

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOSPITAL PROVIDER
COMPLIANCE AUDIT:
VIRTUA OUR LADY OF LOURDES
HOSPITAL**

*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: May 2021

Report No. A-02-18-01018

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



Why OIG Did This Audit

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

Our objective was to determine whether Virtua Our Lady of Lourdes 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 \$20.5 million in Medicare payments to the Hospital for 1,200 claims that were potentially at risk for billing errors. We selected for audit a stratified random sample of 80 inpatient and 20 outpatient claims with payments totaling \$2 million for our 2-year audit period (January 1, 2016, through December 31, 2017).

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

Medicare Hospital Provider Compliance Audit: Virtua Our Lady of Lourdes Hospital

What OIG Found

The Hospital complied with Medicare billing requirements for 60 of the 100 inpatient and outpatient claims we audited. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 40 claims, resulting in overpayments of \$666,021 for the audit period. Specifically, 37 inpatient claims and 3 outpatient claims had billing errors.

On the basis of our sample results, we estimated that the Hospital received overpayments of approximately \$4.8 million 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 refund to the Medicare contractor the portion of the \$4.8 million in estimated overpayments for the audit period for the claims that it incorrectly billed that are within the reopening period; exercise reasonable diligence to identify, report, and return any additional similar overpayments received outside of our audit period, in accordance with the 60-day rule; and strengthen controls to ensure full compliance with Medicare requirements. The detailed recommendations are listed in the body of the report.

In written comments on our draft report, the Hospital generally disagreed with our recommended financial disallowance (first recommendation), including our statistical methods, stated that it complied with the 60-day rule referenced in our second recommendation, and contended that it did not need to implement our third recommendation (strengthen controls) because it does not believe that it needs additional internal controls.

After reviewing the Hospital's comments, we maintain that our findings and recommendations are valid. We carefully considered the Hospital's comments on our statistical methods, and we maintain that our statistical approach resulted in a legally valid and reasonably conservative estimate of the amount overpaid by Medicare to the Hospital. While the Hospital contends it does not need additional internal controls, we maintain that it should strengthen the controls it already has 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. 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 Virtua Our Lady of Lourdes 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 inpatient rehabilitation facilities. CMS implemented the payment system for cost-reporting periods

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

Hospital Outpatient Prospective Payment System

CMS implemented an outpatient prospective payment system (OPPS), which is effective for services furnished on or after August 1, 2000, for hospital outpatient services. Under the OPPS, Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification (APC). CMS uses Healthcare Common Procedure Coding System (HCPCS) codes and descriptors to identify and group the services within each APC group.¹ The HCPCS includes the American Medical Association's Current Procedural Terminology (CPT) codes for physician services and CMS-developed codes for certain nonphysician services.² 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:

- IRF claims,
- inpatient claims billed with Comprehensive Error Rate Testing (CERT) high-error rate DRG codes,³
- inpatient claims billed with high-severity- level DRG codes,
- inpatient mechanical ventilation claims,
- inpatient claims paid in excess of charges,
- outpatient claims paid in excess of \$25,000,

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

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

³ CMS calculates the Medicare Fee-for-Service improper payment rate through the CERT program. Each year, CERT evaluates a statistically valid stratified random sample of claims to determine whether they were paid properly under Medicare coverage, coding, and billing rules. Based on our analysis of CERT data, we have identified 10 DRGs that are most at risk for billing errors: 149, 312, 313, 518, 519, 520, 742, 743, 947, and 948.

- outpatient claims paid in excess of charges,
- outpatient bypass modifier claims,
- outpatient surgeries billed with units greater than one, and
- outpatient skilled nursing facility (SNF) consolidated billing.

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.⁴

Medicare Requirements for Hospital Claims and Payments

Medicare payments may not be made for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Act § 1862(a)(1)(A)). In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§§ 1815(a) and 1833(e)).

Federal regulations state that the provider must furnish to the Medicare contractor sufficient information to determine whether payment is due and the amount of the payment (42 CFR § 424.5(a)(6)).

Claims must be filed on forms prescribed by CMS in accordance with CMS instructions (42 CFR § 424.32(a)(1)). The *Medicare Claims Processing Manual*, Pub. No. 100-04 (the Manual), chapter 1, section 80.3.2.2, requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly. The Manual states that providers must use HCPCS codes for most outpatient services (chapter 23, § 20.3).⁵

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

⁴ 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.

⁵ “Under the hospital outpatient prospective payment system, predetermined amounts are paid for designated services furnished to Medicare beneficiaries. These services are identified by codes established under the Centers for Medicare & Medicaid Services Common Procedure Coding System (HCPCS)” 42 CFR § 419.2(a). Moreover, claims must be filed on forms prescribed by CMS in accordance with CMS instructions (42 CFR § 424.32(a)(1)).

(2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.⁶

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.⁷

Virtua Our Lady of Lourdes Hospital

The Hospital is a 325-bed hospital located in Camden, New Jersey.⁸ According to CMS's National Claims History (NCH) data, Medicare paid the Hospital approximately \$211 million for 11,027 inpatient and 57,066 outpatient claims from January 1, 2016, through December 31, 2017 (audit period).

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$20,509,958 in Medicare payments to the Hospital for 1,200 claims that were potentially at risk for billing errors. We selected for audit a stratified random sample of 100 claims (80 inpatient and 20 outpatient) with payments totaling \$2,003,998. Medicare paid these 100 claims during our audit period.⁹

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

⁶ The Act § 1128J(d); 42 CFR §§ 401.301–401.305; and 81 Fed. Reg. 7654 (Feb. 12, 2016).

⁷ 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.

⁸ During our fieldwork, the Hospital was acquired by Virtua Health and, as of October 2020, does business as Virtua Our Lady of Lourdes Hospital. The Hospital previously operated under the name Our Lady of Lourdes Medical Center and was part of the Trinity Health healthcare network. Per its transfer agreement with Virtua Health, Trinity Health retained responsibility for any overpayment liabilities arising from our audit.

⁹ This audit period reflects the most recent data available at the start of this audit.

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

FINDINGS

The Hospital complied with Medicare billing requirements for 60 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 40 claims, resulting in overpayments of \$666,021 for the audit period. Specifically, 37 inpatient claims had billing errors, resulting in overpayments of \$649,830 and 3 outpatient claims had billing errors, resulting in overpayments of \$16,191. These errors occurred primarily because the Hospital did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$4,765,305 for the audit period.¹⁰ 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.

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 37 of the 80 inpatient claims that we reviewed. These errors resulted in overpayments of \$649,830.

Incorrectly Billed Inpatient Rehabilitation Facility Claims

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

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

Federal regulations require that the patient’s medical record must contain certain documentation to ensure that the IRF coverage requirements are met. The record must include

¹⁰ 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.

(1) a comprehensive preadmission screening that is completed within the 48 hours preceding the admission, (2) a post-admission physician evaluation that is completed within 24 hours of admission and documents the patient's status on admission to the IRF, and includes a comparison with the information in the preadmission screening; and (3) an individualized overall plan of care that is completed within 4 days of admission to the IRF (42 CFR § 412.622 (a)(4)(i-iii)).

According to Federal regulations, the patient must require an interdisciplinary team approach to care, as evidenced by documentation in the medical record of weekly interdisciplinary team meetings. The meetings must be led by a rehabilitation physician, and further consist of a registered nurse, a social worker or case manager, and a licensed or certified therapist from each therapy discipline involved in treating the patient (42 CFR § 412.622(a)(5)(A)).¹¹

For 30 of the 80 selected inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for acute inpatient rehabilitation. Specifically, for 24 of the 30 claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet medical necessity requirements. IRF services for these beneficiaries were not reasonable and necessary because the 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. In addition, for 17 of the 30 incorrectly billed claims, the Hospital incorrectly billed IRF claims that did not meet Medicare documentation requirements.¹² For these claims, the medical record did not contain all required elements for the preadmission screening, post-admission physician evaluation, individualized overall plan of care, or interdisciplinary team meetings. The Hospital did not provide a cause for these errors because its officials contended that these claims met Medicare requirements. Furthermore, Hospital officials did not provide any additional information that would impact our finding.

As a result of these errors, the Hospital received overpayments of \$612,830.

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

¹² The total exceeds 30 because 11 claims contained both medical necessity and documentation errors.

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)). (This is commonly known as the Two-Midnight Rule.) 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 6 of the 80 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, the medical records did not support the necessity for inpatient hospital services. Hospital officials did not provide a cause for these errors because they generally contended that the claims met Medicare requirements. Furthermore, Hospital officials did not provide any additional information that would impact our finding.

As a result of these errors, the Hospital received overpayments of \$34,739.

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 1 of the 80 selected inpatient claims, the Hospital used an incorrect diagnosis code when it billed Medicare, resulting in an incorrect DRG payment to the Hospital. Hospital officials stated that the associated service was billed incorrectly but did not provide a cause.

As a result of the error, the Hospital received an overpayment of \$2,261.

BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 3 of the 20 outpatient claims that we reviewed. These errors resulted in overpayments of \$16,191.

Incorrectly Billed Modifiers

The Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§§ 1815(a) and 1833(e)). Claims must be filed on forms prescribed by CMS in accordance with CMS instructions (42 CFR § 424.32(a)(1)). Acute care hospitals are required to report HCPCS codes, of which CPT codes are a subset, on outpatient claims (the Manual, chapter 4, § 20.1),¹³ and providers are required to complete claims accurately so that Medicare contractors may process them correctly and promptly (the Manual, chapter 1, § 80.3.2.2).

“The ‘59’ modifier is used to indicate a distinct procedural service. This may represent a different session or patient encounter, different procedure or surgery, different site or organ system, separate incision/excision, or separate injury (or area of injury in extensive injuries)” (the Manual, chapter 23, § 20.9.1.1(B)).¹⁴

Effective January 1, 2015, CMS established four new HCPCS modifiers to define subsets of the “59” modifier. The four new HCPCS modifiers to selectively identify subsets of Distinct Procedural Services are: Modifier XE-Separate Encounter, Modifier XS-Separate Structure, Modifier XP-Separate Practitioner, and Modifier XU-Unusual Non-Overlapping Service. CMS will continue to recognize the “59” modifier, but providers should use one of the more descriptive modifiers when it is appropriate (CMS’s Pub. No. 100-20, One-Time Notification, Transmittal 1422, Change Request 8863, dated Aug. 15, 2014).

For 1 of 20 selected outpatient claims, the Hospital incorrectly billed Medicare Part B for a HCPCS code appended with the “59” modifier that was not separate from other services or procedures billed on the same claim. Hospital officials did not provide a cause for this error

¹³ “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)).

¹⁴ This manual provision was revised after our audit period by Change Request 10868, dated Dec. 28, 2018, and effective Jan. 30, 2019.

because they generally contended that this claim met Medicare requirements. Furthermore, Hospital officials did not provide any additional information that would impact our finding.

As a result of this error, the Hospital received an overpayment of \$113.

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)). 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 2 of the 20 selected outpatient claims, the Hospital submitted claims to Medicare with incorrect HCPCS codes that were not supported by the medical record. Hospital officials stated that the associated services were billed incorrectly but did not provide a cause.

As a result of these errors, the Hospital received overpayments of \$16,078.

OVERALL ESTIMATE OF OVERPAYMENTS

The combined overpayments on the 40 sampled claims that did not fully comply with Medicare billing requirements totaled \$666,021. On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$4,765,305 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 Virtua Our Lady of Lourdes Hospital:

- refund to the Medicare contractor the portion of the \$4,765,305 in estimated overpayments for the audit period for claims that it incorrectly billed that are within the 4-year reopening period;¹⁵

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.

- 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 controls to ensure that:
 - all IRF beneficiaries meet Medicare criteria for acute inpatient rehabilitation and all required documentation is included in the medical records,
 - all inpatient beneficiaries meet Medicare requirements for inpatient hospital services,
 - procedure, diagnosis, and HCPCS codes are supported in the medical records and staff are properly trained,
 - the use of bypass modifiers is supported in the medical records.

HOSPITAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

HOSPITAL COMMENTS

In written comments on our draft report, the Hospital generally disagreed with our first recommendation (financial disallowance), stated that it complied with the 60-day rule referenced in our second recommendation, and contended that it did not need to implement our third recommendation (strengthen controls) because it does not believe that it needs additional internal controls.

The Hospital agreed with our determinations for 4 of the 40 sampled claims that we determined did not fully comply with Medicare billing requirements and stated that it would initiate steps to refund the overpayments associated with the 4 sampled claims. However, the Hospital asserted that these errors were not indicative of further errors in the broader population of claims audited. The Hospital contended that it was inappropriate for OIG to use extrapolation to estimate the dollar amount associated with claims that the Hospital incorrectly billed because the Hospital intends to appeal our findings. Additionally, the Hospital stated that the number of errors that it agrees with did not justify the use of extrapolation. The Hospital also requested that OIG remove claims that are beyond the 4-year reopening period from our estimate of overpayments. According to the Hospital, to include amounts that will not be subject to repayment inappropriately risks damaging the Hospital's reputation.

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.

The Hospital stated that our medical review contractor's IRF medical necessity determinations are not supported by Medicare regulations or CMS policies. The Hospital also states that all inpatient admissions were medically necessary and complied with the Two-Midnight Rule. The Hospital also stated that, at an October 2019 meeting, it provided additional documentation related to our findings and expressed disappointment that the information was not shared with our independent medical review contractor and that we did not allow the Hospital an opportunity to discuss our audit findings with the contractor.

Finally, the Hospital asserted that 21 of the 100 claims in our statistical sample were reimbursed under alternative payment models (APMs) sponsored by CMS.¹⁷ The Hospital stated that it does not contend that these claims are not subject to OIG audits. However, it stated that the claims should be excluded from any overpayment determination or extrapolation of estimated overpayments because CMS reconciled the claims.

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 legally valid and reasonably conservative estimate of the amount overpaid by Medicare to the Hospital.

The requirement that a determination of a sustained or high level of payment error must be made before extrapolation applies only to Medicare contractors.¹⁸ Further, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.¹⁹ This is true even when extrapolating medical necessity errors, because the Hospital has the opportunity to challenge the medical necessity determinations and extrapolation on appeal.²⁰ Moreover, the legal standard for use

¹⁷ In both APMs, providers submit claims for services and are paid by Medicare on a fee-for-service basis similar to traditional Medicare. However, in both APMs, CMS reconciles the total cost of care at the end of a designated time period to a target amount established by CMS.

¹⁸ The Act § 1893(f)(3) and CMS, Medicare Program Integrity Manual, Pub. No. 100-08, chapter 8, § 8.4 (effective January 2, 2019).

¹⁹ 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 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

²⁰ 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.

of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.²¹ 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.

Contrary to the Hospital's assertion regarding the additional documentation it provided at the October 2019 meeting, we presented the documentation to the independent medical review contractor, who reviewed the documents and redetermined whether the associated sampled claims complied with Medicare requirements. The medical review contractor applied Medicare regulations or policies established by CMS, including regulations regarding medical necessity and the Two-Midnight Rule.²² Although our contract with the independent medical reviewer does not allow for direct interaction between them and the Hospital, we strived to ensure that the contractor heard and considered the Hospital's opinions.

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, and the Hospital concurs, that the sampled claims were paid under the Medicare fee-for-service payment method and therefore are subject to OIG review. Further, CMS guidance states that providers participating APMs are subject to the existing level of oversight from other review programs, including OIG reviews.²³ In addition, the APM participation agreements state that none of the provisions of the agreements limit or restrict OIG's authority to audit,

²¹ See *John Balko & Assoc. v. Sebelius*, 2012 WL 6738246 at *12 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

²² Specifically, our medical review contractor prepared detailed medical review determination reports supported by Medicare regulation, relevant clinical evidence, and its analysis. Each determination letter included a detailed set of facts based on a thorough review of the entire medical record.

²³ 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>.

evaluate, investigate, or inspect the Accountable Care Organization (ACO) or its participants and preferred providers.²⁴

While the Hospital contends it does not need additional internal controls, we maintain that it should strengthen the controls it already has to ensure compliance with Medicare requirements.

OTHER MATTERS: INCORRECTLY BILLED INPATIENT SHORT STAYS

Of the 80 inpatient claims in our sample, the Hospital incorrectly billed Medicare Part A for 3 beneficiary stays of less than 2 midnights (known as “inpatient short stays”), which it should have billed as outpatient or outpatient with observation. Because the medical records did not support the necessity for inpatient hospital services, the services should have been provided at a more appropriate level of care. As a result of these errors, the Hospital received overpayments totaling \$30,658.

We did not review any of the claims in our sample because they were inpatient short stays; instead, we reviewed them because they fell into one of the high-risk categories discussed in the background section of this report. We voluntarily suspended audits of inpatient short stay claims after October 1, 2013, and the suspension was in effect while we were performing this audit.²⁵ Therefore, we are not including the number and estimated dollar amount of these errors in our overall estimate of overpayments or in our repayment recommendation.

²⁴ ACOs are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high-quality care to their Medicare patients.

²⁵ In November 2020, OIG added a new Work Plan item, a plan to audit hospital inpatient claims after the implementation of and revisions to the Two-Midnight Rule to determine whether inpatient claims with short lengths of stay were incorrectly billed as inpatient and should have been billed as outpatient or outpatient with observation (W-00-20-35857). As part of this Work Plan item, OIG announced, “While OIG previously stated that it would not audit short stays after October 1, 2013, this serves as notification that the OIG will begin auditing short stay claims again, and when appropriate, recommend overpayment collections.”

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$20,509,958 in Medicare payments to the Hospital for 1,200 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 claims (80 inpatient and 20 outpatient) with payments totaling \$2,003,998. 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 records and met Medicare requirements.

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

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

We conducted our audit work from August 2018 through December 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 analysis techniques to identify claims potentially at risk for noncompliance with selected Medicare billing requirements;
- selected a stratified random sample of 80 inpatient claims and 20 outpatient claims totaling \$2,003,998 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;
- used an independent medical review contractor to review documentation provided by the Hospital, including additional and supplemental documentation, 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

According to CMS's NCH database, Medicare paid the Hospital \$211,317,634 for 11,027 inpatient and 57,066 outpatient claims during the audit period.

We obtained a database of claims from the NCH data totaling \$198,314,501 for 6,505 inpatient and 24,840 outpatient claims in 28 risk areas. From these 28 areas, we selected 10 consisting of 8,330 claims totaling \$42,166,479 for further review.

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

- \$0 paid claims,
- claims with certain discharge status and diagnosis codes,
- claims with specific diagnosis and HCPCS codes, and
- claims under review by the Recovery Audit Contractor as of April 23, 2018.

We assigned each claim that appeared in multiple risk areas to just one area on the basis of the following hierarchy: IRF Claims, Inpatient Claims Billed With CERT High Error Rate DRG Codes, Inpatient Claims Billed With High-Severity Level DRG Codes, Inpatient Mechanical Ventilation Claims, Inpatient Claims Paid in Excess of Charges, Outpatient Claims Paid in Excess of \$25,000, Outpatient Claims Paid in Excess of Charges, Outpatient Claims With Bypass Modifiers, Outpatient Surgeries Billed With Units Greater Than One, and Outpatient SNF Consolidated Billing Claims. This resulted in a sample frame of 1,200 Medicare paid claims in 10 high-risk areas totaling \$20,509,958 from which we drew our sample (Table 1 next page).

Table 1: Selected Risk Areas

| Medicare Risk Area | Frame Size | Value of Frame |
|--|-------------------|-----------------------|
| 1. IRF Claims | 414 | 8,643,270 |
| 2. Inpatient Claims Billed with CERT high-error DRG codes | 215 | 1,245,482 |
| 3. Inpatient Claims Billed with High-Severity Level DRGs | 260 | 2,795,897 |
| 4. Inpatient Mechanical Ventilation Claims | 8 | 314,931 |
| 5. Inpatient Claims Paid in Excess of Charges | 2 | 59,092 |
| 6. Outpatient Claims Paid in Excess of \$25,000 | 237 | 7,338,376 |
| 7. Outpatient Claims Paid in Excess of Charges | 5 | 52,817 |
| 8. Outpatient Claims with Bypass Modifiers | 42 | 44,167 |
| 9. Outpatient Surgeries Billed with Units Greater than One | 13 | 12,438 |
| 10. Outpatient SNF Consolidated Billing Claims | 4 | 3,488 |
| Total | 1,200 | \$20,509,958 |

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 type and claim paid amount. Strata 1, 2 and 3 include risk areas 1 through 5 from Table 1 separated by paid amount;²⁶ and stratum 4 includes all outpatient claims from risk areas 6 through 10 from Table 1. All claims were unduplicated, appearing in only one area and only once in the entire sampling frame.

We selected 100 claims for review as shown in Table 2 (next page).

²⁶ Stratum 1 includes claims from all inpatient risk areas (risk areas 1 through 5 from table 1) with total payments less than \$14,679 (lower dollar claims); stratum 2 includes claims from all inpatient risk areas (risk areas 1 through 5 from table 1) with total payments greater than or equal to \$14,679 or less than \$23,821 (moderate dollar claims); stratum 3 includes claims from all inpatient risk areas (risk areas 1 through 5 from table 1) with total payments greater than or equal to \$23,821 (higher dollar claims).

Table 2: Claims by Stratum

| Stratum | Claims Type | Frame Size (Claims) | Value of Frame | Sample Size |
|----------------|---|----------------------------|-----------------------|--------------------|
| 1 | Inpatient Risk Areas Claims, Low Dollar Claims | 505 | \$3,728,077 | 25 |
| 2 | Inpatient Risk Areas Claims, Moderate Dollar Claims | 252 | 4,807,032 | 30 |
| 3 | Inpatient Risk Areas Claims, High Dollar Claims | 142 | 4,523,563 | 25 |
| 4 | All Outpatient Risk Area Claims | 301 | 7,451,286 | 20 |
| | Total | 1,200 | \$20,509,958 | 100 |

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the claims within strata 1 through 4. After generating the random numbers, we selected the corresponding claims in each stratum.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the total amount overpaid to the provider for the claims listed in our sampling frame. 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 | 505 | \$3,728,077 | 25 | \$181,777 | 13 | \$90,785 |
| 2 | 252 | 4,807,032 | 30 | 570,276 | 14 | 270,940 |
| 3 | 142 | 4,523,563 | 25 | 753,115 | 10 | 288,105 |
| 4 | 301 | 7,451,286 | 20 | 498,830 | 3 | 16,191 |
| Total | 1,200 | \$20,509,958 | 100 | \$2,003,998 | 40 | \$666,021 |

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

| | |
|----------------|-------------|
| Point Estimate | \$5,989,864 |
| Lower Limit | 4,765,305 |
| Upper Limit | 7,214,422 |

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 |
|---|------------------------|---------------------------------|----------------------------------|------------------------------|
| Inpatient Claims Billed With CERT high error rate DRG codes | 6 | \$27,923 | 3 | \$13,225 |
| Inpatient Claims Paid in Excess of Charges | 1 | 19,109 | - | - |
| IRF Claims | 55 | 1,184,077 | 30 | 612,830 |
| Inpatient Claims Billed With High-Severity Level DRG Codes | 17 | 237,136 | 4 | 23,775 |
| Inpatient Mechanical Ventilation Claims | 1 | 36,923 | - | - |
| Inpatient Totals | 80 | \$1,505,168 | 37 | \$649,830 |
| | | | | |
| Outpatient Claims with Bypass Modifiers | 3 | \$1,903 | 1 | \$113 |
| Outpatient Claims Paid in Excess of \$25,000 | 16 | 494,498 | 1 | 14,243 |
| Outpatient Claims Paid in Excess of Charges | 1 | 2,429 | 1 | 1,835 |
| Outpatient Totals | 20 | \$498,830 | 3 | \$16,191 |
| | | | | |
| Inpatient and Outpatient Totals | 100 | \$2,003,998 | 40 | \$666,021 |

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

APPENDIX E: HOSPITAL COMMENTS



February 1, 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: Our Lady of Lourdes Medical Center Hospital Compliance Review, OIG Report No: A-02-18-01018

Dear Ms. Tierney:

Trinity Health, on behalf of Our Lady of Lourdes Medical Center ("Lourdes Medical Center"), a previously wholly-controlled subsidiary of Trinity Health¹, 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 review of Lourdes Medical Center. We understand the audit was conducted as part of a series of hospital compliance reviews 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 was not triggered by any specific concerns with Lourdes Medical Center billing practices. Lourdes Medical Center 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 December 15, 2020 (the "Draft Audit Report"). HHS OIG's stated objective of the audit was to determine if Lourdes Medical Center complied with Medicare requirements for inpatient and outpatient services for 100 selected claims paid during calendar years 2016 and 2017.

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

- Lourdes Medical Center complied with Medicare billing requirements for 60 of the 100 inpatient and outpatient claims reviewed.
- Lourdes Medical Center did not fully comply with Medicare billing requirements for the remaining 40 inpatient and outpatient claims reviewed, resulting in overpayments of \$666,021. Based on this determination, HHS OIG calculated an extrapolated estimated overpayment of approximately \$4.8 million. HHS OIG noted this amount includes claims

¹ Trinity Health's membership in Our Lady of Lourdes Medical Center Corporation was transferred to Virtua Health, Inc. effective June 30, 2019. Pursuant to the membership transfer agreement, Trinity Health retains responsibility for all activities prior to the transfer date of June 30, 2019. Any representations made in this response are limited to the time period of Trinity Health's ownership of Our Lady of Lourdes Medical Center.

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 Lourdes Medical Center 1) refund to its Medicare contractor the portion of the \$4.8 million in estimated overpayments that are within the 4-year reopening period²; 2) exercise reasonable diligence to identify and return any additional similar overpayments outside the HHS OIG audit period in accordance with the 60-Day Repayment Rule³; and 3) strengthen its controls to ensure full compliance with Medicare requirements in specific areas identified in the report.

As further described herein, Trinity Health disagrees with all but four (4) of HHS OIG's audit findings in the Draft Audit Report. At the request of HHS OIG, Lourdes Medical Center conducted an extensive internal review of the medical records supporting each claim in the sample, the results of which were provided to HHS OIG in the form of detailed attestations during the audit. In the exit meeting held on June 26, 2019, Lourdes Medical Center/Trinity Health were disappointed to learn this information was never provided to HHS OIG's contracted medical reviewers for reasons not sufficiently explained. At a subsequent meeting held on October 3, 2019, Lourdes Medical Center/Trinity Health presented detailed information to HHS OIG representatives of example substantive errors it believes were made by the contracted medical reviewers, including missed documentation present in the medical records and incorrect application of Medicare regulations. HHS OIG representatives in attendance at the meetings indicated they did not possess the necessary expertise to respond directly to Lourdes Medical Center/Trinity Health's questions concerning the audit findings, including the basis by which certain claims were determined to have not met Medicare requirements. HHS OIG representatives repeatedly deferred to the findings of its independent medical review contractors.

Lourdes Medical Center and Trinity Health have on multiple occasions requested the opportunity to speak with HHS OIG's contracted medical reviewers to discuss the audit findings in order to further understand the basis upon which the medical reviewers made their determinations and to correct numerous substantive errors Lourdes Medical Center/Trinity Health believe were made in the audit. HHS OIG has declined to make its contracted medical reviewers available to discuss the audit findings with Lourdes Medical Center/Trinity Health.

Set forth below is a description of Lourdes Medical Center/Trinity Health's assessment of HHS OIG's findings by each audit area.

Inpatient Rehabilitation Facility Claims

Lourdes Medical Center/Trinity Health disagrees with HHS OIG's findings that Lourdes Medical Center incorrectly billed 30 of the 55 Inpatient Rehabilitation Facility ("IRF") claims sampled in the audit. Lourdes Medical Center/Trinity Health agree an error occurred for one (1) claim (S1-15) resulting in an overpayment of \$2,725. Lourdes Medical Center/Trinity Health disagrees with HHS OIG's conclusions that the remaining 29 denied claims either lacked medical necessity for inpatient rehabilitation level of care or were incorrectly billed due to insufficient documentation of all required elements for acute inpatient rehabilitation services.

² 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.

³ 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 referenced previously, Lourdes Medical Center/Trinity Health conducted an extensive internal review of the medical records supporting each claim in the sample. Lourdes Medical Center's review of the IRF claims in the audit sample concluded that Medicare requirements for medical necessity, documentation, and coding were met in all remaining cases.

At the October 3, 2019 meeting, Lourdes Medical Center/Trinity Health presented numerous documented examples where it believed HHS OIG's contracted medical reviewers failed to consider significant patient comorbidities, applied criteria not contained in the CMS Benefit Policy Manual, incorrectly referenced documents describing prior levels of patient function, or otherwise incorrectly drew conclusions either not supported or refuted by the medical records. Representatives of HHS OIG's contracted medical reviewers did not participate in the October 3, 2019 meeting and HHS OIG representatives present at the October 3 meeting acknowledged they did not possess the necessary expertise to respond directly to Lourdes Medical Center/Trinity Health's questions concerning the audit findings.

HHS OIG's medical reviewers appear to have frequently taken the position that IRF services are not medically necessary unless, along with a specific diagnosis, patients also had a specific medical acuity. In other cases, the medical reviewers' findings suggest that patients whose post-rehabilitation goals may be limited are not eligible to receive IRF care. These views of medical necessity are not supported by Medicare regulations or policies established by CMS and we question the authority by which the denial decisions based on medical necessity were made.

Lourdes Medical Center/Trinity Health believe the medical record documentation for 29 of the 30 IRF claims audited support all Medicare coverage and payment requirements. Lourdes Medical Center/Trinity Health has initiated steps to refund the \$2,725 overpayment for the agreed upon error in one (1) claim to its Medicare contractor. Our review found this error to be individualized, not systemic, and not indicative of further errors in the broader population of claims audited. As explained further herein, Lourdes Medical Center/Trinity Health will pursue all available Medicare administrative appeal rights related to the remaining 29 denied IRF claims and is confident a significant majority of the denials will be overturned upon appeal.

Inpatient Claims

For 6 acute inpatient claims (non-IRF) included in the audit sample, HHS OIG determined that Lourdes Medical Center 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. Lourdes Medical Center/Trinity Health disagrees with HHS OIG's findings and asserts that medical necessity for inpatient admission, including compliance with CMS' Two Midnight Rule requirements, was present in all cases.

At the October 3, 2019 meeting, Lourdes Medical Center presented HHS OIG with several examples where it believes HHS OIG's contracted medical reviewers erred in concluding that medical necessity was not met. Lourdes Medical Center/Trinity Health will pursue all available Medicare administrative appeal rights related to the six (6) denied inpatient claims and is confident a majority of the denials will be overturned upon appeal.

Inpatient Diagnosis-Related Group Coding

For 1 of the 80 sampled inpatient claims, HHS OIG determined that Lourdes Medical Center used an incorrect diagnosis code resulting in an incorrect payment to the hospital. Lourdes Medical Center/Trinity Health agrees with HHS OIG's finding of a coding error for this claim (S1-24). Our review found this error to be individualized, not systemic, and not indicative of further coding errors in the broader population of claims

audited. Lourdes Medical Center/Trinity Health has initiated steps to refund the \$2,261 partial overpayment to its Medicare contractor.

Outpatient Claims

HHS OIG determined that Lourdes Medical Center incorrectly billed Medicare for 3 of 14 outpatient claims sampled in the audit due to coding errors. Lourdes Medical Center/Trinity Health agree that coding errors occurred for 2 claims (S4-16, S4-19) resulting in total overpayments of \$16,078. These findings were self-identified by Lourdes Medical Center in its internal review and disclosed to HHS OIG during the audit. Lourdes Medical Center/Trinity Health has initiated steps to refund the \$16,078 partial overpayment to its Medicare contractor. Our review found these errors to be individualized, not systemic, and not indicative of further coding errors in the broader population of claims audited. Lourdes Medical Center/Trinity Health disputes that a coding error occurred in the one (1) remaining denied claim and will pursue its available Medicare administrative appeal rights.

Alternative Payment Models

As discussed with HHS OIG at the October 3, 2019 meeting, Lourdes Medical Center participated in two Medicare Alternative Payment Models (APMs) sponsored by CMS during 2016 – 2017, the time period covered by the HHS OIG audit. Lourdes Medical Center participated in CMS' Next Generation Accountable Care Organization ("Next Generation Model ACO") model as part of Trinity Health ACO, a Next Generation Model ACO. Lourdes Medical Center also participated in CMS' Bundled Payment for Care Improvement Initiative ("BPCI") as an Episode Initiator. Additional information on both of these APM programs can be found at the following CMS websites:

Next Generation ACO Model

[Next Generation ACO Model | CMS Innovation Center](#)

Bundled Payments for Care Improvement (BPCI) Initiative

[Bundled Payments for Care Improvement \(BPCI\) Initiative: General Information | CMS Innovation Center](#)

In both the Next Generation Model ACO and BPCI, participants such as Lourdes Medical Center assume greater financial risks for the total cost and outcomes of care provided to Medicare beneficiaries over a specified time period (a calendar year for Next Generation Model ACOs, 90-days of continuous care for a bundled payment episode in BPCI). In both models, providers submit claims for services and are paid by Medicare on a fee-for-service basis, like traditional Medicare. However, in both models 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 each model's targeted costs at the end of each respective performance period, with settlement of any net amounts due to or owed by participants.

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 audits⁴. 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 Lourdes Medical Center bear the financial risks of any billing errors. In Advanced APMs, health care providers like Lourdes Medical Center/Trinity Health have no incentive to deliver anything but medically necessary and appropriate care to Medicare beneficiaries.

The HHS OIG audit sample of 100 claims from 2016 and 2017 included 21 claims for Medicare beneficiaries who were either: 1) aligned to Trinity Health ACO; or 2) received a service at Lourdes Medical Center that was included in a BPCI bundled episode of care. Of the 21 claims in the sample, HHS OIG reported errors involving 10 claims totaling \$108,655 in overpayments. **Lourdes Medical Center/Trinity Health do not contend that claims related to Medicare APMs are not subject to HHS OIG audit oversight. We do contend, however, these claims should be excluded from any overpayment determination or extrapolation of estimated overpayments as reconciliation for these APM models has already occurred with CMS.** CMS' reconciliation of Lourdes Medical Center's performance for years 2016 and 2017 in the Next Generation ACO and BPCI models occurred prior to the end of 2018. Lourdes Medical Center/Trinity Health contend that it is inappropriate for HHS OIG to assess overpayments on claims covered by these advanced APM programs that were already subject to separate reconciliation by CMS by the end of 2018. Lourdes Medical Center/Trinity Health will pursue all available Medicare administrative appeal rights related to any denied claims and/or extrapolation involving the Next Generation ACO or BPCI models.

Use of Extrapolation to Estimate \$4.8M Overpayment

In consideration of the disagreements with the audit findings as described herein, Lourdes Medical Center/Trinity Health contends it is inappropriate to perform an extrapolation at this time. As an initial matter, 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.⁵ In the case of Lourdes Medical Center, 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 Lourdes Medical Center. Therefore, we contend that is equally inappropriate for HHS OIG to use extrapolation determined without that predicate. Lourdes Medical Center/Trinity 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 Lourdes Medical Center/Trinity Health has exhausted its available Medicare administrative appeals for the disputed claims described herein. Lourdes Medical Center/Trinity Health contends that only 4 of the 100 claims involved errors and contends such errors are insufficient in number to justify use of extrapolation.

Lourdes Medical Center/Trinity Health believe extrapolation is particularly unwarranted due to the highly fact-dependent, individualized determinations of medical necessity with respect to a specific patient's clinical status

⁴ 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>

⁵ Social Security Act, §1893(f)(3)

at the time services were rendered, such as the findings made with respect to the IRF and 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:⁶

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, Lourdes Medical Center/Trinity Health contends that questions of medical necessity pertaining to the IRF and inpatient admissions in HHS OIG's audit also require individualized determinations and the use of extrapolation is inappropriate. Lourdes Medical Center/Trinity Health will appeal the use of extrapolation to determine estimated repayment liabilities based on claims denied for lack of medical necessity. Lourdes Medical Center/Trinity Health is confident its appeal of the claims at issue through Medicare's administrative appeals process will ultimately result in substantially favorable outcomes.

Response to Audit Recommendations

HHS OIG recommended that Lourdes Medical Center refund to its Medicare contractor the portion of the \$4.8 million extrapolated repayment that are within the 4-year reopening period. **Lourdes Medical Center/Trinity 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 Lourdes Medical Center/Trinity Health.

Lourdes Medical Center/Trinity Health agrees with HHS OIG's findings for the four (4) claims previously discussed herein and has initiated steps to refund the \$21,064 in total overpayments to its Medicare contractor. Lourdes Medical Center/Trinity Health disagrees with HHS OIG's audit findings for the remaining claims and intends to pursue all available Medicare administrative appeals with respect to such denials. Furthermore, Lourdes Medical Center/Trinity Health contends that extrapolation of an error rate is inappropriate until a final determination is made with respect to the appealed claims as explained previously.

HHS OIG also recommended Lourdes Medical Center use reasonable diligence to identify and return any additional similar overpayments outside the HHS OIG audit period in accordance with the 60-Day Repayment Rule. 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.⁷ Lourdes Medical Center/Trinity 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. Therefore, through its exercise of reasonable due diligence leading to the decision to appeal the remaining denied claims, Lourdes Medical Center/Trinity Health has complied with the 60-Day Rule repayment obligations.

HHS OIG further recommended Lourdes Medical Center strengthen its controls to ensure full compliance with Medicare requirements. As noted previously, ownership of Lourdes Medical Center transferred to Virtua Health, Inc. effective June 30, 2019. However, Lourdes Medical Center/Trinity Health contends no additional

⁶ *United States ex rel. Misty Wall v. Vista Hospice Care, Inc.*, 2016 WL 344983, at *12 (N.D. Tex. 2016)

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

internal controls are needed based on its exercise of reasonable due diligence with respect to the audit findings and its response as described herein.

Lourdes Medical Center/Trinity Health appreciates the opportunity to provide its response to the Draft Audit Report. Lourdes Medical Center/Trinity Health takes its compliance efforts very seriously. We respectfully request HHS OIG's reconsideration of the initial findings contained in the Draft Audit Report and would welcome an opportunity for direct discussion with HHS OIG's contracted medical reviewers concerning the audit findings.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael R. Holper", is enclosed in a light gray rectangular box.

Michael R. Holper
Senior Vice President, Integrity & Audit Services
Trinity Health Integrity & Compliance Officer