

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOSPITAL PROVIDER
COMPLIANCE AUDIT:
ST. JOSEPH'S HOSPITAL
HEALTH CENTER**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



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

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Office of Inspector General

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Report in Brief

Date: December 2021

Report No. A-02-20-01004

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. We selected St. Joseph's Hospital Health Center (the Hospital) for a compliance audit through the use of computer matching, data mining, and data analysis techniques, and in consultation with another OIG component that categorized the Hospital as being a high risk for noncompliance based upon its refusal to enter into a Corporate Integrity Agreement after settling two False Claims Act cases.

Our objective was to determine whether 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 \$50 million in Medicare payments to the Hospital for 9,742 claims that were potentially at risk for billing errors. We selected for audit a stratified random sample of 75 inpatient and 25 outpatient claims with payments totaling \$1.4 million for our 2-year audit period (July 1, 2017, through June 30, 2019).

We focused our audit on the risk areas that we identified as a result of prior OIG audits at other hospitals and an OIG analysis of the Hospital's Medicare inpatient and outpatient claims. We evaluated compliance with selected billing requirements and submitted records associated with them to a medical review contractor.

Medicare Hospital Provider Compliance Audit: St. Joseph's Hospital Health Center

What OIG Found

The Hospital complied with Medicare billing requirements for 94 of the 100 inpatient and outpatient claims we audited. However, the Hospital did not fully comply with Medicare billing requirements for the remaining six claims, resulting in overpayments of \$68,897 for the audit period. Specifically, five inpatient claims and one outpatient claim had billing errors.

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$389,000 for the audit period. As of the publication of this report, this amount included claims outside of the Medicare 4-year claim-reopening period.

What OIG Recommends and Hospital Comments

We recommend that the Hospital: (1) refund to the Medicare contractor \$389,000 in estimated overpayments for the audit period for the claims that it incorrectly billed that are within the 4-year claim 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 partially disagreed with our first recommendation, stated that it complied with our second recommendation, and contended that it did not need to implement our third recommendation. Additionally, the Hospital took issue with our sampling and estimation methods.

After reviewing the Hospital's comments, we maintain that our findings and recommendations are valid. We carefully considered the Hospital's comments on our sampling and estimation methods, and we maintain that our statistical approach resulted in a statistically valid and reasonably conservative estimate of the amount overpaid by Medicare to the Hospital. While the Hospital believes it complied with the 60-day rule and contends that it does not need additional internal controls, we disagree with the Hospital's assertion that it complied with its obligation to repay claims pursuant to this rule and maintain that it should strengthen its controls to ensure compliance with Medicare requirements.

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INTRODUCTION

WHY WE DID THIS AUDIT

This audit is part of a series of hospital compliance audits. 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. We selected St. Joseph's Hospital Health Center (the Hospital) for a compliance audit through the use of computer matching, data mining, and other data analysis techniques, and in consultation with another Office of Inspector General (OIG) component that categorized the Hospital as being a high risk for noncompliance based upon its refusal to enter into a Corporate Integrity Agreement (CIA) after settling two False Claims Act cases.¹

OBJECTIVE

Our objective was to determine whether the Hospital complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims from July 1, 2017, through June 30, 2019.

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.

¹ Parties (which can be individuals or entities) are categorized as "high risk" because they pose a significant risk to Federal healthcare programs and beneficiaries. This is because, although OIG determined that these parties needed additional oversight, they refused to enter CIAs sufficient to protect Federal healthcare programs. More information on OIG's Fraud Risk Indicator and risk categories can be found at: <https://oig.hhs.gov/fraud/fraud-risk-indicator/>.

Hospital Outpatient Prospective Payment System

Under the outpatient prospective payment system, 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.² All services and items within an APC group are comparable clinically and require comparable resources.

Hospital Claims at Risk for Incorrect Billing

Previous OIG audits at other hospitals identified types of claims at risk for noncompliance. Out of the areas identified as being at risk, as well as other areas we identified for this provider,³ we focused our audit on the following:

- inpatient hospital-acquired conditions and present on admission indicators (adverse events),
- inpatient claims billed with DRG codes that have high Comprehensive Error Rate Testing (CERT) error rates,⁴
- inpatient high-severity level DRG codes,
- inpatient mechanical ventilation,
- inpatient claims paid in excess of charges,
- inpatient same day discharge and readmit,
- inpatient claims paid in excess of \$150,000,
- inpatient DRG 003 (hospital-specific outlier code),

² The health care industry uses HCPCS codes to standardize coding for medical procedures, services, products, and supplies.

³ As a result of the Hospital's refusal to enter into a CIA, we conducted an analysis to identify high-risk areas not identified in the previous OIG audits as being at risk. We identified DRG and HCPCS codes for which the Hospital's Medicare reimbursements were significantly greater than similar hospitals in New York or substantially increased between calendar years 2013 through 2016. These additional risk areas are noted as "hospital-specific outlier codes."

⁴ CMS calculates the Medicare fee-for-service improper payment rate through the CERT program. Each year, the CERT program evaluates a statistically valid stratified random sample of claims to determine whether they were paid properly under Medicare coverage, coding, and billing rules. Based on our analysis of CERT data, we have identified nine DRGs that are most at risk for billing errors: 149, 312, 313, 518, 519, 520, 742, 947, and 948.

- inpatient DRG 219 (hospital-specific outlier code),
- inpatient DRG 470 (hospital-specific outlier code),
- outpatient bypass modifiers,
- outpatient surgeries billed with units greater than one,
- outpatient claims paid in excess of charges,
- outpatient skilled nursing facility (SNF) consolidated billing,
- outpatient claims paid in excess of \$25,000,
- outpatient annual wellness visits,
- outpatient HCPCS 33249 (hospital-specific outlier code),
- outpatient HCPCS 99285 (hospital-specific outlier code), and
- outpatient HCPCS C9600 (hospital-specific outlier code).

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.⁵

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 Social Security Act (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)).

⁵ 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.

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).⁶

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.⁷

The 6-year lookback period is not limited by OIG's audit period or restrictions on the Government's ability to reopen claims or cost reports. To report and return overpayments under the 60-day rule, providers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.⁸

St. Joseph's Hospital Health Center

The Hospital is a 451-bed hospital located in Syracuse, New York.⁹ According to CMS's National Claims History (NCH) database, Medicare paid the Hospital approximately \$263 million for about 29,000 inpatient and 79,000 outpatient claims from July 1, 2017, through June 30, 2019 (audit period).

HOW WE CONDUCTED THIS AUDIT

Our audit covered about \$50 million in Medicare payments to the Hospital for 9,742 claims that were potentially at risk for billing errors.¹⁰ We selected for audit a stratified random sample of

⁶ "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).

⁷ The Act § 1128J(d); 42 CFR §§ 401.301–401.305; and 81 Fed. Reg. 7654 (Feb. 12, 2016).

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

⁹ The Hospital is part of St. Joseph's Health, a regional nonprofit health care system that is a member of Trinity Health, a national health care system located in Livonia, Michigan.

¹⁰ Total Medicare payments to the Hospital for the audit period were \$49,998,993.

100 claims (75 inpatient and 25 outpatient) with payments totaling \$1,364,530. Medicare paid these 100 claims during our audit period.¹¹

We focused our audit on the risk areas identified as a result of prior OIG audits at other hospitals and an OIG analysis of the Hospital's Medicare inpatient and outpatient claims relative to similar hospitals in New York. We evaluated compliance with selected billing requirements and submitted all claims to an independent medical review contractor to determine whether the claim was supported by the medical record. This report focuses on selected risk areas and does not represent an overall assessment of all claims submitted by the Hospital for Medicare reimbursement.

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

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

FINDINGS

The Hospital complied with Medicare billing requirements for 94 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining six claims, resulting in overpayments of \$68,897 for the audit period. Specifically, five inpatient claims had billing errors, resulting in overpayments of \$68,748 and one outpatient claim had a billing error, resulting in an overpayment of \$149. These errors occurred primarily because the Hospital did not have adequate internal 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 \$389,973 for the audit period.¹² As of the publication of this report, this amount included claims outside of the 4-year claim reopening period.

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

¹¹ This audit period reflects the most recent data available at the start of this audit.

¹² To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 5 of the 75 inpatient claims that we reviewed.¹³ These errors resulted in overpayments of \$68,748.

Incorrectly Billed as Inpatient

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

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

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

For 5 of the 75 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. Specifically, our independent medical reviewers determined that there was insufficient medical documentation to support the medical necessity for inpatient hospital services. The Hospital’s utilization review program controls over inpatient admissions did not prevent these improper billings from occurring or subsequently detect these oversights. Hospital officials agreed with three of these errors but disagreed with the other two. For the errors the Hospital agreed with, Hospital officials identified the cause as human error and/or misunderstanding of the regulations. For the errors the Hospital disagreed with, Hospital officials did not provide a cause because they generally

¹³ The total number of billing errors associated with inpatient claims exceeds five because two claims contained more than one error.

contended that these claims met Medicare requirements. However, Hospital officials did not provide any additional information that would impact our finding.

Overpayments associated with the 5 claims that did not meet Medicare requirements totaled \$68,748.

Incorrectly Billed Diagnosis-Related Group Codes

The Act precludes payment to any provider without information necessary to determine the amount due the provider (§ 1815(a)). DRG codes are assigned to specific hospital discharges based on claims data submitted by hospitals (42 CFR § 412.60(c)), so claims data must be accurate. Consequently, the Manual states: “In order to be processed correctly and promptly, a bill must be completed accurately” (chapter 1, § 80.3.2.2).

For 2 of the 75 selected inpatient claims, the Hospital submitted claims to Medicare that were incorrectly coded, resulting in incorrect DRG payments to the Hospital. Specifically, certain diagnosis codes were not supported by the medical records. In addition, the medical records for both claims did not support the necessity for inpatient hospital services.

Our independent medical reviewers determined that the medical record did not contain documentation to support the coding of the patient's diagnoses used to substantiate the DRGs. The Hospital's training of coding staff in the proper use of diagnosis codes and its clinical documentation improvement department's checks over DRG assignments did not prevent these improper billings from occurring or subsequently detect these oversights. Hospital officials agreed with these errors and identified the cause as human error.

Overpayments associated with these two claims that did not meet Medicare requirements totaled \$19,538.¹⁴

BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 1 of the 25 outpatient claims that we reviewed. This error resulted in an overpayment of \$149.

Incorrectly Billed Healthcare Common Procedure Coding System Codes

The Act precludes payment to any provider without information necessary to determine the amount due the provider (§ 1833(e)).

The Manual states that acute-care hospitals and long-term care hospitals are required to report HCPCS codes (chapter 4, § 20.1). HCPCS codes are also required of rehabilitation hospitals,

¹⁴ The overpayments associated with these errors were not counted in our statistical estimate because these were secondary errors.

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. In addition, the Manual states: “In order to be processed correctly and promptly, a bill must be completed accurately” (chapter 1, § 80.3.2.2).

For 1 of the 25 selected outpatient claims, the Hospital submitted a claim to Medicare Part B with an incorrect HCPCS code that was not supported by the medical record.

Our independent medical reviewers determined that the medical record did not contain documentation supporting a distinct procedural service that was separate from other services billed on the same claim. The Hospital's training of coding staff in the proper use of procedure codes and its claims' software edits did not prevent this improper billing from occurring or subsequently detect the oversight. While Hospital officials agreed with this error and identified the cause as human error, it contended that this claim was underpaid because it did not bill for additional units for a different HCPCS code on the same claim. We reviewed documentation to determine whether the services were supported as billed but did not determine whether the hospital was entitled to payment for services that it did not bill.

The overpayment associated with this claim that did not meet Medicare requirements totaled \$149.

OVERALL ESTIMATE OF OVERPAYMENTS

The overpayments on the six sampled claims that did not fully comply with Medicare billing requirements totaled \$68,897. On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$389,973 for the audit period. As of the publication of this report, this amount included claims outside of the Medicare 4-year claim-reopening period.

RECOMMENDATIONS

We recommend that St. Joseph's Hospital Health Center:

- refund to the Medicare contractor \$389,973 in estimated overpayments for the audit period for claims that it incorrectly billed that are within the 4-year claim reopening period;¹⁵
- based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule¹⁶ and identify any of those returned overpayments as having been made in accordance with this recommendation; and
- strengthen internal controls by:
 - strengthening procedures to verify that all inpatient beneficiaries meet Medicare requirements for inpatient hospital services,
 - strengthening processes to ensure that diagnosis codes and HCPCS codes are supported in the medical records, and
 - providing additional training to coding staff on DRG and HCPCS code assignments.

HOSPITAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Hospital partially disagreed with our first recommendation, stated that it complied with our second recommendation, and contended that it did not need to implement our third recommendation. We summarized the Hospital's objections and provided our response below. After review and consideration of the Hospital's comments, we maintain that our findings and recommendations are valid.

¹⁵ OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a Medicare Administrative Contractor or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

¹⁶ 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.

HOSPITAL COMMENTS

The Hospital agreed with our determinations for three of the six sampled claims that we determined did not fully comply with Medicare billing requirements and stated that it has initiated steps to refund \$52,915 in associated overpayments to its Medicare contractor. However, the Hospital disagreed with our determinations for the remaining three sampled claims and stated that it intends to exercise its Medicare administrative appeal rights as they relate to these claims.

For one of the three claims for which the Hospital disagreed with our determinations, the Hospital agreed with the error but stated that, if the outpatient claim had been properly coded, the Hospital would have received a higher reimbursement than what it received for the claim. Specifically, the Hospital asserted that it provided but did not bill for additional services on the date of the sampled claim. Had it billed Medicare for these services, the Hospital asserted that a payment would have offset the overpayment we identified and resulted in an underpayment. The Hospital stated that underpayments—not only overpayments—should be included in OIG’s extrapolation and referenced a newsletter article describing a Department of Health and Human Services, Office of Medicare Hearings and Appeals administrative law judge’s decision related to underpayments in statistical sampling methodologies to support its position.¹⁷ Additionally, for two inpatient claims, the Hospital disagreed with our determinations and stated that there was a reasonable expectation that the associated beneficiary would require hospital care that would span two midnights; therefore, the claims met medical necessity requirements.

In addition, the Hospital contended that extrapolation was inappropriate because CMS policies prohibit Medicare contractors from using this method to estimate overpayments unless there is a sustained or high level of payment error or there is a failure of documented educational interventions. The Hospital acknowledged that these policies are not binding on OIG; however, it believes the Medicare contractor responsible for processing any associated overpayments connected to this audit is subject to these policies. The Hospital further stated that extrapolation is unwarranted due to the “highly fact-dependent, individualized determinations of medical necessity” at the time services were provided. The Hospital also contended that extrapolation is inappropriate until a final appeals determination is made with respect to the three disputed claims, and that the number of errors that it agrees with did not justify the use of extrapolation. Further, the Hospital requested that OIG remove three claims that are beyond the 4-year reopening period from our estimate of overpayments prior to issuance of the final report because, according to the Hospital, including amounts that are not subject to repayment inappropriately risks damaging the Hospital’s reputation.

The Hospital stated that 1 of the 100 claims in our statistical sample (one that we found to have been claimed in error) was reimbursed under an alternative payment model (APM) sponsored

¹⁷ Health Care Compliance Association, *Report on Medicare Compliance*, Volume 30, Number 25 (July 12, 2021).

by CMS.¹⁸ The Hospital stated that it does not contend that claims related to Medicare APMs are not subject to OIG audits. However, it asserted that the claims should be excluded from any overpayment determination or extrapolation of estimated overpayments because CMS reconciled the claims.

The Hospital believes it demonstrated reasonable due diligence and complied with its obligation to repay claims pursuant to the 60-day rule because it: 1) conducted a thorough review of the medical records for the six claims we found to have been billed in error and determined that, with the exception of three claims it agrees were billed erroneously, the associated services were medically necessary and appropriately billed; 2) believes the audit findings represent individualized, non-systemic errors that do not indicate further errors in the population; and 3) is refunding \$52,915 for the three uncontested claims.

Finally, the Hospital stated that OIG's "nominal" audit findings do not point to any significant systemic Utilization Review, coding, or billing issues and the Hospital's integrity and compliance program is effective. The Hospital stated that it does not believe that specific additional changes to its internal controls are needed based on OIG's audit results and the Hospital's culture of performance improvement.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

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

Regarding the outpatient claim error for which the Hospital agreed with our determination but contended the claim was underpaid because the Hospital inadvertently did not include other services on the claim, inadvertent omission of line items on a claim is not an exception to the deadline for filing claims. Federal regulations state that claims must be filed no later than one calendar year after the date of the service (42 CFR § 424.44(a)). In this case, the date of service occurred more than 3 years ago, in August 2018. No exceptions apply¹⁹ and there is no provision for amending claims after the deadline due to inadvertence, nor is inadvertence good

¹⁸ Under an APM, providers submit claims for services and are paid by Medicare on a fee-for-service basis similar to traditional Medicare. However, CMS reconciles the total cost of care at the end of a designated time period to a target amount established by CMS.

¹⁹ 42 CFR §§ 424.44(b) and (e)

cause for reopening claims for revision or adjustment (42 CFR § 405.986).²⁰ Moreover, the Hospital’s comments regarding our sampling methodology do not apply to the OIG.²¹ Further, the OMHA decision referenced by the Hospital states that unpaid or zero-paid service lines cannot be removed from the population. The case dealt with removing service lines that had been included in a claim. The OMHA decision does not state that Medicare contractors performing medical review and extrapolating errors must create claims or line items (e.g., unbilled HCPCS codes) not submitted by the provider. When an extrapolation is used, OIG projects only to the frame from which the sample was drawn. Given that the sampling frame for this audit consisted of processed, paid Medicare claims, it would be inappropriate to include in the extrapolation any amounts not previously submitted by the provider on a claim.

Regarding the Hospital’s comments about OIG’s use of extrapolation, we note—just as the Hospital noted—that the requirement that a determination of a sustained or high level of payment error must be made before extrapolation applies only to Medicare contractors.^{22, 23} Further, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.²⁴ This is true even when extrapolating medical necessity errors, because the Hospital has the opportunity to

²⁰ CMS explains in guidance: “If a provider fails to include a particular item or service on its initial claim, an adjustment submission to include such an item(s) or service(s) is not permitted after the expiration of the time limitation for filing of the initial claim. There is no longer timely filing period for adjustments” (Medicare Claims Processing Manual, ch. 1, § 70.5).

²¹ We note that, even under provisions detailed in CMS’s Medicare Program Integrity Manual (PIM), the population and sampling frame cover claims or line items (ch. 8, § 8.4.3.2). For Part B claims, the population shall consist of fully and partially paid claims submitted by the provider and may include claims for which no payment was made (PIM, ch. 8, § 8.4.3.2.1.B). There is nothing in the PIM about including claims or line items not submitted to a MAC for payment.

²² The Social Security Act § 1893(f)(3) and CMS, Medicare Program Integrity Manual, Pub. No. 100-08, chapter 8, § 8.4 (effective January 2, 2019).

²³ We also dispute the Hospital’s assertion that the Medicare contractor charged with processing any associated overpayments connected to this audit is subject to the CMS policies it cited. These policies prohibit a Medicare contractor from using extrapolation in its own audits unless there is a sustained or high level of payment error or there is a failure of documented educational interventions. The Medicare contractor is not subject to such limitations in the adjudication of an OIG audit.

²⁴ See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

challenge the medical necessity determinations and extrapolation on appeal.^{25, 26} Moreover, the legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.²⁷ We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. The statistical lower limit that we use for our recommended recovery represents a conservative estimate of the overpayment that we would have identified if we had reviewed each and every claim in the sampling frame. The conservative nature of our estimate is not changed by the nature of the errors identified in this audit.

Regarding the Hospital's request that we remove claims that are beyond the 4-year reopening period from our estimate of overpayments, we note we are recommending that the Hospital refund only the estimated overpayments for incorrectly billed claims that are within the reopening period. Our findings are supported by the legal criteria we have cited and by our independent medical review contractor's determinations. Further, we are obligated by auditing standards to report our findings as they relate to our audit objective.

Regarding the Hospital's assertion that our reported errors and estimated overpayment should exclude claims reimbursed under CMS-sponsored APMs because CMS reconciled these claims, we note that the sampled claims were paid under the Medicare fee-for-service payment method; therefore, they are subject to OIG review. Further, CMS guidance states that providers participating in APMs are subject to the existing level of oversight from other review programs, including OIG reviews.²⁸ In addition, CMS's APM participation agreements state that none of the provisions of the agreements limit or restrict OIG's authority to audit, evaluate, investigate, or inspect APM participants and preferred providers.

Regarding the Hospital's comments about its compliance with the 60-day rule, we reiterate that the rule does not apply to any overpayments that are both within our sampling frame and

²⁵ As we describe in footnote 15, OIG audit recommendations do not represent final determinations by Medicare. Potential overpayments identified in OIG reports based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

²⁶ We note that the court cases cited by the Hospital in its assertion that extrapolation of medical necessity determinations are unwarranted are related to False Claims Act cases that do not apply to OIG audit recommendations and CMS recoveries arising from OIG audits.

²⁷ See *John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at *34-35 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634-37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

²⁸ CMS Announcement *Reducing Medical Record Review for Clinicians Participating in Certain Advanced Alternative Payment Models*, Available online at: <https://www.cms.gov/newsroom/fact-sheets/reducing-medical-record-review-clinicians-participating-certain-advanced-alternative-payment-models>.

refunded based upon the extrapolated overpayment amount. Pursuant to the 60-day rule, the Hospital must exercise reasonable diligence to identify overpayments during a 6-year lookback period that is not limited to our audit period. Therefore, we disagree with the Hospital's assertion that it complied with its obligation to repay claims pursuant to this rule and maintain that our second recommendation is valid.

Finally, while the Hospital contends that it does not need additional internal controls, we maintain that it should strengthen its controls to ensure compliance with Medicare requirements.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$49,998,993 in Medicare payments to the Hospital for 9,742 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 claims (75 inpatient and 25 outpatient) with payments totaling \$1,364,530. Medicare paid these 100 claims from July 1, 2017, through June 30, 2019 (audit period).

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

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

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

- met with Hospital officials to discuss the Hospital's internal controls for compliance with Medicare billing requirements;
- reviewed the Hospital's policies and procedures for inpatient admissions and assigning DRG and HCPCS codes for Medicare claims;
- reviewed a stratified random sample of 75 inpatient claims and 25 outpatient claims to determine if claims were properly billed and reimbursed; and
- discussed with Hospital officials the causes of the identified errors.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- completed an internal control assessment to document the Hospital's internal control structure;

- extracted the Hospital’s inpatient and outpatient paid claims data from CMS’s NCH database for the audit period;²⁹
- used computer matching, data mining, and analysis techniques to identify claims potentially at risk for noncompliance with selected Medicare billing requirements within our audit period;
- selected a stratified random sample of 75 inpatient claims and 25 outpatient claims totaling \$1,364,530 for detailed review (Appendices B and C);
- 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;³⁰
- 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.

²⁹ Specifically, we extracted data for our audit period from databases of claims for the period January 1, 2017, through August 31, 2019.

³⁰ The Hospital declined our request and cited limited staff resources to conduct its own review.

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

Our sampling frame contained 9,742 Medicare paid claims in 19 high-risk areas totaling \$49,998,993 from which we selected our sample (Table 1).³¹ The sampling frame included claims:

- with certain discharge status and diagnosis codes,
- with specific DRG and HCPCS codes,
- with payments greater than \$0, and
- not under review by the Recovery Audit Contractor as of November 4, 2019.

We assigned each claim that appeared in multiple risk areas to just one area on the basis of the following hierarchy: Inpatient Hospital-Acquired Conditions and Present on Admission Indicators (Adverse Events), Inpatient claims billed with DRG codes that have high CERT error rates, Inpatient Claims Billed with High-Severity Level DRGs, Inpatient Mechanical Ventilation Claims, Inpatient Claims Paid in Excess of Charges, Inpatient Same Day Discharge and Readmit, Inpatient Claims Paid in Excess of \$150,000, Inpatient DRG 003 (Hospital-Specific Outlier Code), Inpatient DRG 219 (Hospital-Specific Outlier Code), Inpatient DRG 470 (Hospital-Specific Outlier Code), Outpatient Claims with Bypass Modifiers, Outpatient Surgeries Billed with Units Greater than One, Outpatient Claims Paid in Excess of Charges, Outpatient SNF Consolidated Billing Claims, Outpatient Claims Paid in Excess of \$25,000, Outpatient Annual Wellness Visits, Outpatient HCPCS 33249 (Hospital-Specific Outlier Code), Outpatient HCPCS 99285 (Hospital-Specific Outlier Code), and Outpatient HCPCS C9600 (Hospital-Specific Outlier Code).

³¹ The sampling frame contained the totality of sample units from which the sample was drawn.

Table 1: Risk Areas

Medicare Risk Area³²	Frame Size	Value of Frame
1. Inpatient Hospital-Acquired Conditions and Present on Admission Indicators (Adverse Events)	877	\$10,615,193
2. Inpatient claims billed with DRG codes that have high CERT error rates	213	1,049,168
3. Inpatient Claims Billed with High-Severity Level DRGs	419	4,547,455
4. Inpatient Mechanical Ventilation Claims	2	73,752
5. Inpatient Claims Paid in Excess of Charges	38	801,965
6. Inpatient Same Day Discharge and Readmit	2	11,300
7. Inpatient Claims Paid in Excess of \$150,000	1	151,063
8. Inpatient DRG 003 (Hospital-Specific Outlier Code)	43	3,702,399
9. Inpatient DRG 219 (Hospital-Specific Outlier Code)	52	2,642,953
10. Inpatient DRG 470 (Hospital-Specific Outlier Code)	725	8,748,467
11. Outpatient Claims with Bypass Modifiers	331	240,447
12. Outpatient Surgeries Billed with Units Greater than One	1	9,125
13. Outpatient Claims Paid in Excess of Charges	53	250,242
14. Outpatient SNF Consolidated Billing Claims	17	1,452
15. Outpatient Claims Paid in Excess of \$25,000	250	6,990,724
16. Outpatient Annual Wellness Visits	9	1,148
17. Outpatient HCPCS 33249 (Hospital-Specific Outlier Code)	0	0 ³³
18. Outpatient HCPCS 99285 (Hospital-Specific Outlier Code)	6,225	5,750,395
19. Outpatient HCPCS C9600 (Hospital-Specific Outlier Code)	484	4,411,744
Total	9,742	\$49,998,993³⁴

SAMPLE UNIT

The sample unit was a Medicare paid claim.

³² We refer to risk areas 1 through 7 as “general inpatient risk areas” and risk areas 8 through 10 as “hospital-specific inpatient risk areas.”

³³ All claims in risk area 17 were removed due to their presence in risk area 15.

³⁴ Individual Medicare risk area values do not add up to the total amount due to rounding.

SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified random sample. We stratified the sampling frame into six strata on the basis of claim type, relative risk of improper payment based on OIG’s analysis of the Hospital’s reimbursements and previous OIG audit work and claims paid amount. Strata 1, 2 and 3 include all general inpatient risk area claims separated by paid amount,³⁵ stratum 4 includes all hospital-specific inpatient risk area claims, and strata 5 and 6 include all outpatient claims from risk areas 11 through 19 from Table 1 separated by paid amount.³⁶ All claims were unduplicated, appearing in only one risk area and only once in the entire sampling frame.

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

Table 2: Claims by Stratum

Stratum	Claims Type	Frame Size (Claims)	Value of Frame	Sample Size
1	Inpatient General Risk Areas Claims, Lower Dollar Claims	904	\$5,690,739	20
2	Inpatient General Risk Areas Claims, Moderate Dollar Claims	474	6,150,700	20
3	Inpatient General Risk Areas Claims, Higher Dollar Claims	174	5,408,458	15
4	Inpatient Hospital-Specific Risk Area Claims	820	15,093,819	20
5	Outpatient Risk Areas Claims, Lower Dollar Claims	6,618	6,036,758	15
6	Outpatient Risk Areas Claims, Higher Dollar Claims	752	11,618,519	10
	Total	9,742	\$49,998,993	100

SOURCE OF RANDOM NUMBERS

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

³⁵ Stratum 1 includes claims with total payments less than \$9,916 (lower dollar claims), stratum 2 includes claims with total payments greater than or equal to \$9,916 or less than \$20,130 (moderate dollar claims), and stratum 3 includes claims with total payments greater than or equal to \$20,130 (higher dollar claims).

³⁶ Stratum 5 includes claims with total payments less than \$6,972 (lower dollar claims) and stratum 6 includes claims with total payments greater than or equal to \$6,972 (higher dollar claims).

METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the claims within strata 1 through 6. 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 Details and 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	904	\$5,690,739	20	\$ 107,208	2	\$7,293
2	474	6,150,700	20	240,908	1	12,119
3	174	5,408,458	15	535,491	2	49,336
4	820	15,093,819	20	272,539	0	0
5	6,618	6,036,758	15	14,952	1	149
6	752	11,618,519	10	193,431	0	0
Total	9,742	\$49,998,993	100	\$1,364,530³⁷	6	\$68,897

ESTIMATES

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

Point estimate	\$1,254,921
Lower limit	389,973
Upper limit	2,119,869

³⁷ Individual stratum values do not add up to the total amount due to rounding.

APPENDIX D: RESULTS OF AUDIT BY RISK AREA

Table 4: Sample Results by Risk Area

Risk Area	Selected Claims	Value of Selected Claims	Claims With Overpay-ments	Value of Overpay-ments
Inpatient Hospital-Acquired Conditions and Present on Admission Indicators (Adverse Events)	39	\$ 507,720	2	\$32,949
Inpatient claims billed with DRG codes that have high CERT error rates	5	20,277	0	0
Inpatient Claims Billed With High-Severity Level DRGs	7	104,547	2	7,293
Inpatient Mechanical Ventilation Claims	1	40,003	0	0
Inpatient Claims Paid in Excess of Charges	2	59,998	1	28,506
Inpatient Claims Paid in Excess of \$150,000	1	151,063	0	0
Inpatient DRG 003 (Hospital-Specific Outlier Code)	1	6,632	0	0
Inpatient DRG 219 (Hospital-Specific Outlier Code)	1	49,069	0	0
Inpatient DRG 470 (Hospital-Specific Outlier Code)	18	216,838	0	0
Inpatient Totals	75	\$1,156,147	5	\$68,748
Outpatient Claims with Bypass Modifiers	1	\$308	0	0
Outpatient Claims Paid in Excess of \$25,000	6	160,101	0	0
Outpatient HCPCS 99285 (Hospital-Specific Outlier Code)	14	14,643	1	\$149
Outpatient HCPCS C9600 (Hospital-Specific Outlier Code)	4	33,330	0	0
Outpatient Totals	25	\$208,383³⁸	1	\$149
Inpatient and Outpatient Totals	100	\$1,364,530	6	\$68,897

³⁸ Individual risk area values of selected claims do not add up to the total amount due to rounding.

Notice: Table 4 (previous page) illustrates the results of our audit by risk area. In it, we have organized inpatient and outpatient claims by the risk areas we reviewed. However, we have organized this report's findings by the types of billing errors we found at the Hospital. Because we have organized the information differently, the information in the individual risk areas in this table does not match precisely with this report's findings.

APPENDIX E: HOSPITAL COMMENTS



September 16, 2021

Brenda M. Tierney
Regional Inspector General for Audit Services
Office of Audit Services, Region II
26 Federal Plaza, Room 3900
New York, NY 10278

RE: St. Joseph's Hospital Health Center Compliance Audit, OIG Report No: A-02-20-01004

Dear Ms. Tierney:

St. Joseph's Hospital Health Center ("St. Joseph's Health"), a Health Ministry of Trinity Health, appreciates the opportunity to submit this letter in response to the draft findings of the Department of Health and Human Services Office of Inspector General ("HHS OIG") hospital compliance audit of St. Joseph's Health. We understand the audit was conducted as part of a series of hospital compliance audits performed in recent years by HHS OIG focusing on areas deemed by HHS OIG to be at-risk of noncompliance with Medicare billing requirements and because St. Joseph's Health declined to enter into a Corporate Integrity Agreement. We appreciate the opportunity to demonstrate the strengths and effectiveness of both our Medicare billing practices and our Integrity and Compliance Program. St. Joseph's Health and Trinity Health take seriously our commitment to compliance and to excellence in all aspects of the care we provide, including billing and reimbursement matters.

HHS OIG's preliminary findings are contained in the draft report dated August 3, 2021 (the "Draft Audit Report"). HHS OIG's stated objective of the audit was to determine whether St. Joseph's Health complied with Medicare requirements for inpatient and outpatient services for 100 selected claims paid from 7/1/17 to 6/30/2019.

The principal findings contained in the Draft Audit Report are as follows:

- St. Joseph's Health complied with Medicare billing requirements for 94 of the 100 inpatient and outpatient claims reviewed.
- St. Joseph's Health did not fully comply with Medicare billing requirements for the remaining 5 inpatient claims and 1 outpatient claim reviewed, resulting in overpayments of \$68,897. Based on this determination, HHS OIG calculated an extrapolated estimated overpayment of approximately \$389,000. HHS OIG noted this amount includes claims outside of the 4-year reopening period and that the final determination of an overpayment is the responsibility of the Centers for Medicare and Medicaid Services ("CMS").

- HHS OIG recommends St. Joseph’s Health 1) refund to the Medicare contractor the portion of the \$389,000 in estimated overpayments that are within the 4-year reopening period¹; 2) exercise reasonable diligence to identify, report and return any overpayments in accordance with the 60-Day Repayment Rule² and identify any of those returned overpayments as having been made in accordance with this recommendation and 3) strengthen its controls to ensure full compliance with Medicare requirements.

As further described herein, St. Joseph’s Health disagrees with two (2) of the five (5) HHS OIG inpatient audit findings in the Draft Audit Report. We agree with the single outpatient finding but believe that if the claim had been properly coded based on the documentation submitted to the HHS OIG contracted medical reviewers St. Joseph’s Health should have received more reimbursement than the original payment, not less. In other words, St. Joseph’s Health was underpaid not overpaid.

St. Joseph’s Health will be contesting and appealing 3 out of the 6 allegedly incorrectly billed claims. In addition another 3 out of the 6 claims are not within the 4-year claim reopening period and therefore should be excluded from the final extrapolation. Further HHS OIG excluded a known underpayment from the calculation. Finally, St. Joseph’s Health contends it is inappropriate to perform an extrapolation in determining an overpayment in this matter.

Set forth below is a description of St. Joseph’s Health’s assessment of HHS OIG’s findings by each audit area.

Inpatient Claims

For 5 acute inpatient claims included in the audit sample, HHS OIG determined that St. Joseph’s Health incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for inpatient status, and thus should have been billed as outpatient or outpatient with observation services. St. Joseph’s Health disagrees with HHS OIG’s findings and asserts that medical necessity for inpatient admission, including compliance with CMS’ Two Midnight Rule requirements, is present in two (2) of the five (5) cases.

St. Joseph’s Health believes HHS OIG’s contracted medical reviewers erred in concluding that medical necessity was not met in two of the five cases. In both cases, St. Joseph’s Health contends that there is evidence of a reasonable expectation that the patient’s condition and comorbidities required hospital care that would span at least two midnights. St. Joseph’s Health was provided a “Summary of Errors” and “Medical Review Determinations Letters” on April 7, 2021 outlining the HHS OIG contracted medical reviewer’s rationale but St. Joseph’s Health was not afforded an opportunity to rebut or discuss the claims with the representatives of HHS OIG’s contracted medical reviewers after receiving their findings. Therefore, St. Joseph’s Health will pursue all available Medicare administrative appeal rights related to the two (2) denied inpatient claims and is confident they will be overturned upon appeal.

Inpatient Alternative Payment Models

¹ HHS OIG acknowledges that its recommendations do not represent final determinations by Medicare, and that CMS, acting through a Medicare administrative contractor or other contractor, will determine whether overpayments exist, will recoup any overpayments consistent with its policies and procedures, and that providers have a right to appeal those determinations.

² The 60-Day Repayment Rule is codified at 1128J(d) of the Social Security Act and 42 C.F.R. Part 401, Subpart D.

As discussed with HHS OIG at the April 29, 2021 Exit Conference, St. Joseph's Health participated in the CMS' Bundled Payment for Care Improvement Initiative ("BPCI"); a Medicare Alternative Payment Model (APM) sponsored by CMS during 2017 – 2019, the time period covered by the HHS OIG audit. The HHS OIG audit sample included a claim with an alleged inpatient error for a Medicare beneficiary who received a service at St. Joseph's Health that was included in a BPCI bundled episode of care.

BPCI participants such as St. Joseph's Health assume greater financial risks for the total cost and outcomes of care provided to Medicare beneficiaries over the 90-days of continuous care for a bundled payment episode. Providers submit claims for services and are paid by Medicare on a fee-for-service basis, like traditional Medicare. However, CMS reconciles the total cost of care at the end of the designated time period to a target amount established by CMS. Participants that are successful in delivering coordinated, high quality care at lower costs are rewarded by sharing in the savings achieved by Medicare. Participants are also responsible for financial losses if the total cost of care provided to Medicare beneficiaries exceeds the established targets. CMS reconciles total costs to targeted costs at the end of each respective performance period, with settlement of any net amounts due to or owed by participants.

St. Joseph's Health does not contend that claims related to Medicare APMs are not subject to HHS OIG audit oversight. However, St. Joseph's Health does believe these claims should be excluded from any overpayment determination and extrapolation of estimated overpayment as reconciliation for these APM models has already occurred with CMS. St. Joseph's Health believes that it is inappropriate for HHS OIG to assess overpayments on claims covered by an advanced APM program that were already subject to separate reconciliation by CMS. St. Joseph's Health will pursue all available Medicare administrative appeal rights related to any denied claims and/or extrapolation involving BPCI models.

It is important to note that CMS has previously stated that providers participating in advanced APMs (those APMs that feature significant upside and downside financial risk) are considered "lower risk" to the Medicare Trust Fund and previously directed CMS contractors to consider health care providers participating in advanced APMs to be "low priority" for CMS audits³. The reason for CMS' position is understandable: the potential impact of any billing errors by a health care provider participating in an advanced APM are largely nullified in a total cost of care financial model where providers like St. Joseph's Health bear the financial risks of any billing errors. In Advanced APMs, health care providers like St. Joseph's Health have no incentive to deliver anything but medically necessary and appropriate care to Medicare beneficiaries.

Inpatient Diagnosis-Related Group Coding

For 2 of the 75 sampled inpatient claims, HHS OIG determined that St. Joseph's Health used an incorrect secondary diagnosis code resulting in an incorrect MS DRG assignment and payment to the hospital. St. Joseph's Health agrees with HHS OIG's finding of a coding error for both claims. Our review found this error to be individualized, not systemic, and not indicative of further coding errors in the broader population of claims audited.

The inpatient status of both claims is discussed in the "Inpatient Claims" section above. Both claims were determined by the HHS OIG contracted medical reviewers and St. Joseph's Health to be incorrectly billed as

³ Centers for Medicare and Medicaid Services *Reducing Medical Record Review for Clinicians Participating in Certain Advanced Alternative Payment Models* Oct. 13, 2016. <https://www.cms.gov/newsroom/fact-sheets/reducing-medical-record-review-clinicians-participating-certain-advanced-alternative-payment-models>

Inpatient and included in that error rate. Outpatient claims are paid under the Outpatient Prospective Payment System and not under the Inpatient Prospective Payment System (MS DRGs) and therefore MS DRG assignment is not relevant. HHS OIG removed the reported overpayments associated with these errors from their statistical estimate because these were secondary errors.

Outpatient Claims

HHS OIG determined that St. Joseph's Health incorrectly billed Medicare for 1 of 25 outpatient claims sampled in the audit. St. Joseph's Health agrees that HCPCS code 96360 Intravenous infusion, hydration; initial, 31 minutes to 1 hour was incorrectly reported on the claim for an overpayment of \$149.06. We also believe that based on the documentation provided to the HHS OIG contracted medical reviewers 8 units of HCPCS code 96361 Intravenous infusion, hydration; each additional hour was inadvertently left off the claim for an underpayment of (\$231.04). In total St. Joseph's Health was underpaid \$81.98 not overpaid.

St. Joseph's Health shared this information with HHS OIG on the "OIG Internal Controls Questionnaire" for sample S5-14 submitted on April 23, 2021 and during the April 29, 2021 Exit Conference but the extrapolation calculation was not adjusted.

St. Joseph's Health disputes that only HCPCS code overpayments should be used in the extrapolation calculation and not underpayments. Recent court decisions outlined in the "Report on Medicare Compliance Vol. 30, Number 25 July 12, 2021 reported that "an administrative law judge (ALJ) invalidated a Medicare auditor's statistical sampling method because it removed underpayments, and the chief statistician for a Medicare Administrative Contractor (MAC) came to a similar conclusion in an unrelated appeal." Which supports St. Joseph's Health this position related to extrapolation. Therefore, St. Joseph's Health will pursue its available Medicare administrative appeal rights.

Use of Extrapolation to Estimate \$389,000 Overpayment

In consideration of the disagreements with the audit findings as described herein, St. Joseph's Health believes it is inappropriate to perform an extrapolation. It should be noted that by law, Medicare contractors cannot use extrapolation unless 1) there is a sustained or high level of payment error, or 2) there is a failure of documented educational interventions.⁴ In the case of St. Joseph's Health, the Medicare contractor has not historically found a high level of payment errors with respect to Medicare hospital claims. Furthermore, HHS OIG has not alleged a sustained or high level of payment error or the failure of documented educational interventions with St. Joseph's Health. Therefore, we contend that it is inappropriate for HHS OIG to use extrapolation determined without that predicate. St. Joseph's Health acknowledges that CMS policies are not binding on HHS OIG. However, the Medicare contractor charged with the responsibility to process any associated overpayments connected to the HHS OIG audit is subject to CMS policies.

Extrapolation is allowed under the statute only if a final determination on the claims at issue demonstrates a high error rate. Such determination will only occur after St. Joseph's Health has exhausted its available Medicare administrative appeals for the disputed claims described herein. St. Joseph's Health's position is that since only 3 of the 100 claims involved errors this is an insufficient number of claims to justify use of extrapolation.

St. Joseph's Health believes extrapolation is particularly unwarranted due to the highly fact-dependent, individualized determinations of medical necessity with respect to a specific patient's clinical status at the time

⁴ Social Security Act, §1893(f)(3)

services were rendered, such as the findings made with respect to the hospital inpatient status claims. In potential False Claims Act liability situations, courts have found as follows with respect to the application of extrapolation to medical necessity questions:⁵

Because "each and every claim at issue [is] "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 case [is] not "suited for statistical sampling."

Similarly, St. Joseph's Health contends that questions of medical necessity pertaining to the inpatient admissions in HHS OIG's audit also require individualized determinations and the use of extrapolation is inappropriate.

St. Joseph's Health will appeal the use of extrapolation to determine estimated repayment liabilities based on claims denied for lack of medical necessity, the insignificant error rate and the exclusion of known underpayments. St. Joseph's Health is confident its appeal of the claims at issue through Medicare's administrative appeals process will ultimately result in favorable outcomes.

Response to Audit Recommendations

HHS OIG recommended that St. Joseph's Health refund to its Medicare contractor the portion of the \$389,000 extrapolated repayment that are within the 4-year reopening period. St. Joseph's Health requests HHS OIG to remove those claims that are beyond the 4-year reopening period from the repayment and extrapolated repayment amounts prior to issuance of the final audit report. To include amounts that will not be subject to repayment in a public report inappropriately risks damaging the reputation of St. Joseph's Health.

St. Joseph's Health agrees with HHS OIG's findings for the three (3) claims previously discussed herein and has initiated steps to refund the \$52,914.53 in total overpayments to its Medicare contractor. St. Joseph's Health disagrees with HHS OIG's audit findings for the remaining (3) claims and intends to pursue all available Medicare administrative appeals with respect to such denials. Furthermore, St. Joseph's Health contends that extrapolation of an error rate is inappropriate as explained previously and certainly not until a final determination is made with respect to the appealed claims.

HHS OIG also recommended that based on the results of the audit St. Joseph's Health exercise reasonable diligence to identify, report and return any overpayments in accordance with the 60-Day Repayment Rule and identify any of those returned overpayments as having been made in accordance with this recommendation. The 60-Day Repayment Rule requires repayment of overpayments within 60 days of the overpayment being "identified." Guidance implementing the 60-Day Repayment Rule requires providers to conduct reasonable due diligence to confirm or contest an audit's findings.⁶ St. Joseph's Health has conducted a thorough review of the medical records at issue and has determined, with the exception of the three claims referenced previously, the services were medically necessary and appropriately billed. St. Joseph's Health believes that the minimal findings indicate individualized, not systemic errors and are not indicative of further billing or coding errors in the broader population. Therefore, due to the positive audit findings, the refunding of the pending \$52,914.53 for the 3 uncontested claims and our review and appeal of the 3 denied claims, St. Joseph's Health has demonstrated exercise of reasonable due diligence and complied with the 60-Day Rule repayment obligations.

⁵ United States ex rel. Misty Wall v. Vista Hospice Care, Inc., 2016 WL 344983, at *12 (N.D. Tex. 2016)

⁶ 81 Fed. Reg. 7654, 7667 (Feb. 12, 2016)

HHS OIG further recommended St. Joseph's Health strengthen its controls to ensure full compliance with Medicare requirements. The nominal HHS OIG audit findings do not point to any significant systemic Utilization Review (UR), coding or billing issues at St. Joseph's Health. Rather, the HHS OIG's findings indicate that St. Joseph's Health has an effective Integrity and Compliance program. St. Joseph's Health always strives to ensure that all inpatient beneficiaries meet Medicare requirements for inpatient hospital services through its strong Utilization Review (UR) Program which reassesses and revises its policies and procedures on an on-going basis. St. Joseph's Health ensures it complies with laws, regulations, and Medicare policies related to Coding Practices through proper Coder Certification, routine, targeted and on-going education & training, a robust audit program, coding and billing claim edits and cross checks, collaboration with the Clinical Documentation Improvement team among other controls. Based on the favorable audit results and St. Joseph Health's culture of performance improvement we do not believe that specific additional changes are needed.

In conclusion, St. Joseph's Health agrees that three (3) of one hundred (100) claims were in error and is actively processing refunds with the MAC. It is St. Joseph's Health's reasonable assessment that each of these errors are unique and do not represent systemic errors or lack of controls. For the three (3) claims that remain, St. Joseph's Health will exercise its appeal rights for medical necessity of Part A stays for two (2) claims, and for the third claim, where St. Joseph's Health was underpaid and did not receive an overpayment. St. Joseph's Health will also include the extrapolation methodology in our appeal efforts

St. Joseph's Health appreciates the opportunity to provide its response to the Draft Audit Report. St. Joseph's Health takes its compliance efforts very seriously. We respectfully request HHS OIG's reconsideration of the initial findings and overpayment extrapolations contained in the Draft Audit Report.

Sincerely,

Kristin Dooley

Kristin Dooley
Director, Integrity & Compliance

(518) 935-8419
kristin.dooley@sjhsyr.org