Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE HOSPITAL PROVIDER COMPLIANCE AUDIT: SUNRISE HOSPITAL & MEDICAL CENTER

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Office of Inspector General

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Report in Brief

Date: March 2021 Report No. A-04-19-08075

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

Why OIG Did This Audit

This audit is part of a series of hospital compliance audits. Using computer matching, data mining, and data analysis techniques, we identified hospital claims that were at risk for noncompliance with Medicare billing requirements. For calendar year 2018, Medicare paid hospitals \$179 billion, which represents 47 percent of all fee-forservice payments for the year.

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

How OIG Did This Audit

Our audit covered about \$41 million in Medicare payments to the Hospital for 2,117 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 85 inpatient and 15 outpatient claims with payments totaling \$2.4 million for our 2-year audit period (January 1, 2017, through December 31, 2018).

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

Medicare Hospital Provider Compliance Audit: Sunrise Hospital & Medical Center

What OIG Found

The Hospital complied with Medicare billing requirements for 46 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 54 claims, resulting in net overpayments of \$999,950 for the audit period. Specifically, 50 inpatient claims and 4 outpatient claims had billing errors.

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$23.6 million for the audit period. During the course of our audit, the Hospital submitted five of these claims for reprocessing, and we verified those claims as correctly reprocessed. Accordingly, we have reduced the recommended refund by \$8,914.

What OIG Recommends and Hospital Comments

We recommend that the Hospital: (1) refund to the Medicare contractor \$23.6 million in net estimated overpayments for the audit period for claims that it incorrectly billed that are within the reopening period; (2) based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation; and (3) strengthen controls to ensure full compliance with Medicare requirements. The detailed recommendations are listed in the body of the report.

In written comments on our draft report, the Hospital disagreed with most of our findings and recommendations. The Hospital disagreed with the inpatient rehabilitation facility claims that we identified as incorrectly billed and the majority of the other errors identified in this report. In addition, the Hospital disagreed with our medical review contractor and extrapolation.

After review and consideration of the Hospital's comments, we maintain that our findings and recommendations are correct. We submitted the claims selected for review to an independent medical review contractor that reviewed the medical records in their entirety to determine whether the services were medically necessary and provided in accordance with Medicare coverage and documentation requirements. The medical reviewer was board certified in physical medicine and rehabilitation, pain management, and spinal cord injury medicine. The use of statistical sampling to determine overpayment amounts in Medicare is well established and has repeatedly been upheld on appeal in Federal courts.

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INTRODUCTION

WHY WE DID THIS AUDIT

This audit is part of a series of hospital compliance audits. Using computer matching, data mining, and other data analysis techniques, we identified hospital claims that were at risk for noncompliance with Medicare billing requirements. For calendar year 2018, Medicare paid hospitals \$179 billion, which represents 47 percent of all fee-for-service payments; accordingly, it is important to ensure that hospital payments comply with requirements.

OBJECTIVE

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

BACKGROUND

The Medicare Program

Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge, and Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program. CMS uses Medicare contractors to, among other things, process and pay claims submitted by hospitals.

Hospital Inpatient Prospective Payment System

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

Hospital Inpatient Rehabilitation Facility Prospective Payment System

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

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

Hospital Outpatient Prospective Payment System

CMS implemented an outpatient prospective payment system (OPPS), which is effective for services furnished on or after August 1, 2000, for hospital outpatient services. Under the OPPS, Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification (APC). CMS uses Healthcare Common Procedure Coding System (HCPCS) codes and descriptors to identify and group the services within each APC group.¹ All services and items within an APC group are comparable clinically and require comparable resources.

Hospital Claims at Risk for Incorrect Billing

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

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

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

For the purposes of this report, we refer to these areas at risk for incorrect billing as "risk areas." We reviewed these risk areas as part of this audit.²

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*, Pub. No. 100-04 (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. The Manual states that providers must use HCPCS codes for most outpatient services (chapter 23 § 20.3).³

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

The 6-year lookback period is not limited by OIG's audit period or restrictions on the Government's ability to reopen claims or cost reports. To report and return overpayments

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

³ "Under the hospital outpatient prospective payment system, predetermined amounts are paid for designated services furnished to Medicare beneficiaries. These services are identified by codes established under the Centers for Medicare & Medicaid Services Common Procedure Coding System (HCPCS)" 42 CFR § 419.2(a). Moreover, claims must be filed on forms prescribed by CMS in accordance with CMS instructions (42 CFR § 424.32(a)(1)).

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

under the 60-day rule, providers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.⁵

Sunrise Hospital & Medical Center

The Hospital is a 599-bed short-term, acute care, for profit hospital, located in Las Vegas, Nevada. According to CMS's National Claims History (NCH) data, Medicare paid the Hospital approximately \$245 million for 15,000 inpatient and 25,308 outpatient claims from January 1, 2017, through December 31, 2018 (audit period).

HOW WE CONDUCTED THIS AUDIT

Our audit covered about \$41 million in Medicare payments⁶ to the Hospital for 2,117 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 claims (85 inpatient and 15 outpatient) with payments totaling \$2.4 million.⁷ Medicare paid these 100 claims during our 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 claim was supported by the medical record. This report focuses on selected risk areas and does not represent an overall assessment of all claims submitted by the Hospital for Medicare reimbursement.

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

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

FINDINGS

The Hospital complied with Medicare billing requirements for 46 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 54 claims, resulting in net overpayments of \$999,950 for the audit period. Specifically, 50 inpatient claims had billing errors, resulting in net

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

⁶ The total Medicare payments were \$40,691,082.

⁷ The total paid was \$2,406,660.

overpayments of \$1,002,049, and 4 outpatient claims had billing errors, resulting in net underpayments of \$2,099. These errors occurred primarily because the Hospital did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors. As of the publication of this report, this amount includes claims outside of the 4-year claim reopening period.

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$23,615,809 for the audit period. See Appendix B for our statistical sampling methodology, Appendix C for sample results and estimates, and Appendix D for the results of our audit by risk area.

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 50 of the 85 inpatient claims that we reviewed. These errors resulted in net overpayments of \$1,002,049, as shown in Figure 1.

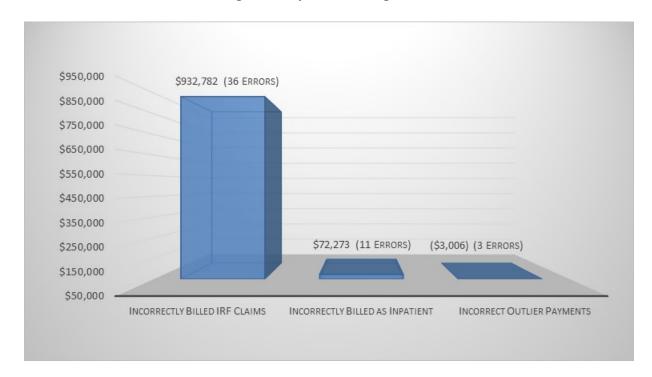


Figure 1: Inpatient Billing Errors

⁸ 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.

Incorrectly Billed Inpatient Rehabilitation Facility Claims

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

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

For 36 of the 85 selected inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for acute inpatient rehabilitation. IRF services for these beneficiaries were not reasonable and necessary because these beneficiaries did not require the active and ongoing therapeutic intervention of multiple therapy disciplines; generally did not require and could not reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program; were not sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation program; or did not require supervision by a rehabilitation physician.

Hospital officials did not provide a cause for these errors because they generally contended that these claims met Medicare requirements. Furthermore, Hospital officials did not provide any additional information that would impact our finding.

As a result of these errors, the Hospital received overpayments of \$932,782.

Incorrectly Billed as Inpatient

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

A payment for services furnished to an individual may be made only to providers of services that are eligible and only if, "with respect to inpatient hospital services . . . , which are furnished over a period of time, a physician certifies that such services are required to be given on an

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

inpatient basis for such individual's medical treatment . . ." (the Act, § 1814(a)(3)). Federal regulations require an order for inpatient admission by a physician or other qualified provider at or before the time of the inpatient admission (42 CFR § 412.3(a)-(c)).

In addition, the regulations provide that an inpatient admission, and subsequent payment under Medicare Part A, is generally appropriate if the ordering physician expects the patient to require care for a period of time that crosses two midnights (42 CFR § 412.3(d)(1)). Furthermore, the regulations provide that the expectation of the physician "should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration" (42 CFR § 412.3(d)(1)(i)).

For 11 of the 85 selected inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for inpatient status that should have been billed as outpatient or outpatient with observation. The medical records did not support the necessity for inpatient hospital services. Hospital officials stated that they agreed with one of these errors but did not provide a cause for the error. Hospital officials did not provide a cause for the remaining ten errors because they generally contended that these claims met Medicare requirements. Furthermore, Hospital officials did not provide any additional information that would impact our finding.

As a result of these errors, the Hospital received overpayments of \$72,273. For three of these claims, the Hospital refunded \$8,684 of the overpayments after the start of our audit. This refund resulted in remaining net actual overpayments totaling \$63,589. 10

Incorrect Outlier Payments

The Act requires Medicare to pay an additional amount beyond the basic DRG payment for outlier cases (§ 1886(d)(5)(A)). In addition, section 1815(a) of the Act states: "The Secretary shall periodically determine the amount which should be paid under this part to each provider of services with respect to the services furnished by it, and the provider of services shall be paid, at such time or times as the Secretary believes appropriate (but not less often than monthly) and prior to audit or settlement by the General Accounting Office, from the Federal Hospital Insurance Trust Fund, the amounts so determined, with necessary adjustments on account of previously made overpayments or underpayments; except that no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider under this part for the period with respect to which the amounts are being paid or any prior period."

¹⁰ We gave the Hospital credit for the refunded amount in our repayment recommendation, but we used total improper payments to determine the extrapolated overpayment amount.

For 3 of the 85 selected inpatient claims, the Hospital incorrectly billed units of service and charges on the claims, which resulted in incorrect outlier payments. Hospital officials stated that these errors occurred because of human error or lack of documentation. Hospital officials did not provide any additional information that would impact our finding.

As a result of these errors, the Hospital experienced underpayments of \$3,006.

BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 4 of the 15 outpatient claims that we reviewed. These errors resulted in net underpayments of \$2,099, as shown in figure 2.

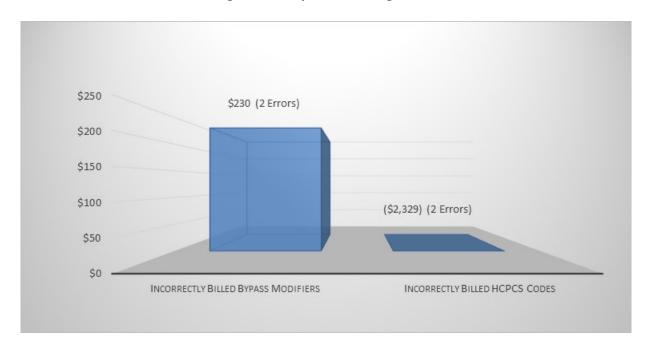


Figure 2: Outpatient Billing Errors

Incorrectly Billed Modifiers

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, ch. 4, § 20.1), 11 and providers are required to complete claims accurately so that Medicare contractors may process them correctly and promptly (the Manual, ch. 1, § 80.3.2.2).

[&]quot;Under the hospital outpatient prospective payment system, predetermined amounts are paid for designated services furnished to Medicare beneficiaries. These services are identified by codes established under the Centers for Medicare & Medicaid Services Common Procedure Coding System (HCPCS)" (42 CFR § 419.2(a)).

"The '59' modifier is used to indicate a distinct procedural service. This may represent a different session or patient encounter, different procedure or surgery, different site or organ system, separate incision/excision, or separate injury (or area of injury in extensive injuries)" (the Manual, ch. 23, § 20.9.1.1(B)).¹²

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

For 2 of 15 selected outpatient claims, the Hospital incorrectly billed Medicare Part B for HCPCS codes appended with the "59" modifier that were not separate from other services or procedures billed on the same claim. Hospital officials stated that these errors occurred because of human error. They did not provide any additional information that would impact our finding.

As a result of these errors, the Hospital received overpayments of \$230. For these claims, the Hospital refunded all of the \$230 in overpayments after the start of our audit. This resulted in remaining net actual overpayments totaling \$0.13

Incorrectly Billed Healthcare Common Procedure Coding System Codes

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

The Manual, chapter 1, section 80.3.2.2 requires providers to complete bills accurately so that Medicare contractors may process them correctly and promptly. In addition, the Manual, chapter 4, section 20.1, states that reporting of HCPCS codes is required of acute care hospitals and long-term care hospitals. HCPCS codes are also required of rehabilitation hospitals, psychiatric hospitals, hospital-based Rural Health Clinics, hospital-based Federally Qualified Health Centers, and Critical Access Hospitals. HCPCS codes are required for all outpatient hospital services unless granted a specific exception in Manual instructions.

For 2 of the 15 outpatient claims, the Hospital submitted claims to Medicare Part B with incorrect HCPCS codes that were not supported by the medical record. Hospital officials stated that one of these errors occurred because of human error and did not provide a cause for the

¹² This manual provision was revised after our audit period by Change Request 10868, dated December 28, 2018, and effective January 30, 2019.

¹³ We gave the Hospital credit for the refunded amount in our repayment recommendation, but we used total improper payments to determine the extrapolated overpayment amount.

other error because its officials generally contended that these claims met Medicare requirements. Furthermore, Hospital officials did not provide any additional information that would impact our finding.

As a result of the errors on these two claims, the Hospital received net underpayments of \$2,329. For one claim, the Hospital received an overpayment of \$174, and for the other claim the Hospital experienced an underpayment of \$2,503.

OVERALL ESTIMATE OF OVERPAYMENTS

The net overpayments on the 54 sampled claims that did not fully comply with Medicare billing requirements totaled \$999,950. On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$23,615,809 for the audit period. During the course of our audit, the Hospital submitted for reprocessing five of the claims that did not fully comply, and we verified those claims as correctly reprocessed. Accordingly, we have reduced the recommended refund by \$8,914.

RECOMMENDATIONS

We recommend that Sunrise Hospital & Medical Center:

- refund to the Medicare contractor \$23,606,895 (\$23,615,809 less \$8,914 that the Hospital has already repaid) in net estimated overpayments for the audit period for claims that it incorrectly billed that are within the 4-year reopening period;¹⁴
- based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule¹⁵ and identify any of those returned overpayments as having been made in accordance with this recommendation; and
- strengthen controls to ensure that:

¹⁴ 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 reestimated depending on CMS determinations and the outcome of appeals.

¹⁵ This recommendation does not apply to any overpayments that are both within our sampling frame (i.e., the population from which we selected our statistical sample) and refunded based upon the extrapolated overpayment amount. Those overpayments are already covered in the previous recommendation.

- o all IRF beneficiaries meet Medicare criteria for acute inpatient rehabilitation and all required documentation is included in the medical records,
- all inpatient beneficiaries meet Medicare requirements for inpatient hospital services,
- outlier payments are calculated correctly by billing the correct units of service and charges on the claim and staff are properly trained,
- the use of bypass modifiers is supported in the medical records and staff are properly trained, and
- o HCPCS codes are supported in the medical records and staff are properly trained.

HOSPITAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Hospital disagreed with almost all of our findings and recommendations. We summarized the Hospital's agreements, disagreements, and objections below. After review and consideration of the Hospital's comments, we maintain that our findings and recommendations are correct. However, some of the incorrectly billed claims that we identified are now outside of the Medicare reopening period. Therefore, for our first recommendation, we acknowledge that the Hospital should refund only the estimated overpayments for incorrectly billed claims that are within the reopening period.

MEDICAL REVIEW CONTRACTOR

Hospital Comments

The Hospital stated that it requested that we make our medical reviewer available at the exit conference for a clinical discussion with the Hospital's IRF Medical Director, but we refused to include any reviewer in the exit conference or to discuss any specific clinical findings during that conference. The Hospital again asked for an opportunity, prior to the issuance of our draft audit report, to meet with our medical reviewer and discuss the audit findings. The Hospital stated that we refused to schedule a meeting with our medical reviewer and that such a meeting was not a part of our audit process.

The Hospital stated that our refusal to re-engage our medical reviewer prior to issuing the draft report ¹⁶ was inappropriate and unacceptable generally but particularly during an ongoing pandemic and a multi-year backlog at the administrative law judge (ALJ) level of appeal. The

¹⁶ The Hospital also stated that at some unspecified time prior to issuance of the draft report we told them that, "in all likelihood," we would not re-engage our contracted medical reviewer prior to issuance of our final report. The Hospital did not ask that we re-engage our contracted medical reviewer at any time between the issuance of our draft report and final report.

Hospital stated that we should engage another medical reviewer to review the denied admissions, one who is board-certified in physical medicine and rehabilitation and who has the training and recent experience in IRF care necessary to re-evaluate the claims and to consider the information that the Hospital provided in its response.

The Hospital expressed concerns about the likelihood the medical reviewer is one of the contractors used by CMS within its administrative appeals process (i.e., a MAC or Qualified Independent Contractor). Given the contractors' role in adjudicating the Hospital's appeals of the claim determinations, the Hospital believes it is improper for us to rely on such a contractor, given the possibility of future bias or even incentives against overturning any of the claims that we determined to be improperly paid. The Hospital stated that it should be allowed to know the identity of the medical reviewer to ensure that its due process rights are protected during appeals.

Office of Inspector General Response

We obtained an independent medical review to determine the medical necessity for all inpatient claims in our sample, including the 36 incorrectly billed IRF claims. We gave the Hospital numerous opportunities to submit additional documentation that it did not originally provide in response to the medical necessity determinations by our medical reviewer, but the Hospital provided no additional documentation. Although our contract with the independent medical reviewer does not allow for direct interaction between them and the Hospital, we strived to ensure that the contractor heard and considered the Hospital's opinions. Because the Hospital provided no new additional documentation, the reviewer's original determinations stand.

We understand the hardships that the ongoing pandemic have created and fully understand the backlog of ALJ appeals, but, if no additional documentation, outside of what has already been provided, is available for our medical reviewer to assess, then our original decision stands. In addition, the physician who reviewed the IRF claims is board certified in physical medicine and rehabilitation, pain management, and spinal cord injury medicine. The Hospital's assertion is without merit that the physician who reviewed the IRF claims was not board certified in physical medicine or rehabilitation and does not have training or recent experience in IRF care.

With respect to the Hospital's concerns about the likelihood of the medical reviewer being one of the contractors used by CMS, we note that any contract that our medical reviewer has with CMS is entirely separate from our medical review contract. Each of these contracts makes use of a separate team of contractor employees who are responsible for meeting the requirements of separate and distinct statements of work. The Hospital's claims to the contrary notwithstanding, we provided the identity of our medical review contractor to the Hospital on numerous occasions.

INPATIENT REHABILITATION FACILITY CLAIMS

Hospital Comments

For IRF claim denials, the Hospital stated that we should defer to the admission decisions of treating physicians. Further, the Hospital claimed that CMS stated in the IRF Prospective Payment System Final Rule for Fiscal Year 2010 that the IRF coverage regulation places "more weight on the rehabilitation physician's decision to admit the patient to the IRF." ¹⁷

The Hospital also stated that our medical reviewer misunderstood the interrelationship between therapy and physician supervision in the IRF setting; i.e., sometimes patients were too sick to participate in therapy and other times patients were not sick enough to require physician supervision. The Hospital added that the medical reviewer appeared to require a high level of medical stability to justify an expectation that the patient could participate in an intensive therapy program and a high level of baseline function to support a determination that the patient could benefit from intensive therapy. Conversely, the reviewer required a high level of medical complexity, or even instability, to justify the need for supervision by a rehabilitation physician. Patients that did not fit into the medical reviewer's categories of "too sick" or "not sick enough" were deemed more appropriate for a lower level of care. In other words, the Hospital alleged that our medical reviewer used a "Goldilocks" standard.

The Hospital further stated that the above flaws were typical of other OIG IRF audits. The Hospital believed that we should revise our processes and improve our knowledge of IRF care because our medical reviewer repeated many of the errors apparent in other IRF audits, in which Medicare contractors audited IRFs without a proper understanding of the intricacies and complexities of IRF care. For example, contractors routinely misapplied the coverage criteria for determining whether IRF services should be reimbursed and also strictly applied guidance from the Manual as grounds for denying claims, which is contrary to the Supreme Court's decision in *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019). The Hospital contended that reviewer who audited the Hospital's IRF claims made errors applying improper standards and treating manual guidance as binding.

Office of Inspector General Response

Contrary to the Hospital's assertion, it is not CMS's policy that in the IRF setting post-payment medical reviewers must give deference to admission decisions of treating physicians. For the FY 2010 IRF PPS Final Rule, CMS had proposed to strengthen the requirement for a comprehensive preadmission screening. In responding to a comment on the Proposed Rule that expressed concern that acute care hospital staff are not trained to perform a preadmission screening and that such screening should be performed by the rehabilitation physician in the IRF, CMS stated:

¹⁷74 Fed. Reg. 39762, 39791 (Aug. 7, 2009).

¹⁸ 74 Fed. Reg. at 39790-39798.

As we are placing more weight on the rehabilitation physician's decision to admit the patient to the IRF, we believe that it is important to require that the rehabilitation physician document the reasoning behind this decision, to enable medical reviewers to understand the rationale for the decision. We realize that this level of detail may exceed what some IRFs may have included in the patient's medical record in the past, but we believe that it will benefit both the IRFs and the Medicare contractors who are reviewing IRF claims to have the rationale for the reasoning behind the admission decision recorded in each patient's medical record.¹⁹

It is clear when the Hospital's abridged quote is put into context that CMS did not say that post-payment medical reviewers must show deference to admission decisions made by IRF treating physicians. Indeed, CMS said that IRF physicians must document their reasoning for admitting an IRF patient so that post-payment medical reviewers could perform medical review of IRF claims.

Conversely to the Hospital's assertion that our medical reviewers strictly applied Manual guidance as grounds for denying claims in contravention of Azar v. Allina Health Services, for all medical necessity decisions our medical reviewer applied 42 CFR § 412.622(a)(3)(i-iv), which states that, for an IRF claim to be considered reasonable and necessary, Federal regulations require that there be a reasonable expectation that, at the time of admission, the patient (1) requires the active and ongoing therapeutic intervention of multiple therapy disciplines; (2) generally requires and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program; (3) is sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation program; and (4) requires physician supervision by a rehabilitation physician. It is evidence from our medical reviewer's written determinations, which were provided to the Hospital, that our medical reviewer's decisions were based on the foregoing regulatory requirements. Our medical reviewer did not apply anything whatsoever from a CMS Manual that had changed the terms and conditions of coverage or payment set forth in statute or regulation.

Lastly, our medical reviewer is steeped in knowledge of Medicare IRF requirements, has a proper understanding of the intricacies and complexities of IRF care, and did not apply a Goldilocks standard in making medical necessity determinations. We submitted the claims to our contractor who reviewed the medical records in their entirety to determine whether the services were medically necessary and provided in accordance with Medicare coverage and documentation requirements. We worked with the medical reviewer to ensure that they applied the correct Medicare criteria and that they used professionals with appropriate medical expertise. Our medical reviewer considered the patient's entire clinical picture, including other

¹⁹ 74 Fed. Reg. at 39791. CMS also stated, "We agree that the assessment would best be performed by the rehabilitation physician or IRF clinical staff designated by the rehabilitation physician. We believe that the commenter may have misunderstood our proposal in that we do not expect the acute care hospital staff to be performing the preadmission screenings for the IRF." Ibid.

medical needs and comorbid conditions, and found that these beneficiaries: (1) did not require the active and ongoing therapeutic intervention of multiple therapy disciplines; (2) generally did not require and could not reasonably be expected to actively participate in, or benefit from, an intensive rehabilitation therapy program; (3) were not sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation program; or (4) did not require supervision by a rehabilitation physician. Again, our medical reviewer was board certified in physical medicine and rehabilitation, pain management, and spinal cord injury medicine. This physician has been board certified in physical medicine and rehabilitation since 1996. On the basis of the medical reviewer's conclusions, we maintain that our findings and recommendations are correct.

ACUTE INPATIENT ADMISSIONS

Hospital Comments

For claims that were incorrectly billed as inpatient, the Hospital contends that the inpatient admissions were medically reasonable and necessary. The Hospital stated that our medical reviewer routinely overlooked or minimized critical elements of a patients' medical conditions and necessary care. The Hospital believes that its internal controls have successfully prevented the vast majority of billing errors, and those controls worked appropriately for most of the claims that we reviewed. The Hospital intends to appeal 9 of the 11 errors we identified.

Office of Inspector General Response

We disagree with the Hospital's assertion that 9 of the 11 inpatient hospital admissions that did not comply with requirements were not errors because the inpatient admissions were medically reasonable and necessary. Based on determinations by our independent medical review, the medical records did not support the necessity for inpatient hospital services and should have been billed as outpatient or outpatient with observation.

INCORRECTLY CODED HCPCS CODES

Hospital Comments

For claims that included incorrect HCPCS codes, the Hospital disagreed with one claim determination and intends to appeal. The Hospital stated no reason for its disagreement. The Hospital also stated that it did not refund \$174 (attributable to sample 96); instead the Hospital refunded \$109 (attributable to sample 97). The Hospital plans to appeal sample 96 if we maintain that this claim was paid in error. The Hospital further stated that the draft report incorrectly listed the net underpayments that the Hospital received as \$2,329 but should have listed net underpayments as \$2,394.

Office of Inspector General Response

The Hospital is correct in its assertion that it did not refund \$174 for sample 96; we have made the necessary changes to the report to reflect this change. We maintain that this claim is in error, and, as such, the amount stated in our draft report of \$2,329 in net underpayments is correct. Furthermore, we revised our recommended refund amount to include that the Hospital did not repay \$174 for this claim. In addition, for sample 97, our independent medical reviewer did not find this claim to be error. Therefore, because the \$109 refunded amount does not pertain to the samples that we identified as being in error in our original finding, we cannot deduct the \$109 refunded amount from the total finding.

INAPPROPRIATE AND PREMATURE EXTRAPOLATION

Hospital Comments

The Hospital objects to our use of extrapolation as being "grossly excessive" and the threat of it places an unreasonable burden on the Hospital. The Hospital contends that a re-review of the 36 IRF errors would result in significantly fewer denials, if any. In addition, the Hospital stated that the individualized nature of IRF admissions makes these claims particularly inappropriate for extrapolation. Similarly, the decision whether to admit a patient into an acute care unit is subjective and based on the individual factors of the case. The Hospital asserted that, as recognized by a Federal court, "[t]he essence of the science of inferential statistics is that one may confidently draw inferences about the whole from a representative sample of the whole." 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 action."21 The Hospital alleged that we "did not identify routine and related documentation errors that might serve as some indicator of errors in other claims within the universe." Instead, it said that we made medical necessity determinations, and the nature of those claims requires an individualized determination that cannot be replaced by an examination of a sample that is then projected to the whole. When medical necessity is involved, according to the Hospital, courts have rejected the use of extrapolation.²² The Hospital said that, because "each and every claim at issue" was "fact-dependent and wholly unrelated to each and every other claim," and determining eligibility for "each of the patients involved a highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient," the

²⁰ *In re Chevron U.S.A., Inc.* 109 F.3d 1016, 1019-20 (5th Cir. 1997); *see also United States v. Pena*, 532 F. App'x 517, 520 (5th Cir. 2013).

²¹ Tyson Foods, Inc. v. Bouaphakeo, 136 S. Ct. 1036, 1046 (2016).

²² United States ex rel. Wall v. Vista Hospice Care, Inc., No. 3:07-CV-00604-M, 2016 WL 3449833, at *11-13 (N.D. Tex. June 20, 2016); United States ex rel. Michaels v. Agape Senior Cmty., Inc., No. CA 0: 12-3466-JFA, 2015 WL 3903675, at *2 (D.S.C. June 25, 2015).

court found that the case was not "suited for statistical sampling." Thus, extrapolating the alleged errors in the sampled IRF and acute care claims to the entirety of similar Hospital claims is unsupportable.

The Hospital stated that, based on the fact-specific and individualized nature of the admission errors that we alleged, only a claim-by-claim examination and determination process is appropriate for IRF and acute-care claims. Therefore, we should recommend to the MAC that no extrapolated overpayment be assessed until the Hospital has exhausted its appeal rights, and the true amount of the overpayments is known.

Office of Inspector General Response

We disagree that only a claim-by-claim examination and determination process is appropriate for IRF and acute-care claims. The Hospital is wrong in stating that, when medical necessity is involved, courts have rejected the use of extrapolation. The cases cited by the Hospital to support this assertion rejected the use of extrapolation to establish liability in false claim cases, not the use of extrapolation for purposes of post-payment medical review of Medicare claims. Moreover, 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 use of statistical sampling to determine overpayment amounts in Medicare is well established and has repeatedly been upheld on appeal in Federal courts.²⁴ The legal standard for the use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.²⁵ We properly executed our statistical sampling methodology by defining our sampling frame, sampling unit, and strata; selecting a stratified random sample; applying relevant criteria in evaluating the sample items; and using

²³ Agape Senior Cmty, Inc., at *2, *8; see also U.S. v. Medco Phys. Unlimited, No. 98-C-1622, 2000 U.S. Dist. LEXIS 5843, at *23 (N.D. III. Mar. 15, 2000).

²⁴ Yorktown Med. Lab., Inc. v. Perales, 948 F.2d 84 (2d Cir. 1991); Illinois Physicians Union v. Miller, 675 F.2d 151 (7th Cir. 1982); Momentum EMS, Inc. v. Sebelius, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); Anghel v. Sebelius, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); Miniet v. Sebelius, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); Bend v. Sebelius, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

²⁵ See John Balko & Assoc. v. Sebelius, 2012 WL 6738246 at *12 (W.D. Pa. 2012), aff'd 555 F. App'x 188 (3d Cir. 2014); Maxmed Healthcare, Inc. v. Burwell, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), aff'd, 860 F.3d 335 (5th Cir. 2017); Anghel v. Sebelius, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); Transyd Enters., LLC v. Sebelius, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. 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 medical necessity errors identified in this audit.

With respect to the Hospital's contention that it expects some of the claim errors that form the basis of the extrapolation to be overturned on appeal, we will provide an updated estimate of overpayments, if necessary, at the conclusion of the appeals process. As the Hospital has noted in its response, nothing in this audit limits its appeal rights.

OUR RECOMMENDATIONS

Hospital Comments

The Hospital disagrees with our first and second recommendations because it plans to appeal all denials with which it does not agree. The Hospital has noted that it routinely carries out auditing and compliance monitoring, especially with respect to its IRF, and these audits will continue in the normal course of business. For our third recommendation, the Hospital stated that its admission coding and billing practices, policies, and procedures fully comply with Medicare requirements. The Hospital will continue its regular review of its compliance practices, policies, and procedures and will update its education for staff as needed to address any identified systemic errors or changes in Medicare requirements.

Office of Inspector General Response

Regarding the Hospital's claim that it plans to appeal the majority of the reported errors and, therefore, does not agree with the first and second recommendation, we maintain that our findings are valid and that this audit report constitutes credible information about potential overpayments. We stand by our recommendation to identify and return overpayments in accordance with the 60-day rule.

See Appendix E for the Hospital's comments on our draft report. We did not include any of the Hospital's attachments²⁶ to its comments because they contained protected information. However, we are providing the Hospital's comments in their entirety to CMS.

²⁶ The Hospital's response included two Appendixes. The first Appendix was by the Medical Director for the IRF unit at the Hospital. The second Appendix was by the American Medical Rehabilitation Providers Association, American Academy of Physical Medicine and Rehabilitation, and the Federation of American Hospitals.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$40,691,082 in Medicare payments to the Hospital for 2,117 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 claims (85 inpatient and 15 outpatient) with payments totaling \$2,406,660. Medicare paid these 100 claims from January 1, 2017, through December 31, 2018 (audit period).

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

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

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

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Hospital's inpatient and outpatient paid claims data from CMS's NCH database for the audit period;
- used computer matching, data mining, and analysis techniques to identify claims potentially at risk for noncompliance with selected Medicare billing requirements;
- selected a stratified random sample of 85 inpatient claims and 15 outpatient claims totaling \$2,406,660 for detailed review (Appendix B);
- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been cancelled or adjusted;
- reviewed the itemized bills and medical record documentation provided by the Hospital to support the sampled claims;

- requested that the Hospital conduct its own review of the sampled claims to determine whether the services were billed correctly;
- reviewed the Hospital's procedures for assigning DRG and admission status codes for Medicare claims;
- used an independent medical review contractor to determine whether all claims complied with selected billing requirements;
- discussed the incorrectly billed claims with Hospital personnel to determine the underlying causes of noncompliance with Medicare requirements;
- calculated the correct payments for those claims requiring adjustments;
- used the results of the sample review to calculate the estimated Medicare overpayment to the Hospital (Appendix C); and
- discussed the results of our audit with Hospital officials.

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

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

Our sample frame contained 2,117 Medicare paid claims in 10 high-risk areas totaling \$40,691,082 from which we selected our sample (Table 1).

We performed data filtering and analysis of the claims within each of the 10 high-risk areas. The specific filtering and analysis steps performed varied depending on the Medicare issue but included such procedures as removing:

- claims with certain discharge status and diagnosis codes,
- paid claims less than or equal to \$0, and
- claims under review by the Recovery Audit Contractor as of May 13, 2019.

We assigned each claim that appeared in multiple risk areas to just one area on the basis of the following hierarchy: IRF Claims, Inpatient Claims Billed with CERT DRG Codes, Inpatient Claims Billed with High-Severity Level DRG Codes, Inpatient Mechanical Ventilation Claims, Inpatient Claims Paid in Excess of \$25,000, Inpatient Same Day Discharge and Readmit, Outpatient Claims with Bypass Modifiers, Outpatient Claims in Excess of \$25,000, Outpatient Claims Paid in Excess of Charges, and Outpatient SNF Consolidated Billing Claims.

Table 1: Risk Areas

	Frame	Value of
Medicare Risk Area	Size	Frame
1. IRF Claims	1,210	\$30,249,928
2. Inpatient Claims Billed with CERT DRG Codes	244	1,572,478
3. Inpatient Claims Billed with High Severity Level DRGs	401	4,751,995
4. Inpatient Mechanical Ventilation Claims	21	815,103
5. Inpatient Claims Paid in Excess of \$25,000	4	715,766
6. Inpatient Same Day Discharge and Readmit	3	26,748
7. Outpatient Claims with Bypass Modifiers	153	349,465
8. Outpatient Claims Paid in Excess of \$25,000	76	2,207,646
9. Outpatient Claims Paid in Excess of Charges	1	1,076
10. Outpatient SNF Consolidated Billing Claims	4	877
Total	2,117	\$40,691,082

SAMPLE UNIT

The sample unit was a Medicare paid claim.

SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified random sample. We stratified the sampling frame into five strata on the basis of claim type, relative risk of improper payment based on previous OIG audit work and claims paid amount. Stata 1 and 2 include risk areas 1 and 2 from Table 1 separated by paid amount;²⁷ strata 3 and 4 include risk areas 3 through 6 from Table 1 separated by paid amount,²⁸ and stratum 5 includes all outpatient claims from risk areas 7 through 10 from Table 1. All claims were unduplicated, appearing in only one area and only once in the entire sampling frame.

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

²⁷ Paid claims less than \$25,968 are in stratum 1 and paid claims \$25,968 or greater are in stratum 2.

²⁸ Paid claims less than \$23,126 are in stratum 3 and paid claims \$23,126 or greater are in stratum 4.

Table 2: Claims by Stratum

Stratum	Claims Type	Frame Size (Claims)	Value of Frame	Sample Size
Stratum	7.	(Claiiiis)		
1	Inpatient Risk Areas 1-2, Low Dollar Claims	916	\$14,788,881	26
2	Inpatient Risk Areas 1-2, High Dollar Claims	538	17,033,526	24
3	Inpatient Risk Areas 3-6, Low Dollar Claims	375	3,719,952	18
4	Inpatient Risk Areas 3-6, High Dollar Claims	54	2,589,659	17
5	All Outpatient Claim Risk Areas	234	2,559,064	15
	Total	2,117	\$40,691,082	100

SOURCE OF RANDOM NUMBERS

We generated the random numbers using the Office of Inspector General, Office of Audit Services (OIG/OAS) statistical software Random Number Generator.

METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the claims within strata 1 through 5. After generating the random numbers, we selected the corresponding claims in each stratum.

ESTIMATION METHODOLOGY

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

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 3: Sample Results

Stratum	Frame Size (Claims)	Value of Frame	Sample Size	Value of Sample	Number of Incorrectly Billed Claims in Sample	Value of Overpayments or Underpayments in Sample
1	916	\$14,788,881	26	\$398,010	22	\$356,830
2	538	17,033,526	24	772,872	20	611,266
3	375	3,719,952	18	173,890	5	36,959
4	54	2,589,659	17	918,835	3	(3,006)
5	234	2,559,064	15	143,053	4	(2,099)
Total	2,117	\$40,691,082	100	\$2,406,660	54	\$999,950

ESTIMATES

Table 4: Estimates of Overpayments in the Sampling Frame for the Audit Period

Limits Calculated for a 90-Percent Confidence Interval

Point estimate	\$27,001,618
Lower limit	23,615,809
Upper limit	30,387,427

APPENDIX D: RESULTS OF AUDIT BY RISK AREA

Table 5: Sample Results by Risk Area

Risk Area	Selected Claims	Value of Selected Claims	Claims With Overpayments	Value of Overpayments
IRF Claims	41	\$1,117,517	36	\$932,782
Inpatient Claims Billed with CERT DRG Codes	9	53,365	6	35,314
Inpatient Claims Billed with High-Severity Level DRG Codes	25	436,183	4	30,703
Inpatient Mechanical Ventilation Claims	7	299,572	1	(970)
Inpatient Claims Paid in Excess of \$25,000	2	350,714	2	(2,036)
Inpatient Same Day Discharge and Readmit	1	6,256	1	6,256
Inpatient Totals	85	\$2,263,607	50	\$1,002,049
Outpatient Claims With Bypass Modifiers	11	23,009	4	(2,099)
Outpatient Claims Paid in Excess of \$25,000	4	120,044	0	
Outpatient Totals	15	\$143,053	4	\$(2,099)
Inpatient and Outpatient Totals	100	\$2,406,660	54	\$999,950

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



December 14, 2020

VIA FEDEX AND ELECTRONIC MAIL: Lori.Pilcher@oig.hhs.gov

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

RE: Sunrise Hospital & Medical Center Response to OIG Draft Report Number: A-04-19-08075

Dear Ms. Pilcher:

Sunrise Hospital & Medical Center ("Sunrise") appreciates the opportunity to comment on the U.S. Department of Health and Human Services, Office of the Inspector General's ("OIG's") draft report entitled *Medicare Hospital Provider Compliance Audit: Sunrise Hospital & Medical Center* ("the Draft Report"). Sunrise is committed to complying with all statutes, regulations, and other standards governing participation in federal health care programs, including Medicare, and works continuously to update and improve its internal compliance controls and monitoring processes. Sunrise is proud of the fact that it has had a consistent and reliable track record on Medicare compliance for years. Sunrise stands by its coverage and payment decisions and believes that the audit upon which the Draft Report is based was fundamentally flawed. Therefore, the Draft Report should be withdrawn.

Sunrise strongly disagrees with most of the conclusions and recommendations contained in the Draft Report. OIG conducted a stratified sample of 100 inpatient and outpatient claims from calendar years ("CYs") 2017 and 2018 and alleges that Sunrise did not fully comply with Medicare billing requirements for 54 inpatient claims and four outpatient claims, resulting in net overpayments of \$999,950. OIG used that flawed determination to calculate an extrapolated overpayment of \$23.6 million. It also recommended that Sunrise use reasonable diligence to identify and return any similar overpayments outside the OIG audit period and strengthen its controls to ensure full compliance with Medicare requirements. Based upon its review of the claims at issue, Sunrise believes that OIG grossly overstated the net overpayments, which actually total only \$8,933.

I. Executive Summary

Sunrise Hospital is the most comprehensive acute care hospital in the State of Nevada, serving primary, secondary, tertiary, and quaternary care needs for patients in Nevada, Arizona, Utah, and California. Sunrise is also the largest Medicaid provider in the State of Nevada, providing care for one in four Medicaid patients in southern Nevada. In 2019, Sunrise was the largest provider of community benefit services (inclusive of charity care) of any hospital in the State of Nevada, providing nearly \$150 million in services. Sunrise has an excellent history of compliance and a strong internal system of policies, procedures, controls, and ongoing education and training to ensure its services are consistent with good medical practice and program integrity. As described in more detail below, the Draft Report, if finalized, has the potential to improperly harm Sunrise's reputation and ongoing mission of benefitting the community it serves.

Sunrise disputes the vast majority of the audit findings memorialized in the Draft Report, especially that 36 inpatient rehabilitation facility ("IRF") claims were not payable. Sunrise has a rigorous process for admitting IRF patients and stands behind the medical necessity of its admissions. The summaries of the 36 IRF claims make clear that OIG's contracted reviewer profoundly misunderstands rehabilitation medicine. The majority of the denials stem from a skewed interpretation of the coverage criteria in which the reviewer alleged that patients were either too sick to participate in intensive therapy or not sick enough to require supervision by a rehabilitation physician. This interpretation is an impossible standard that excludes virtually all patients from IRF care. The reviewer's impossible standard is also contrary to the Medicare IRF coverage regulations and is incompatible with contemporary, widely-accepted standards of medical practice.

We therefore believe that OIG should re-audit the 36 IRF claims using a different physician reviewer, one who is board-certified in physical medicine and rehabilitation and has training and recent experience in IRF care. We also believe the auditor should recognize that a review of paper records cannot replace an in-person examination by a treating rehabilitation physician, and the auditor should defer to the treating physician's admission decision, unless that decision is clearly contradicted by the paper record.

We raised many of these concerns with OIG during the audit and afterwards, to no avail. OIG repeatedly has refused to reexamine any of the claims, despite multiple opportunities to do so, and that refusal will obligate Sunrise to appeal all 36 IRF claims through the multi-year, backlogged Medicare appeals process. While we feel confident that Sunrise eventually will be vindicated, the hospital should not be subject to unreasonable, extrapolated repayment obligations while it wades through that appeals process, especially given the global pandemic and the severe impact it has had on Sunrise and healthcare providers nationwide.

Lori S. Pilcher December 14, 2020 Page 3 of 22

With respect to the other 11 inpatient claims identified as overpaid by OIG, Sunrise acknowledges that two claims were billed to Medicare in error but does not agree that the remaining nine claims were inappropriate inpatient admissions. Sunrise employs thorough controls on its admission and billing processes and stands behind the admissions at issue. The remaining claims identified as incorrectly paid constituted *underpayments* to Sunrise related to outlier claims.

Regarding the 15 outpatient claims reviewed for incorrect billing, OIG identified two claims where the modifier for billing a separate and distinct service was inappropriately applied and two claims where the billed HCPCS codes were not supported by the medical record. Sunrise has already refunded the two claims involving incorrect use of the modifier. The claims identified as incorrectly coded included one identified as underpaid; Sunrise disagrees with OIG's unfavorable determination on the remaining claim and will appeal any unfavorable determination made by the Medicare Administrative Contractor ("MAC").

Sunrise also objects to OIG's decision to use extrapolation to calculate an estimated overpayment in excess of \$23 million—especially since it is based upon claims OIG knows are disputed by Sunrise. This is an excessive figure that assumes that Sunrise will not prevail in appeals on even one of the 45 claims at issue. While Sunrise believes it will prevail on the vast majority of its appeals, the delay in the administrative appeals process may require Sunrise to pay an extrapolated overpayment and harm its ability to provide and expand critical healthcare services. Moreover, it would expose the government to interest payments on overturned claims. Thus, OIG should recommend recoupment of only the claims that it actually audited, and an extrapolated overpayment should not be calculated at this time.

Because OIG's audit is so seriously flawed, there is no basis for its recommendations. Sunrise disagrees that it should refund \$23.6 million, an extrapolated figure based solely on flawed claim determinations, and that it should conduct additional audits of IRF claims. Sunrise agrees with OIG's determinations for a very few non-IRF claims, but those claims represent isolated occurrences that are unlikely to be replicated. Finally, Sunrise disagrees that it should strengthen its internal controls. Sunrise's current process for admitting patients—to the IRF and the general acute care units—is rigorous and ensures that all patients meet Medicare coverage requirements.

II. Background of Audit and Sunrise's Work With OIG

On May 9, 2019, Sunrise received OIG's Medicare Compliance Audit Engagement letter and OIG's initial request for specific documentation. Over the following months, Sunrise worked with OIG and submitted all requested documentation. Sunrise also provided additional

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requested information, including making personnel available for onsite interviews. On June 6, 2020, and June 9, 2020, Sunrise received the initial results of OIG's audit, alleging errors in 54 of the 100 claims reviewed. Sunrise was then asked by OIG to complete an Internal Controls Questionnaire ("ICQ").

Sunrise submitted the completed ICQ to OIG on July 22, 2020. In its ICQ response, Sunrise strongly disputed the IRF and acute admission findings and explained in detail its internal controls, including its admission procedures and its compliance monitoring practices. Sunrise provided similar responses to the other audited areas as well.

OIG did not respond to Sunrise's detailed ICQ submission and instead proceeded directly to the exit conference, on August 17, 2020. Sunrise specifically requested that OIG make its contracted reviewers available at the exit conference for a clinical discussion with Sunrise's IRF Medical Director, Dr. Mark Steinhauer. Sunrise identified three patient files that illustrate why the disputed IRF claims should be payable, but OIG refused to include any reviewers in the exit conference or to discuss any specific clinical findings during that conference.

At the exit conference, OIG conceded that it lacks the expertise to determine the medical necessity of Medicare claims and relies upon contractors to do so. Nonetheless, Dr. Steinhauer discussed the three patients and explained why their admissions were reasonable and necessary. Sunrise again asked for an opportunity, prior to the issuance of OIG's draft audit report, to meet with OIG's contracted reviewer and discuss the audit findings. Sunrise suggested that such a meeting would allow a clinical dialogue that could help to reconcile the differing viewpoints on the IRF patients at issue. OIG refused, stating that such a meeting was not part of its process, and indicated that it would not re-engage its contracted reviewer prior to issuing the Draft Report and, in all likelihood, prior to issuing the Final Report.

We strongly believe that this intransigence is inappropriate and unacceptable generally, but particularly so during an ongoing pandemic and a multi-year backlog at the administrative law judge ("ALJ") level of appeal. The failure to correct erroneous denials now will cause payment for medically necessary claims to be denied to Sunrise *for years*. OIG should engage another contractor to review the denied admissions, one who is board-certified in physical medicine and rehabilitation and who has the training and recent experience in IRF care necessary to reevaluate the claims and consider the information provided by Sunrise with this response.

Because Sunrise will appeal all 36 of the denied IRF claims and expects to prevail on the vast majority of those, recommending an extrapolated recoupment of over \$20 million from Sunrise would be highly inequitable, especially during an ongoing pandemic that is taxing hospitals and healthcare providers in unprecedented ways. Such a recommendation would also

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challenge Sunrise's mission of continuing to provide and expand its critical healthcare services and its ability to care for the most vulnerable patients in the community.

In providing all levels of care to citizens from at least four states, Sunrise has focused on developing new services and service lines (such as a Ventricular Assistance Device program, burn unit, and full-service ECMO) that previously were not available to residents of Nevada and the surrounding areas. As the largest Medicaid provider and the largest provider of community benefit services (inclusive of charity care) in the state, in 2019, Sunrise provided over \$148 million of community benefit to the most vulnerable patients.

Finally, the OIG has failed to consider the adverse impact that its findings may have on taxpayers. The ALJ backlog exposes the government to enormous liability for interest payments that will be owed to Sunrise when it prevails, as it expects, on its appeals. If Sunrise prevails at the ALJ level, the government's liability at the typical interest rate on underpayments of approximately 10% annually would be enormous after a multi-year delay. It is short-sighted for OIG to ignore this probability and plow ahead now, without a more considered review of the claims in dispute.

III. OIG's Audit of IRF Services Is Flawed and Should Be Performed Again

OIG's contracted reviewer demonstrates a profound lack of understanding of rehabilitation medicine. Given that, OIG should re-audit the IRF claims, using a different reviewer who is a physician board-certified in physical medicine and rehabilitation and has recent experience in inpatient hospital rehabilitation. OIG should also afford a more appropriate level of deference to the admission decisions of treating physicians and the documentation that supports the medical necessity of those admissions. To do otherwise forces Sunrise into a multi-year appeals process and exposes the hospital and its IRF personnel to unfair and unwarranted public scrutiny.

A. Sunrise Complies with Medicare IRF Coverage Criteria

Sunrise complies with the IRF coverage criteria established by CMS. Sunrise completes a comprehensive preadmission and post-admission screening process to ensure that all admitted patients meet CMS coverage requirements for an IRF stay. Each patient admitted to the Sunrise IRF is reasonably expected to require and participate in an intensive therapy program under the supervision of a rehabilitation physician.

For Medicare to cover an IRF admission, a patient must need an interdisciplinary approach to care and be stable enough at admission to participate in intensive rehabilitation. There must be a "reasonable expectation" that the patient will need multidisciplinary therapy,

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intensive rehabilitation, and supervision by a rehabilitation physician.¹ The interdisciplinary approach to care is demonstrated by weekly meetings of the rehabilitation team, led by the rehabilitation physician.² The requirement for multidisciplinary therapy must include physical or occupational therapy.³ Intensive rehabilitation is defined as three hours per day, five days per week (or 15 hours per week).⁴ The therapy must be reasonably likely to result in measurable, practical improvement to the patient's functional capacity or adaptation to impairments.⁵ The rehabilitation physician must see the patient at least three times per week.⁶

Sunrise employs a comprehensive preadmission screening process to ensure that all IRF admissions meet Medicare coverage requirements. Sunrise complies with the federal regulation requiring that, at the time of admission, there is a reasonable expectation that the patient meets all of the following:

- (1) The patient requires the active and ongoing intervention of multiple therapies, including physical or occupational therapy;
- (2) The patient is sufficiently stable and able to participate actively in and demonstrate measurable functional improvement in an intensive rehabilitation therapy program; and
- (3) The patient requires supervision by a rehabilitation physician to assess the patient medically and functionally and to modify the course of treatment to maximize the patient's capacity to benefit from the rehabilitation process.⁷

Further, the OIG review confirms that Sunrise consistently completes all documentation required by 42 C.F.R. § 412.622. Absolutely none of the IRF denials resulted from documentation errors. Sunrise's documentation addresses each patient's ongoing need for physician supervision and the physician and staff's efforts to address medical complexities.

Within the 48 hours immediately preceding a patient's admission to the IRF, a qualified medical professional (a Clinical Rehabilitation Specialist or "CRS") at Sunrise conducts a preadmission screening assessment to evaluate the patient's ability to tolerate an

¹ 42 C.F.R. § 412.622(a)(3), (5).

² Id. § 412.622(a)(5).

³ Id. § 412.622(a)(3)(i).

⁴ Id. § 412.622(a)(3)(ii).

⁵ *Id*.

⁶ Id. § 412.622(a)(3)(iv).

⁷ 42 C.F.R. § 412.622(a)(3). We are aware that certain aspects of the regulations governing Medicare coverage of IRF admissions were revised as part of the Fiscal Year 2021 Inpatient Rehabilitation Facility Prospective Payment System final rule, issued on September 18, 2020. Because the OIG audit covered CYs 2017 and 2018, all regulatory citations herein refer to the regulations as they existed when the services were rendered.

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intensive rehabilitation program and to determine if the expected functional gains warrant IRF care. Following the assessment, a physician board certified in physical medicine and rehabilitation reviews and approves the assessment and the patient's admission to the IRF. In general, the CRS and admitting rehabilitation physician communicate closely throughout the preadmission assessment process and develop the preadmission screening document together.

This thorough preadmission process results in Sunrise admitting, on average, only 54% of patients referred for potential admission. These numbers are significant, with nearly half of all referrals made to Sunrise's IRF rejected under the preadmission screening process. These figures help demonstrate that Sunrise's safeguards ensure that only appropriate patients are admitted to the IRF.

Sunrise also complies with post-admission documentation requirements. Following admission, Sunrise practitioners regularly assess whether patients continue to require active and ongoing therapeutic intervention from multiple therapy disciplines, including physical or occupational therapy. Sunrise has staff members, known as "PPS Coordinators," who routinely review patient medical records to confirm that an individualized overall plan of care is completed within four days of admission; the rehabilitation physician is conducting face-to-face visits at least three times per week; the patients are receiving the required minutes of therapy per week; and interdisciplinary team conferences are held weekly.

Post-admission, Dr. Steinhauer works closely with the nursing and therapy staff to ensure that each patient's medical and functional needs are addressed. Dr. Steinhauer provides medical supervision and management, coordinates care, consults with specialists, and uses diagnostically appropriate tests to keep patients stable enough to participate in intense therapy services. This medical management enables patients to progress and regain functional abilities, as demonstrated by Functional Independence Measure ("FIM") score gains, and ultimately to be discharged home or to a home-like setting.

To achieve these results, Dr. Steinhauer is present at the IRF full-time and manages each patient through formal bedside rounds. He also oversees patients during therapy, interacting with them when appropriate. The therapy rounds allow Dr. Steinhauer to see the patients engaged in intensive rehabilitation and to review each patient's therapy notes to assess ongoing needs and progress. As a result of this outstanding care, none of the 36 patients required readmission for acute medical care, all of the 36 patients made adequate FIM score gains as expected, and all but one of the 36 patients were successfully discharged home or to a home-like setting. This is an enviable track record for any IRF and demonstrates the value Medicare beneficiaries received from the IRF services provided by Sunrise.

B. OIG's Denials Are in Error and Should be Reversed

Despite Sunrise's rigorous admission process, OIG's contracted reviewer nonetheless determined that 36 IRF claims were inappropriate for reimbursement. Sunrise stands by the IRF admissions, as does Dr. Steinhauer, who was the admitting and treating physician for all of the patients. Sunrise staff, including Dr. Steinhauer and other key clinical leadership, have reviewed the medical records and prepared case summaries of each unfavorable determination. *See* Appendix A.⁸ They fully support Sunrise's decision to oppose OIG's findings and appeal any unfavorable determinations.

In the course of Sunrise's clinical review of the 36 claims, we identified several repetitive themes in the OIG reviewer's assessments that demonstrate a lack of expertise in IRF admission criteria. The reviewer denied many of the claims based on one of three assertions:

- (1) The patient could not fully participate in and benefit from intensive therapy services;
- (2) The patient did not need the oversight of a rehabilitation physician; or
- (3) The patient could have been served adequately in a less intensive setting.

The contracted reviewer clearly misunderstood the interrelationship between therapy and physician supervision in the IRF setting, sometimes finding that patients were too sick to participate in therapy and at other times finding that patients were not sick enough to require physician supervision. The reviewer failed to understand that therapy and physician oversight go hand in hand. The physician ensures that medically fragile patients remain medically stable enough to participate in intensive rehabilitation therapy. In other cases, the physician manages comorbidities that have the potential to prevent patients from participating in therapy. The rehabilitation physician accomplishes these goals both through medical management and by leading the rehabilitation team.

The contracted reviewer appeared to require a high level of medical stability to justify an expectation that the patient could participate in an intensive therapy program and a high level of baseline function to support a determination that the patient could benefit from intensive therapy. Conversely, the reviewer also required a high level of medical complexity, or even instability, in order to justify the need for supervision by a rehabilitation physician. All patients that did not fit neatly into the reviewer's extremely narrow window between "too sick" and "not sick enough" for IRF care were deemed more appropriate for a lower level of care.

⁸ Appendix A contains summaries of the 36 patient records at issue. Since it likely contains protected health information ("PHI"), it should be omitted from the published version of the final report.

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However, neither medical complexity nor availability of care in a less intensive setting are appropriate standards to be applied in determining whether a patient qualifies for an IRF admission. Instead, IRF coverage regulations require that IRFs base admissions on the interrelationship between therapy and medical needs. Two examples highlight the errors of OIG's contracted reviewer.

Patient Sample 3: The patient in Sample 3 was an extremely elderly man admitted to an acute care unit at Sunrise with urosepsis. His blood cultures were negative for infection, and he was successfully treated with intravenous antibiotics. He had a history of recurrent urinary tract infections ("UTIs") due to obstructive uropathy. As a result of his sepsis, he was encephalopathic and had significant functional decline from his baseline of modified independence in mobility, self-care, and cognition. The patient's past medical history included benign prostatic hypertrophy with associated recurrent UTIs, osteoarthritis, obesity, hypertension, and signs of multiple prior small strokes. Prior to his hospitalization, the patient was independent to modified independent in all mobility and self-care, living with his spouse and son.⁹

When screened for admission to the IRF, the patient required moderate (50%) assistance from two people for gait and transfers, maximal (75%) assistance for stairs and lower body dressing, minimal (25%) assistance for gait, supervision for grooming and hygiene, and moderate assistance for functional transfers and bathing. Upon admission to the IRF, it was determined that one of the main drivers of the patient's disability was his cognitive status, which was assessed to be moderately impaired.

During his IRF admission, the patient's preexisting joint pain flared and needed medical management. He also required ongoing medical management of his urosepsis and therapy to address his cognitive deficits, as well as pain management and aggressive management of his blood pressure in order to ensure full and safe therapy participation. Ultimately, the patient achieved a 20-point improvement in his FIM scores and was able to be discharged back to his home four days sooner than originally estimated.

At the time of admission, this patient required multiple skilled therapy disciplines, including physical and occupational therapies and, as evaluated, speech-language pathology. He was sufficiently stable at the time of admission to actively participate in the intensive therapy program, and he could participate in and did benefit from the intensive rehabilitation program. It also was clear that the patient had sufficient medical complications to warrant active

⁹ IRFs assess each patient upon admission, discharge and throughout the course of their stay by measuring their functional ability (e.g., "independent;" "requires maximal assistance") to perform a variety of tasks and skills.

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rehabilitation physician oversight, especially during the required medical workup of his encephalopathy and medication simplification.

OIG's contracted reviewer asserted that the documentation did not support the medical necessity of an intensive program of rehabilitation and that there were no acute medical problems or comorbidities that required a rehabilitation physiatrist's oversight three times a week. The reviewer noted the patient's cognitive status as a detractor from the patient's satisfaction of the coverage criteria and stated that the patient's comorbidities were uncomplicated and would not have been expected to complicate a rehabilitative course.

Contrary to the reviewer's findings, this patient had comprehensive disability in many domains, necessitating intensive rehabilitation to address his functional deficits. In addition, this patient's cognitive problems were mild and posed no barrier to his intensive rehabilitation. The reviewer's comments about cognitive deficits suggests an improper "rule of thumb" that IRF care generally should be denied to cognitively impaired Medicare beneficiaries. Furthermore, the cognitive deficits had not been noted in acute care, and the rehabilitation physician was instrumental in developing a treatment plan to remediate those deficits, with the goal of improving the patient's baseline.

Patient Sample 33: OIG's findings in Sample 33 were equally erroneous. The patient was a man in his mid-50s who experienced a seizure, causing him to fall and suffer cranial trauma. After several days of worsened speech and right-sided weakness, the patient sought acute care at Sunrise. He was diagnosed with a traumatic brain injury with a left subdural hematoma, and he underwent a craniotomy for evacuation of the hematoma. He also was diagnosed with liver disease and had some risk of complications related to his liver damage. His speech and lateralizing weakness persisted after surgery, so he was referred for inpatient rehabilitation.

The patient's past medical history included idiopathic seizure disorder with inability to achieve full control, despite much neurological care, resulting in frequent falls; gastroesophageal reflux disease; diabetes mellitus type 2; left tibial fracture with surgical repair; hypertension; and diverticulitis status post-colostomy. Prior to his hospitalization, he was independent in mobility and self-care (including colostomy management). He lived in a home with a family member, and the home had five steps to enter.

At the time of the preadmission screening, the patient was substantially more disabled than his baseline. He required moderate (50%) assistance for gait to ambulate 90 feet and moderate (50%) to maximal (75%) assistance for self-care. He also received a FIM score of 1/7 in the cognitive domain. Holistically, this patient had activity limitations across the board at the

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time of his preadmission assessment and was therefore deemed appropriate for intensive rehabilitation.

The OIG reviewer asserted that the patient's functional deficits did not support the medical necessity of an intensive program of rehabilitation and that he did not have complex medical nursing and rehabilitation needs requiring admission to an IRF. In support of this conclusion, the reviewer noted the patient's ability to ambulate 90 feet at admission and the patient's verbal aphasia and cognitive deficits. The reviewer claimed that it was not clear, at the time of admission, that the patient would reasonably be expected to actively participate in, and benefit significantly from, the intensive rehabilitation therapy program in an IRF facility.

While there is no standard for IRF admission that requires a patient's nursing and rehabilitation needs to be "complex," this individual had complex needs based on the interplay between his cognitive-linguistic and physical disabilities that required specialized understanding on the part of the treating therapists. That the patient had expressive aphasia says nothing about his ability to understand language or respond effectively to non-verbal communication; in fact, the aphasia may have made evaluating the patient's cognitive deficits through formalized testing more difficult, further pointing towards the need for specialized rehabilitation services.

Ultimately, the therapy notes do not indicate that the patient had any difficulty with understanding instructions and training, as modified for his expressive language impairment. In other words, the patient's cognitive and linguistic deficits posed no obstacle to rehabilitation. Again, the reviewer's assessment indicates a preconceived prejudice against treating cognitively impaired Medicare beneficiaries in the IRF setting. This patient's progress proves the reviewer wrong.

As to the patient's medical needs, the rehabilitation physician successfully implemented an important plan for medication simplification to decrease the patient's fall risk, managed the patient's difficulty with voiding due to the interplay of benign prostatic hypertrophy and relative immobility to avoid intermittent catheterization, and addressed the patient's blood pressure fluctuations. Ordinarily, this patient had hypertension, but during his stay at the IRF he experienced low blood pressure and required monitoring and adjustment to his medications as a result. This management in turn helped stabilize the patient's cognitive function. Furthermore, during his stay, the patient experienced an episode of chest pain, which required the IRF's rapid response team to assess the patient for a possible myocardial infarction.

In light of these significant medical management needs and the patient's functional and cognitive deficits, this patient met all criteria for admission to, and continued stay at, the IRF. He required physical and occupational therapies and speech-language pathology, and could participate in and benefit from intensive rehabilitation. He was sufficiently stable at the time of

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admission to actively participate but still required rehabilitation physician supervision for care simplification and medical treatment of his active comorbidities and complications of immobility. As a result of Sunrise's care, the patient achieved modified independence in mobility and self-care, including ambulating 500 feet and 16 steps to return to his home.

As these two examples illustrate, the OIG reviewer misapplied the Medicare coverage criteria to require medical complexity and instability beyond what is required under the regulations. The reviewer also applied incorrect standards, especially by improperly assuming that patients with cognitive deficits are unable to participate in and benefit from an intensive rehabilitation program.

<u>Conclusions from Review of Patient Samples 3 and 33</u>: Sunrise's review of the records leaves us with very serious concerns about the contracted reviewer's qualifications, understanding of rehabilitation diagnoses, and basic knowledge of the therapy services provided in an IRF. Throughout the audit, the reviewer repeatedly made statements indicating that the patient must somehow be unstable or have new medical conditions to justify admission to an IRF. This is flatly wrong—to the contrary, Medicare regulations require that the patient be stable upon admission.

The contracted reviewer also made statements that reflect a lack of understanding of the levels of function that must be attained in order to permit safe discharge to a patient's prior living situation (in these cases, usually a private home), assessing relatively low distances for ambulation as adequate, often without regard for the level of assistance required by the patient for the distance reached.

These observations call into question the qualifications of the contracted reviewers used by the OIG during its audit. While the OIG identified the reviewer as a qualified physician, the irregularities in terminology and medical interpretation create serious doubts about the reviewers' actual qualifications and experience.

C. OIG Should Rereview the Denied Claims Using a Qualified Rehabilitation Physician With Appropriate Deference to the Treating Physician

As demonstrated by the attached clinical summaries of each of the 36 IRF claims and the previously provided medical records, Sunrise appropriately admitted and treated the patients audited by OIG. Sunrise urges OIG to engage a new medical reviewer to reassess the 36 claims, one who is board-certified in physical medicine and rehabilitation and has recent experience in inpatient hospital rehabilitation. CMS's regulation is clear that only "a licensed physician with specialized training and experience in inpatient rehabilitation" is qualified to assess whether a

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patient requires IRF care.¹⁰ Also, the reviewer should give appropriate deference to the rehabilitation physician who actually examined and treated the patients at issue. As CMS has acknowledged, the IRF coverage regulation places "more weight on the rehabilitation physician's decision to admit the patient to the IRF."¹¹

It is critical that OIG use a physician with training and experience in inpatient hospital rehabilitation to re-review Sunrise's IRF claims. Under the IRF regulation, IRF physician documentation requirements are extensive and designed to ensure that the treating physician addresses all coverage requirements. This heightens the rehabilitation physician's role under the IRF regulations, and CMS itself has acknowledged that the treating physician is solely qualified to assess coverage. This important distinction warrants at least some deference to the treating physician.

Aside from these serious concerns about the qualifications and experience of OIG's medical reviewers, Sunrise has one additional concern. While OIG has declined to identify the medical reviewer it utilized during its audit of Sunrise, based on our understanding of how OIG contracts for these services, in all likelihood the reviewer is one of the contractors used by CMS within its administrative appeals process (e.g., a MAC or Qualified Independent Contractor ("QIC")).

Given such a contractor's likely role in adjudicating Sunrise's appeals of the claim determinations, Sunrise believes it is improper for OIG to rely on such a contractor, given the possibility of future bias or even incentives against overturning any of the claims determined by OIG to be improperly paid. At minimum, Sunrise should be allowed to know the identity of the contracted reviewer in order to ensure that its due process rights are protected during the appeals process. Therefore, OIG should disclose the full identity of the contracted reviewer and engage an independent qualified medical reviewer to re-review the audited claims.

D. OIG's Audit Exhibits Many of the Flaws of Prior IRF Audits

The serious flaws in OIG's audit of Sunrise are typical of other OIG IRF audits. We believe this demonstrates that OIG should revise its processes and improve its knowledge of IRF care. OIG's contracted reviewer repeated many of the errors apparent in other IRF audits, possibly due to OIG using one of the private companies that also serves as a QIC in the Medicare appeals process. The IRF field has for years urged the Medicare program to improve the quality

¹⁰ 42 C.F.R. §§ 412.622(a)(3)(iv), (a)(4)(i)(D).

¹¹ Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2010, 74 Fed. Reg. 39,762, 39,791 (Aug. 7, 2009) (final rule) [hereinafter "IRF Final Rule Fiscal Year 2010"]. ¹² Id.

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of its IRF reviewers, including QICs, who do not seem to understand this specialized setting of care.

For example, OIG issued a report that was been widely criticized by the IRF community and stands in stark contrast to audits conducted in the same year by the Comprehensive Error Rate Testing ("CERT") contractor, which found a far lower IRF error rate. OIG's report is also contradicted by a global settlement CMS reached with IRF providers in 2018 that refunded between 69% and 100% of IRF claims pending in the administrative appeals system.¹³

Unfortunately, Medicare contractors audit IRFs without a proper understanding of the intricacies and complexities of IRF care. An IRF is a hospital, but it differs from a general acute care hospital because IRF patients generally are medically stable. The core purpose of the IRF is intensive rehabilitation coupled with medical management to ensure that the patient remains stable enough to participate in an intensive rehabilitation therapy program to achieve functional outcomes. Contractors routinely misapply the coverage criteria for determining whether IRF services should be reimbursed. AMRPA, AAPM&R, and FAH perfectly described the incorrect and impossible-to-satisfy standards that contractors impose:

The 2010 IRF regulations were designed to create objective standards for IRF coverage, but Medicare contractors frequently return to pre-2010 subjective standards that discount or ignore the judgment of the treating rehabilitation physician. Several Medicare audit contractors have misconstrued the coverage regulations to impose a "Goldilocks" coverage standard—the patient must be sick enough to require *acute* hospital care but not too sick for intensive rehabilitation. The patient's medical condition must meet an ill-defined "just right" standard.

Appendix B, p. 6. Contractors also strictly apply manual guidance as grounds for denying claims—which is directly contrary to the Supreme Court's decision in *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019). The holding in this case established that guidance documents—such as the Medicare Benefits Policy Manual—cannot be enforced to deny payment when such guidance is not subject to public notice and comment. The reviewer who audited Sunrise's IRF claims made these same errors, both applying the improper Goldilocks standard and treating manual guidance as binding.

The contractors also audit without using qualified personnel. At the center of IRF care is the rehabilitation physician, with essential experience and training in rehabilitation medicine,

¹³ See Appendix B, American Medical Rehabilitation Providers Association ("AMRPA"), American Academy of Physical Medicine & Rehabilitation ("AAPM&R), and Federation of American Hospitals ("FAH") Response to OIG Report on Inpatient Rehabilitation Hospitals and Units (IRFs): A-01-15-00500.

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whose role is to help patients overcome physical deficits and return to functioning in daily life and living as independently as possible, while recovering from or managing other medical conditions. Reviewers without appropriate qualifications and with access only to the written record should not overturn the medical judgment of the highly-qualified rehabilitation physician who directly treated the patient.

IV. OIG's Assessment of Acute Inpatient Admissions

OIG also determined that 11 of the remaining 44 sampled inpatient claims were improperly billed as inpatient claims. For one claim, Sunrise determined, upon self-audit, that there was not a reasonable expectation of the patient's stay lasting at least two midnights. Therefore, Sunrise has repaid this claim. Sunrise also determined that one of the 11 claims identified as overpaid by OIG was, in fact, incorrectly billed to Medicare. This claim should have been billed to a hospice organization instead and has, therefore, also been repaid. For two additional claims identified as overpaid, Sunrise contends that the inpatient admissions were medically reasonable and necessary. Sunrise's internal review revealed that the DRG coding for the two cases required corrections, and Sunrise has repaid the difference between the billed DRG and the correct DRG. Sunrise intends to appeal OIG's determinations that these patients should not have been admitted at all. In total, Sunrise has repaid \$15,188 related to the incorrectly billed DRG codes.

Sunrise disputes OIG's findings on the remaining claims (nine in total) and intends to appeal if the MAC seeks to recoup the payments. In making its determinations, OIG's medical reviewer routinely overlooked or minimized critical elements of the patients' medical conditions and necessary care. In response to OIG's initiation of this audit, each of the sampled records was carefully reviewed by Sunrise and a nationally-recognized, independent healthcare consultant specializing in forensic evaluations of hospital inpatient and outpatient medical records. The resulting reviews overwhelmingly supported the initial determinations made by Sunrise that the patients were appropriately admitted as inpatients.

For example, Sample 18 involves a 73-year-old woman with a history of hypertension, diabetes mellitus, congestive heart failure, end-stage renal disease requiring hemodialysis, atrial fibrillation, hyperlipidemia, pacemaker placement, and anemia who presented for evaluation of lightheadedness and near syncope during dialysis. She was admitted for further evaluation and management of her syncope with associated hypotension.

After admission, the patient had an extensive evaluation that included consultative care by Cardiology and Nephrology, pacemaker interrogation, continuous telemetry, multiple diagnostic tests (including an EKG, echocardiogram, brain CT, and carotid ultrasound), and frequent neurologic checks. To facilitate this care and ensure the patient's health, an inpatient

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order was entered in the evening of the first night, indicating continued medical management of syncope as the reason for the admission. The order specified that there was an expectation of at least two midnights of care, based on the patient's history and physical. Further, the expectation of a 2-midnight stay was realized as this patient received extensive services in the inpatient unit for her elevated risks for rapid clinical deterioration and was not discharged until the day after her second midnight of admission.

The OIG reviewer determined that, because the patient was allegedly restored to her baseline in the emergency department and test results were normal, expecting care in the hospital setting to last for more than two midnights was not reasonable. This determination was made despite the patient's risk for a rapid and uncontrolled change in her medical condition and the clearly documented plan of care that involved extensive medical oversight and continued diagnostic testing. This type of determination by the reviewer, where the clearly developed plan of care and the ongoing diagnostic and therapeutic needs of the patient are disregarded, is inappropriate. Thus, Sunrise maintains that the majority of OIG's findings in this area are incorrect.

The billing errors for the claims that OIG correctly disallowed were caused by disparate factors that did not otherwise manifest in the rest of the sample; similarly, Sunrise believes that the DRG coding errors represent isolated errors. Sunrise's internal controls reflect the scope and focus of CMS's requirements to ensure the appropriateness of inpatient admissions. Sunrise's processes comport with the Medicare 2-Midnight Rule and CMS guidance related to that rule. The Medicare Program Integrity Manual ("MPIM") explains how Medicare contractors should conduct medical record reviews for purposes of determining the appropriateness of Part A payment. The 2-midnight presumption is used to determine which claims are appropriate for review, and the 2-midnight benchmark is used to guide the review process.

Per the 2-midnight presumption, Medicare contractors shall presume hospital stays spanning two or more midnights after the beneficiary is formally admitted as an inpatient are reasonable and necessary for Part A payment. Based on this presumption, Medicare contractors are directed not to 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.

Per the 2-midnight benchmark, hospital stays are generally payable under Part A if the admitting practitioner expects the beneficiary to require medically necessary

¹⁴ See MPIM, CMS Pub. 100-08, ch. 6, § 6.5,2.

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hospital care spanning two or more midnights, and such reasonable expectation is supported by the medical record documentation.¹⁵

As part of its controls in this area, Sunrise takes steps, prior to discharge, to review Medicare inpatient stays to confirm the presence of a signed physician's order for the inpatient stay. Sunrise uses an internally developed "Medicare Order Form" ("MOF") to assist physicians in determining and documenting the patient's expected length of stay. This MOF, as well as physician-directed education, clearly instructs the attending practitioner to order outpatient status if the practitioner is unsure whether the patient's condition will require hospital services across two midnights. Thus, Sunrise takes a conservative approach to progress the patient to inpatient status, if warranted.

Sunrise believes that these internal controls have successfully prevented all but isolated and occasional billing errors. Specifically, Sunrise believes these controls worked appropriately with respect to the overwhelming majority of the claims sampled and reviewed by OIG, and Sunrise intends to appeal all but two of OIG's unfavorable findings.

V. OIG's Assessment of Outlier Payments Associated with Inpatient Hospital Claims

OIG determined that three of the 44 reviewed acute inpatient claims contained errors that impacted the amount of outlier payments to Sunrise. Sunrise also identified these errors during its self-audit. Notably, the billing errors involved the undercounting (and consequently, underbilling) of various units of service or medical items provided to the patients. All of the three claims identified by OIG as incorrectly billed were in connection with very extensive inpatient stays ranging from six weeks to over four months, with very high accumulated charges. Given the duration of the stays and the sheer volume of line items charged, the data shows that charges billed in error represent an extremely small percentage of the billed charges, resulting from isolated human errors and lack of documentation.

Sunrise has a number of controls in place and strives to assure appropriate charge capture on inpatient claims. Sunrise and its vendor, Parallon Business Performance Group ("Parallon"), are committed to conducting regular charge validation efforts, including, but not limited to, reviewing charts, scheduling of tests or procedures, surgery records, and other sources where charges may be posted. In addition, Sunrise and Parallon's systems contain automated safeguards designed to catch potentially duplicative charges. Further, Sunrise and Parallon routinely monitor claims on both a pre-bill and post-bill basis to verify that charges are accurate and supported by documentation. Given that all of the outlier payment billing errors identified

¹⁵ MPIM, ch. 6, § 6.5.2.

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by OIG resulted in individual and net *underpayments* to Sunrise, the hospital believes its internal controls are effective.

VI. OIG's Assessment of Outpatient Risk Areas

As a much smaller portion of OIG's review, 15 outpatient claims were also reviewed for modifiers and coding. Of those 15 claims, OIG identified two where the modifier for billing a separate and distinct service was inappropriately applied and two where the billed HCPCS codes were not supported by the medical record. Sunrise also identified the two claims involving incorrect use of the modifier in its self-audit and refunded a total of \$230. With respect to OIG's findings on HCPCS coding, Sunrise identified one of the two claims during its self-audit and disclosed the claim (which represented an underpayment). For the other claim identified by OIG as incorrectly coded, Sunrise disagrees with OIG's conclusion and will appeal any unfavorable determination made by the MAC.

Sunrise notes that, with respect to the claims reviewed for proper HCPCS coding, the Draft Report states, "As a result of the errors on these two claims, the Hospital received net underpayments of \$2,329. For one claim, the Hospital refunded an overpayment of \$174 after the start of our audit." However, Sunrise did not refund \$174 (attributable to Sample 96); instead Sunrise refunded \$109 (attributable to Sample 97). To the extent that OIG maintains its assertion that Sample 96 was improperly paid, Sunrise disagrees with that determination and will appeal. Also, as a result of the error in the amount noted to be refunded by Sunrise, the Draft Report is incorrect and should state the amount of the net underpayment to Sunrise as \$2,394.

Sunrise has robust correct coding and quality assurance processes in place to prevent both types of outpatient billing errors. Despite these processes, however, occasional human error can occur, as it did with the two incorrect modifiers and one incorrect HCPCS code identified by OIG. If any errors appear to be recurrent, they will be identified through the quality assurance process, with the management team alerted and job aids/education updated to address the cause of the error.

VII. OIG's Use of Extrapolation to Estimate an Overpayment Amount of \$23.6 Million Is Inappropriate

Sunrise strongly objects to OIG's use of extrapolation at this point in the process, if ever. OIG currently estimates an overpayment to Sunrise of \$23,615,809. This amount is grossly excessive and the threat of it places an unreasonable burden on Sunrise, one of the many healthcare providers experiencing the unprecedented challenges created by the global pandemic. Hospitals nationwide, including Sunrise, are encountering new difficulties on a daily basis in

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trying to serve the needs of patients. The OIG's announcement of more than \$23 million in (disputed) recoupments could hinder Sunrise's efforts to meet the needs of its patients.

A. OIG's Use of Extrapolation Is Premature

Sunrise believes that an independent re-review of the 36 IRF claims, if completed by a qualified physician with rehabilitation training and experience, will result in significantly fewer denials, if any. In addition, Sunrise maintains that the claims were properly submitted and intends to appeal. We are aware that IRFs experience a high rate of reversal on appeal, and given the strength of the claims at issue, it is highly probable that the final error rate will be quite low.

The likelihood that appeals will lower the error rate has significant implications for OIG's extrapolation. For each claim that is ultimately determined to be proper following appeal, the extrapolated amount will decrease accordingly. Further, Sunrise anticipates that at least some of the estimated overpayment amount may be recouped while appeals are pending at the ALJ level. Given the high value of OIG's current estimate, and the lengthy backlog of ALJ appeals, the application of extrapolation will have a disproportionate and extremely detrimental impact on Sunrise.

B. OIG's Use of Extrapolation for IRF Claims Is Inappropriate

The requirements for coverage of IRF services and related documentation supporting admission under Medicare are very specific—much more specific than almost any other covered item or service. By regulation, careful individualized determinations must be made by a specialized physician in order for IRF care to be reimbursable. The individualized nature of IRF admissions makes these claims particularly inappropriate for extrapolation. Similarly, the decision whether to admit a patient into an acute care unit is subjective and based on the individual facts of the case.

As recognized by a federal court, "[t]he essence of the science of inferential statistics is that one may confidently draw inferences about the whole from a representative sample of the whole." 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 action." OIG did not identify routine and related documentation errors that might serve as some indicator of errors in other claims within the universe.

¹⁶ In re Chevron U.S.A., Inc. 109 F.3d 1016, 1019-20 (5th Cir. 1997); see also United States v. Pena, 532 F. App'x 517, 520 (5th Cir. 2013).

¹⁷ Tyson Foods, Inc. v. Bouaphakeo, 136 S. Ct. 1036, 1046 (2016).

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Instead, OIG made medical necessity determinations, and the nature of these claims requires an individualized determination that cannot be replaced by an examination of a sample that is then projected to the whole. When medical necessity is involved, courts have rejected the use of extrapolation. Because "each and every claim at issue" was "fact-dependent and wholly unrelated to each and every other claim," and determining eligibility for "each of the patients involved a highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient," the court found the case was not "suited for statistical sampling." Thus, extrapolating the alleged errors in the sampled IRF and acute care claims to the entirety of similar Sunrise claims is unsupportable.

Based on the fact-specific and individualized nature of the admission errors alleged by OIG, only a claim-by-claim examination and determination process is appropriate for IRF and acute-care claims. Therefore, OIG should recommend to the MAC that no extrapolated overpayment be assessed until Sunrise has exhausted it appeal rights, and the true amount of the overpayments is known.

VIII. Sunrise's Response to OIG's Recommendations

OIG's Draft Report makes three recommendations. First, OIG recommends that Sunrise refund \$23,615,809 (less \$9,088 already repaid). Second, OIG recommends that Sunrise exercise reasonable diligence in identifying and refunding any additional overpayments similar to those identified by OIG's audit, in accordance with the "60-day rule." Third, OIG recommends that Sunrise strengthen its controls to ensure full compliance with Medicare requirements. Because Sunrise disagrees with OIG's findings, Sunrise also disagrees with these recommendations.

Sunrise already has repaid two claims for acute inpatient admissions, two claims with DRG adjustments, one claim with an incorrect HCPCS code, and two claims with incorrect modifiers. Sunrise also disclosed three claims for incorrect outlier payments, one claim with a DRG adjustment, and one claim with an incorrect HCPCS code—these five claims resulted in underpayments, so no refund was made; however, four of the claims have been reprocessed. Sunrise intends to exercise its right to appeal the remaining claims and has not refunded those claims.

¹⁸ United States ex rel. Wall v. Vista Hospice Care, Inc., No. 3:07-CV-00604-M, 2016 WL 3449833, at *11-13 (N.D. Tex. June 20, 2016); United States ex rel. Michaels v. Agape Senior Cmty., Inc., No. CA 0:12-3466-JFA, 2015 WL 3903675, at *2 (D.S.C. June 25, 2015).

¹⁹ Agape Senior Cmty, Inc., at *2, *8; see also U.S. v. Medco Phys. Unlimited, No. 98-C-1622, 2000 U.S. Dist. LEXIS 5843, at *23 (N.D. Ill. Mar. 15, 2000).

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Regarding the 60-day rule, Sunrise has conducted a thorough review of its policies and procedures, as well as a self-audit of the claims reviewed by OIG. Of the overpayments identified by OIG with which Sunrise agrees, the sources for the errors that led to improper billing were determined to be isolated errors unlikely to be replicated in any systemic way. As to Sunrise's IRF claims, OIG's determinations are in error, and Sunrise intends to appeal 100% of any denials. Sunrise also believes that the vast majority of the acute inpatient admissions identified as overpaid by OIG were correctly billed and intends to appeal those claims as well. Therefore, Sunrise does not agree that it must investigate further under the 60-day rule. However, as noted in its ICQ responses to OIG, Sunrise routinely carries out auditing and compliance monitoring, especially with respect to its IRF. These audits will continue in the normal course of business for Sunrise.

Sunrise's admission, coding, and billing practices, policies, and procedures fully comply with Medicare requirements. It has an especially strong process for assessing patients for admission to the IRF and, as confirmed by OIG's medical reviewer, complies with all documentation requirements for IRF services. Sunrise will continue its regular review of its compliance practices, policies, and procedures and will update its education for staff as needed to address any identified systemic errors or changes in Medicare requirements.

IX. Conclusion

Sunrise strongly disagrees with the vast majority of OIG's conclusions and recommendations. OIG's audit of Sunrise is fundamentally flawed due to its reliance on questionable medical reviews, its misapplication of coverage criteria, its refusal to further review the denied claims, and its inappropriate use of extrapolation. If finalized, OIG's report will harm Sunrise's reputation, jeopardizing its patient care mission and its ability to continue serving the health care needs of the community.

Sunrise regrets that OIG did not take advantage of the many opportunities for us to work together to reach an understanding on the issues identified in this response. Sunrise sincerely hopes that this final set of comments and feedback, as well as its thorough rebuttal of the individual determinations, will lead OIG either to correct its serious errors in the final report of this audit or withdraw the Draft Report entirely. Again, we appreciate the opportunity to respond in depth to OIG's draft report.

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Sincerely,

Γodd Sklamberg, CEO

Sunrise Hospital & Medical Center