Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE HOSPITAL PROVIDER COMPLIANCE AUDIT: THE OHIO STATE UNIVERSITY 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 2020

Report No. A-05-18-00042

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

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-forservice payments for the year.

Our objective was to determine whether The Ohio State University Hospital (the Hospital) complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims.

How OIG Did This Audit

We selected for review a stratified random sample of 123 inpatient and 22 outpatient claims with payments totaling \$4.1 million for our 2-year audit period (Jan. 1, 2016, through Dec. 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.

Medicare Hospital Provider Compliance Audit: The Ohio State University Hospital

What OIG Found

The Hospital complied with Medicare billing requirements for 98 of the 145 inpatient and outpatient claims we audited. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 47 claims, resulting in net overpayments of \$335,832 for the audit period. Specifically, 26 inpatient claims had billing errors, resulting in overpayments of \$291,998, and 21 outpatient claims had billing errors, resulting in overpayments of \$43,834.

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$3.7 million for the audit period.

What OIG Recommends and Hospital Comments

We recommend that the Hospital refund to the Medicare contractor \$3.7 million in estimated overpayments for incorrectly billed services that are within the 4-year claim reopening period; exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule; and strengthen controls to ensure full compliance with Medicare requirements. The detailed recommendations are included in the body of the report.

In written comments on our draft report, the Hospital disagreed with most of our findings and recommendations. The Hospital agreed with some of the errors identified in the sample and repaid Medicare \$396,025. However, the Hospital disagreed with OIG's extrapolation, audit design, and methodology. In addition, the Hospital disagreed with several of the medical review determinations and the application of the 60-day rule for specific claims.

After review and consideration of the Hospital's comments, we maintain that our findings and the associated recommendations are valid. The use of statistical sampling to determine overpayment amounts in Medicare is well established and has repeatedly been upheld on appeal in Federal courts. We submitted the claims selected for review to an independent medical review contractor that reviewed the medical records in their entirety to determine whether the services were medically necessary and provided in accordance with Medicare coverage and documentation requirements. Regarding the Hospital's claim that the 60-day repayment rule is not applicable to specific claims, we maintain that our findings are valid and that this audit report constitutes credible information of potential overpayments.

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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 (CY) 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 The Ohio State University 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 contracts with Medicare administrative contractors (MACs) to, among other things, process and pay claims submitted by hospitals.

Hospital Inpatient Facility Prospective Payment System

CMS pays hospital costs at predetermined rates for patient discharges under the inpatient prospective payment system. 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 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 92 distinct case-mix groups (CMGs). The assignment to a CMG is based on a beneficiary's clinical characteristics and expected resource needs.

Inpatient Psychiatric Facility Prospective Payment System

CMS pays inpatient psychiatric facilities (IPFs) a standardized Federal per diem payment per discharge and represents reimbursement in full for the inpatient operating and capital-related costs of furnishing Medicare-covered services in an IPF. The payment for an individual patient is further adjusted for factors such as the DRG classification, age, length of stay, and the presence of specified comorbidities. Additional payments are provided for cost outlier cases, qualifying emergency department, and electroconvulsive therapy treatments. The IPFs affected by the prospective payment system are freestanding psychiatric facilities, distinct-part psychiatric units of acute-care hospitals, and distinct-part units of critical access hospitals.

Hospital Outpatient Prospective Payment System

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

Hospital Claims at Risk for Incorrect Billing

Our previous work at other hospitals identified these types of claims at risk for noncompliance:

- inpatient rehabilitation facility,
- inpatient mechanical ventilation,
- inpatient hospital-acquired conditions and "present on admission"² indicator reporting,
- inpatient claims billed with high-severity-level DRG codes,

¹ HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

² "Present on admission" refers to diagnoses that are present at the time the order for inpatient admission occurs. Conditions that develop during an outpatient encounter, including emergency department, observation, or outpatient surgery, are also considered present on admission. Acute-care hospitals are required to complete the present-on-admission indicator field on the Medicare inpatient claim for every diagnosis billed.

- inpatient elective procedures,
- inpatient Comprehensive Error Rate Testing (CERT) high error DRG codes,
- inpatient claims paid in excess of \$150,000,
- inpatient claims paid in excess of charges,
- inpatient psychiatric facility emergency adjustments,
- outpatient right heart catheterizations (RHCs),
- outpatient claims paid in excess of charges, and
- outpatient surgeries billed with units greater than one.

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.³

Medicare Requirements for Hospital Claims and Payments

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

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

Claims must be filed on forms prescribed by CMS in accordance with CMS instructions (42 CFR § 424.32(a)(1)). The *Medicare Claims Processing Manual* (the Manual), requires providers to complete claims accurately so that Medicare contractors may process them correctly and

³ 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.

promptly (Pub. No. 100-04, chapter 1, § 80.3.2.2). The Manual states that providers must use HCPCS codes for most outpatient services (chapter 23 § 20.3).⁴

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.⁵

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.⁶

The Ohio State University Hospital

The Hospital, which is part of The Ohio State University Wexner Medical Center, is a 900-bed acute-care hospital located in Columbus, Ohio. Medicare paid the Hospital approximately \$479 million for 24,295 inpatient and 302,448 outpatient claims for services provided to beneficiaries during CYs 2016 and 2017.

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$62,487,853 in Medicare payments to the Hospital for 3,817 claims that were potentially at risk for billing errors. We selected a stratified random sample of 145 claims paid to the Hospital during CYs 2016 and 2017 (audit period) for services provided to Medicare beneficiaries with payments totaling \$4,073,825 for audit. These claims consisted of 123 inpatient and 22 outpatient claims.

We focused our audit on the risk areas that we had identified during prior OIG audits at other hospitals. We evaluated compliance with selected billing requirements and submitted these claims for focused medical review to determine whether the services met medical necessity

⁴ "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)).

⁵ The Act § 1128J(d); 42 CFR §§ 401.301-401.305; and 81 Fed. Reg. 7654 (Feb. 12, 2016).

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

and coding 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.

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

FINDINGS

The Hospital complied with Medicare billing requirements for 98 of the 145 inpatient and outpatient claims we audited. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 47 claims, resulting in net overpayments of \$335,832 for the audit period. Specifically, 26 inpatient claims had billing errors, resulting in net overpayments of \$291,998 and 21 outpatient claims had billing errors, resulting in overpayments of \$43,834. These errors occurred primarily because of human errors and controls that did not prevent incorrect billing of Medicare claims within the selected risk areas that contained errors.

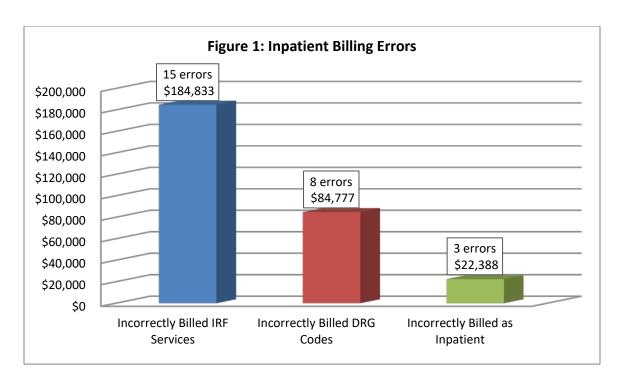
On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$3.7 million⁷ for the audit period.⁸ As of the publication of this report, this amount included claims outside of the 4-year claim reopening period. See Appendix B for our sample design and methodology, Appendix C for our sample results and estimates, and Appendix D for the results of our audit by risk area.

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 26 of 123 sampled inpatient claims, which resulted in net overpayments of \$291,998, as shown in Figure 1 (next page).

⁷ The actual number was \$3,736,490.

⁸ To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.



Incorrectly Billed Inpatient Rehabilitation Facility Services

Medicare may not pay 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) required the active and ongoing therapeutic intervention of multiple therapy disciplines; (2) generally required and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program; (3) was sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation program; and (4) required 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 (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 (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)). In addition, Federal regulations require that the Hospital use a patient classification system to classify patients in inpatient rehabilitation facilities into mutually exclusive case-mix groups (CMGs). CMGs are classes of Medicare patient discharges organized according to functionally related groups based on a patient's impairment, age, comorbidities,

functional capabilities, and other factors that may improve the ability of the functionally related groups to estimate variations in resource use (42 CFR § 412.620).

For 15 of the 123 sampled inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for acute inpatient rehabilitation.

For 12 of these 15 claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria stating that acute inpatient rehabilitation must be reasonable and necessary. IRF services for these beneficiaries were not considered reasonable and necessary because these beneficiaries (1) did not require the active and ongoing therapeutic intervention of multiple therapy disciplines; (2) generally did not require and could not reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program; (3) were not sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation program; or (4) did not require supervision by a rehabilitation physician. For 3 of the 15 incorrectly billed claims, the Hospital submitted to Medicare IRF claims that were incorrectly coded, resulting in incorrect CMG payments to the Hospital. Specifically, the CMG was not applied correctly based on the patient's clinical characteristics and expected resource needs.

The Hospital did not provide a cause for the errors because it believes that the majority of these claims met Medicare requirements and stated that "actions have been taken to increase the clarity of documentation and coding processes to more precisely exhibit compliance with regulatory standards." However, Hospital officials did not provide any additional information that would impact our finding.

As a result of these errors, the Hospital received net overpayments totaling \$184,833.

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 8 of the 123 sampled inpatient claims, the Hospital billed Medicare with incorrect DRG codes, which resulted in payments that were either higher or lower than what should have been made. For these claims, the Hospital used incorrect diagnosis codes to determine the DRG codes. The Hospital stated that the claims were inadvertently coded incorrectly due to human error.

As a result of these errors, the Hospital received net overpayments totaling \$84,777.

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)).

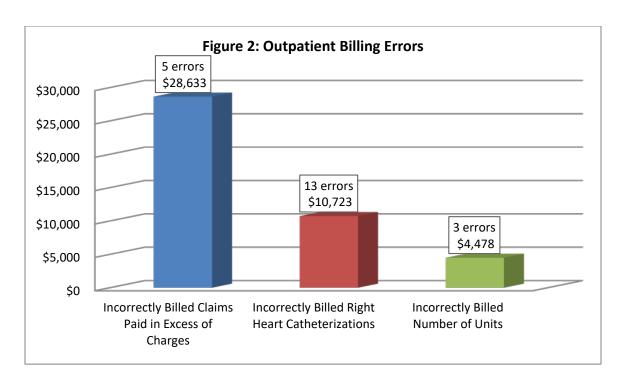
In addition, the regulations provide that an inpatient admission, and subsequent payment under Medicare Part A, is generally appropriate if the ordering physician expects the patient to require care for a period of time that crosses two midnights (42 CFR § 412.3(d)(1)). The regulations further state that the "expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event" (42 CFR § 412.3(d)(1)(i)). Moreover, "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 3 of the 123 sampled inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for inpatient status and should have been billed as outpatient or outpatient with observation services. The Hospital did not provide a cause for the errors identified because it believes that the medical record documentation supports the medical necessity and the billing of the claims. However, Hospital officials did not provide any additional information that would impact our finding.

As a result of these errors, the Hospital received overpayments of \$22,388.

BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 21 of 22 sampled outpatient claims, which resulted in net overpayments totaling \$43,834, as shown in Figure 2 (next page).



Incorrectly Billed Claims Paid in Excess of Charges

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

The Manual, chapter 1, § 80.3.2.2, requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly.

The Manual, chapter 4, section 20.1, states that acute-care hospitals and long-term-care hospitals must report HCPCS codes. Rehabilitation hospitals, psychiatric hospitals, hospital-based rural health clinics, hospital-based federally qualified health centers, and critical access hospitals also must report HCPCS codes. HCPCS codes are required for all outpatient hospital services unless specifically excepted in the Manual. Thus, codes are required for surgery, radiology, other diagnostic procedures, clinical diagnostic laboratory, durable medical equipment, orthotic-prosthetic devices, take-home surgical dressings, therapies, preventative services, immunosuppressive drugs, other covered drugs, and most other services.

For 5 of the 22 sampled outpatient claims, the Hospital submitted claims to Medicare with HCPCS codes that were not supported by the medical records. The Hospital stated that these errors were missed because its outlier audits included only a review of inpatient claims.

As a result of these errors, the Hospital received overpayments totaling \$28,633.

Incorrectly Billed Right Heart Catheterizations

The Manual, chapter 1, § 80.3.2.2, requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly.

"The '-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)).

Effective January 1, 2015, CMS established four new HCPCS modifiers to define subsets of modifier 59. The four new HCPCS modifiers used to 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 modifier 59, but providers should use one of the more descriptive modifiers in place of modifier 59 when it is appropriate (Pub. No. 100-20, "One Time Notification," Transmittal 1422, Aug. 15, 2014).

For 13 of the 22 sampled outpatient claims, the Hospital incorrectly billed Medicare for RHC procedures performed during the same patient encounter as heart biopsy procedures. The Hospital incorrectly appended modifier 59 on all 13 claims, indicating that the RHCs were separate and distinct procedures from the heart biopsies even though the medical record documentation did not support the use of the modifier. Although additional steps taken during the encounters, such as measuring hemodynamic pressures, may have been reasonable and necessary, the documentation showed that obtaining the heart biopsies was the primary purpose of the RHCs. Therefore, the RHCs were an inherent component of the heart biopsies, and the payments for the biopsies already covered the RHCs. Hospital officials stated that they agree that the claims were billed in error due to their interpretation of the indicators of when it was appropriate to assign modifier 59.

As a result of these errors, the Hospital received overpayments totaling \$10,723.

Incorrectly Billed Number of Units

The Manual states that the definition of service units is the number of times the service or procedure being reported was performed (chapter 4 § 20.4). 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).

⁹ This manual provision was revised after our audit period by Change Request 10868, dated Dec. 28, 2018, and effective Jan. 30, 2019.

For 3 of the 22 sampled outpatient claims, the Hospital incorrectly billed Medicare for multiple units for outpatient surgery procedures when it should have billed for only 1 unit. Hospital officials stated that these errors occurred because a control edit was inadvertently disabled.

As a result of these errors, the Hospital received net overpayments totaling \$4,478.

OVERALL ESTIMATE OF OVERPAYMENTS

The combined net overpayments on our sampled claims totaled \$335,832. On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$3.7 million for the audit period.

RECOMMENDATIONS

We recommend that The Ohio State University Hospital:

- refund to the Medicare contractor \$3,736,490 (of which \$335,832 was net overpayments identified in our sample) in estimated overpayments for incorrectly billed services that are within the 4-year claim reopening period;¹⁰
- based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule¹¹ and identify any of those returned overpayments as having been made in accordance with this recommendation; and
- strengthen controls to ensure full compliance with Medicare requirements; specifically, ensure that:
 - o all IRF beneficiaries meet Medicare criteria for acute inpatient rehabilitation,
 - o all inpatient beneficiaries meet Medicare criteria for inpatient hospital services,

¹⁰ OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be reestimated depending on CMS determinations and the outcome of appeals.

¹¹ This recommendation does not apply to any overpayments that are both within our sampling frame (i.e., the population from which we selected our statistical sample) and refunded based on the extrapolated overpayment amount. Those overpayments are already covered in the previous recommendation.

- diagnosis and discharge status codes are supported in the medical records and staff are properly trained, and
- medical records accurately document the appropriate number of units and distinct procedural services and that staff are properly trained.

OTHER MATTERS

For 14 of the 123 selected inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays of less than two midnights (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 lower level of care. As a result of these errors, the hospital received overpayments totaling \$204,244. None of the claims in this audit were targeted because they were short stays but rather because they fell into one of the high-risk categories discussed in the background section of this report. OIG voluntarily suspended audits of inpatient short-stay claims after October 1, 2013. As such, we are not including the number and estimated dollar amount of these errors in our overall estimate of overpayments and our repayment recommendation.

HOSPITAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

HOSPITAL COMMENTS

In written comments on our draft report, the Hospital disagreed with most of our findings and recommendations. The Hospital agreed with some of the errors identified in the sample and repaid Medicare \$396,025. However, the Hospital disagreed with OIG's extrapolation, audit design, and methodology. In addition, the Hospital disagreed with several of the medical review determinations and the application of the 60-day rule for specific claims.

Regarding extrapolation, the Hospital stated that its review did not find a persistent pattern or a high level of error. The Hospital stated that, based on CMS guidance, extrapolation is appropriate when there is a high error rate (50 percent or more). The Hospital also stated that OIG, in its corporate integrity agreements, does not require independent review organizations to review a full sample of claims for extrapolation purposes when a provider's error rate is below 5 percent. The Hospital stated that it believes that many claim denials would be reversed on appeal and that, in the interim, the Hospital would suffer unnecessary reputational harm. Further, the Hospital stated that:

- The Hospital is unable to replicate the audit due to vaguely defined risk area audit sampling terms.
- Removal of 14 short-stay claims after the audit sample was selected compromises the statistical validity of the sample and subsequent extrapolation.

- OIG's sampling methodology was misleading because it used both random sampling and judgemental sampling in the stratified random sample.
- Questions of the medical necessity of IRF services require individualized determinations that undercut any contention that one claim is like another, much less serving as a representation of a larger universe.

In addition, the Hospital stated that extrapolation is improper because the Hospital did not have an opportunity to challenge OIG's conclusion that IRF claims failed to meet Medicare coverage or documentation requirements before extrapolation was performed. The Hospital stated that it is confident that a large portion of OIG's determinations would have been reversed if the Hospital had been able to challenge them.

The Hospital stated that for many of the claims OIG concluded should not have been paid, in fact, met Medicare coverage and billing requirements. Specifically, the Hospital stated that in the medical judgment of 1 or more of its physicians, for 32 of the 35 IRF claims in our sample, the patients would not have been effectively served at a lower level of care. The Hospital also stated that it disagreed with OIG's calculation of overpayments for claims incorrectly billed as inpatient because it does not take into account the applicable reimbursement the Hospital would have received under Part B. Lastly, the Hospital disagreed that the 60-day repayment rule is applicable or appropriate for specific claims.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

After review and consideration of the Hospital's comments, we maintain that our findings and the associated recommendations are valid. However, some of the incorrectly billed claims that we identified are now outside of the Medicare reopening period. Therefore, for our first recommendation, we acknowledge that the Hospital should refund only the estimated overpayments for incorrectly billed claims that are within the reopening period.

Regarding the Hospital's comments on our extrapolation, we note that the use of statistical sampling to determine overpayment amounts in Medicare is well established and has repeatedly been upheld on appeal in Federal courts. ¹² The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most

¹² Yorktown Med. Lab., Inc. v. Perales, 948 F.2d 84 (2d Cir. 1991); Illinois Physicians Union v. Miller, 675 F.2d 151 (7th Cir. 1982); Momentum EMS, Inc. v. Sebelius, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); Anghel v. Sebelius, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); Miniet v. Sebelius, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); Bend v. Sebelius, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

precise methodology.¹³ We properly executed our statistical sampling methodology in that we defined our sampling frame, sampling unit, and strata;¹⁴ selected a stratified random sample; applied relevant criteria in evaluating the sample items; and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. These formulas fully accounted for the stratified nature of the sampling design. The statistical lower limit that we use for our recommended recovery represents a conservative estimate of the overpayment that we would have identified if we had reviewed every claim in the sampling frame. The conservative nature of this approach is not affected by the type of errors identified in this audit.

Although the Hospital stated that it believes that many claim denials would be reversed on appeal and that, in the interim, the Hospital would suffer unnecessary reputational harm, we are obligated to report all of our findings. Moreover, as we note in footnote 10, OIG audit recommendations do not represent final determinations by Medicare, and potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

Regarding the Hospital's claim that it did not have an opportunity to challenge the conclusion that IRF claims failed to meet Medicare coverage or documentation requirements prior to extrapolation and that therefore the extrapolation is improper, citing Chaves County Home Health Services v. Sullivan, the Hospital is mistaken. In Chaves County Home Health Services v. Sullivan, 732 F. Supp. 188 (D.C.D.C. 1990), the provider alleged that the use of statistical sampling and extrapolation without individual review of each claim was illegal. The District Court held otherwise and the Court of Appeals affirmed, finding that the provider had the opportunity to challenge the statistical validity of both the sample and the extrapolation on appeal (Chaves County Home Health Services v. Sullivan, 931 F.2d 914 (DC Cir. 1991)). The Hospital has five levels of appeal to challenge the statistical validity of both the sample and the extrapolation on appeal.

Provisions in CMS's *Medicare Program Integrity Manual* requiring that statistical sampling and extrapolation be used only when it has been determined that a sustained or high level of payment error exists apply to CMS contractors, not to OIG. See the Act § 1893(f)(3) and the CMS *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 8.4, § 8.4.1.4 (effective Jan. 2, 2019). Further, extrapolation in OIG audits is consistent with our previous application of a 5-percent threshold in corporate integrity agreements (CIAs). The 5-percent threshold that we previously used in CIAs was applied to a probe sample and was used to determine whether a

¹³ 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).

¹⁴ A valid stratified design may include strata covering multiple risk areas and strata for which all claims are reviewed.

full sample needed to be selected. It was not a threshold we used to determine when extrapolation may be used.

The Hospital indicated that it has been unable to validate our extrapolation methodology because of vaguely defined risk area audit sampling terms such as "High Severity Level DRGs" or "High Risk CERT DRGs." OIG explained the extrapolation process and will provide the information to Hospital officials and their MAC to replicate the extrapolation from the audit findings.

The inclusion of claims that did not span two midnights in this report is limited to the "Other Matters" section. We used the same medical review process for these claims as for all other claims in this report, and they are included in the "Other Matters" section for information purposes only. OlG's decision to not include overpayments associated with short stays in our findings does not preclude us from looking at other aspects of those claims. If those claims were found to be incorrectly paid based on these other aspects, then the resulting overpayments would be included in our findings and extrapolated overpayment. When calculating our statistical estimate, we did not remove other claims from our sample; instead, we reduced overpayment amounts to exclude the overpayments associated with short stays.

Although the Hospital stated that in the medical judgment of one or more of its physicians, for 32 of the 35 IRF claims in our sample, the patients would not have been effectively served at a lower level of care, we obtained an independent medical review for all claims in our sample. We submitted the claims to a contractor that reviewed the medical records in their entirety to determine whether the services were medically necessary and provided in accordance with Medicare coverage and documentation requirements. We worked with the medical reviewers to ensure that they applied the correct Medicare criteria and that they used professionals with appropriate medical expertise, including physicians with training and expertise in rehabilitation. We appropriately assessed the medical record documentation to determine whether it supported the Medicare payments. Services must be appropriately documented, and Medicare must have the ability on a post-payment basis to determine whether a payment was made in accordance with program requirements.

Regarding the Hospital's disagreement with the calculated overpayment amounts for inpatient claims because they did not reflect the applicable outpatient reimbursement, we cannot offset Medicare Part A overpayments with amounts that may be payable under Medicare Part B. We cannot judge the value of the Part B claims that have yet to be submitted. Historically, CMS has not allowed rebilling as an exception to the timely refunding of an overpayment when a claim is denied. CMS has stated that hospitals are responsible for determining whether submission of a Part A or Part B claim is appropriate within the applicable timeframe and that adopting an exception to the timely filing requirements would allow hospitals to avoid the responsibility of correctly submitting claims to Medicare.

Regarding the Hospital's claim that the 60-day repayment rule is not applicable to specific claims because it disagrees with some of our findings, some findings are individualized, or

errors occurred during a limited time period, we maintain that our findings are valid and that this audit report constitutes credible information about potential overpayments. We stand by our recommendation to identify and return overpayments in accordance with the 60-day rule.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$62,487,853 in Medicare payments to the Hospital for 3,817 claims that were potentially at risk for billing errors. These claims consisted of 123 inpatient and 22 outpatient claims that had dates of service in CY 2016 or 2017 (audit period) for services provided to Medicare beneficiaries. We selected a stratified random sample of 145 claims with payments totaling \$4,073,825 for review.

We focused our audit on the risk areas that we had identified during prior OIG audits at other hospitals. We evaluated compliance with selected billing requirements and submitted 145 claims for focused medical review to determine whether the services met medical necessity and coding requirements.

We limited our review of the Hospital's internal controls to those applicable to the inpatient and outpatient areas of audit 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 data obtained from the National Claims History file, but we did not assess the completeness of the file.

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

We conducted our fieldwork from August 2018 through September 2019.

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 National Claims History file for the audit period;
- used computer matching, data mining, and data analysis techniques to identify claims potentially at risk for noncompliance with selected Medicare billing requirements;
- selected a stratified random sample of 145 claims (123 inpatient and 22 outpatient) totaling \$4,073,825 for detailed review (Appendix B);
- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been cancelled or adjusted;

- reviewed the itemized bills and medical record documentation provided by the Hospital to support the sampled claims;
- requested that the Hospital conduct its own review of the sampled claims to determine whether the services were billed correctly;
- reviewed the Hospital's procedures for submitting Medicare claims;
- used an independent medical review contractor to determine whether all 145 sampled claims met medical necessity and coding 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 overpayments 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: SAMPLE DESIGN AND METHODOLOGY

SAMPLING FRAME

Medicare paid the Hospital approximately \$479 million for 24,295 inpatient and 302,448 outpatient claims (CMS's National Claims History data) for services provided to beneficiaries during the audit period.

We downloaded claims from the National Claims History database totaling \$343,496,004 for 14,408 inpatient and 62,362 outpatient claims in 32 risk areas. From these 32 risk areas, we selected 12, consisting of 10,561 claims (10,469 inpatient and 92 outpatient claims) totaling \$202,292,324 for further review.

We performed data analysis of the claims within each of the 12 risk areas. The specific data filtering and analysis steps we performed varied depending on the risk area and Medicare issue but included such procedures as removing:

- \$0 paid claims,
- claims with certain patient discharge status codes,
- claims with specific diagnosis and HCPCS codes,
- claims under review by the Recovery Audit Contractor as of May 30, 2018, and
- all duplicated claims within individual risk areas.

We assigned each claim that appeared in multiple high-risk areas to just one area based on the following hierarchy: Inpatient Rehabilitation Facility, Inpatient Mechanical Ventilation, Inpatient Hospital-Acquired Conditions and "Present on Admission" Indicator Reporting, Inpatient Claims Billed with High-Severity-Level DRG Codes, Inpatient Elective Procedures, Inpatient CERT High Error DRG Codes, Inpatient Claims Paid in Excess of \$150,000, Inpatient Claims Paid in Excess of Charges, Inpatient Psychiatric Facility Emergency Adjustments, Outpatient Right Heart Catheterizations, Outpatient Claims Paid in Excess of Charges, and Outpatient Surgeries Billed with Units Greater Than One. This assignment hierarchy resulted in a sample frame of 3,817 unique Medicare paid claims in 12 risk areas totaling \$62,487,853 (Table 1, next page).

Table 1: Risk Areas Sampled

Risk Area	Number of Claims	Amount of Payments
Inpatient Rehabilitation Facility	694	\$14,173,254
Inpatient Mechanical Ventilation	5	183,815
Inpatient Hospital-Acquired Conditions and "Present on Admission" Indicator Reporting	234	3,403,803
Inpatient Claims Billed with High-Severity-Level DRG Codes	285	3,882,769
Inpatient Elective Procedures	538	7,947,117
Inpatient CERT High Error DRG Codes	2,024	30,924,749
Inpatient Claims Paid in Excess of \$150,000	5	1,600,708
Inpatient Claims Paid in Excess of Charges	8	247,453
Inpatient Psychiatric Facility Emergency Adjustments	2	38,085
Outpatient Right Heart Catheterizations	13	36,631
Outpatient Claims Paid in Excess of Charges	6	39,288
Outpatient Surgeries Billed with Units Greater Than One	3	10,182
Total	3,817	\$62,487,853

SAMPLE UNIT

The sample unit was a Medicare paid claim.

SAMPLE DESIGN

We used a stratified random sample. We stratified the sampling frame into 10 strata based on the risk area.

SAMPLE SIZE

We selected 145 claims for audit, as follows (next page):

Table 2: Sampled Claims by Stratum

		Claims in Sampling	Claims in
Stratum	Risk Area	Frame	Sample
1	Inpatient Rehabilitation Facility	694	35
_		094	33
2	Inpatient Mechanical Ventilation, Inpatient Hospital-		
	Acquired Conditions and "Present on Admission" Indicator		
	Reporting, Inpatient Claims Billed with High-Severity-Level		
	DRG Codes, Inpatient Elective Procedures	1,062	25
3	Inpatient CERT High Error DRG Codes > \$30,000	122	15
4	Inpatient CERT High Error DRG Codes < \$30,000	1,902	33
5	Inpatient Claims Paid in Excess of \$150,000	5	5
6	Inpatient Claims Paid in Excess of Charges	8	8
7	Inpatient Psychiatric Facility Emergency Adjustments	2	2
8	Outpatient Right Heart Catheterizations	13	13
9	Outpatient Claims Paid in Excess of Charges	6	6
10	Outpatient Surgeries Billed With Units Greater Than One	3	3
	Total	3,817	145

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the claims within strata 1 through 4. After generating the random numbers for these strata, we selected the corresponding frame items. We selected all claims in strata 5 through 10.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the total amount of overpayments paid to the Hospital during the audit period. To be conservative, we recommend recovery of any 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.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 3: Sample Results

Stratum	Frame Size (Claims)	Value of Frame	Sample Size	Total Value of Sample	Number of Incorrectly Billed Claims in Sample	Value of Overpayments in Sample
1	694	\$14,173,254	35	\$687,945	15	\$184,833
2	1,062	15,417,503	25	324,310	1	10,361
3	122	6,788,219	15	707,486	2	35,054
4	1,902	24,136,530	33	381,737	5	22,393
5	5	1,600,708	5	1,600,708	0	0
6	8	247,453	8	247,453	3	39,357
7	2	38,085	2	38,085	0	0
8	13	36,631	13	36,631	13	10,723
9	6	39,288	6	39,288	5	28,633
10	3	10,182	3	10,182	3	4,478
Total	3,817	\$62,487,853	145	\$4,073,825	47	\$335,832

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

 Point estimate
 \$5,764,048

 Lower limit
 3,736,490

 Upper limit
 7,791,606

APPENDIX D: RESULTS OF AUDIT BY RISK AREA

Table 5: Sample Results by Risk Area

		Value of	Claims With	
	Sampled	Sampled	Under/Over-	Value of
Risk Area	Claims	Claims	payments	Overpayments
Inpatient				
Inpatient Rehabilitation Facility	35	\$687,945	15	\$184,833
Inpatient Mechanical Ventilation,				
Inpatient Hospital-Acquired Conditions				
and "Present on Admission" Indicator				
Reporting, Inpatient Claims Billed with				
High-Severity-Level DRG Codes, and				
Inpatient Elective Procedures	25	324,310	1	10,361
Inpatient CERT High Error DRG Codes >				
\$30,000	15	707,486	2	35,054
Inpatient CERT High Error DRG Codes <				
\$30,000	33	381,737	5	22,393
Inpatient Claims Paid in Excess of				
\$150,000	5	1,600,708	0	0
Inpatient Claims Paid in Excess of				
Charges	8	247,453	3	39,357
Inpatient Psychiatric Facility Emergency				
Adjustments	2	38,085	0	0
Inpatient Totals	123	\$3,987,724	26	\$291,998
Outpatient				
•	12	\$26,621	12	¢10.722
Outpatient Right Heart Catheterizations	13	\$36,631	13	\$10,723
Outpatient Claims Paid in Excess of	_			
Charges	6	39,288	5	28,633
Outpatient Surgeries Billed with Units				
Greater Than One	3	10,182	3	4,478
Outpatient Totals	22	\$86,101	21	\$43,834
Inpatient and Outpatient Totals	145	\$4,073,825	47	\$335,832

We submitted these claims for a focused medical review to determine whether the services met medical necessity and coding requirements.

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 area we audited. 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 4, 2020

Report A-05-18-00042

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

Dr. Ms. Fulcher:

The Ohio State University Wexner Medical Center (OSUWMC), on behalf of Ohio State University Hospitals, is submitting this letter in response to the draft audit report, *Medicare Hospital Provider Compliance Audit: The Ohio State University Hospital*, of the Department of Health and Human Services Office of Inspector General ("OIG") resulting from an audit of selected claims of Ohio State University Hospitals calendar years 2016 and 2017.

OSUWMC takes seriously its commitment to compliance and to the continued pursuit of excellence in all aspects of the care it provides, including billing and reimbursement. OSUWMC does agree that some of the reviewed claims were incorrect and has repaid those claims to CMS.

Briefly, the OIG audit report states the Hospital:

- Complied with 98 of the 145 inpatient and outpatient claims reviewed.
- Did not completely comply with applicable billing rules for 26 inpatient claims, resulting in a net overpayment amount of \$291,998.
- Did not completely comply with applicable billing rules for 21 outpatient claims, resulting in an overpayment calculation of \$43,834.
- Has an estimated net overpayment, inclusive of extrapolation, of \$3,736,490.

Briefly, the OIG's draft report makes the following recommendations:

1. OSUWMC should refund to its Medicare contractor \$3,736,490, of which \$335,832 is the net amount OIG calculates as the overpayments the OIG deemed to be billed in error.



- 2. OSUWMC should exercise reasonable diligence to identify and return any additional similar overpayments in accordance with the 60 day rule.¹
- 3. OSUWMC should strengthen controls to ensure full compliance with Medicare requirements to ensure that:
 - All IRF beneficiaries meet Medicare criteria for acute care inpatient rehabilitation;
 - All inpatient beneficiaries meet Medicare criteria for inpatient hospital services;
 - Diagnosis and discharge status codes are supported in the medical records and staff are properly trained; and
 - Medical records accurately document the appropriate number of units and distinct procedural services and that staff are properly trained.

OSUWMC's Response:

OIG's audit was conducted as part of a series of hospital compliance reviews and focused on areas it deemed at risk of noncompliance with Medicare billing requirements. OIG's report was not triggered by any particular concerns with OSUWMC, specifically. While we disagree with some of the OIG's factual assertions, audit methodology, findings and recommendations, we appreciate the care and diligence the OIG put into the review.

OSUWMC has repaid \$396,024.55 of the recommended, extrapolated value of \$3,736,490. OSUWMC expended due care and diligence in reviewing all the 145 claims under review. \$390,405.10 of these repayments occurred during Phase I of the audit, after our own self review and before we received the OIG's determination. For the claims that the OIG asserts had an error, multiple OSUWMC internal reviewers concluded that \$292,313.72 were appropriately billed to Medicare.

I first address the improper use of extrapolation in the OIG's recommendation to OSUWMC's Medicare contractor and then address each of the review areas. As to the use of extrapolation:

• OSUWMC's review did not find a persistent pattern of improper billing of the selected claims nor a high level of error.² OIG's errors in determining whether services are medically necessary and meet other coverage criteria are exacerbated by the extrapolation of audit findings to the universe of the hospital's claims. In 2018, the Centers for Medicare & Medicaid Services (CMS) issued guidance to its contractors explaining that extrapolation is appropriate when there is a high error rate, which CMS defined as 50% or more. And, in its corporate integrity agreements, the OIG does not require an independent review organization even to review a full sample of claims for purposes of extrapolation where a provider's error

¹ The 60 Day Repayment Rule is codified at 1128J (d) of the Social Security Act and 42 C.F.R. Part 401, Subpart D.

² Social Security Act § 1893(f); CMS Program Integrity Manual Section 8.4.1.4



rate is below 5%. Yet, in provider compliance audits, the OIG fails to provide sufficient information to the hospital for the hospital to confirm an error rate; which confuses hospitals and raises questions about what standards CMS applies in cases where it has adopted OIG's findings wholesale.

Many claims that the OIG concluded should not have been paid, in fact, met Medicare coverage and billing requirements. If CMS were to agree with the OIG and deny those claims, OSUWMC believes those denials would be reversed on appeal. In the interim, OSUWMC would suffer unnecessary reputational harm because an extrapolated repayment demand would be published in the media and never corrected, even after the hospital significantly reduced the amount of the demand through its appeals. As a result, the use of extrapolation is inappropriate for this audit.

- The OIG's audit design and methodology is flawed. OSUWMC is unable to replicate the audit due to vaguely defined risk area audit sampling terms, such as "High Severity Level DRGs", or "High Risk CERT DRGs." In the absence of OIG defining these terms, OSUWMC is left to look at every DRG and every CMS CERT report: a herculean task that would go far beyond any diligence standard. Auditing standards include transparency in the subject of the audit; yet the OIG rejected OSUWMC's requests for information on what—in in the OIG's view—qualified as "High Severity Level DRGs," "High Risk CERT DRGs" and "Elective Procedures."
- The OIG did not adhere to its own auditing methodology, as described in the "Other Matters" section of the draft report. Removal of 14 short stay claims after the audit sample was selected compromises the statistical validity of the sample and subsequent extrapolation. It is not clear when the claims meeting that same short stay criteria were removed from the sampling frames. The removal both impacts the potential paid errors rate and any extrapolation calculations. Accordingly, the extrapolation is biased and should not be used. The contractor did not supply OSUWMC with sufficient documentation to reproduce the frame internally³ or reproduce the sample.⁴
- OIG's assertion that it conducted a stratified random sample of 145 claims is contrary to what the OIG audits verbally communicated to OSUWMC: Random sampling was used for inpatient claims involving: Rehabilitation claims; High severity level DRG codes; Elective procedures; Hospital acquired conditions and present on admission indicator reporting; Mechanical ventilation; CERT DRG codes over \$30,000; and CERT DRG codes under \$30,000. Judgmental sampling was used for inpatient: Claims in excess of \$150,000, Claims paid in excess of charges, and Psych facility emergency room adjustments; as well as outpatient: Right heart catheterizations with hemodynamic data, Claims paid in excess of charges, and Surgeries billed with units greater than 1. Mixing of sampling types in the draft report is misleading.

OSUWMC medical staff and coders reviewed each of the sampled claims carefully and thoughtfully. OSUWMC disagrees that all 145 claims were applicably subjected to a correctly calculated

p. 3

³ CMS Program Integrity Manual Section 8.4.2.2.

⁴ CMS Program Integrity Manual Sections 8.4.4.2 and Section 8.4.4.1.1



extrapolation. For the claim types that the OIG believes could be subject to extrapolation, persistent patterns of proper billing were identified.

Questions of medical necessity pertaining to the inpatient rehabilitation services at issue here require individualized determinations that undercut any contention that one claim is like another, much less serving as a representation of a larger universe. We therefore request that OIG remove its recommendation that there be an extrapolation of these claims.

The OIG asserts that high risk claims should be known to hospitals via the publication of dozens of hospital Medicare Compliance Reports over the past 9 years, which address at least 32 so-called 'risk areas'. Some of the risk areas are fairly straightforward, others are not. For example, a general description of inpatient Comprehensive Error Rate Testing (CERT) high error DRG codes, inpatient elective procedures, and high severity level DRG codes are not defined in any of the published reviews, nor identified in the OIG's review of OSUWMC. This is compounded by the opacity of the "specific data filtering and analysis steps" performed on the specified risk area, which are referenced in these (historical) reports, yet never outlined or defined. Absent specificity, hospitals are left to conduct their own data mining in a vacuum and are unable to replicate OIG's audits, as key audit criteria are hidden from the hospital.

The OIG's acknowledgment of improper inclusion of short stays is warranted, as "Other Matters" in the draft report describes the OIG's audit flaws. As the OIG "voluntarily suspended audits of inpatient short stays after October 1, 2013" and the OIG selected the OSUWMC claims sampled, the OIG's entire sampling methodology is flawed and unsound. Inclusion of the OIG's conclusions of the review of the 14 short stay inpatient claims is prejudicial to OSUWMC. "Other Matters" is relevant to the audit insofar as the section highlights OIG sampling flaws and results in a biased extrapolation due to not excluding these same short stay cases from the sampling frame.

Set forth below is a description of OSUWMC's assessment of the OIG's findings broken down by the type of error for the given risk areas, as well as a description of OSUWMC's further actions with respect to each such error and area.

INPATIENT CLAIMS:

Inpatient Rehabilitation Facility Claims

Medical necessity of acute inpatient rehabilitation is based on the patient being medically stable enough to benefit from IRF, a need for coordinated care from multiple therapy services, expectation that the patient will benefit from intense rehab services, and the need for close medical supervision to support participation in an intense therapy program.

The medical judgment of the OSUWMC board certified Physical Medicine and Rehabilitation (PM&R) physicians for 32/35 selected claims reflects that medically complex patients would not



have been effectively served at a lower level of care. IRF provider specialization, certified clinical expertise, a multi-disciplinary approach, access to select services/resources, and close medical monitoring allowed for expectation of improved functional ability through optimized participation in rehabilitation, decreased burden of care, and enhanced quality of life. These aspects are not routinely available as a collective whole within a lower level of care.

OSUWMC agreed that 3 of the samples were billed in error and OSUWMC has since refunded \$71,554.32 of these IRF claims back to Medicare.

OSUWMC disagrees with the OIG regarding the medical necessity of the other IRF claims the OIG found did not meet Medicare requirements. In light of the fact that OSUWMC did not have an opportunity to challenge the OIG's conclusion that claims failed to meet Medicare coverage or documentation requirements *prior to extrapolation*, we believe extrapolation is improper. Courts that have upheld sampling and extrapolation to determine overpayments on Medicare claims have done so only where there are protections in place. For example, in Chaves County Home Health Services v. Sullivan, the court recognized the importance of being able to challenge each individual claim denial as well as the statistical validity of the extrapolation. But OSUWMC has not had that right.

We are confident that a very large proportion of the claims the OIG said should have been denied would have been reversed on appeal had OSUWMC been able to challenge them. And the OIG's sampling and extrapolation methodologies also may have been called into question. By extrapolating to the universe of claims *before* permitting OSUWMC to appeal the OIG's findings, the audit report has grossly overstated the alleged overpayment on IRF claims.

We further note that the OIG's narrow view of IRF coverage runs counter to CMS's recent approach to IRF claims. Last year, the agency agreed to settle IRF claim denials that had been appealed for 69 cents on the dollar. See https://www.cms.gov/Medicare/Appeals-and-

Grievances/OrgMedFFSAppeals/Appeals-Settlement-Initiatives/Inpatient-Rehabilitation-Facility-Appeals-Initiative. Those claims were denied by CMS contractors and yet CMS still thought settlement was warranted. Here, Medicare contractors found OSUWMC's IRF claims payable, but the OIG disagreed. We believe CMS's actions heighten concerns that the OIG is taking an unduly restrictive view of the medical necessity for IRF services which may result in harm to patients if they are placed in a less intense level of care than is medically appropriate.

In sum, OSUWMC disagrees that a repayment of \$184,833 and the additional IRF-related portion of the OIG's extrapolation is due to Medicare and disagrees that the 60 day repayment rule applies beyond the refiling/refunding of three identified claims.

Similarly, there are no additional controls that OSUWMC needs to implement in this area. Rather, OSUWMC will continue its routine, internal auditing to ensure that the services rendered in its inpatient rehabilitation unit continue to meet the medical needs of Medicare beneficiaries admitted to the inpatient rehabilitation unit.



Incorrectly Billed DRG Codes

OSUWMC agrees that 8/123 sampled inpatient claims were incorrectly coded due to human error. OSUWMC has refunded \$169,309.22 of these claims back to Medicare.

As the OIG declined to provide to OSUWMC the specific DRGs subject to the audit, OSUWMC is unable to replicate the audit. Notwithstanding the coding errors, application of the 60 day rule is not appropriate, as OSUWMC's notice by the OIG about errors was, at best, opaque.

Since OIG's findings with respect to this subset of claims are all individualized, OSUWMC does not view these findings as being credible information of other potential errors. Thus, it is not conducting a follow-on audit pertaining to this claims subset.

OSUWMC has strengthened its controls in this area as a result of this audit and has focused coder education, extensive auditing and testing in place and uses numerous systems edits and scrubbers to ensure accurate claim submission.

Claims Incorrectly Billed as Inpatient

The OIG asserts that 3/123 of the sampled claims were improperly billed as inpatients. OSUWMC disagrees. OSUWMC did refund \$64,482.85 for 4 identified errors, which the OIG also identified as errors. The remaining patients underwent physician advisor reviews and otherwise met Milliman admission criteria. OSUWMC contends that internal controls did not fail and the cases were billed appropriately. The OIG auditors removed 13 of these initial 16 claims from their audit (as described in "Other Matters").

We also disagree with the OIG's calculated overpayments for all the listed claims, as they do not reflect, nor take into account, the applicable outpatient reimbursement that OSUWMC would have received even if the case was not appropriate for an inpatient level of care.

OSUWMC has strong controls in place to ensure accuracy in determinations for inpatient admissions. Controls include training of physicians and staff as well as systems workflows by utilization review staff and revenue cycle clinical support staff.

OUTPATIENT CLAIMS:

Incorrectly Billed Claims in Excess of Charges (Incorrect HCPCS)

Contrary to OIG's assertions in its draft report, it is OSUWMC's understanding that outpatient claims paid in excess of charges is based on a judgmental basis, not sampled by stratum as described in Appendix A-D.



OSUWMC agrees that the 5 identified claims were billed in error and has refunded Medicare \$33,474.58.

OSUWMC has improved its controls as a result of this audit and is now reviewing outpatient claims paid in excess of charges prebilling.

Application of Modifier 59 for Right Heart Catheterization / (RHC) Endomyocardial Biopsies

It is OSUWMC's understanding that the application of modifier 59 for RHC claims was selected on a judgmental basis, not sampled by stratum as described in Appendix A-D.

OSUWMC agrees that the 13 identified claims were billed in error and has refunded \$36,631.03. Based on its review, OSUWMC has fulfilled its 60 day repayment rule obligation and has reviewed and refunded previous years' RHC claims consistent with the OIG's March 2017 audit⁵—a look back period available to CMS auditors.

OSUWMC has improved its controls via education and training of physicians and coding staff, auditing and testing of the claims, and improvements in systems and workflows.

Incorrect Surgical Units (Surgical Units in Excess of 1)

It is OSUWMC's understanding that incorrect surgical units (surgical units in excess of 1) claims were selected on a judgmental basis, not sampled by stratum as described in Appendix A-D.

OSUWMC disagrees with OIG's assertions in its draft audit report that surgical units in excess of 1 is a randomly selected sample, as described in Appendix A-D, rather, it is based on a judgmental basis. OSUWMC agrees that the 3 identified claims were billed in error and has refunded Medicare \$10,181.89.

The errors were due to a three week time period when a claims editor was inadvertently disabled. OSUWMC has improved its controls as a result of this audit.

In conclusion, OSUWMC thanks the OIG for the opportunity to provide feedback on its draft report, and we appreciate the professionalism and cooperative spirit of its auditors, as well as the information furnished through the audit process. As we trust was demonstrated through OIG's review, OSUWMC takes its compliance efforts very seriously. We believe we exercised reasonable diligence in our review and refunded to CMS claims made in error. We also looked back for certain

⁵ The OIG reviewed procedures performed CYs 2011 and 2012 and 5 years later it published its report. As hospitals nationwide diligently work to ensure claim accuracy, a high error rate for any claim type is unlikely, much less a 92% error rate. The net effect of the OIG's March 2017 audit was a new coding standard for CMS and hospitals on these claims https://oig.hhs.gov/oas/reports/region1/11300511.pdf.



claim types, consistent with our findings. As indicated above, we agree with OIG's assessment that certain areas require improvement, and we appreciate OIG's having brought these matters to our attention. As to those areas where we are not in agreement, we request that OIG reconsider its initial findings, and in any event, we request that OIG not extrapolate any medical necessity, inpatient admissions, or DRG findings.

Sincerely,

/Kathleen Ojala/

Kathleen Ojala, JD, RN, CHC, CPC Administrative Director and Privacy Officer, Compliance and Integrity, OSU Wexner Medical Center