

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOSPITAL PROVIDER
COMPLIANCE AUDIT:
ST. FRANCIS HOSPITAL**

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Office of Inspector General

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Report in Brief

Date: October 2020
Report No. A-05-18-00048

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



Why OIG Did This Audit

This audit is part of a series of hospital compliance audits. Using computer matching, data mining, and other data analysis techniques, we identified hospital claims that were at risk for noncompliance with Medicare billing requirements. For calendar year 2017, Medicare paid hospitals \$206 billion, which represents 55 percent of all fee-for-service payments; accordingly, it is important to ensure that hospital payments comply with requirements.

Our objective was to determine whether St. Francis Hospital (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 \$44 million in Medicare payments to the Hospital for 3,192 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 claims with payments totaling \$1.6 million for our audit period (January 1, 2016, through December 31, 2017).

We focused our audit on the risk areas identified because of prior OIG audits at other hospitals. We evaluated compliance with selected billing requirements.

Medicare Hospital Provider Compliance Audit: St. Francis Hospital

What OIG Found

The Hospital complied with Medicare billing requirements for 86 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 14 claims, resulting in overpayments of \$204,265 for the audit period. Specifically, 11 inpatient claims had billing errors, resulting in overpayments of \$203,524, and 3 outpatient claims had billing errors, resulting in overpayments of \$741. These errors occurred primarily because the Hospital did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$1.6 million for the audit period.

What OIG Recommends and Hospital Comments

We recommend that the Hospital refund to the Medicare contractor \$1.6 million in estimated overpayments for the audit period for claims that it incorrectly billed that are within the reopening period; exercise reasonable diligence to identify, report, and return any 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 strengthen its controls to ensure full compliance with Medicare requirements.

In written comments on our draft report, the Hospital disagreed with most of our findings and recommendations. The Hospital agreed with 6 of the 14 payment errors identified in the sample. However, the Hospital disagreed with: OIG's determination of eight IRF payment errors in the sample; OIG's extrapolation methodology; and the application of the 60-day rule.

After review and consideration of the Hospital's comments, we maintain that our findings and the associated recommendations are valid. The use of statistical sampling to determine overpayment amounts in Medicare is well established and has repeatedly been upheld on appeal in Federal courts. An independent medical review contractor, employing licensed health professionals with appropriate medical expertise, including physicians with training and expertise in rehabilitation, determined whether the medical records supported Medicare payments. We also maintain that the 60-day repayment rule is applicable.

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INTRODUCTION

WHY WE DID THIS AUDIT

This audit is part of a series of hospital compliance audits. Using computer matching, data mining, and other data analysis techniques, we identified hospital claims that were at risk for noncompliance with Medicare billing requirements. For calendar year 2017, Medicare paid hospitals \$206 billion, which represents 55 percent of all fee-for-service payments; accordingly, it is important to ensure that hospital payments comply with requirements.

OBJECTIVE

Our objective was to determine whether St. Francis Hospital (the Hospital) complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims from January 1, 2016, through December 31, 2017.

BACKGROUND

The Medicare Program

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

Hospital Inpatient Prospective Payment System

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

Hospital Inpatient Rehabilitation Facility Prospective Payment System

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

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

Hospital Outpatient Prospective Payment System

CMS implemented an outpatient prospective payment system (OPPS), which is effective for services furnished on or after August 1, 2000, for hospital outpatient services. Under the OPPS, Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification (APC). CMS uses Healthcare Common Procedure Coding System (HCPCS) codes and descriptors to identify and group the services within each APC group.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 adverse events,
- IRF claims,
- inpatient claims paid in excess of \$150,000,
- inpatient claims paid greater than charges,
- inpatient high-severity-level DRG codes,
- inpatient comprehensive error rate testing (CERT) DRG codes,
- inpatient elective procedures,
- inpatient mechanical ventilation,
- outpatient surgeries billed with units greater than one, and

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

- outpatient right heart catheterizations with hemodynamic data.

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

The Office of Inspector General (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.³

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

³ The Act § 1128J(d); 42 CFR §§ 401.301-401.305; and 81 Fed. Reg. 7653, 7654 (Feb. 12, 2016).

under the 60-day rule, providers may request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.⁴

St. Francis Hospital

The Hospital is part of The Sisters of the Third Order of St. Francis and is a 648-bed, acute-care, nonprofit hospital located in Peoria, Illinois. According to CMS's National Claims History (NCH) data, Medicare paid the Hospital approximately \$242 million for 13,776 inpatient and 43,424 outpatient claims between January 1, 2016, and December 31, 2017 (audit period).

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$44,144,449 in Medicare payments to the Hospital for 3,192 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 claims (95 inpatient and 5 outpatient) with payments totaling \$1,590,619. Medicare paid these 100 claims during our audit period (January 1, 2016, through December 31, 2017).

We focused our audit on the risk areas identified because of prior OIG audits at other hospitals. We evaluated compliance with selected billing requirements and submitted all claims to an independent medical review contractor to determine whether the claims were supported by the medical record. This report focuses on selected risk areas and does not represent an overall assessment of all claims submitted by the Hospital for Medicare reimbursement.

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

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

FINDINGS

The Hospital complied with Medicare billing requirements for 86 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 14 claims, resulting in overpayments of \$204,265 for the audit period. Specifically, 11 inpatient claims had billing errors, resulting in overpayments of \$203,524, and 3 outpatient claims had billing errors, resulting in overpayments of \$741. 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.

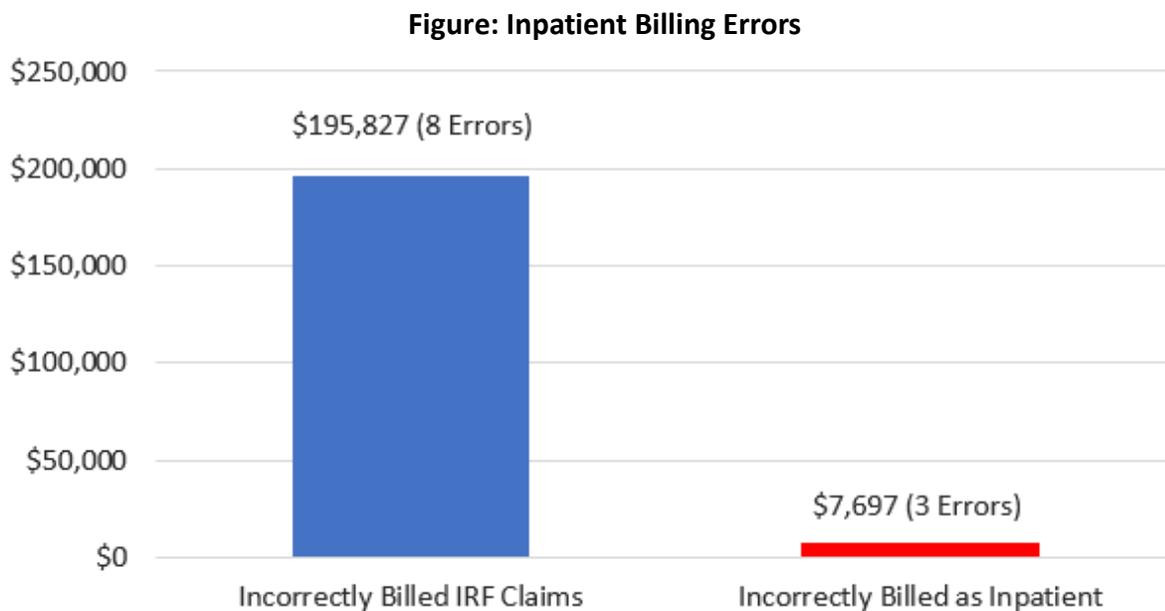
⁴ 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); The *Provider Reimbursement Manual – Part 1*, Pub. No. 15-1, § 2931.2; 81 Fed. Reg. at 7670.

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$1,620,452 for the audit period.⁵ As of the publication of this report, this amount includes claims outside of the 4-year claim reopening period.

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

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 11 of the 95 inpatient claims that we reviewed. These errors resulted in overpayments of \$203,524, as shown in the Figure.



Incorrectly Billed Inpatient Rehabilitation Facility Claims

Medicare payments may not be made for items or services “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

⁵ 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.

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 8 of the 95 selected inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for acute inpatient rehabilitation. IRF services for these beneficiaries were not considered reasonable and necessary because these beneficiaries did not require the active and ongoing therapeutic intervention of multiple therapy disciplines; generally did not require and could not reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program; were not sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation program; or, did not require physician supervision by a rehabilitation physician. The Hospital did not provide a cause for these errors because officials contended that these claims met Medicare requirements. However, Hospital officials did not provide any additional information that would impact our finding.

As a result of these errors, the Hospital received overpayments totaling \$195,827.

Incorrectly Billed as Inpatient

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

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

In addition, the regulations provide that an inpatient admission, and subsequent payment under Medicare Part A, is generally appropriate if the ordering physician expects the patient to require care for a period of time that crosses two midnights (42 CFR § 412.3(d)(1)).⁶ The regulations further state that the “expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and

⁶ The *Medicare Benefit Policy Manual* states that physicians “should use the expectation of the patient to require hospital care that spans at least two midnights period as a benchmark, i.e., they should order admission for patients who are expected to require a hospital stay that crosses two midnights and the medical record supports that reasonable expectation” (Pub. No. 100-02, chapter 1, § 10).

symptoms, current medical needs, and the risk of an adverse event” (42 CFR § 412.3(d)(1)(i)). Moreover, “[t]he 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 2 of the 95 selected inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria, which should have billed as outpatient or outpatient with observation. The medical records did not support the necessity for inpatient hospital services. The Hospital did not provide a cause for these errors because officials contended that these claims met Medicare requirements. However, Hospital officials did not provide any additional information that would impact our finding.

For 1 of the 95 selected inpatient claims, the Hospital was underpaid because a discharge code was incorrect. The Hospital indicated human error led to the incorrect discharge code.

As a result of these three errors, the Hospital received overpayments totaling \$7,697.

BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS – OPERATING ROOM SERVICES GREATER THAN ONE

Bills are to be completed accurately, including service units equal to the times the service or procedure was performed.⁷

The Hospital incorrectly billed Medicare for three of the five outpatient claims that we reviewed. For these three outpatient claims, review of the medical records showed that the Hospital incorrectly billed Medicare for two units of operating room services on each claim. Only one unit of service was appropriate. Hospital officials stated that the incorrect billing occurred because of human error related to inconsistent application or interpretation of information from available revenue and usage reports.

As a result of these errors, the Hospital received overpayments totaling \$741.

OVERALL ESTIMATE OF OVERPAYMENTS

The combined overpayments on our sampled claims totaled \$204,265. On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$1.6 million for the audit period.

⁷ The *Medicare Claims Processing Manual*, Pub. No. 100-04, chapters 1 and 4, §§ 80.3.2.2 and 20.4, respectively.

RECOMMENDATIONS

We recommend that St. Francis Hospital:

- refund to the Medicare contractor the portion of the \$1,620,452 in estimated overpayments for the audit period for claims that it incorrectly billed that are within the 4-year reopening period;⁸
- based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule⁹ and identify any of those returned overpayments as having been made in accordance with this recommendation; and
- strengthen controls to ensure full compliance with Medicare requirements; specifically, ensure that:
 - all IRF beneficiaries meet Medicare criteria for acute inpatient rehabilitation,
 - all inpatient beneficiaries meet Medicare requirements for inpatient hospital services,
 - procedure and diagnosis codes are supported in the medical records and staff are properly trained, and
 - medical records accurately document distinct procedural services and staff are properly trained.

OTHER MATTERS

Of the 95 inpatient claims in our sample, the Hospital incorrectly billed Medicare Part A for 3 beneficiary stays of less than two-midnights (known as inpatient short stays), which it should have billed as outpatient or outpatient with observation. Because the medical records did not

⁸ OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

⁹ This recommendation does not apply to any overpayments that are both within our sampling frame (i.e., the population from which we selected our statistical sample) and refunded based on the extrapolated overpayment amount. Those overpayments are already covered in the previous recommendation.

support the necessity for inpatient hospital services, the services should have been provided at a lower level of care. These errors caused the Hospital to receive overpayments totaling \$56,090.

However, none of the claims in this audit were targeted because they were inpatient short-stay claims but rather because they fell into one of the risk areas discussed in the background section of this report. OIG voluntarily suspended reviews of inpatient short-stay claims after October 1, 2013. As such, we are not including the number and estimated dollar amount of these errors in our overall estimate of overpayments or our repayment recommendation.

HOSPITAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

HOSPITAL COMMENTS

In written comments on our draft report, the Hospital disagreed with most of our findings and recommendations. The Hospital stated that the OIG lacked authority to use statistical sampling and extrapolation and disagreed with the OIG's extrapolation methodology. The Hospital agreed with the three inpatient and three outpatient errors reported, but disagreed with the medical review determinations for the eight inpatient IRF errors reported. Finally, the Hospital disagreed with the application of the 60-day rule.

Regarding OIG's use of statistical sampling and extrapolation and extrapolation methodology, the Hospital stated:

- The Medicare Program Integrity Manual states that Medicare contractors cannot use statistical sampling and extrapolation to estimate an overpayment absent evidence of sustained or high levels of errors (50 percent or more) or of failed educational intervention, neither of which OIG describes in this report. The Hospital also stated that it is "CMS's practice . . . to adopt the OIG's findings without question," somehow "putting the OIG on par with a Medicare contractor." Therefore, according to the Hospital, OIG cannot recommend that a Medicare contractor recoup an alleged overpayment that was calculated inconsistently with the *Medicare Program Integrity Manual*.
- OIG's small sample size resulted in the selection of a small number of unique data fields associated with each audited claim. The Hospital stated that OIG's 100 sampled claims contain only 59 of the 773 unique diagnosis codes found in the sample frame. The Hospital stated that OIG's findings of error apply only to a narrow range of patient conditions reflected in a thin slice of diagnosis codes and cannot reliably be used to conclude that physicians were making similar errors across a broad range of conditions reflected in other diagnosis codes. Therefore, OIG cannot reliably extrapolate its findings or should reduce its estimated recovery for the unrepresented sub-groups.

Regarding medical review determinations for the eight inpatient IRF errors reported, the Hospital stated that the IRF claims in question met the coverage requirements for a reasonable and necessary IRF admission. The Hospital stated that OIG applied the wrong standards and criteria, incorrectly assessed clinical evidence, and made factual errors or omitted facts when evaluating reasonableness and medical necessity and reviewing the medical records for the eight reported IRF claims. The Hospital said that OIG misinterpreted CMS guidance regarding concepts, such as “actively participate,” “benefit from,” and “intensive rehabilitation therapy.” The Hospital included additional comments related to the eight IRF claims denied, describing OIG’s medical review as in error in its determinations. Furthermore, the Hospital stated that it submitted claim-specific response for each of the eight IRF errors and that we would not take these into consideration before issuing a report.

Regarding application of the 60-day Rule, the Hospital stated that it plans to appeal the recommendations in this report; accordingly, the audit report is not credible information of a potential overpayment. The Hospital also stated that it is premature to say whether the audit report is credible information of a potential overpayment for claims outside of the Audit Period. Moreover, the Hospital contended that the 60-day Rule does not obligate it to report and return an overpayment without actual knowledge.

The Hospital’s comments, from which we have removed two appendices, appear as Appendix E.¹⁰

OFFICE OF INSPECTOR GENERAL RESPONSE

After review and consideration of the Hospital’s comments, we maintain that our findings and the associated recommendations, as revised, are valid.¹¹ 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.

¹⁰ The Hospital included a comprehensive exhibit as part of its comments on our draft report. This exhibit contained a claim-by-claim rebuttal of findings in our draft report. However, because this exhibit contained personally identifiable information, the Hospital requested that we exclude this exhibit from this report. In addition, the Hospital hired an external consulting firm and included the firm’s opinions in another exhibit. Because the Hospital included its concerns regarding our statistical sampling and estimation methodology in the body of its comments, we excluded this exhibit from this report.

¹¹ See Appendix E, Footnote 1.

Regarding the Hospital’s comments on our extrapolation, we note that the use of statistical sampling to determine overpayment amounts in Medicare is well established¹² and has repeatedly been upheld on appeal in Federal courts for sample sizes less than 100.¹³ The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology. We properly executed our statistical sampling methodology in that we defined our sampling frame, sampling unit, and strata; selected a stratified random sample; applied relevant criteria in evaluating the sample items; and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

The differences between the sample and the sampling frame that were identified by the provider are an expected part of the sampling process and are accounted for through our use of the lower limit to calculate the recommended recovery. The statistical lower limit represents a conservative estimate of the overpayment that we would have identified if we had reviewed every claim in the sampling frame. We use the lower limit of a two-sided 90-percent confidence interval, which is designed to be less than the actual overpayment amount 95 percent of the time. This conservative approach gives the provider the benefit of the doubt for the uncertainty in the sampling process, including uncertainty due to the number of unique diagnosis codes appearing in the sample as compared with the sampling frame.

The requirement that a determination of a sustained or high level of payment error or documented failed educational intervention must be made before extrapolation applies only to Medicare contractors.¹⁴ The Medicare Program Integrity Manual (PIM) and the statutory provisions upon which the PIM guidelines are based do not prohibit CMS from accepting and acting upon our monetary recommendation. Furthermore, the Hospital’s assertion that CMS and its contractors blindly adopt our findings and recommendations, putting the OIG “on par” with Medicare contractors, does not alter section 1893(f)(3) of the Social Security Act.

We disagree with the Hospital’s claim that we (1) applied the wrong standards and criteria, (2) incorrectly assessed clinical evidence, (3) made factual errors or omitted facts when evaluating reasonableness and medical necessity and reviewing the medical records, or (4) misinterpreted CMS guidance. We obtained an independent medical review for all claims in our sample. We

¹² *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).

¹³ *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 10 (E.D.N.Y.2012) (upholding a sample size of 95 claims) and *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *30-31 (S.D. Tex. 2012) (upholding a sample size of 30 claims).

¹⁴ Social Security Act § 1893(f)(3) and CMS Medicare Program Integrity Manual, Pub. No. 100-08, ch. 8.4, § (effective January 2, 2019).

submitted the claims to a contractor that reviewed the medical records in their entirety to determine whether the services were medically necessary and provided in accordance with Medicare requirements. We worked with the medical reviewers to ensure that they applied the correct Medicare criteria and that they used professionals with appropriate medical expertise, including physicians with training and expertise in rehabilitation.

We appropriately assessed the medical record documentation to determine whether it supported the Medicare payments. The medical reviewer considered the patient's entire clinical picture, including other medical needs and co-morbid conditions, and found that these beneficiaries (1) did not require the active and ongoing therapeutic intervention of multiple therapy disciplines; (2) generally did not require and could not reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program; (3) were not sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation program; or (4) did not require supervision by a rehabilitation physician. The claim-specific responses provided by the Hospital contained assessments of medical records that differed from our contractor's but did not include additional information for the contractors to consider.

With respect to the Hospital's intention to appeal our recommendations and assertion that the audit report is not credible information of a patient overpayment (within or outside our Audit Period) as a result, we refer the Hospital and other readers to this sentence from footnote 9 of this report: "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." That is no reason, however, to withdraw or modify our recommendation. Moreover, the Hospital's argument that the 60-Day Rule does not obligate it to report and return overpayments without actual knowledge is incorrect. The UnitedHealthcare Ins. Co. v. Azar, 330 F.Supp.3d 173 (D.C.D.C. 2018) decision relied up by the Hospital is inapplicable because it is a False Claims Act case and states that a False Claims Act action for failure to return overpayments requires actual knowledge, reckless disregard, or deliberate ignorance. The OIG continues to believe that this audit report constitutes credible information of potential overpayments.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$44,144,449 in Medicare payments to the Hospital for 3,192 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 claims (95 inpatient and 5 outpatient) with payments totaling \$1,590,619. Medicare paid these 100 claims from January 1, 2016, through December 31, 2017 (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 record.

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

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

We conducted our fieldwork from February 2018 through April 2020.

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 data analysis techniques to identify claims potentially at risk for noncompliance with selected Medicare billing requirements;
- selected a stratified random sample of 95 inpatient claims and 5 outpatient claims totaling \$1,590,619 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

We obtained paid claims data from CMS's NCH database totaling \$242 million for 13,776 inpatient and 43,424 outpatient claims in 50 risk areas. From these 50 areas, we selected 10, consisting of 8,906 claims totaling \$122,331,987 for further review.

We performed data filtering and analysis of the claims within each of the 10 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 revenue codes,
- paid claims equal to or less than \$0, and
- claims under review by the Recovery Audit Contractor as of June 28, 2018.

We assigned each claim that appeared in multiple risk areas to just one area on the basis of the following hierarchy: Inpatient Adverse Events, IRF Claims, Inpatient Claims Paid In Excess of \$150,000, Inpatient Claims Paid Greater than Charges, Inpatient Claims Billed with High Severity Level DRGs, Inpatient Comprehensive Error Rate Testing (CERT) DRG, Inpatient Elective Procedures, Mechanical Ventilation Claims, Outpatient Surgeries Billed with Units Greater than One, and Outpatient Right Heart Catheterizations with Hemodynamic Data. This resulted in a sample frame of 3,192 Medicare paid claims in 10 risk areas, totaling \$44,144,449, from which we drew our sample (Table 1).

Table 1: Risk Areas

Medicare Risk Area	Frame Size	Value of Frame
Inpatient Adverse Events Claims	385	\$4,768,989
Inpatient Rehabilitation Services Claims	390	10,204,634
Inpatient Claims Paid in Excess of \$150,000	2	356,845
Inpatient Claims Paid Greater than Charges	4	156,497
Inpatient Claims Billed with High Severity Level Diagnosis Related Group (DRG) Codes	446	5,204,724
Inpatient Comprehensive Error Rate Testing (CERT) DRG	1,176	13,516,899
Inpatient Elective Procedures	758	9,619,444
Inpatient Mechanical Ventilation	8	261,040
Outpatient Surgeries Billed with Units Greater than One	21	50,406
Outpatient Right Heart Catheterizations with Hemodynamic Data	2	4,971
Total	3,192	\$44,144,449

SAMPLE UNIT

The sample unit was a Medicare paid claim.

SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified random sample. We stratified the sampling frame into four strata on the basis of claim dollar value. Stratum 1 includes high dollar inpatient claims (payment amounts greater than or equal to \$21,244), stratum 2 includes moderate dollar claims (payment amounts less than \$21,244 but greater than or equal to \$12,332), stratum 3 includes low dollar claims (payment amounts of less than \$12,332), and stratum 4 includes all outpatient claims. All claims were unduplicated, appearing in only one area and only once in the entire sampling frame.

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

Table 2: Claims by Stratum

Stratum	Claims Type	Frame Size (Claims)	Value of Frame	Sample Size
1	Inpatient High Dollar Claims	463	\$13,918,187	31
2	Inpatient Moderate Dollar Claims	1,098	15,687,247	33
3	Inpatient Low Dollar Claims	1,608	14,483,637	31
4	Outpatient Claims	23	55,377	5
	Total	3,192	\$44,144,449	100

Notice: The table includes rounded totals.

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the claims within strata 1 through 4. 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 in Sample
1	463	\$13,918,187	31	\$873,303	8	\$195,827
2	1,098	15,687,247	33	441,688	0	0
3	1,608	14,483,637	31	267,357	3	7,697
4	23	55,377	5	8,270	3	741
Total	3,192	\$44,144,449	100	\$1,590,619	14	\$204,265

Notice: The table includes rounded totals.

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

Point estimate	\$3,327,408
Lower limit	1,620,452
Upper limit	5,034,365

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 Over-Payments	Value of Overpayments
Adverse Events	9	\$121,615	-	-
Rehabilitation Services	16	458,568	8	\$195,827
Paid Greater than Charges	1	38,456	-	-
High Severity Level Diagnosis Related Group (DRG) Codes	4	78,669	-	-
Comprehensive Error Rate Testing (CERT) DRG	41	496,554	2	10,689
Elective Procedures	23	353,348	1	(2,992)
Mechanical Ventilation	1	35,139	-	-
Inpatient Total	95	\$1,582,349	11	\$203,524
Surgeries Billed with Units Greater than One	4	\$5,838	3	741
Right Heart Catheterizations with Hemodynamic Data	1	2,432	-	-
Outpatient Total	5	\$8,270	3	\$741
Inpatient and Outpatient Total	100	\$1,590,619	14	\$204,265

Notice: The table above includes rounded totals and illustrates the results of our review 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.



OSF[®] HEALTHCARE

June 26, 2020

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

RE: Medicare Hospital Provider Compliance Audit: St. Francis Hospital.
 Draft Report No. A-05-18-00048

Dear Ms. Fulcher,

St. Francis Hospital (“St. Francis” or the “Hospital”) respectfully submits this letter in response to OIG Draft Report No. A-05-18-00048, *Medicare Hospital Provider Compliance Audit: St. Francis Hospital*, dated April 7, 2020 (the “Draft Report”). As discussed below, St. Francis believes the Draft Report contains legal and factual errors with respect to the claims that were subject to review. St. Francis urges the OIG to make the changes described herein before finalizing the Draft Report.

I. Summary of Draft Report

The Draft Report summarizes a hospital audit undertaken by the OIG to determine St. Francis’s compliance with Medicare requirements for billing inpatient and outpatient services. The audit involved Medicare claims paid during a two-year audit period (January 1, 2016 through December 31, 2017) (“Audit Period”) and focused on 10 risk areas identified by the OIG. The OIG selected for review a stratified random sample of 100 claims. The OIG submitted the claims to an independent review contractor to determine whether each claim met the Medicare coverage requirements as supported by the medical record.

The OIG found that a total of 14 of the 100 inpatient and outpatient claims reviewed did not comply with Medicare billing or coverage requirements, resulting in overpayments of \$204,265. Specifically, 11 inpatient claims had alleged billing errors—eight of which were associated with inpatient rehabilitation facility (“IRF”) claims—resulting in overpayments of \$203,542, and three outpatient claims had alleged billing errors, resulting in overpayments of \$741. On the basis of those sample results, the OIG estimated that the Hospital received overpayments of \$1,620,452 for the Audit Period.¹

¹ The OIG originally estimated the overpayment in the Draft Report as \$1,787,643. St. Francis informed the OIG of errors in the paid claims data of the sample frame due a MAC payment error. The OIG addressed this error by recalculating the overpayment estimate to \$1,620,452.

St. Francis concurs with the OIG’s findings as to the three outpatient claims. It also concurs in the findings with regard to the three acute care inpatient claims. St. Francis does not concur in the OIG’s findings with regard to the eight IRF claims and believes the OIG reached those conclusions in error. Further, St. Francis does not concur in the OIG’s findings with regard to an estimated overpayment for the Audit Period. As explained below, the 100 claim sample was heavily skewed toward a small number of admitting diagnostic codes which undercuts the reliability of applying the sample results to the entire sample frame.

II. Executive Summary of St. Francis’s Response

St. Francis does not concur with the OIG’s review, findings, and recommendations for certain areas of the Draft Report. Specifically, St. Francis’s objects to the following:

- **The OIG lacks authority to use statistical sampling and extrapolate an overpayment without finding a sustained or high rate of error.** There are limited circumstances in which Medicare contractors may use statistical sampling and extrapolation to estimate an overpayment. The Draft Report fails to demonstrate that an extrapolation is appropriate here. Further, the OIG cannot recommend that a Medicare contractor recoup an alleged overpayment that was calculated inconsistently with the Medicare Program Integrity Manual, which Medicare contractors must follow in order to initiate a recoupment.
- **The OIG improperly extrapolated the alleged errors to the Audit Period.** The OIG’s small sample size results in the selection of a small number of unique data fields associated for each audited claim. The OIG cannot reliably extrapolate its findings to the Audit Period for this reason.
- **The audited IRF claims met Medicare’s coverage requirements and all material documentation standards.** The medical records for each audited IRF claim demonstrate that the IRF services were reasonable and necessary services. The OIG’s findings to the contrary in eight cases were the result of failure to correctly apply the Medicare coverage criteria.
- **The Medicare 60-day rule does not obligate St. Francis to review IRF claims outside the Audit Period and uses a legally invalid constructive knowledge standard.** St. Francis disputes OIG’s findings and intends to appeal any effort by a Medicare Administrative Contractor (“MAC”) to recoup payments on any of the bases contained in the Draft Report. Accordingly, the Draft Report is not credible information of a potential overpayment for claims outside the Audit Period. Additionally, based on recent federal case law, a provider must act with actual knowledge in order to be liable for failing to report and return an overpayment under the 60-day rule. Due to the errors in the OIG’s audit findings—particularly the bias that has been introduced as a result of the small sample size—St. Francis does not have actual knowledge of an overpayment, and thus lacks an obligation to report and return any overpayment to the Medicare program.

III. Claims for Inpatient and Outpatient Services

A. The OIG lacks authority to use statistical sampling and extrapolate an overpayment without finding a sustained or high rate of error.

There are limited circumstances in which Medicare auditors may use statistical sampling and extrapolation to estimate an overpayment, none of which apply here. In the Medicare Modernization Act (“MMA”) Congress limited the Secretary’s use of extrapolation in determining overpayments to the following narrow set of circumstances:

A Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise, unless the Secretary determines that-

- (A) there is a sustained or high level of payment error; or
- (B) documented educational intervention has failed to correct the payment error.²

In the Medicare Program Integrity Manual (“MPIM”), CMS has emphasized the MMA establishes the *exclusive* grounds for extrapolation:

The [MMA], mandates that before using extrapolation (i.e., projection, extension, or expansion of known data) to determine overpayment amounts to be recovered by recoupment, offset, or otherwise, *there must be* a determination of *sustained* or high level of payment error, *or* documentation that educational intervention has failed to correct the payment error.³

The MPIM also clarifies that these limitations apply to a Medicare auditor’s ability to use statistical sampling:

The contractor shall use statistical sampling when it has been determined that a sustained or high level of payment error exists. The use of statistical sampling may be used after documented educational intervention has failed to correct the payment error.

The MPIM also provides a non-exhaustive list of methods Medicare auditors may use to identify the type of “sustained or high level of payment error” necessary “[f]or purposes of extrapolation,” including “high error rate determinations by the contractor or by other medical reviews (i.e., greater than or equal to 50 percent from a previous pre- or post-payment review).”⁴

Under these rules, the Draft Report cannot provide the basis for the use of extrapolation. Apart from the Draft Report findings, the OIG has cited to no evidence that St. Francis has demonstrated a “sustained” rate of payment error. There is no mention of any prior audit

² 42 U.S.C. § 1395ddd(f)(3).

³ MPIM (Pub. 100-08), Ch. 8, § 8.4.1.2 (emphasis added).

⁴ *Id.* at 8.4.1.4.

findings from the OIG or Medicare contractor. Nor is there any mention of failed educational intervention. Instead, the OIG has relied entirely upon the Draft Report findings—which do not meet the 50 percent error rate threshold established in the MPIM—to determine that extrapolation is warranted. Even if, contrary to the MMA and CMS’s instructions in the MPIM, the OIG could solely rely upon draft audit findings to determine a “sustained” payment error rate, it could not do so in this instance. Here, the OIG’s alleged claims error rate is only 14 percent with an error rate of 12.8 percent of the dollars paid, far below the 50 percent threshold CMS requires its contractors to follow. Thus, the Draft Report’s recommendation that the MAC recoup an alleged overpayment based on an extrapolated estimate violates CMS’s guidance because no sustained error rate was identified during the OIG’s audit.

St. Francis is aware that the OIG has previously identified its position, in an entirely separate published report, that the MMA and the MPIM apply only to Medicare contractors, and not the OIG.⁵ This position is disingenuous. While the Draft Report acknowledges that “CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments *consistent with its policies and procedures*,” the OIG’s position on recoupment disregards the fact that the Draft Report constitutes a strong recommendation as to its findings and relies upon the fact that CMS rarely, if ever, invests the resources to conduct its own review of OIG compliance audit findings.⁶ In other words, CMS’s practice is to adopt the OIG’s findings without question, putting the OIG on par with a Medicare contractor. Thus, the OIG points the finger at CMS as the party responsible for making the decision to extrapolate the audit results, knowing that CMS relies wholeheartedly on the OIG’s recommendation. It is precisely because MACs are bound by the limits imposed by the MMA and MPIM, that the OIG should not recommend that a MAC recoup an alleged overpayment calculated using a methodology that violates those authorities.

B. The OIG’s methodology to extrapolate the alleged overpayment amount is improper.

When it received the Draft Report, St. Francis engaged (through outside legal counsel) FTI Consulting, a nationally recognized healthcare consultant to review the OIG’s sampling and extrapolation methodology. FTI provided the report at Exhibit A (the “FTI Analysis”).

Due to the limitation of the OIG’s audit, the results cannot be properly extrapolated to the Audit Period. As described in Exhibit A, FTI performed a data analysis to identify various types of claims for which the OIG applied its extrapolation results, but were not included in the OIG sample review. Using data analysis techniques at the claim level, FTI quantified the total number of claims and total payment dollars associated with these claims and arrayed claim categories, or certain claim characteristics, identified in the OIG’s sample frame data. FTI then determined whether these claim types or claim characteristics were either (1) not included in the statistical sample; or (2) included in the statistical sample, but not found to be a claim error. If a certain claim category or claim characteristic was determined to be excluded from the sample, or not associated with a payment error in the sample, then St. Francis quantified the dollar paid

⁵ See, e.g., OIG Report No. A-02-17-01016, p. 16 (“We also note that the MPIM applies to Medicare contractors—not the OIG.”)

⁶ Draft Report, n.7 (emphasis added).

amount in the sample frame that had no representation in the OIG's sample with respect to those claim characteristics. If the claims in the sample frame with these characteristics are unable to be found in error even if they had been reviewed by the OIG, then it would be improper to apply the OIG payment error findings to those claims or claim characteristics in the sample frame. In other words, if many claims with certain characteristics were not sampled but were otherwise present in the sample frame, then applying the OIG payment error findings to those claims leads to an improper estimate. In this case, our recommendation is that OIG reduce the estimated overpayment by the percent of total claims (or reimbursements of claims) in the sample frame to the extrapolated amount quantified by OIG.

The FTI Analysis did in fact find that certain claim types or claim characteristics identified in the sample frame were excluded from the sample or were not identified with an alleged payment error. One example is the patient's diagnosis code. A patient's diagnosis code is strongly linked to the OIG's alleged findings of payment error. In all eight claims the OIG found to be in error, the OIG reviewers found that the medical record did not substantiate the physician's determination that, at the time of admission, the patient met the Medicare standards for coverage of IRF inpatient care—namely that the patient's condition was such that he or she could both participate in and benefit from intensive inpatient rehabilitation services. See 42 CFR § 412.622. Of course, a patient's condition upon admission is reflected in the diagnosis code. But the types of conditions, as reflected in diagnosis codes, that would support inpatient IRF admission are far narrower than the conditions that support acute inpatient care. For example, IRF admission is generally inappropriate for ventilator patients, patients with a psychiatric diagnosis, patients with chest tubes, patients with active respiratory or bacterial infections, patients on certain cardiac medications, terminally ill patients and patients who are neutropenic. All of these conditions, of course, could support an inpatient stay in an acute care facility. In addition, there are certain conditions, such as severe chest pain and pneumonia, which are far less likely to lead to the need for inpatient rehabilitation services than others (such as amputation of a limb due to diabetic necrosis). If the OIG's sample, or payment errors in the sample, focused on a narrow band of patient diagnosis, then its review most reliably tested whether the physicians were making the appropriate admission decisions *for that narrow range of conditions*. The OIG's results would say nothing from a statistical perspective about the physicians' ability to make admission decision in the much broader range of conditions that present at a medical center like St. Francis which includes both an inpatient acute care medical surgical unit and an inpatient IRF unit. Said another way, the OIG's findings of error apply only to a narrow range of patient conditions reflected in a thin slice of diagnosis codes and cannot be reliably applied to conclude that physicians were making similar errors across a broad range of conditions reflected in other diagnosis codes.

FTI's analysis supports this critique. FTI found that the OIG's sampling frame of 3,192 claims contained 773 unique diagnosis codes, paid at a total of \$44,144,449. But only 59 unique codes were included in the sample of 100 claims. Said another way, 714 unique admitting diagnosis codes from the sample frame were not audited. These diagnosis codes accounted for a total amount paid of \$23,257,482—more than one half of the total value of the sample frame. The OIG's findings should take these errors into account and conclude that its findings cannot be reliability applied to half of the sample frame and restate its estimated overpayment amount by 50 percent.

IV. The Audited IRF Claims Met Medicare’s Coverage Requirements

Notwithstanding the numerous legal and procedural deficiencies in the Draft Report, all of the audited IRF claims were nonetheless for reasonable and necessary services. The Draft Report alleges that for 8 of the 95 selected IRF claims, the hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for acute inpatient rehabilitation. IRF services for these beneficiaries were not considered reasonable and necessary. As a result of these alleged errors, the OIG finds that the hospital received overpayments totaling \$213,233.

St. Francis contends that each of the 8 claims in question met the coverage requirements for a reasonable and necessary IRF admission. Additionally, St. Francis contends that the OIG’s findings for each of the 8 claims contain errors that invalidate the OIG’s conclusions for each claim. These errors include:

- Application of the wrong standard to assess medical necessity;
- Misapplication of one or more of the medical necessity coverage criteria;
- Incorrect assessments regarding clinical evidence; and
- Factual errors and/or factual omissions in reviewing the medical record.

IRF Coverage Criteria. Under section 1862(a)(1) of the Social Security Act, IRF services are considered reasonable and necessary upon a finding by the rehabilitation physician of a reasonable expectation that the patient meets all of the following four requirements at the time of the patient's admission to the IRF. The patient:

- 1) Must require active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy), one of which must be physical or occupational therapy.
- 2) Must be reasonably expected to actively participate in, and benefit from, an intensive rehabilitation therapy program.
- 3) Must be sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation therapy program
- 4) Must require medical supervision by the rehabilitation physician of face-to-face visits with the patient at least 3 days per week throughout the patient's stay in the IRF to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.

See 42 CFR § 412.622. *See also* MBPM, Ch. 1 § 110.2.

Through rulemaking and subregulatory guidance, CMS elaborated on its regulatory coverage criteria to further define the contours of the terms “actively participate,” “benefit from,” and “intensive rehabilitation therapy” as they are used in the IRF coverage criteria.

Actively Participate

CMS explained its “actively participate” requirement as follows: “At the time of admission to the IRF, there must be a reasonable expectation that the patient is able to tolerate and benefit from the intensive rehabilitation services . . . so that he or she can progressively make the improvements needed to achieve results of practical value towards his or her functional capacity or adaptation to impairment.” 74 Fed. Reg. 39762, 39793 (Aug. 7, 2009). CMS was clear that the patient’s medical problems need not be “fully resolved when they are admitted to IRFs.” *Id.* Instead, CMS requires that a “patient’s medical condition be such that it can be successfully managed in the IRF setting *at the same time that the patient is participating* in the intensive rehabilitation therapy program provided in an IRF.” *Id.* (emphasis in original).

CMS further defined its “active participation” standard in subregulatory guidance. A “patient’s condition must be such that he or she can safely tolerate the level of rehabilitation therapy program provided in an IRF. Also, the intensity of therapy provided in the IRF must further the patient’s progress in meeting his or her functional goals, rather than setting the patient back in those goals by overtaxing him or her.” *Clarifications for the IRF Coverage Requirements* at 28 (No. 8).⁷

Benefit From

CMS has also clarified its requirement regarding benefiting from IRF therapy. The Medicare Benefit Policy Manual defines “significant benefit” standard as follows:

The patient must reasonably be expected to actively participate in, and benefit significantly from, the intensive rehabilitation therapy program that is defined in section 110.2.2 at the time of admission to the IRF. *The patient can only be expected to benefit significantly from the intensive rehabilitation therapy program if the patient’s condition and functional status are such that the patient can reasonably be expected to make measurable improvement (that will be of practical value to improve the patient’s functional capacity or adaptation to impairments) as a result of the rehabilitation treatment, as defined in section 110.3, and if such improvement can be expected to be made within a prescribed period of time. The patient need not be expected to achieve complete independence in the domain of self-care nor be expected to return to his or her prior level of functioning in order to meet this standard.*

MBPM, Ch. 1 § 110.2 (Emphasis added).

Intensive Rehabilitation Therapy

⁷ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/Complete-List-of-IRF-Clarifications-Final-Document.pdf>

CMS has also clarified its standard regarding the intensity of rehabilitation services necessary for coverage. The intensity of rehabilitation services is typically demonstrated in IRFs by the provision of intensive therapies at least 3 hours per day at least 5 days per week. But, CMS “d[id] not intend for this to be the only way such intensity can be demonstrated (that is, [CMS does] not intend for this measure to be used as a ‘rule of thumb’ for denying an IRF claim). Rather, [CMS] suggest[s] that this is one generally accepted way of demonstrating the intensity of services provided in an IRF.” 74 Fed. Reg. at 39794. Specifically, CMS contemplated a scenario where a patient may not be able to tolerate therapy on a predictable basis due to, e.g., concurrent chemotherapy, and, therefore, permits flexibility in the 15 hours per week schedule to accommodate the fact that IRF patients often deal with several co-morbidities or medical conditions while undergoing therapy. *Id.* If a significant change in the patient’s condition is expected to be temporary such that the patient will be able to resume their full course of treatment in the IRF for the 7 consecutive day period, then “the ‘missed’ therapy time can be made up on a subsequent day and the IRF stay may continue.” *Clarifications for the IRF Coverage Requirements* at 28 (No. 7).

OIG Errors Regarding the Medical Necessity of Audited IRF Claims. Notwithstanding the numerous legal and procedural deficiencies in the OIG’s findings, all of the audited IRF claims were nonetheless for reasonable and necessary services. The OIG alleged that eight IFR claims were incorrectly paid. In particular, for each claim, the OIG alleged there was no reasonable expectation that the patient, at the time of admission, met all of the IRF coverage requirements. The OIG also alleged that the patient did not require an interdisciplinary approach to care, as evidenced by the documentation in the record of weekly interdisciplinary meetings.

St. Francis submitted a claim-specific response for each of the eight claims along with evidence in the medical record showing that the IRF services in question were medically necessary. St. Francis submitted these letters to the OIG on or around June 26, 2019. St. Francis was informed that the OIG would not take these submissions into consideration before OIG issued the Draft Report. These claim specific responses are now included as Exhibit B, and St. Francis urges the OIG to review these submissions before finalizing its audit results.⁸ As discussed below, and supported by the medical records and responses in Exhibit B, St. Francis highlights the following types of errors the OIG relied upon in its written rationale for one or more of each of the eight IRF claims.

- **For all claims the OIG determined that, at the time of admission, there was no reason to believe that an intensive rehabilitation therapy would significantly impact the patient’s condition differently compared with therapy provided at a less intense level.**

This is not the standard of review for evaluating the medical necessity of IRF claims per the relevant authorities, noted above. The relevant authorities do not require that the rehabilitation

⁸ Exhibit B contains medical records and related summaries that contain protected health information (“PHI”) and should be omitted from the final published report to be issued by the OIG.

physician determine that IRF therapy would significantly impact the patient's condition differently compared to therapy provided at a less intense level. Rather, the standard of review is whether the patient meets the IRF criteria at the time of admission without regard to a comparative analysis to a lower level of care. The OIG's use of this standard is an arbitrary and subjective opinion that is unpublished and unsupported by Medicare guidance. In each of the eight cases, documentation by the rehabilitation physician in the pre-admission assessment, post-admission evaluation, and overall plan of care established that the rehabilitation physician's reasonable expectation that the patients would make a measurable improvement of practical value to improve their functional capacity and/or to adapt to their impairments. The OIG disregarded these clinical determinations and, instead, applied its own arbitrary standard summarized by a conclusory opinion without providing specific evidence from the patient's medical record.

Even by the OIG's incorrect standard, however, the medical records in each case demonstrate that a lower level of care would not have been appropriate. In Sample #1, for example, the patient is a 74-year old male with recent colon resection after stage IIIB colon cancer. The patient had a complicated post-operative course including: an anastomotic leak, abdominal wound dehiscence, colostomy reversal, anxiety, cholecystitis, gout, congestive heart failure, hemorrhagic shock and renal failure. The patient was started on hemodialysis during the acute hospitalization at the Mayo Clinic that continued when he was admitted to Inpatient Rehabilitation. During his IRF admission there were nursing needs for new wound care, new ostomy care, drain cares, and complex patient education. Under these circumstances, the patient required an interdisciplinary team to address his need for multiple therapy types including nephrology for his hemodialysis and wound and ostomy care along with his physical and occupational therapy. The patient required 24-hour rehabilitation for bowel and bladder retraining and reinforcement of transfer training techniques learned in physical and occupational therapy. The rehabilitation physician determined that the patient's needed care on these new medical issues along with the patient's physical limitations required physical therapy and occupational therapy at a level of acuity that would have been too high to safely discharge to a lower level of care such as at a skilled nursing facility.

Similarly, in Sample #12, the patient is a 47-year old male with impaired activities of daily living, mobility dysfunction, and phantom limb pain after right above-knee amputation resulting from a MRSA infection. The patient had comorbid conditions including COPD, chronic kidney disease and obesity. The rehabilitation physician determined that the patient required multiple therapies including physical therapy, occupational therapy, and neuro-psychology services. The patient's functional status at the time of admission was minimal to moderate assistance required for mobility and self-care, demonstrating that there was an expected need to modify the patient's treatment to maximize the patient's capacity to benefit from rehabilitation and did require supervision at the acute rehabilitation level. The patient's complicated medical history, in combination with his pain medication regimen and co-morbidities demonstrated that the patient's

needs could not have adequately been met at a lower level of care such as a skilled nursing facility.

In another example, Sample #17, the patient is an 87-year old male with lower limb ischemia and had undergone lower extremity bypass and pseudoaneurysm resection procedures. His comorbid conditions included coronary artery disease. The patient had a Foley catheter in place due to urinary retention and also was on deep vein thrombosis prevention, which required the use of sequential compression devices on his legs. The deep vein thrombosis prevention therapy meant that there was an expected need to modify the patient's treatment and provide supervision at the acute rehabilitation level. These conditions, along with the patient's impaired mobility, meant that the patient required a multidisciplinary team approach to address his rehabilitation needs with care coordination. And, in this instance, the decision to admit the patient for IRF services was potentially lifesaving. The patient did, in fact, develop deep vein thrombosis during the IRF stay. Had that patient been discharged to a lower level of care, it was likely that the patient would have required a readmission to the acute hospital setting for treatment. Instead, the patient was able to receive treatment while still receiving and participating in therapy.

In yet another example, Sample #30, the patient is a 67-year old male with impaired mobility and self-care skills related to critical illness myopathy developing during the acute hospital course. There were multiple factors demonstrating why the patient needed intensive therapy at the IRF level of care. The factors included that he was receiving IV heparin which cannot be administered at a lower level such as a skilled nursing facility; he was still on cardiac telemetry monitoring which could not be done at a lower level such as at a skilled nursing facility; and he was noted to have critical potassium levels which required frequent lab draws for monitoring. These factors, as noted in the medical record, were central to the physician's decision to admit the patient for IRF services that could not have been safely provided at a lower level of care.

- **For five claims, the OIG determined that the patient was limited by the severity of his comorbid medical conditions, and for three of those claims, the patient was not able to safely fully participate in or benefit from a required intensity of an acute rehabilitation therapy program.**

Here, again, the OIG applies the wrong standard. Under the relevant authorities, each case must be assessed as to whether the rehabilitation physician had a *reasonable expectation at the time* that IRF services were medically necessary based on the facts in existence at the time of admission. For these cases, the OIG's finding that "the patient was limited by the severity of his comorbid medical conditions" is inconsequential, therefore, as the rehabilitation physician's assessment at the time of admission in each case was that, despite the patient's medical conditions, the patient *would* be able to fully participate in the rehabilitation program. And the OIG has provided no evidence from the medical record to support the conclusion that the physician was wrong or unreasonable in making that initial assessment. In relevant instances, the rehabilitation physician acknowledged the patient's comorbidities *as support* for the expectation that the patient requires intensive rehabilitation therapy. This example highlights the

untenable double standard underlying the OIG's errors. The OIG cites the patient's heightened acuity when determining that a patient is unable to actively participate in the therapy but then ignores the complexity and severity of the patient's condition when examining whether the patient requires the intensity of rehabilitation services.

What's more, in each case, the OIG's finding that the patient could not be expected to actively participate is directly contradicted by evidence in the medical record showing that the patient did fully participate and complete the recommended courses of intense therapy. In Sample #12, for example, although the patient was limited by pain at the start of his rehabilitation program, he still actively participated and met his required therapy minutes each week. When he did miss 30 minutes of physical therapy due to pain, he made up that time within the week, as documented in the medical record. Similarly, when the patient in Sample # 23 had to reduce the intensity of his therapy due to chest pain, he made up that time in the following days.

Finally, in each case, the patient's medical record showed that the patient was able to benefit from the therapy. For example, in Samples #1 and #23, the weekly team conference notes showed a steady progression in the patient's functional independence measures consistent with the plan of care. The patients progressed in all areas including discharging at their therapy goals. In Sample #12, the medical records demonstrate that the patient's functional independence measures show progress from one week to the next, even citing "excellent progress" in one of the team conference notes.

- **For four claims, the OIG determined that there is no evidence more intensive rehabilitation provides better outcomes including shorter period of disability or more rapid return to the community for persons requiring rehabilitation for post-acute deconditioning.**

The OIG's assessment regarding the clinical evidence is wrong. There is clinical evidence that more intensive rehabilitation provides better outcomes including shorter period of disability and a more rapid return to the community. Specifically, a comprehensive national study published by Dobson DaVanzo measured the clinical outcomes of patients treated in IRFs to those treated in SNFs.⁹ Over a two-year study period, IRF patients who were clinically comparable to SNF patients, on average, displayed better clinical outcomes including lower mortality, fewer readmissions and ER visits, and more days at home than rehabilitation in SNFs for the same conditions. Specifically, the report found that IRF patients who were clinically comparable to SNF patients, on average:

- Returned home from their initial stay two weeks earlier;
- Remained home nearly two months longer;
- Stayed alive nearly two months longer;

⁹ https://amrpa.org/Portals/0/Dobson%20DaVanzo%20Final%20Report%20-%20Patient%20Outcomes%20of%20IRF%20v_%20SNF%20-%207_10_14%20redated.pdf.

- IRF patients experienced an eight percent lower mortality rate during the two-year study period than SNF patients;
- IRF patients experienced five percent fewer emergency room visits per year than SNF patients; and
- IRF patients experienced significantly fewer hospital readmissions per year than SNF patients.

The study concluded that better clinical outcomes could be achieved by treating patients in an IRF across all conditions. In this instance, the OIG not only failed to incorporate this evidence but, moreover, entirely failed to acknowledge its existence.

- **In five cases, the OIG auditor made significant factual errors in its findings that materially undermine the outcome of its medical necessity determination.**

The OIG made significant factual errors and/or factual omissions when reviewing the medical record in each case. In Sample #12, for example, the OIG noted twice in the findings that patient was not a candidate for a prosthesis. This was not accurate, as it was addressed in the discharge summary that the patient would be meeting to discuss prosthesis at a later date, after he had worn his stump shrinker and the stump healed well. In Sample #29, the OIG found that there were no complex wound care or pain management issues but overlooked that the patient had cellulitis and complications at the incision cite where he was intubated. In Sample #21, the OIG found that the patient had no complex wound care or pain management issues, failing to acknowledge that the patient documented complaints of uncontrolled pain in the medical record during the IRF stay, requiring careful monitoring of his pain and medications to ensure the treatment was working. Similarly, in Sample #31 OIG found that the patient had no complex wound care or pain management issues, yet pain management was included in the summary of the patient’s rehabilitation course. In Sample #30, the OIG determined that the start of the patient’s therapy was limited by the patient’s debility but the patient participated in therapy from day one of his IRF stay. Because IRF medical necessity determinations are fact-specific assessments, these errors materially affect the OIG’s analysis regarding the appropriateness of IRF admissions.

V. The Medicare 60-day rule does not obligate St. Francis to review IRF claims.

The Draft Report recommends that St. Francis “exercise reasonable diligence to identify, report and return any overpayments in accordance with the 60-day rule,”¹⁰ including overpayments relating to IRF claims. The Draft Report further advises that the 60-day rule’s six-year lookback period “is not limited by OIG’s audit period or restrictions on the Government’s ability to reopen claims or cost reports.”¹¹ The OIG should omit this recommendation because it is premature to say whether the Draft Report constitutes credible information of potential overpayment. St.

¹⁰ Draft Report, 8.

¹¹ *Id.* at 3.

Francis disputes the OIG’s findings and intends to appeal through the MAC appeal process should a recoupment occur.

Under the Affordable Care Act, a person who has received an overpayment must “report and return the overpayment” by “the date which is 60 days after the date on which the overpayment was *identified*,” or by the date the corresponding cost report is due, whichever is later (the “Overpayment Statute”). Under the regulations governing the Medicare fee-for-service program (collectively the “FFS 60-Day Rule”), an overpayment may be “identified” through actual or constructive knowledge. Specifically, the regulations provide:

A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise *reasonable diligence* and the person in fact received an overpayment.¹²

The term “reasonable diligence” is not defined in statute or regulations. In the preamble to the relevant rulemaking, CMS discussed the standard at length, explaining:

“Reasonable diligence” includes both proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments and investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining *credible information* of a potential overpayment.¹³

CMS explained, “credible information includes information that supports a reasonable belief that an overpayment may have been received.”¹⁴ The agency also acknowledged: “Determining whether information is sufficiently credible to merit an investigation is a fact-specific determination.”¹⁵

When a provider appeals a contractor or government audit, the provider is not required to investigate similar conduct outside the Audit Period while the appeal is pending. In the preamble, CMS stated that while “contractor overpayment determinations are always a credible source of information for other potential overpayments,” a provider may dispute audit findings and the audit should not be treated as “credible information” during an appeal. Specifically, the agency explained:

If the provider appeals the contractor identified overpayment, the provider may reasonably assess that it is premature to initiate a reasonably diligent investigation into the nearly identical conduct in an additional time period until such time as the

¹² 81 Fed. Reg. 7654, 7661 (Feb. 12, 2016) (emphasis added).

¹³ *Id.*

¹⁴ *Id.* at 7662.

¹⁵ *Id.* at 7663.

contractor identified overpayment has worked its way through the administrative appeals process.¹⁶

Even if the provider's appeal is unsuccessful, contractor or government audit findings only constitute "credible information of receiving a potential overpayment beyond the scope of the audit if the practice that resulted in the overpayment also occurred outside the audited timeframe."¹⁷ In other words, if a provider has a reasonable basis to believe it resolved the practice underlying an overpayment identified in an audit report, then the report may not be credible information that the provider was overpaid on claims billed after implementing the corrective action. Absent credible information of an overpayment for claims billed following the corrective action, the provider would not have a duty under the FFS 60-Day Rule to undertake a reactive investigation.

Furthermore, the Draft Report is not credible evidence as it acknowledges the preliminary nature of the OIG's determinations:

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.¹⁸

It is, therefore, premature for the OIG to suggest its findings amount to the type of "credible information" that might compel the hospital to investigate whether claims outside the Audit Period are affected by the issues described in Draft Report when (i) CMS and the MAC will decide whether to begin a recoupment of the audited and extrapolated claims and (ii) St. Francis intends to pursue all available remedies should such a recoupment occur.

Finally, the 60-Day Rule as applied in the Medicare Part C context was vacated in the case of *UnitedHealthcare Ins. Co. v. Azar* 330 F.Supp.3d 173 (D.D.C. 2018), *appeal filed*, Case No. 18-5326 (D.C. Cir.). That 60-Day Rule for Part C applies the same negligence standard as the Medicare Fee-for-Service 60-Day Rule applicable here. Thus, in the wake of *United*, the FFS 60-Day Rule is also invalid as interpreted by CMS and should be interpreted as requiring actual knowledge for an overpayment to constitute an obligation for purposes of the FCA.

¹⁶ *Id.* at 7667.

¹⁷ *Id.*

¹⁸ Draft Report at n.7.

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Thank you for considering our comments to the Draft Report. If you have further questions pertaining to the responses in this letter, please contact C.J. Tonozzi at Clinton.J.Tonozzi@osfhealthcare.org.