independent review of these claims. LWCI's reports are enclosed as **Exhibit C**.

[5] Given the uniquely fact-intensive nature of medical necessity determinations (and the fact that the OIG medical reviewer's second-guessing of the treating physician's reasonable determinations account for 18 of the 23 contested claims), SMH requests that OIG provide its medical reviewers the enclosed reports and ask them to reconsider their findings and, if their opinions remain the same, explain why they disagree with the independent medical reviewers SMH engaged.

[6] The Draft Report states that OIG conducted this audit in accordance with generally accepted government auditing standards. Draft Report at 5. Generally accepted government auditing standards provide that government auditors, like OIG, should not only "obtain and report the views of responsible officials of the audited entity," but also that where, as here, "the audited entity's comments are inconsistent or in conflict with the findings, conclusions, or recommendations in the draft report, the auditors should evaluate the validity of the audited entity's comments." U.S. Government Accountability Office, Government Auditing Standards, Standard 9.52, p. 234 (2024 Revision). "If the auditors disagree with the comments, they should explain in the report their reasons for disagreement." *Id.* "Conversely, the auditors should modify their report as necessary if they find the comments valid and supported by sufficient, appropriate evidence." *Id.* To satisfy these standards—and for fundamental fairness—OIG should meaningfully consider the rebuttals, which, in this context, means providing the rebuttals to the OIG medical reviewers. If OIG declines to do so, it should qualify its statement about following all generally accepted government auditing standards.

- OIG's audit fails to consider the effect of the COVID-19 public health emergency ("PHE"), in some instances improperly second-guessing—with the benefit of hindsight, several years removed from the PHE—the reasonable, contemporaneous determinations of treating physicians regarding their admission decisions for patients experiencing symptoms of and, in many instances, diagnosed with COVID-19. Any review of the reasonableness of the admitting physician's judgment requires consideration of the information available at the time the admission decision was made, including information about the broader circumstances in which the admission decision was made. Context matters.

- In many cases, OIG misapplies the governing legal standard. For example, one claim for inpatient hospital services was determined to be improper because OIG could not locate a signed admission order, even though there is no requirement for the medical record to contain an inpatient admission order (because that requirement was eliminated in 2018). In another instance, in an improper application of the two-midnight rule, a claim for inpatient hospital services was determined to be noncompliant because the patient only spent one midnight at the hospital after the admission order, even though the patient had already spent two midnights receiving medically necessary hospital services and guidance from the Centers for Medicare & Medicaid Services ("CMS") provides that pre-admission time counts towards the two-midnight benchmark.

- The use of statistical sampling and extrapolation in the context of this case is inappropriate. For one, the majority of the disputed claims reflect nothing more than a difference of clinical judgment applied to a variety of patients, each with their own unique medical complications and clinical circumstances and generally involving different treatment teams. Medical necessity is a highly fact-intensive inquiry that is inappropriate for extrapolation, particularly where, as here, there is no homogeneity in clinical decision-making and no sustained high error rate. In addition, even if OIG were correct on the merits of each of the 30 claims, the overpayment calculation it used for extrapolation is wrong. OIG miscalculated the alleged overpayment for two claims, resulting in an overstatement of the alleged overpayment amount.

SMH's more detailed response follows.

I. BACKGROUND ON SMH

SMH is a regional medical center located in Sarasota, Florida. SMH is one of the largest public health systems in Florida, founded in 1925. Its world-class services include expertise in vascular, cancer, and orthopedic services, a Level II trauma center, and top-ranked inpatient and outpatient rehabilitation services. SMH has been recognized consistently as one of the nation's

best hospitals by CMS,[7] the Leapfrog Group,[8] and other organizations.[9] SMH is an integral part of the Sarasota community and surrounding area. It serves as a regional safety net hospital and provides substantial charity care, reflecting its commitment to all members of the community, regardless of ability to pay. SMH's reach is felt around the greater Sarasota County area through a network of 17 other facilities providing cancer services, nursing and rehabilitation, and urgent care, among other services.

II. SMH'S COMPLIANCE PROCESSES

SMH is committed to excellence in compliance with best billing practices and takes appropriate actions when it identifies errors. Utilization review ("UR") at SMH is guided by the UR Committee, which sets system-wide standards for the medical necessity of inpatient admission and monitors for compliance with regulations and payor guidance. SMH's concurrent and retrospective audits, and ongoing education and training illustrate a culture of compliance and continuing efforts for improvement and accountability. Importantly, these steps were taken on SMH's own initiative, and most actions were taken prior to receiving notice of the audit.

Medical Necessity Reviews. SMH engages in continuous process improvements to prevent the billing of inappropriate inpatient admissions. The Medical Director of Integrated Case Management ("ICM") is responsible for day-to-day UR functions, such as review of medical necessity determinations and outliers. SMH employs physician advisors and UR nurses. UR nurses perform real-time reviews of inpatients, typically within 24 hours of admission, to confirm medical necessity in collaboration with the treating practitioner. If the determination of medical necessity is unclear, the UR nurse discusses the case with the primary physician and, if those discussions do not result in a clear determination, escalates the case to a physician advisor for review. Cases may be escalated directly to a physician advisor for review at any time. If a patient is admitted but, through the UR process, is determined to not meet admission criteria, a physician advisor in collaboration with the attending physician will review the case and convert the patient to outpatient status using Code 44. ICM has tracked use of Code 44 since 2016. Since then, cases where the patient's status has been converted from inpatient to outpatient have occurred in no more than 3.1% of total Medicare inpatient claims, and in most years, less than 2%. The low frequency with which SMH must use Code 44 illustrates the effectiveness of its standards and its training. SMH's robust UR processes—including its use of Code 44 to proactively detect and correct potential billing errors—demonstrate SMH's commitment to compliance.

As an additional safeguard for IRF admissions, every case is reviewed in-depth by a board-certified rehabilitation physician prior to admission to ensure compliance with CMS criteria. The physicians who review preadmission screenings are well-versed in the requirements and consistently apply them. For each potential patient, an SMH clinician reviews the patient's clinical notes to ensure a comprehensive evaluation in addition to the prepared prescreening

[7] SMH is the only hospital in Florida to earn the highest 5-star overall quality rating from CMS in all reporting periods since the program's inception in 2016 through 2025.

[8] SMH has earned "A's" on every patient safety report card from The Leapfrog Group from 2016 to 2025.

[9] For instance, SMH has been listed among Newsweek's *World's Best Hospitals* from 2019 to 2025. SMH is also the only hospital in the region to earn Magnet Status from the American Nurses Credentialing Center, which is the nation's highest honor for nursing, and one of fewer than 2% of hospitals in the country to earn the designation five times.

documentation. To promote ongoing compliance, SMH utilizes real-time dashboards that monitor key documentation and predictive compliance elements, enabling immediate feedback and corrective action when needed.

Post-Payment Reviews. SMH also performs retrospective, post-payment reviews for medical necessity and appropriate patient status to ensure SMH's compliance processes are functioning effectively.

UR nurses conduct short stay reviews with the assistance of evidence-based third-party software to resolve cases with an exception to the two-midnight rule (e.g., acute care transfer, expired, inpatient only procedure, left against medical advice). If an exception does not apply, the UR nurse places a billing hold on the claim and escalates the case to a physician advisor for review. The physician advisor, admitting physician, and, when appropriate, a second member of the UR Committee, collaborate to determine whether the case satisfies inpatient admission criteria. If it does not, the inpatient admission is self-denied using Occurrence Code W2, and the claim is appropriately billed as outpatient. ICM at SMH began tracking self-denied claims in 2023. Since then, self-denied claims have made up approximately 2% of Medicare inpatient claims.

Training and Education. SMH physicians have extensive residency training with a strong foundational knowledge of medical necessity. SMH also takes steps to ensure its clinicians are well-versed in relevant regulatory requirements. Medical staff receive education throughout the year, and attending physicians receive regular training in specialized areas, including the two-midnight rule. The ICM Medical Director meets monthly with hospitalist medical directors and conducts education sessions with medical staff throughout the year, rotating through surgical and medical specialties.

Physician advisors and non-physician ICM leaders routinely participate in educational conferences and webinars and circulate regulatory bulletins. Physician advisors and UR nurses receive education throughout the year. The ICM Medical Director provides education to UR nurses through staff meetings. Physician advisors and non-physician ICM leaders collaborate to identify case examples to review practical, real-world application with the UR team in staff meetings, weekly huddles, and one-on-one meetings. UR nurses also receive annual training via Compass through the American Case Management Association ("ACMA") and have access to ACMA membership resources.

All physicians who review and accept patients for IRF admission are board-certified in Physical Medicine and Rehabilitation, bringing extensive expertise in assessing medical necessity for inpatient rehabilitation admissions. To ensure that admissions are clinically appropriate, compliant, and aligned with CMS medical necessity standards, SMH provides structured training for all clinicians involved in the IRF admission process, including physicians, therapists, nursing, admissions liaisons, and case management/social work staff. Education is focused on CMS criteria for medical necessity, documentation of therapy intensity and functional potential, and the interdisciplinary requirements for IRF level of care:

- Physicians are trained to document medical complexity and hospital-level oversight.

- Therapy staff are instructed on accurately capturing therapy tolerance, intensity, and measurable improvement.

- Nursing education emphasizes medical management, safety risks, and interdisciplinary care planning through team conferences.

- Admissions staff receive specialized instruction on completing comprehensive preadmission screenings that capture all CMS-required elements and clearly outline the rationale for IRF-level placement versus alternative levels of care. All admission liaisons are certified through the Uniform Data System ("UDS") (now part of McBee) as IRF Admission Liaisons, completing a three-day training program and certification exam covering CMS regulations, documentation standards, and compliance best practices.

Training is further reinforced through case-based reviews, random chart audits, and frequent participation in national webinars offered by UDS and CMS that focus on IRF documentation and medical necessity.

Other Compliance Processes. In addition to the above-referenced auditing, monitoring, training, and education, SMH has taken other steps to minimize the risk of compliance errors, including the following:

- SMH develops an annual risk-based audit plan, which includes a strong focus on topics relevant to the medical necessity of inpatient admission. UR nurses and physician advisors actively participate in these audits. Before, during, and after OIG's audit, SMH performed audits on topics including Program to Evaluate Payment Patterns Electronic Report ("PEPPER") 2-Day Stays, IPPS Short Stays under the Two-Midnight Rule, and IPPS Claims Paid in Excess of Charges.

- SMH has a PEPPER Work Group comprised of the Corporate Compliance Officer, ICM Medical Director, designated physician advisors, ICM non-physician leaders, and revenue cycle leaders (e.g., Revenue Integrity, Coding, Billing, and Clinical Documentation Improvement).

- Prior to the CMS suspension of PEPPER in 2024, the Work Group met quarterly to review all PEPPER indicators, including all of those described by CMS as potentially indicative of inappropriate inpatient admissions. SMH consistently demonstrated very few high outliers. For example, in Q2 of FY 2023 (which covers three years of performance), SMH ranked 2,960th of 3,177 hospitals nationwide by number of high outlier instances. In this context, the fewer the number of high outliers, the lower the hospital is ranked.

III. RESPONSE TO OIG'S FINDINGS

A. Inpatient Hospital Claims

OIG found that 13 out of the 65 inpatient claims were noncompliant based on medical necessity of the inpatient admission, failure to satisfy technical documentation requirements,

incorrect coding, or missing documentation.[10] Notably, despite these alleged errors, for 10 of the 13 allegedly noncompliant claims, OIG's medical reviewer determined the documentation supported the medical necessity of hospital care, and the reports from SMH's independent medical reviewers support that the claims were correctly billed. SMH disputes all but two of these findings.

1. Medical Reasonableness and Necessity of Inpatient Admission

For 11 of the claims, OIG found that the documentation did not support that, at the time the inpatient order was written, it was reasonable for the admitting physician to have expected that hospital care was required for a period that crosses two or more midnights. SMH disputes these findings.

For each of these claims, as reflected by the medical records and the reports of SMH's medical reviewers, the admitting physician reasonably expected, at the time of the admission order, that the hospital stay would cross two midnights. This clinical judgment is supported by the rebuttal statements, enclosed as **Exhibit B** and **Exhibit C**. Below we highlight several aspects of the relevant legal standards, and we describe the ways in which OIG's medical reviewers failed to account for them.

General Background on Two-Midnight Rule. Under what is commonly referred to as the "two-midnight rule," inpatient admission generally is appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights.[11] Medicare regulations and guidance recognize this is a medical judgment based on complex medical factors such as:

- Patient history and comorbidities;
- Severity of the patient's signs and symptoms;
- Patient's current medical needs;
- Risk of the patient experiencing an adverse event;
- Need for diagnostic studies; and
- Availability of diagnostic procedures.[12]

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[10] The Draft Report also explains these claims did not meet InterQual Level of Care Criteria. While SMH does not concede these findings are correct, as explained in the Draft Report, "[f]ailure to meet InterQual Level of Care Criteria does not equate with failure to meet Medicare requirements." OIG explains that references to these criteria are purely for informational purposes. Therefore, SMH will not address these findings further in its response.

[11] 42 C.F.R. § 412.3(d)(1). *See also* CMS, *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates* [abbreviated for ease of reference], 78 Fed. Reg. 50496, 50946 (Aug. 19, 2013) ("We reiterate our stance that the decision to hospitalize a beneficiary is a complex medical decision made by the physician in consideration of various risk factors, including the beneficiary's age, disease processes, comorbidities, and the potential impact of sending the beneficiary home. It is up to the physician to make the complex medical decision of whether the beneficiary's risk of morbidity or mortality dictates the need to remain at the hospital because the risk of an adverse event would otherwise be unacceptable under reasonable standards of care, or when the beneficiary may be discharged home. If the resultant length of stay for medically necessary hospitalization is expected to surpass 2 midnights, the ***physician should admit the patient as an inpatient.***") (emphasis added).

[12] 42 C.F.R. § 412.3(d)(1)(i); Medicare Benefit Policy Manual ("MBPM"), Pub. No. 100-02, Chapter 1, § 10.

The expectation for a stay that crosses two midnights is inferred from the record—no separate attestation of the expected length of stay is required.[13] Importantly, the inpatient admission is generally payable if the medical record supports the admitting physician's judgment was ***reasonable***.[14]

Whether the admitting physician's judgment was reasonable requires consideration of the medical evidence available at the time the admission decision was made. Post-admission information can only be used to support a finding that admission was appropriate. In providing guidance for reviews of hospital admissions to Quality Improvement Organizations ("QIOs"), CMS explained:

> Under original Medicare, the [QIO], for each hospital is responsible for deciding, during review of inpatient admissions on a case-by-case basis, whether the admission was medically necessary. . . . In making these judgments, however, QIOs consider only the medical evidence which was available to the physician at the time an admission decision had to be made. They do not take into account other information (e.g., test results) which became available only after admission, ***except in cases where considering the post-admission information would support a finding that an admission was medically necessary***.[15]

Stated differently, clinical information available post-admission is only relevant to the extent it supports the medical reasonableness and necessity of admission. As explained in more detail below and in the rebuttal statements, enclosed as **Exhibit B** and **Exhibit C**, OIG's medical reviewers incorrectly failed to consider post-admission information that would support the finding that the admission was medically reasonable and necessary, but ignored it when it helped SMH, which is precisely opposite of what the rule says.

For example, for one beneficiary **(Sample #36)**, the OIG physician reviewer notes the beneficiary was treated with hydration and monitoring after admission but ignores documentation evidencing the beneficiary's instability and the concomitant medical interventions. The beneficiary complained of chest discomfort, necessitating a cardiology consultation. Throughout the admission, the beneficiary's blood pressure fluctuated, requiring adjustment of her Isosorbide

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[13] Medicare Program Integrity Manual ("MPIM"), Pub. No. 100-08, Chapter 6, § 6.5.2.

[14] 78 Fed. Reg. at 50946 (explaining that "the [two-midnight] regulation is framed upon a *reasonable and supportable expectation*, not the actual length of care, in defining when hospital care is appropriate for inpatient admission") (emphasis added); *id.* at 50944 (explaining that "a reasonable expectation of a stay crossing 2 midnights, which is based on complex medical factors and is documented in the medical record, will provide the justification needed to support medical necessity of the inpatient admission, regardless of the actual duration of the hospital stay and whether it ultimately crosses 2 midnights"); CMS, *Fact Sheet: Two-Midnight Rule* (Oct. 30, 2015), *available at* https://www.cms.gov/newsroom/fact-sheets/fact-sheet-two-midnight-rule-0 ("Inpatient admissions would generally be payable under Part A if the admitting practitioner expected the patient to require a hospital stay that crossed two midnights and the medical record supported that reasonable expectation.").

[15] MBPM, Chapter 1, § 10 (emphasis added).

dose. Additionally, the OIG physician reviewer disregarded repeat laboratory studies that were performed to monitor rehydration efforts and rule out etiologies of encephalopathy.

Pre-Admission Hospitalization. In disputing certain claims, the OIG medical reviewer emphasized the fact that, at the time of inpatient admission, the patient had already been hospitalized for one or more midnights. The reviewer appears to cite this fact to support its finding of noncompliance. This analysis is inappropriate. To the contrary, CMS has explained that, under the two-midnight benchmark, "the decision to admit the patient should be based on the cumulative time spent at the hospital beginning with the initial outpatient service," [16] and "the starting point for the 2-mindnight benchmark will be when the beneficiary begins receiving hospital care on either an inpatient basis or outpatient basis."[17] So if, for example, the patient has already passed one midnight in observation status, the two-midnight benchmark will be met even if the physician only expects the patient to require one additional midnight in the hospital.[18]

For example, for one patient **(Sample #24)**, the OIG medical reviewer improperly discounted the time the patient spent in observation status. This 87-year-old patient was suspected to have COVID-19 pneumonia during the early stages of the PHE. On presentation to the ER, the patient appeared ill and was frail. Based on indicators at the time of admission (namely, blood pressure and age), the patient had a CURB-65 score that supported inpatient admission. OIG stated the patient had improved symptoms and was not hypoxic; however, the patient continued to have symptoms, including fever and poor intake, and the patient was a high-risk, frail, and elderly patient. The OIG reviewer also noted the patient was discharged a day after admission and had already been hospitalized across two midnights. This supports the admission decision. The time the patient spent in observation counts toward the patient's total length of stay.

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[16] 78 Fed. Reg. at 50950 ("In this final rule, we specify that the ordering physician may consider time the beneficiary spent receiving outpatient services (including observation services, treatments in the emergency department, and procedures provided in the operating room or other treatment area) for purposes of determining whether the 2-midnight benchmark is expected to be met and therefore inpatient admission is generally appropriate."). *See id.* (For example, "if upon beneficiary presentation, the physician is unable to make an evaluation and corresponding expected length of stay determination, the physician may first monitor the beneficiary in observation or continue to perform diagnostics in the outpatient arena. If the beneficiary's medical needs and condition after 1 midnight in outpatient status dictate the need for an additional midnight within the hospital receiving medically necessary care, the physician may consider the care in the outpatient setting when making his or her admission decision. Medicare review contractors would similarly apply the 2-midnight benchmark to all time spent within the hospital receiving medically necessary services in their claim evaluation."); *see also* CMS, *Reviewing Short Stay Hospital Claims for Patient Status: Admissions On or After October 1, 2015* (last updated Nov. 9, 2015), *available at* https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-ffs-compliance-programs/medical-review/downloads/reviewinghospitalclaimsforadmissionmemo.pdf ("Whether the beneficiary receives services in the ED as an outpatient prior to inpatient admission (for example, receives observation services in the ED) or is formally admitted as an inpatient upon arrival at the hospital (for example, inpatient admission order written prior to an elective inpatient procedure), the starting point for the 2 midnight timeframe for medical review purposes will be when the beneficiary starts receiving services following arrival at the hospital.").

[17] 78 Fed. Reg. at 50952.

[18] 78 Fed. Reg. at 50946; *see also* CMS, One-Time Notification, Pub. 100-20, Transmittal 1334 (Change Request 8586) (Jan. 24, 2014) ("The 2 midnight benchmark allows hospitals to account for total hospital time in determining if the beneficiary is expected to meet the 2 midnight benchmark (receiving medically necessary services) for inpatient admission.").

Two-Midnight Presumption. OIG found several claims to be noncompliant for patients admitted for longer than two midnights. It failed, however, to account for the "two-midnight presumption," which is the policy under which hospital stays that span two or more midnights after inpatient admission are generally presumed to be reasonable and necessary. As described by CMS:

> Medicare contractors shall presume hospital stays spanning 2 or more midnights after the beneficiary is formally admitted as an inpatient are reasonable and necessary for Part A payment. Medicare contractors shall not focus their medical review efforts on stays spanning 2 or more midnights after formal inpatient admission absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-midnight presumption.[19]

OIG acknowledges this presumption in the Draft Report yet alleges no facts to rebut it. OIG asserts in an appendix describing the audit scope and methodology that it is "not constrained by the two-midnight presumption ***for the purpose of selecting claims for review***," but it does not stake out a position as to whether its medical reviewers are obligated to account for the rule, nor does it identify any "evidence of systematic gaming, abuse, or delays in the provision of care" that might rebut the presumption.[20] SMH recognizes this rule is directed to Medicare contractors. OIG will, however, refer this matter to a Medicare contractor. To ignore the rule in the audit is to misapply the standard to which SMH ultimately will be held, and, in this case where a small number of findings are extrapolated to a large universe of claims, doing so creates a misleading narrative that furthers no discernible policy interest.

As an example, the OIG medical reviewer concluded the inpatient admission for one patient **(Sample #49)** was not medically necessary based on imaging results and improved symptoms. This 88-year-old patient was ultimately admitted for one week after presenting to the hospital intoxicated with toxic encephalopathy. The OIG medical reviewer cited no evidence of systematic gaming, abuse, or delays to overcome the two-midnight presumption. Moreover, there was ample evidence in the record that the two-midnight benchmark was met and this inpatient stay was medically necessary. The patient had complicated issues, including advanced age and chronic history of hypertension, lipid abnormalities, and alcohol abuse. Objective evidence also included an abnormal electrocardiogram ("EKG") and elevated serial troponin, which is a blood test indicative of a heart attack. Not only is there no evidence to rebut the two-midnight presumption, but the record also strongly supports admitting physician's reasonable expectation that the hospital stay would cross two midnights and, therefore, the medical necessity of the admission.

Short Stay Claims. The OIG medical reviewers also found several claims to not be compliant simply because the patient was discharged before two midnights had passed. This is inappropriate. The assessment of medical necessity is based on "the physician's expectation based

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[19] MPIM, Chapter 6, § 6.5.2.

[20] Draft Report at 14, n.21 (emphasis added).

on the information available to the admitting practitioner at the time of the inpatient admission."[21] A patient still may have been appropriately admitted as an inpatient when, as in these cases, the patient's stay does not cross two midnights because subsequent "unforeseen circumstances that result in a shorter stay than the physician's reasonable expectation."[22] OIG cannot use the benefit of hindsight to undermine the physician's reasonable expectation based on the information available at the time of admission.

For one claim, **(Sample #51)**, the patient had an unexpected and rapid recovery, resulting in the patient's discharge the day after admission. Seemingly based on this fact, in finding the claim to be noncompliant, the OIG medical reviewer overlooked the seriousness of the patient's condition on admission. This 94-year-old, frail, and unvaccinated patient with a history of coronary artery disease and asthma presented to the ER with fever, cough, and shortness of breath; she tested positive for COVID-19. In September 2021, during the PHE, mortality was high for an unvaccinated, elderly patient with COVID-19 and a history of asthma. Furthermore, while in the ER, the patient experienced an episode of tachypneic (rapid) labored breathing, necessitating the administration of supplemental oxygen via nasal cannula. The patient's oxygen saturation dropped to 88% with movement. Although OIG dismissed this sign as "mild" hypoxia, it was consistent with acute respiratory failure. The combination of frailty, a history of cardiovascular disease with EKG changes from a previous study, and possible new pleural effusions, exacerbated the risk of the patient's COVID-19 infection. The patient was discharged, at her insistence, prior to the second midnight. Nevertheless, due to the high risk of an adverse event, it was reasonable for the admitting physician to have expected the patient to require hospital care that crosses two or more midnights.

In short, the medical records support these claims. The rebuttal statements, enclosed as **Exhibit B** and **Exhibit C**, explain how the medical records support the claims and highlight how the OIG medical reviewer made numerous errors in its clinical analysis, including failure to consider:

- The patient's frailty;
- The complexity of the patient's medical conditions that contribute to the hospital stay;
- The intensity of care applied during the hospital stay;
- Additional onsets that occur post-admission; and
- High-risk conditions that require more intense monitoring (e.g., prolonged QT intervals, which could be related to a depletion of potassium that could result in atrial fibrillation; multiple premature ventricular contractions; very low hemoglobin, which requires both determination of the underlying cause and close monitoring to ensure the levels do not drop further with hydration or active bleeding).

These clinical errors underscore the need for OIG to review, or direct its contracted reviewers to review, the enclosed rebuttals.

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[21] CMS, Frequently Asked Questions, *2 Midnight Inpatient Admission Guidance & Patient Status Reviews for Admissions on or after October 1, 2013* (last visited Sept. 17, 2025), *available at* https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medical-review/downloads/qasforwebsiteposting_110413-v2-clean.pdf.

[22] *Id.*

2. Coding Issues

OIG found that for two of the claims, the principal diagnosis code was not supported by the medical records, which resulted in incorrect diagnosis-related group ("DRG") payments. While SMH does not dispute these findings, one coding change resulted in an underpayment; for the other, OIG grossly overestimated the resulting overpayment amount.

Specifically, for one claim **(Sample #77)**, OIG found that the code billed resulted in an underpayment of $434.50. SMH does not dispute this overpayment amount. For the other claim **(Sample #63)**, OIG incorrectly calculated the overpayment amount. As illustrated by the DRG payment calculator, enclosed as **Exhibit D**, the revised payment amount should be $31,151.69, not the amount calculated by OIG ($29,311.11). Had OIG calculated the revised payment correctly, the overpayment would be reduced from $2,298.80, as calculated by OIG, to $458.22. When netted against the underpayment, these inpatient coding issues would result in a net overpayment of only $23.72.

In addition, in the Draft Report, OIG highlights this claim **(Sample #63)**, setting it off in a text box as if to suggest it is a key finding, and asserts that "[o]ne patient was admitted was admitted to the Hospital with an incorrect principal diagnosis code used for pain caused by internal prosthetic devices (e.g., bone plates or joint replacements) when the actual cause of admission was a complicated related to breast implants."[23] The reference to orthopedic implants ("bone plates or joint replacements") is erroneous. The OIG medical reviewer does not refer to a code related to orthopedic implants; rather, the reviewer states that ICD-10 code T85.848A (pain due to other internal prosthetic devices) was used, when the more specific diagnosis code related to capsular contracture (T85.44XA) should have been used.[24] This error should be fixed. Furthermore, OIG should consider whether this lone claim warrants highlighting in the manner shown in the Draft Report.

3. Inpatient Order

OIG found for one claim **(Sample #50)** that an inpatient admission order was not included in the medical record. Although SMH has not located an inpatient admission order, it disputes that this claim is noncompliant.

In the interest of "reduc[ing] unnecessary administrative burden on physicians and providers," CMS has explained that medical reviewers should focus on the medical reasonableness and necessity of the admission rather than inadvertent technical issues unrelated to the medical necessity of the stay.[25] To this end, in 2018, CMS removed language from the regulations requiring

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[23] Draft Report at 6.

[24] The diagnosis code specific to pain from orthopedic implants (like bone plates or joint replacements) is T84.84. SMH did not use this code, nor did the OIG medical reviewer refer to it.

[25] CMS, *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2019 Rates* [abbreviated for ease of reference], 83 Fed. Reg. 41144, 41507 (Aug. 17, 2018).

the physician order to be present in the medical record in order to receive payment.[26] As explained in the rebuttal in **Exhibit C**, notwithstanding the missing order, the medical record evidences the attending physician's intent to admit the patient as an inpatient. Moreover, the medical record supports the reasonable expectation that the patient would require treatment for two or more midnights. The 78-year-old patient presented to the ER with difficulty getting a deep breath, oxygen saturation of 84%, and a chest x-ray suggesting emphysema with superimposed infectious or inflammatory disease, possibly diffuse bronchiectasis. Thus, it was reasonable to admit the patient as an inpatient to the medical respiratory floor. OIG's conclusion to the contrary is largely based on the absence of the inpatient admission order, which as explained above, is an inappropriate basis upon which to find the claim noncompliant.

B. Inpatient Rehabilitation Facility Claims

OIG found that 10 of the 20 IRF claims were noncompliant based on failure to provide sufficient documentation to support that the services rendered were medically reasonable and necessary or failure to satisfy technical documentation requirements. SMH disputes all of these findings, and the independent medical reviewers' findings support that the claims were compliant as billed.

To ensure IRF admissions meet CMS medical necessity criteria, each patient undergoes a structured preadmission screening by a licensed clinician that documents medical necessity, functional deficits, and the expectation that the patient can tolerate and benefit from intensive therapy. This screening is reviewed and approved by a rehabilitation physician, who confirms that the patient requires hospital-level care rather than a lower level of service. Upon admission, an interdisciplinary team ("IDT"), including therapy, nursing, case management, and physician leadership develops an individualized plan of care within four days, specifying therapy intensity, goals, and medical management. Throughout the stay, the rehabilitation physician provides at least three face-to-face visits per week, and the team conducts weekly conferences to verify progress and ongoing appropriateness. As with all patients, medical conditions or functional status can change during the stay. When that occurs, the team promptly evaluates the situation and makes the best determination for the patient at that time, ensuring care remains both medically appropriate and patient-centered. This process ensures compliance with CMS regulations while safeguarding that patients admitted truly require and can tolerate the intensity of IRF services.

1. Medical Reasonableness and Necessity of the IRF Stay

Reasonable Expectation of Need for Supervision by a Rehabilitation Physician. OIG alleges that seven claims are noncompliant because there was not a reasonable expectation at the

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[26] *See* 42 C.F.R. § 412.3. The prior version, which was effective through September 2018 (prior to the dates of service at issue), stated: "This physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A." 42 C.F.R. § 412.3(a) (2018). This language was removed effective October 1, 2018. Furthermore, even historic Medicare guidance acknowledged that there could be circumstances where the admission order was missing or defective, "yet the intent, decision, and recommendation of the physician (or other practitioner who can order inpatient services) to admit the beneficiary as an inpatient can clearly be derived from the medical record." CMS, *Hospital Inpatient Admission Order and Certification* (Jan. 30, 2014), *available at* https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/downloads/ip-certification-and-order-01-30-14.pdf.

time of admission that the patients required supervision by a rehabilitation physician, while nevertheless concluding in each case that "the documentation support[s] that the rehabilitation physician conducted face-to-face visits with the patient at least 3 days per week throughout the patient's stay in the IRF to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process." SMH disagrees for two reasons.

First, OIG erroneously separates the need for rehabilitation physician supervision from the weekly face-to-face-visit requirement.[27] These are not separate requirements. The reasonable expectation of the need for supervision by a rehabilitation physician is *demonstrated by*—not a requirement separate from—the three weekly face-to-face visits:

> In order for an IRF claim to be considered reasonable and necessary . . . , there must be a reasonable expectation that . . . at the time of the patient's admission to the IRF [the patient] requires physician supervision by a rehabilitation physician. ***The requirement for medical supervision means*** that the rehabilitation physician must conduct face-to-face visits with the patient at least 3 days per week throughout the patient's stay in the IRF to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.[28]

By the plain terms of the regulation, this requirement is satisfied when the rehabilitation physician conducts face-to-face visits with the patient three times a week to assess the patient medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.[29]

The regulatory history supports this plain-language interpretation.[30] In the regulation text quoted above, the term "medical supervision" comes from the longstanding requirement that IRFs provide "close medical supervision."[31] In 2009, recognizing both advances in rehabilitation

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[27] *Compare* Task Order A-04-23-08098 – Review Results, Sample IDs 2, 3, 6, 8, 9, 10, 19, Question 26 ("Does the documentation support that upon admission to the IRF there was a reasonable expectation that the patient required physician supervision by a rehabilitation physician?") *with* Question 27 ("Does the documentation support that the rehabilitation physician conducted fact-to-face visits with the patient at least 3 days per week through the patient's stay in the IRF to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process?").

[28] 42 C.F.R. § 412.622(a)(3)(iv) (emphasis added).

[29] *See* 42 C.F.R. § 412.622(a)(3)(iv).

[30] The requirements at 42 C.F.R. § 412.622(a)(3) were added effective January 1, 2010. *See* CMS, *Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2010*, 74 Fed. Reg. 39762 (Aug. 7, 2009).

[31] *See* Health Care Finance Administration, *Medicare Program; Prospective Payment System for Hospital Inpatient Services; Redesignation of Rules* (Mar. 29, 1985) (redesignating as 42 C.F.R. §§ 412.23(b)(4) and 412.29(c) the rules that require IRFs and distinct part rehabilitation units, respectively, to "[e]nsure that patients receive close medical supervision").

medicine and increased medical complexity of rehabilitation patients, CMS promulgated the requirement that rehabilitation physicians conduct face-to-face visits three times a week to ensure that this close medical supervision comes in the form of the weekly visits with a rehabilitation physician:

> One of the primary reasons for a patient to receive rehabilitation therapy services in an inpatient hospital (that is, IRF) setting is that the patient's medical conditions require close medical supervision. In the past, the definition of close medical supervision has been vague. During the past 25 years, it was often assumed that "close medical supervision" was demonstrated by frequent changes in orders due to a patient's fluctuating medical status. Currently, however, patients' medical conditions can be more effectively managed so that they are less likely to fluctuate and interfere with the rigorous program of therapies provided in an IRF.
>
> In addition, the medical complexity of rehabilitation patients has increased over time and they often require the services of multiple physicians to manage their medical conditions and ensure that they are able to maximize their rehabilitation potential in the IRF. Therefore, while multiple specialists may visit the patient at the IRF, we believe that ***it is the unique responsibility of the rehabilitation physician to coordinate the patient's medical needs with his or her functional rehabilitation needs*** while in the facility. Thus, we proposed to require that a ***rehabilitation physician conduct face-to-face visits with the patient at least 3 days per week throughout the patient's IRF stay*** to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the intensive rehabilitation program provided in the IRF.[32]

This new regulation, CMS explained, "mirrors the concepts in the long-standing facility classification requirements in the existing § 412.23 and § 412.29," including "the need to provide close medical supervision by qualified personnel[.]"[33] CMS makes no mention of the creation of an independent requirement, nor does it make even passing reference to the text that OIG has applied as an additional condition that must be met.

Here, for each of the seven claims OIG found noncompliant for the lack of a reasonable expectation of the need for supervision by a rehabilitation physician, OIG's medical reviewers found that the three-times-per-week criterion was met but nevertheless determined that there was no reasonable expectation that the patient required supervision by a rehabilitation physician. Specifically, the OIG medical reviewers found that, in all seven cases, "the documentation support[s] that the rehabilitation physician conducted face-to-face visits with the patient at least 3

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[32] 74 Fed. Reg. at 39795-96.

[33] *Id.* at 39788-89.

days per week throughout the stay in the IRF to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process."[34] That finding is dispositive. The claims met the rehabilitation physician supervision criterion.

Second, even if OIG disagrees with the foregoing and seeks to reimagine the regulation to include an independent requirement that it was reasonable to expect at the time of admission that the patient required rehabilitation physician supervision, it fails to explain why the claims at issue do not meet this requirement. CMS has emphasized the importance of respecting the professional judgment of the rehabilitation physician at the time of admission.[35] Yet, OIG's medical reviewers provide no deference to the judgment of the rehabilitation physicians in this case, nor does OIG appear to have considered the responses from SMH's reviewers, which are supported by its outside medical reviewers.

As explained in more detail in the rebuttal statements in **Exhibit B** and **Exhibit C**, the medical records support these claims. For instance, in one case **(Sample # 5)**, the patient, who underwent an elective left hip arthroplasty for left hip arthrosis and avascular necrosis, had severe alcohol use disorder, impacting safety with mobility and self-care. Though the OIG reviewer found the patient had no signs or symptoms of alcohol withdrawal, there were no such signs for a good reason: The patient was admitted to rehabilitation actively consuming vodka, because withdrawal protocols had not yet been started. The alcohol withdrawal protocol required physician monitoring. Contrary to the OIG reviewer's assertion, the patient had significant changes in baseline medical conditions, such as worsening dyspnea, which required substantial treatment and monitoring by the rehabilitation physician. Moreover, the patient had a history of deep vein thrombosis ("DVT") and other comorbidities, which increased his risk for DVT post-hip surgery.

As another example **(Sample # 8)**, a 79-year-old patient with history of coronary artery disease, bilateral traumatic subdural hematomas, bladder cancer, benign prostate hyperplasia, and hypertension, tested positive for COVID-19 with severe pneumonia/acute respiratory distress syndrome, which impaired functional mobility and self-care. The patient was admitted in December 2020, during a period before a vaccine was available; added caution and medical management was needed due to the unfamiliar nature of the disease and the significant risk for mortality. Contrary to the statement of the OIG medical reviewer, the patient experienced significant changes in baseline medical conditions, such as worsening dyspnea. Additionally, the patient experienced new-onset hypoxic respiratory failure, putting the patient at risk for clinical decompensation and death, and acute onset of chest pain in the context of a history of coronary artery disease and angina, putting the patient at risk of severe cardiac complications during therapy. The supervision of a rehabilitation physician was required to monitor respiratory complications, which were heightened due to the patient's pulmonary comorbidities.

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[34] *See* Task Order A-04-23-08098 – Review Results, Sample IDs 2, 3, 5, 8, 9, 10, 19, Question 27.

[35] CMS, *Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2010*, 74 Fed. Reg. 21052, 21070 (May 6, 2009) ("[W]e recognize the importance of the professional judgment of a rehabilitation physician in the review of the preadmission screen at the time an admission decision is made. This information is more useful in reviewing the IRF admission decision than aspects of the IRF stay that would either be unknown or outside the control of the rehabilitation physician at the time of admission").

Stability to Actively Participate in Rehabilitation. OIG found one claim **(Sample #13)** to be noncompliant on the grounds that the documentation does not support a reasonable expectation at the time of admission that the patient was sufficiently stable to be able to actively participate in a rehabilitation program. SMH disputes this finding.

The goal of the IRF benefit is to provide intensive rehabilitation in a resource-intensive inpatient setting for patients who, due to the complexity of their nursing, medical management, and rehabilitation needs, require inpatient treatment and an interdisciplinary approach to the delivery of rehabilitation care.[36] For an IRF claim to be considered reasonable and necessary, there must be a reasonable expectation that the patient is sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation therapy program.[37] As noted in the Draft Report, during the PHE, the "intensive" nature of the rehabilitation therapy in this requirement was waived, as was the separate requirement that the patient generally requires and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation program.[38]

OIG imposes too fine a line between being ill enough to require rehabilitation services and being too ill to participate in therapy. As indicated in the SMH physician statement, enclosed as **Exhibit E**, there was a reasonable expectation that the patient was sufficiently stable at the time of admission to be able to actively participate in the rehabilitation therapy program. According to this statement, even though the patient had active comorbidities increasing the complexity of the stay, the record documented tolerance for therapy consistent with the regulatory requirements. This is evidenced by the clear therapy benefit with demonstrated functional progress. And, in any case, this claim involved dates of service in February and March 2021, squarely during the PHE, and during which time the intensity of rehabilitation therapy requirement was waived, meaning the bar for patient stability was lower than is asserted in the Draft Report. OIG should correct the error in the Draft Report (in which it asserts the patient was admitted for inpatient rehabilitation services "after the COVID-19 PHE")[39] and ensure that its medical reviewer applies the correct standard of review.

OIG's findings also neglect to consider the role of a rehabilitation physician, which is to monitor the patient's medical and functional status and revise the plan of care as needed.[40] As explained in **Exhibit C**, OIG emphasizes that the patient experienced pain and lethargy; however, pain is a common complaint, which is treated with medication, adapting schedules, and progressive functional activities, and lethargy in this case was related to the use of opiates, which the rehabilitation physician was able to adjust as needed. Because of medical and therapeutic intervention, the patient did in fact participate in and benefit from treatment.

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[36] MBPM, Chapter 1, § 110.

[37] 42 C.F.R. § 412.622(a)(3)(iii); MBPM, Chapter 1, § 110.3.

[38] *See* Draft Report at 8. *See also* 42 C.F.R. § 412.622(a)(3)(ii).

[39] Draft Report at 8.

[40] MBPM, Chapter 1, § 110.2 ("[T]he rehabilitation physician must conduct face-to-face visits with the patient at least 3 days per week throughout the patient's stay in the IRF to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.").

2. Interdisciplinary Team Documentation[41]

OIG found for one claim **(Sample #20)** that documentation did not support that all required participants attended the IDT meeting. Specifically, it found that speech therapy services began on October 22, 2021, and that the speech therapist did not attend the October 27, 2021 meeting. Although the documentation does not indicate the speech therapist attended this IDT meeting, SMH disputes that this claim is noncompliant.

IRF patients must require an interdisciplinary approach to care, as evidenced by documentation in the patients' medical record of weekly IDT meetings.[42] IDT meetings must include a licensed or certified therapist from each therapy discipline involved in treating the patient.[43] CMS guidance indicates the documentation "should generally" include the names and professional designations of the IDT participants.[44] CMS contemplates that missing or conflicting information could be explained in the documentation.[45] Furthermore, CMS guidance indicates contractors must "***consider*** completion of the requirements at 42 CFR § 412.622(a)(3), (4), and (5) in a patient's IRF medical record when determining whether an IRF admission was reasonable and necessary."[46] In other words, completion of the documentation is only part of the reviewer's consideration in assessing whether the services rendered are medically necessary.

As explained in the rebuttal in **Exhibit C**, the October 27 IDT meeting started at 12:38 PM. Shortly thereafter, at 1:00 PM, the speech therapist had a visit with the patient and the patient's spouse, where the therapist completed discharge from speech therapy services. The patient was discharged from the IRF the next day, on October 28, and the home health plan of care at discharge did not include speech therapy. Accordingly, as of the time of the October 27 IDT meeting, speech therapy was no longer a "therapy discipline involved in treating the patient,"[47] and, therefore, the speech therapist was not required to attend the IDT meeting.[48] Moreover, the IDT meeting notes

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[41] The OIG medical reviewer letters found the documentation does not support that each IDT meeting was led by a rehabilitation physician. In its Draft Report, following its review of SMH's May 2, 2025 correspondence about this issue, OIG stated it did not find SMH to be noncompliant with this requirement. Therefore, SMH will not address these findings further in its response.

[42] 42 C.F.R. § 412.622(a)(5).

[43] 42 C.F.R. § 412.622(a)(5)(i).

[44] MBPM, Chapter 1, § 110.2.5.

[45] CMS, IRF Training Call (Nov. 12, 2024), *available at* https://www.cms.gov/medicare/medicare-fee-for-service-payment/inpatientrehabfacpps/downloads/irf-training-call_version_4.pdf (stating in the context of clarification regarding preadmission screening documentation: "If missing or conflicting information is not reasonably explained in the appropriate document in the IRF medical record, then the IRF claim could be subject to denial.").

[46] MBPM, Chapter 1, § 110.1 (emphasis added).

[47] *See* 42 C.F.R. § 412.622(a)(5)(i).

[48] In fact, one could take the position that the October 27 IDT meeting was not required to meet Medicare coverage criteria. The regulations require that IDT meetings occur at least once per week. 42 C.F.R. § 412.622(a)(5)(ii). "Week" means "a period of 7 consecutive calendar days beginning with the date of admission to the IRF." *Id.* at § 412.622(c). The patient was admitted on October 15, 2021, meaning the first week ran from that date through October 21. The first IDT meeting occurred October 20. The second week ran from October 22 through October 28. As noted above, the patient was discharged on October 28—i.e., before the end of the second week. Thus, strictly speaking, no additional IDT meeting was required. *See* CMS, IRF Training Call (Nov. 12, 2024), *available at*

indicate collaboration with the speech therapist. The purpose of the IDT is to "foster frequent, structured, and documented communication among disciplines to establish, prioritize, and achieve treatment goals."[49] The medical record reflects this goal was satisfied here.

Importantly, OIG found SMH satisfied all medical necessity criteria for this claim. To find the services rendered were medically reasonable and necessary—which is the fundamental inquiry in a medical record review—yet find the claim to be noncompliant because of failure to list a single discipline on the IDT documentation for a single meeting improperly elevates form over substance.

3. Preadmission Screening

For one claim **(Sample #11)**, OIG found the documentation did not support that the preadmission screening included the expected length of time to achieve the level of improvement needed. SMH disputes this finding.

Medicare regulations require that the patient's medical record include a comprehensive preadmission screening. That screening must include "a detailed and comprehensive review of each patient's condition and medical history, ***including***[,]" among other things, the patient's "expected level of improvement[] and the expected length of time necessary to achieve that level of improvement."[50] Although in this case the expected length of time was not expressly stated in the preadmission screening document, the plan of care in the physician history and physical, which was prepared within hours of the preadmission screening document, includes an expected length of therapy of three weeks, as explained in the rebuttal in **Exhibit C**. As noted above, the applicable regulations describe the preadmission screening in broad terms, including a "comprehensive review of [the] patient's condition and medical history" that "includ[es] … the expected length of time necessary to achieve [the expected] level of improvement."[51]

Furthermore, as above with respect to the IDT documentation, OIG again found SMH satisfied all medical necessity criteria for this claim. What is, at worst, a minor technical documentation issue should not undermine the claim where there is ample medical record documentation to demonstrate the services rendered were medically reasonable and necessary.[52]

C. Outpatient Claims

1. Coding Issues

OIG found that 6 out of the 15 outpatient claims were noncompliant based on coding issues. SMH is not disputing these claims and will take appropriate steps to issue a refund.

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https://www.cms.gov/medicare/medicare-fee-for-service-payment/inpatientrehabfacpps/downloads/irf-training-call_version_4.pdf (stating, in a provider training call, that "[t]hough it is good practice to discuss a patient's care in the IRF as often as possible throughout the patient's IRF stay, it is not technically required for the IRF to have an interdisciplinary team meeting for a patient who is in the facility fewer than 7 days").

[49] *See* MBPM, Chapter 1, § 110.2.5.

[50] 42 C.F.R. § 412.622(a)(4)(i)(B) (emphasis added).

[51] *Id.*

[52] *See supra* note 45.

However, OIG incorrectly calculated the overpayment for one claim **(Sample #87)**. Specifically, OIG found CPT code 29581 (application of multi-layer compression system; leg) to be noncompliant. Medicare paid SMH $50.80 for this service, as evidenced by the remittance advice, enclosed as **Exhibit F**. OIG incorrectly calculated the overpayment amount to be $1,232.92. This is the amount Medicare paid SMH for CPT code 15271 (application of skin substitute graft to trunk, arms, legs), which was billed with the same date of service, and which OIG found to be compliant. Therefore, the total overpayment amount for the outpatient claims should be $470.05 rather than $1,652.17, as calculated by OIG.

2. Medical Necessity

OIG found that for one claim **(Sample #99)**, the medical record did not include any clinical information to support the medical necessity of a billed laboratory test, resulting in an overpayment of $5. SMH is not disputing this claim and will take appropriate steps to issue a refund.

IV. OIG'S USE OF STATISTICAL SAMPLING AND EXTRAPOLATION WAS INAPPROPRIATE

A. OIG Did Not Make the Threshold Finding to Justify the Use of Extrapolation

A threshold requirement for the use of extrapolation to determine overpayment amounts is that a determination must be made that (1) there has been a sustained or high level of payment error, or (2) documented educational intervention has failed to correct the payment error.[53] This is a statutory requirement and CMS does not offer any concessions for meeting this requirement.

OIG did not provide evidence that it had made this threshold finding. In its February 13, 2023 Audit Notification Letter, OIG informed SMH that it would use statistical sampling and extrapolation, stating "[r]esults from statistically sampled claims may be projected to all claims in the sampling frame." The Audit Notification Letter made no mention of SMH having a sustained or high level of payment error, or any educational interventions that may have failed. In the Draft Report, OIG explained it selected SMH because SMH "had a significant number of claims submitted to Medicare in areas OIG designated as high-risk." OIG makes no allegation that SMH has had a history of payment errors. In fact, OIG goes on to acknowledge that "[s]ubmitting claims at-risk for noncompliance does not by itself mean the claims were noncompliant." Rather than targeting a hospital with a demonstrated history of noncompliance that poses a risk to federal healthcare program beneficiaries and funds, OIG targeted SMH because it is a large hospital that treats a significant number of patients, and, therefore, submits a high number of claims.[54] This is an insufficient basis upon which to subject SMH to the use of statistical sampling and extrapolation.

Furthermore, even if OIG could use this audit as a basis to justify the use of extrapolation, which SMH disputes,[55] the error rate is too low to establish a sustained or high level of payment

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[53] 42 U.S.C. § 1395ddd(f)(3); *see also* MPIM, Chapter 8, § 8.4.1.2.

[54] SMH has nearly 50,000 admissions per year, the majority of which are Medicare and Medicaid beneficiaries.

[55] The threshold determination must be made prior to the audit. Medicare guidance explains that "***before*** using extrapolation . . . there must be a determination of sustained or high level of payment error, or documentation that

error. The Medicare guidance in effect during the Audit Period defined a high error rate as "greater than or equal to 50 percent from a previous pre- or post-payment review."[56] Neither OIG's inflated error rate of 30% based on claims nor its alleged financial error rate of 21.7% reaches this threshold level.

Although SMH recognizes the statutory threshold requirement for extrapolation is applicable to Medicare contractors and is not, strictly speaking, binding on OIG, because a Medicare contractor will ultimately process the overpayment associated with this audit, it is essential that the basis for the overpayment is appropriate under Medicare laws and guidance. OIG acknowledges in the Draft Report: "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***."[57] The Draft Report repeatedly emphasizes that its findings are merely recommendations for CMS, yet fails to explain why its recommendations would be based on something other than CMS policies and procedures. Although OIG's Draft Report states it conducted this audit "in accordance with generally accepted government auditing standards," OIG neither explains which standards it used nor why, in an audit of Medicare claims, it was appropriate to disregard CMS's key threshold inquiry for statistical sampling and extrapolation. For this reason alone, the use of statistical sampling and extrapolation, as well as the recommendation regarding refunding the extrapolated overpayment, must be set aside.

B. Use of Statistical Sampling in the Context of an Analysis of Medical Necessity is Inappropriate

The use of statistical sampling to extrapolate the overpayment amount across the universe of claims in the context of these subjective determinations of medical necessity is inappropriate. Most of OIG's allegations of error are based on its findings that the services are not medically reasonable and necessary. This is necessarily a subjective determination based on an individualized review of the records and observations of the patient in real-time. Furthermore, the services here were rendered during the PHE where medical guidance was continually evolving and signs and symptoms that were historically minor could lead to catastrophic outcomes, further underscoring the need for a case-by-case review.

It is well established that the "permissibility of statistical sampling turns on 'the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of

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educational intervention has failed to correct the payment error." MPIM, Chapter 8, § 8.4.1.2 (emphasis added). The scope of the review is based on factors such as how long the pattern of sustained or high level of payment error is believed to have existed. MPIM, Chapter 8, § 8.4.3.1. If the scope of the audit is determined by how long a high or sustained level of payment error has existed, it logically follows that this determination must be made ***before*** the contractor conducts the audit. Furthermore, the requirements for determining when statistical sampling may be used are included within the procedures for ***initiating*** the audit (e.g., Section 8.4.1 – Introduction [to Use of Statistical Sampling for Overpayment Estimation] and Section 8.4.3 – Selection of Period to be Reviewed and Composition of Universe), which further underscores that the threshold findings must be made at the beginning, not the end, of the audit.

[56] MPIM, Chapter 8, § 8.4.1.4 (Rev. 906, Issued 09-26-19).

[57] Draft Report at 11, n.17 (emphasis added).

action.'"[58] Here, where the determination of medical necessity is highly subjective and fact-intensive, the use of statistical sampling to draw conclusions about the larger universe of claims is not a reliable method of determining SMH's liability for overpayments. In determining whether to permit statistical sampling in a case involving a similar determination of medical necessity, one court held:

> Distilled to its essence, each claim asserted here presents the question of whether certain services . . . were medically necessary. Answering that question for each of the patients involved in this action is highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient. As the Court has acknowledged, some cases are suited for statistical sampling and, indeed, in many cases that method is the only way that damages may be proved. This civil action, however, is not such a case.[59]

A case-by-case assessment in these circumstances is essential. During the exit conference, OIG explained that, historically, it would audit up to 500 claims. Now, however, it audits only 100 claims because a broader review is "not efficient." In response to SMH's supplemental requests, OIG acknowledged this approach is not "the most precise methodology." Given the highly individualized assessment of medical necessity, the overpayment calculations should be limited to the claims OIG actually audited.[60]

C. OIG Has Failed to Adequately Explain Its Statistical Sampling Methodology

The sample includes 100 claims assigned to 11 risk areas. OIG grouped the claims into four strata based on risk areas. Stratum 1 includes IRF claims and is comprised of 20 claims. Stratum 2 includes certain inpatient claims classified as "low dollar claims" (i.e., less than or equal to $14,684 per claim) and is comprised of 33 claims. Stratum 3 includes certain inpatient claims classified as "high dollar claims" (i.e., more than $14,684 per claim) and is comprised of 32 claims. Stratum 4 includes certain outpatient claims and is comprised of 15 claims. OIG has not explained why it chose the number of claims for each stratum or "sub-sample" that it did. This casts doubt on the reliability of the statistical analysis. The number of claims also reflects no apparent relationship to SMH's operations. For example, paid IRF claims during the Audit Period totaled approximately $45 million, a number that was dwarfed by paid outpatient claims (approximately $146.3 million) and paid inpatient claims (approximately $424 million), yet 20% of the claims in the sample were IRF claims. Again, OIG has not offered any explanation as to why it selected the number of claims it did for each stratum.

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[58] *United States v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833, at *11 (N.D. Tex. June 20, 2016) (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016)).

[59] *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. CA 0:12-3466-JFA, 2015 WL 3903675, *8 (D.S.C. June 25, 2015).

[60] *See Vista Hospice Care*, 2016 WL 3449833, at *13 ("If individual review of each chart were impractical, Relator was not required to pursue all potential . . . claims . . . . These choices, made by Relator, do not reduce her burden to produce reliable evidence of liability.").

In addition, OIG's sampling methodology gives the impression that one of the risk areas used to select claims was simply whether the claim was an IRF claim. There is no further qualification of these claims. But it is clear that OIG excluded certain IRF claims from this risk area. As noted above, SMH's total paid IRF claims during the Audit Period were approximately $45 million. The sampling methodology lists the value of the IRF claims frame as roughly $34 million. The OIG medical reviewer letters offer some insight into this discrepancy. The letters routinely state, in support of the position that skilled nursing care would have been sufficient in lieu of IRF care, "The patient did not require rehabilitation physician oversight for a complex neurological condition or management of complex wound care, tube feedings, tracheostomy management or management of neurogenic bowel or bladder." It appears OIG may have excluded IRF claims that involve ICD-10 diagnosis codes describing these conditions, as, perhaps, these diagnosis codes tend to be supportive of the IRF level of care. OIG has broad discretion to define risk areas, but adopting a narrower definition that removes some IRF claims viewed to not be "as risky" as other IRF claims, and not explaining the approach clearly in the Draft Report, obscures important information and misleads the reader.

D. The Plain Errors in OIG's Analysis Invalidate its Extrapolation

As described above, SMH disagrees with most of OIG's findings. If in any case OIG reverses its findings, it must redo the extrapolation, as the sample on which the extrapolation is based has changed. In fact, even if OIG does not reverse any of its substantive findings, it must redo the extrapolation. As noted above, in two claims **(Sample #63 and Sample #87)**, OIG incorrectly calculated the alleged overpayment. As a result, the value of the net overpayments is two of the strata of the sample is incorrectly stated and the estimate of all overpayments in the sampling frame is incorrect.

V. SMH DOES NOT CONCUR WITH OIG RECOMMENDATIONS

For the reasons set forth above, SMH does not concur with any of the three recommendations set forth in the Draft Report.

OIG Recommendation #1: "[R]efund to the Federal government $17,705,581 in estimated net overpayments for the Audit Period for claims that it incorrectly billed."[61]

SMH Response: SMH does not concur with this recommendation. As SMH explains above and as its medical reviewers explain in the rebuttals, OIG's findings are clinically and legally erroneous. For the limited number of claims for which SMH agrees with OIG's findings, SMH will take appropriate steps to issue a refund. If the Medicare Administrative Contractor reverses its initial determinations for any of the remaining claims OIG alleges are noncompliant, SMH will vigorously challenge those findings through the Medicare administrative appeals process.

[61] Draft Report at 11.

OIG Recommendation #2: "[C]onsider conducting internal audits or investigations for claims beyond our Audit Period based on the risks identified by this audit, to identify any similar overpayments and return any identified overpayments to the Medicare program."[62]

SMH Response: SMH does not concur with this recommendation. The limited issues identified by OIG's audit are isolated instances of potential noncompliance, and they provide no reason to believe that SMH should conduct additional audits beyond those it routinely conducts as part of its robust compliance processes. Additionally, because the claims at issue in this audit are in the unique context of the PHE, SMH does not have reason to believe any errors extend beyond this unusual period.

OIG Recommendation #3: "[P]rovide additional training to clinical and billing personnel on its policies and procedures related to the following:

- the two-midnight rule;
- medical necessity of inpatient and outpatient services;
- IRF admissions and documentation requirements;
- billing of services provided; and
- inpatient and outpatient coding."[63]

SMH Response: SMH does not concur with this recommendation. SMH's compliance processes, including its training and education on its policies and procedures, are robust and appropriately designed to detect and correct noncompliance. The fact that there were a limited number of isolated issues of potential noncompliance does not justify OIG's recommendation.

VI. CONCLUSION

SMH understands and takes seriously its obligation to comply with Medicare billing requirements, and it appreciates the opportunity to comment on the Draft Report. For the reasons described herein, OIG's findings are flawed. SMH respectfully requests that OIG consider the information provided with this letter and revise its findings accordingly.

Sincerely,

Travis G. Lloyd

cc: Lisa Totten (via email)
David Evans (via email)

Enclosures

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[62] *Id.*

[63] *Id.* at 11-12.

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