

Department of Health and Human Services  
**Office of Inspector General**



Office of Audit Services

June 2026 | A-03-23-00001

# **Lehigh Valley Hospital Received At Least \$17.8 Million in Medicare Overpayments**



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### Why OIG Did This Audit

- For calendar year 2021, Medicare paid hospitals \$182 billion, which represents 46 percent of all fee-for-service payments; accordingly, it is important that hospital payments comply with requirements.
- This audit is part of a series of audits examining hospitals with a high volume of claims previously identified as high-risk for noncompliance.
- Lehigh Valley Hospital (the Hospital) was selected because it submitted a substantial number of potentially high-risk claims to Medicare.

### What OIG Found

- The Hospital complied with Medicare billing requirements for 62 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 38 claims, resulting in net overpayments of \$433,723 from October 1, 2020, through September 30, 2022 (audit period).
- On the basis of our sample results, we estimated that the Hospital received net overpayments of at least \$17.8 million for the audit period.
- These errors occurred primarily because the Hospital did not always follow its written policies and procedures to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

### What OIG Recommends

We recommend that the Hospital refund to the Federal government the \$17.8 million in estimated net overpayments, consider conducting internal audits for claims after our audit period based on the risks identified by this audit, and provide additional training regarding Medicare billing requirements. Our complete recommendations are found in the audit report.

The Hospital disagreed with most of our findings and all of our recommendations.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

For calendar year 2021, Medicare paid hospitals \$182 billion, which represented 46 percent of all fee-for-service payments. This audit is part of a series of hospital compliance audits. Previous Office of Inspector General (OIG) audits at other hospitals identified certain types of inpatient and outpatient hospital claims as being at risk for noncompliance.<sup>1</sup> Using computer matching, data mining, and other data analysis techniques, we identified hospitals with a disproportionate number of these claims. We selected Lehigh Valley Hospital (the Hospital) for this audit because it was one of those hospitals that had a substantial number of claims submitted to Medicare in areas OIG designated as high risk.<sup>2</sup>

### OBJECTIVE

Our objective was to determine whether the Hospital complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims from October 1, 2020, through September 30, 2022 (audit period).<sup>3</sup>

### BACKGROUND

#### The Medicare Program

Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for enrollees 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 Administrative Contractors (MACs) 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 enrollee discharges.<sup>4</sup> The rates vary according to the diagnosis-related group (DRG) to which an enrollee's stay is assigned and the severity level of the enrollee's

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<sup>1</sup> Hospital compliance audit reports issued by OIG are published on the [OIG Website](#).

<sup>2</sup> Submitting claims at risk for noncompliance does not by itself mean the claims were noncompliant. Determination of noncompliance is completed by independent medical review.

<sup>3</sup> This was the most recent data available at the time we started this audit.

<sup>4</sup> The IPPS pays the costs of inpatient stays at acute care hospitals, also known as "subsection (d) hospitals" because they are defined at section 1886(d)(1)(B) of the Social Security Act (the Act). Inpatient Rehabilitation Facilities (IRFs) are excluded from this definition and are not paid under the IPPS. We discuss and treat IRF claims separately.

diagnosis. The DRG payment is, with certain exceptions, intended to be payment in full to the hospital for all inpatient costs associated with the enrollee'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 enrollees who require a hospital level of care, including an 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 PPS for IRFs. Under the payment system, CMS established Federal prospective payment rates for distinct case-mix groups (CMGs). The assignment to a CMG is based on the enrollee's clinical characteristics and expected resource needs.

### **Hospital Outpatient Prospective Payment System**

Under the hospital outpatient PPS, Medicare pays for hospital outpatient services on a 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.<sup>5</sup> All services and items within an APC group are comparable clinically and require similar resources. The HCPCS includes the American Medical Association's (AMA's) Current Procedural Terminology (CPT®)<sup>6, 7</sup> codes for physician services and CMS-developed codes for certain nonphysician services.<sup>8</sup>

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<sup>5</sup> The health care industry uses HCPCS codes to standardize coding for medical procedures, services, products, and supplies.

<sup>6</sup> *CPT copyright 2020 American Medical Association. All rights reserved.*

*Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.*

*CPT is a registered trademark of the American Medical Association.*

<sup>7</sup> **U.S. Government End Users.** CPT is commercial technical data, which was developed exclusively at private expense by the American Medical Association (AMA), 330 North Wabash Avenue, Chicago, Illinois 60611. Use of CPT in connection with this product shall not be construed to grant the Federal Government a direct license to use CPT based on FAR 52.227-14 (Data Rights - General) and DFARS 252.227-7015 (Technical Data - Commercial Items).

<sup>8</sup> 45 CFR § 162.1002(c)(1); *The Medicare Claims Processing Manual*, Publication No. 100-04 (the *Manual*), chapter 4, § 20.1.

## Hospital Claims at Risk for Incorrect Billing

We reviewed the following OIG-designated high-risk areas as part of this audit:

- IRF claims
- Inpatient claims of less than 2 midnights
- Inpatient claims with the following:
  - Same day discharge and readmission
  - Elective procedures
  - Comprehensive error rate testing (CERT) error prone DRG codes<sup>9</sup>
  - High-severity level DRG codes
  - DRGs for severe malnutrition
  - Claims paid in excess of charges
- Outpatient claims with the following:
  - Multiple units of surgery
  - Bypass modifiers<sup>10</sup>

For the purposes of this report, we refer to these areas at risk for incorrect billing as “risk areas.”

## 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

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<sup>9</sup> 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. As a result of our CERT data analysis, we identified 15 DRGs that are most at risk for billing errors: 069, 149, 313, 469, 470, 472, 473, 516, 519, 520, 553, 554, 556, 563, and 605.

<sup>10</sup> A bypass modifier refers to a two-character code appended to a medical procedure code (CPT or HCPCS) on a claim submitted for reimbursement by Medicare. The modifier serves to override edits that otherwise prevent payment for two or more services billed together.

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*) (chapter 1, section 80.3.2.2) requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly.

### **Limitation on Recovery of Overpayments**

MACs may reopen a claim for good cause within 4 years from the date of the initial determination or redetermination.<sup>11</sup> Novitas Solutions, Inc., the Hospital's MAC, reopened all claims in our audit sampling frame within 4 years from the date of the initial determination of each of those claims.

Section 1870 of the Act prohibits the recovery of Medicare fee-for-service overpayments if the provider was without fault with respect to the overpayment.<sup>12</sup> A provider is presumed to be without fault for Medicare fee-for-service overpayments if the overpayment determination is made by the Medicare program after the fifth year following the year in which notice of such payment was sent to the provider.<sup>13</sup> MACs typically waive recovery in accordance with this presumption but have the authority to determine whether there is sufficient evidence to rebut the presumption.

### **Lehigh Valley Hospital**

The Hospital is a 729-bed short-term, acute-care hospital located in Allentown, Pennsylvania. According to CMS's National Claims History (NCH) data, Medicare paid the Hospital approximately \$456 million for 17,674 inpatient and 31,496 outpatient claims during the audit period.

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<sup>11</sup> 42 CFR § 405.980(b)(2).

<sup>12</sup> Section 1870; 78 Fed. Reg. 74230, 74445 (Dec. 10, 2013); *Medicare Financial Management Manual*, chapter 3, §§ 70.3 and 80.

<sup>13</sup> Section 1870; 78 Fed. Reg. 74230, 74445 (Dec. 10, 2013); *Medicare Financial Management Manual*, chapter 3, §§ 70.3 and 80.

## HOW WE CONDUCTED THIS AUDIT

Our audit covered roughly \$80 million in Medicare payments made to the Hospital for 6,464 claims in the risk areas identified above.<sup>14</sup> We selected for review a stratified random sample of 100 claims (65 inpatient, 20 IRF, and 15 outpatient) with Medicare payments totaling about \$1.3 million made during our audit period.<sup>15</sup>

We evaluated compliance with selected billing requirements and submitted all claims to an independent medical review contractor to determine whether the claim was supported by the medical record. This report focuses on selected risk areas and does not represent an overall assessment of all claims submitted by the Hospital for Medicare reimbursement.

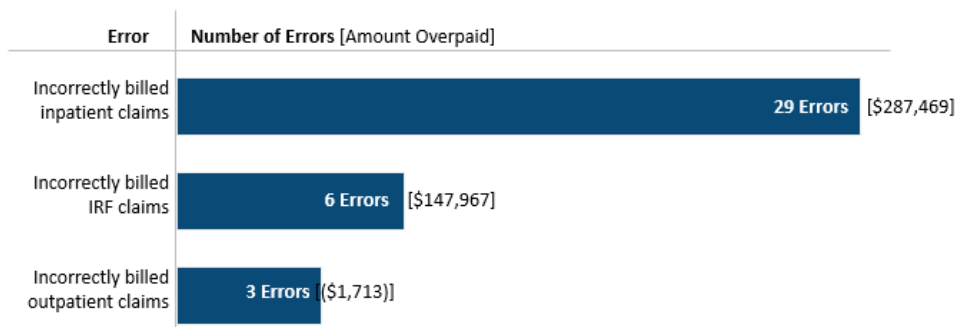
We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives.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

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

## FINDINGS

The Hospital complied with Medicare billing requirements for 62 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 38 claims, resulting in net overpayments of \$433,723. Figure 1 provides a breakdown of the error types, the number of claims in error, and the associated net overpayments.

**Figure 1: Inpatient and Outpatient Billing Errors**



<sup>14</sup> The total Medicare payments were \$80,365,554.

<sup>15</sup> The total Medicare payments were \$1,255,591.

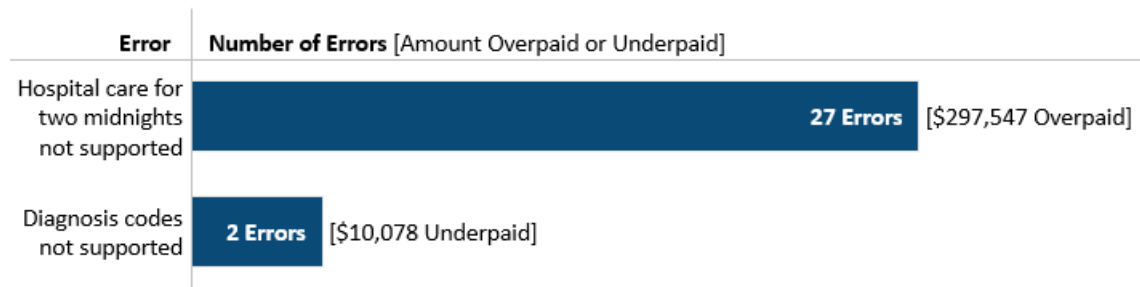
These errors occurred primarily because the Hospital did not always follow its policies and procedures to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

On the basis of our sample results, we estimate that the Hospital received net overpayments of at least \$17.8 million for the audit period.<sup>16</sup> See Appendix B for statistical sampling methodology, Appendix C for sample results and estimates, and Appendix D for the results of our audit by risk area.

### INCORRECTLY BILLED INPATIENT CLAIMS

For 29 of the 65 selected inpatient claims, our independent medical review contractor determined that the Hospital incorrectly billed Medicare Part A for enrollee stays that did not meet Medicare criteria for inpatient services at acute care hospitals. These errors resulted in net overpayments totaling \$287,469. Figure 2 provides a breakdown of the error types, the number of claims in error, and the associated net overpayments.

**Figure 2: Inpatient Billing Errors**



### Hospital Care for Two-Midnights Not Supported

No payment may be made under Medicare Part A for any expenses incurred 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)).

Federal regulations provide that an inpatient admission, and subsequent payment under Medicare Part A, is appropriate if the ordering physician expects the enrollee to require care for a period that crosses 2 midnights (42 CFR § 412.3(d)(1)).<sup>17</sup>

<sup>16</sup> Our actual estimate is \$17,838,422. 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.

<sup>17</sup> We refer to this regulation as the “Two-Midnight Rule” throughout the report.

### **Admission Did Not Meet Inpatient Expectation**

One enrollee was admitted for left hip and lower back pain with impaired ambulation (difficulty in walking). The enrollee was treated and evaluated by a physician, then was discharged after assessment by an occupational therapist. Documentation at the time of admission did not justify an expectation of hospital care for a period that crosses 2 midnights.

For 27 of the 65 selected inpatient claims, the medical records did not support that it was reasonable for the admitting physician, at the time the inpatient order was written, to have expected that hospital care was required for a period that crosses 2 or more midnights.<sup>18</sup> Overpayments associated with these 27 claims totaled \$297,547.

### **Diagnosis Codes Not Supported**

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.

For 2 of the 65 selected inpatient claims, the Hospital submitted claims to Medicare that had principal diagnosis codes that were not supported by the medical records. The incorrectly coded claims resulted in incorrect DRG payments to the Hospital. Incorrect DRG payments made to the Hospital associated with these two claims resulted in a net underpayment of \$10,078.

### **Diagnosis Code with Complication or Comorbidity Not Supported**

One enrollee was admitted for acute inpatient services after a fall with lower back pain. The clinical indicators, including physical exam findings, orders, and diagnostic studies, did not provide evidence of a complication or comorbidity. Consequently, the documentation justifies only a diagnosis code without a complication or comorbidity.

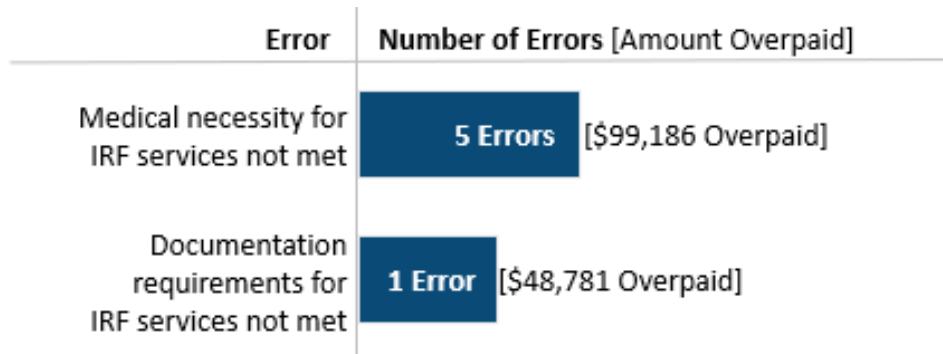
### **INCORRECTLY BILLED INPATIENT REHABILITATION FACILITY CLAIMS**

For 6 of the 20 selected IRF claims, our independent medical review contractor determined that the hospital incorrectly billed Medicare Part A for enrollee stays that did not meet Medicare criteria for inpatient rehabilitation services. These errors resulted in overpayments totaling \$147,967. Figure 3 provides a breakdown of the error types, number of claims in error, and the associated overpayments.

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<sup>18</sup> Our medical review contractor also determined that these 27 claims did not meet InterQual® Level of Care Criteria for inpatient hospital admission. These criteria are evidence-based clinical decision support tools that many hospitals use to help assess clinical appropriateness and strengthen patient outcomes. Failure to meet InterQual Level of Care Criteria does not equate with failure to meet Medicare requirements, but we believe this is useful information for the Hospital for its quality assurance efforts. See the Other Matters section for additional information.

**Figure 3: Inpatient Rehabilitation Facility Billing Errors**



**Medical Necessity for Inpatient Rehabilitation Facility Services Not Met**

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 enrollee: (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 supervision by a rehabilitation physician (42 CFR § 412.622(a)(3)(i-iv)). During the COVID-19 Public Health Emergency, the second requirement and the “intensive” nature of rehabilitation therapy in the third requirement were waived (42 CFR § 412.622(a)(3)(ii-iii)).

For 5 of the 20 selected IRF claims, the Hospital incorrectly billed Medicare Part A for enrollee stays where there was not a reasonable expectation that the patient required supervision by a rehabilitation physician. Overpayments associated with these five claims totaled \$99,187.

**IRF Admission for Hip Fracture Not Necessary**

One enrollee was admitted for inpatient rehabilitation services after a fall resulting in a right hip fracture that was surgically repaired without complications. The enrollee had no postoperative complications, active comorbidities, or other active issues requiring rehabilitation physician evaluation and care. The enrollee’s recovery, rehabilitation, and convalescence could have been overseen by a non-rehabilitation physician and did not require an IRF stay.

**Documentation Requirements for Inpatient Rehabilitation Facility Services Not Met**

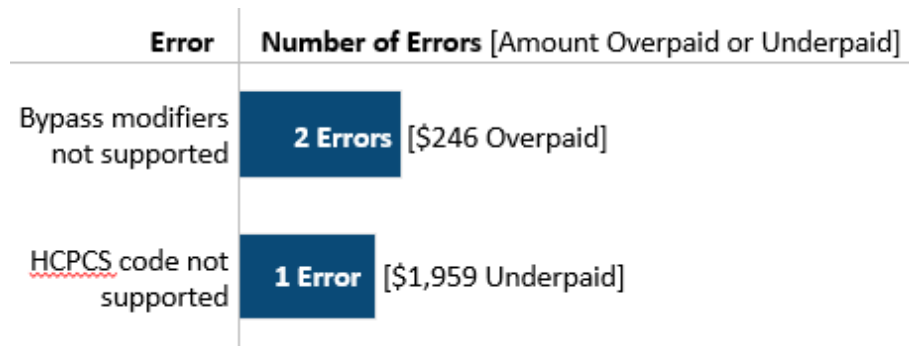
Federal regulations mandate that the enrollees must require an interdisciplinary team (IDT) approach to care, as evidenced by documentation in the enrollee’s medical record of weekly IDT meetings. The meetings are led by a rehabilitation physician and consist of a registered nurse, a social worker or case manager, and a licensed or certified therapist from each discipline involved in treating the enrollees (42 CFR § 412.622(a)(5)).

For 1 of the 20 selected IRF claims, the Hospital billed Medicare Part A for enrollee stays that did not meet IRF Medicare documentation requirements. Specifically, the documentation did not support that the IDT meetings occurred at least once per week throughout the stay. Overpayments associated with this claim totaled \$48,781.

### INCORRECTLY BILLED OUTPATIENT CLAIMS

For 3 of the 15 selected outpatient claims, our independent medical review contractor determined that the Hospital incorrectly billed Medicare Part B for claims that did not meet Medicare criteria for outpatient services. These errors resulted in net underpayments totaling \$1,713. Figure 4 provides a breakdown of the error types, number of claims in error, and the associated net underpayments.

**Figure 4: Outpatient Billing Errors**



### Bypass Modifiers Not Supported

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), 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).

Under certain circumstances, it may be necessary to indicate that a procedure or service was distinct or independent from other non-E/M [Evaluation/Management] services performed on the same day. Modifier 59 is used to identify procedures/services, other than evaluation and management services, that are not normally reported together but are appropriate under certain circumstances. Documentation must support a different session, different procedure or surgery, different site or organ system, separate incision or excision, separate lesion, or separate injury (or area of injury in extensive injuries) not ordinarily encountered or performed on the same day by the same individual (*Medicare National Correct Coding Initiative (NCCI)*

*Policy Manual*, chapter 1, section E).<sup>19</sup>

For 2 of 15 selected outpatient claims, the Hospital incorrectly billed Medicare Part B using HCPCS codes with bypass modifier 59, even though the services were not separate and distinct from other procedures on the same claim. Overpayments associated with these two claims totaled \$246.

### **HCPCS Code Not Supported**

The Act precludes payment to any provider of services or other person without information necessary to determine the amount due to 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 on outpatient claims (the *Manual*, chapter 4, § 20.1), 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).

For 1 of 15 selected outpatient claims, the hospital incorrectly coded the repair of a hand injury. The hospital billed for a general complex closure rather than the specific extensor tendon repairs performed. Correcting this to the correct HCPCS code resulted in a net underpayment of \$1,959.

### **HOSPITAL STAFF DID NOT CONSISTENTLY FOLLOW PROCEDURES TO PROPERLY BILL HOSPITAL SERVICES**

The 38 incorrectly billed claims did not comply with Medicare requirements because staff did not consistently follow the Hospital's written policies designed to prevent noncompliance with the Two-Midnight Rule, medical necessity, IRF admissions, documentation, billing, and coding. Although Hospital officials contended that the claims met Medicare requirements, they did not provide any additional information that would affect our findings.

### **Modifier 59 Not Supported for Shoulder Treatment**

One claim was incorrectly coded with modifier 59. The enrollee was given an intravenous push of fentanyl during the treatment of left shoulder dislocation, which was incorrectly coded as a distinct procedure.

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<sup>19</sup> *The responsibility for the content of any "National Correct Coding Policy" included in this product is with the Centers for Medicare and Medicaid Services and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable to or related to any use, nonuse or interpretation of information contained in this product.*

## RECOMMENDATIONS

- We recommend that the Hospital refund to the Federal government the estimated \$17,838,422 in net overpayments for incorrectly billed claims, excluding amounts presumed to be unrecoverable under the Section 1870 waiver of liability provision.<sup>20, 21</sup>
- We recommend that the Hospital consider conducting one or more internal audits or investigations for claims beyond our audit period, based on the risks identified by this audit, to identify any similar overpayments the Hospital might have received and return any identified overpayments to the Medicare program.
- We recommend that the Hospital provide additional training to clinical and billing personnel on its policies and procedures related to the following:
  - Two-Midnight Rule
  - The medical necessity of inpatient services
  - IRF admissions
  - IRF documentation requirements
  - Inpatient and outpatient coding

## HOSPITAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Hospital disagreed with most of our findings and all our recommendations. The Hospital stated the OIG's findings largely reflect a difference in medical opinion about the enrollees' conditions and that these differences do not provide a basis for claims denials. In addition, the Hospital disagreed with OIG's sampling methodology, asserting it failed to meet the legal standards required to calculate and extrapolate audit results.

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<sup>20</sup> OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

<sup>21</sup> Novitas Solutions, Inc. retains the authority to determine whether there is sufficient evidence to rebut the Section 1870 "fifth year following" "without fault" presumption that might limit the recovery of any of these overpayments.

We summarized the Hospital's agreements, disagreements, and objections below.<sup>22</sup>

After reviewing the Hospital's comments, we removed one error based on additional information provided by the hospital related to IRF documentation for an IDT meeting. As a result, we updated our findings, estimated overpayment amount, and our first recommendation. We maintain that our findings and recommendations, as revised, are correct.

The Hospital's comments, excluding their exhibits, are included as Appendix E.<sup>23</sup>

## **AUDIT RECOMMENDATIONS**

### **Hospital Comments**

The Hospital did not concur with any of our recommendations. Regarding our first recommendation, the Hospital said that our findings are fundamentally flawed, except for the two claims that resulted in underpayments and one undisputed outpatient claim. The Hospital said it engaged with a healthcare consulting firm that disagreed with most of OIG's findings and found the Hospital appropriately billed the claims. The Hospital also said that our extrapolated overpayment from the 100 audited claims is invalid, as explained in a report prepared by an adjunct professor of statistics. The Hospital further stated that it intends to vigorously challenge through the Medicare administrative appeals process any outstanding claims denials and the statistical sampling and extrapolation methodology used to calculate the overpayment.

Regarding our second recommendation, the Hospital argued that it exercised reasonable diligence by engaging with a qualified outside reviewer to determine if any of the claims highlighted in this audit were billed in error. Based on those findings, the Hospital said it had no legal obligation to conduct further reviews beyond its routine auditing and monitoring processes already in place.

Regarding our third recommendation, the Hospital maintained that additional training was unnecessary because the findings of its healthcare consulting firm refuting most of OIG's findings showed that it has an effective compliance program that ensured claims are coded and billed appropriately.

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<sup>22</sup> We list the Hospital's agreements, disagreements, and objections by subject matter because the Hospital addressed several topics across multiple headings. We have responded to the Hospital's comments within each topic area.

<sup>23</sup> The Hospital submitted two additional documents—labeled Exhibit 1 (healthcare consulting firm's opinion) and Exhibit 2 (statistical consultant's opinion). Although these exhibits are not included in this report, we considered them in their entirety and will provide them to CMS.

## Office of Inspector General Response

We disagree with the Hospital's assertion that our findings represent no more than a difference in medical opinion. We submitted the selected claims to an independent medical review contractor who reviewed the medical records to determine whether the services were provided in accordance with Medicare requirements. We ensured that their review was conducted by experienced professionals, including physicians and coders, with relevant expertise, and that the appropriate Medicare criteria were applied. As stated below, our extrapolation was proper and conformed to all requirements. The Hospital has the right to appeal any action taken by CMS or the MAC, as previously stated in the report.

We also disagree that the errors do not warrant conducting one or more internal audits or investigations for claims beyond our audit period, based on the risks identified by this audit. We identified multiple errors in several categories—such as the Two-Midnight Rule and incorrectly coded claims—that indicate these errors are not isolated and similar issues may exist. We continue to believe that it would be prudent and, in the Hospital's best interest, to consider performing internal audits or investigations for claims beyond our audit period.

Finally, we do not agree with the Hospital that additional training is unnecessary. We identified multiple errors in several categories despite the Hospital's existing compliance and training programs. We believe additional training should be provided to increase compliance with Medicare requirements.

## INPATIENT CLAIMS

### Hospital Comments

The Hospital stated that, for each of the 27 claims we found did not comply with the Two-Midnight Rule, the medical records “reflect that the admitting physician reasonably expected, at the time of the admission order, that the Hospital stay would cross 2 midnights as required by the applicable legal standards.” The Hospital stated that the expectation for a stay that crosses two midnights “is inferred from the record—no separate attestation of the expected length of stay is required.” Moreover, the Hospital stated that “the inpatient admission is generally payable if the medical record supports the admitting physician’s judgment was **reasonable**.” The Hospital further stated that “[w]hether the admitting physician’s judgment was reasonable requires consideration of the medical evidence available **at the time** the admission decision was made.” In other words, “clinical information available post-admission is ... relevant to the extent it supports the medical reasonableness and necessity of admission.”<sup>24</sup>

The Hospital stated that the OIG’s medical reviewers “failed to consider post-admission information that supported the reasonableness and necessity of admission” and that the OIG

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<sup>24</sup> The Hospital referenced the *Medicare Benefit Policy Manual*, chapter 1, § 10.

“can point to no evidence that would rebut the presumption that these were medically necessary admissions.”

The Hospital stated that, of the four claims the OIG denied for various coding errors, the Hospital agreed with one. The Hospital disputed the remaining three inpatient coding findings because they stated that the claims were properly coded and the relevant codes were supported.

### **Office of Inspector General Response**

We disagree with the Hospital that our medical reviewer did not apply the Two-Midnight Rule correctly and should have considered post-admission information in their review. We maintain that all 27 inpatient admissions at issue did not satisfy the Two-Midnight Rule.

The Two-Midnight Rule states that an inpatient admission, and subsequent payment under Medicare Part A, is appropriate if the ordering physician expects the enrollee to require care for a period that crosses 2 midnights (42 CFR § 412.3(d)(1)). While the Hospital is correct that no separate attestation of the expected length of stay is required, our medical reviewer did not look for one when determining compliance with the Two-Midnight Rule. And while the Hospital is correct that the admitting physician’s expectation is reviewed under a reasonableness standard, which our medical reviewer did, there is no presumption of medical necessity that must be rebutted by the OIG, a MAC, or any other Medicare contractor performing post-payment medical review. The Act and 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 (the Act, § 1815(a); 42 CFR § 424.5(a)(6)). Moreover, the Two-Midnight Rule states that the “complex medical factors” upon which the physician’s expectation should be based “must be documented in the medical record in order to be granted consideration” (42 CFR § 412.3(d)(1)(i)). Our medical reviewers determined that 27 of 65 inpatient admissions reviewed did not comply with the Two-Midnight Rule because the medical records did not support that it was reasonable for the admitting physician, at the time the inpatient order was written, to have expected that hospital care was required for 2 or more midnights.

We disagree with the Hospital’s contention that our medical reviewer should have considered post-admission information that would support the finding that an admission was medically reasonable and necessary. CMS guidance to QIOs for reviews of hospital admissions is not relevant criteria because QIOs do not perform post-payment medical reviews and the *Medicare Benefit Policy Manual’s* guidance cannot alter regulations such as the Two-Midnight Rule. In guidance to Medicare contractors who perform post-payment medical review, CMS has said that “Medicare review contractor reviews shall assess the information available at the time of the original physician/practitioners’ decision” (*Medicare Program Integrity Manual (MPIM)*, chapter 6, § 6.5.2.B). After our audit period, CMS clarified this guidance with the following: “The entire medical record shall be reviewed to support or refute the reasonableness of the practitioner’s expectation, but entries after the point of the admissions order are only used in

the context of interpreting what the practitioner knew and expected at the time of admission.”<sup>25</sup> Our medical review contractor examined the medical records in their entirety to determine whether they supported that it was reasonable for the admitting physician, *at the time the inpatient order was written*, to have expected that hospital care was required for a period that crosses 2 or more midnights.

Regarding the coding errors, we only questioned two of the four inpatient claims the Hospital listed as denied in their comments.<sup>26</sup> The Hospital agreed that one of the two claims was miscoded. We maintain that the other sample item was coded with a diagnosis code with complication or comorbidity that was not supported.

## **INPATIENT REHABILITATION FACILITY CLAIMS**

### **Hospital Comments**

The Hospital disputes our finding that five IRF claims did not satisfy the requirement that, at the time of admission, there was a reasonable expectation that the patient required supervision by a rehabilitation physician. The Hospital said that this requirement “represents a medical judgment made at the time of admission based on the physician’s observations of the patient, and **not** a retrospective decision made based on a cold medical record.” The Hospital added that “CMS regulations give deference to physicians’ real-time judgment that there is a reasonable expectation the patient needs supervision by a rehabilitation physician.” The Hospital said that the draft report “demonstrates OIG has not afforded deference to physicians’ real-time judgment regarding reasonable expectations of rehabilitation physicians’ supervision for the five IRF claims in question.”

The Hospital also disputes our finding that two claims did not satisfy the requirement to have weekly IDT meetings. The Hospital stated that “CMS does not require a specific form to document IDT meetings” and an IRF may use “notes in the patients’ general medical record to document these meetings.” According to the Hospital, OIG denied claims where a patient was missing a specific IDT form even when the medical record itself made clear that the IDT met and documented their assessment of the patient.

### **Office of Inspector General Response**

The Federal regulation that requires there be a reasonable expectation that, at the time of admission, the enrollee requires supervision by a rehabilitation physician (42 CFR § 412.622(a)(3)(iv)) does not state expressly nor implicitly that Government auditors give deference to the clinical judgment of the admitting physician. The Hospital’s assertion that

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<sup>25</sup> On September 12, 2025 *MPIM* Chapter 6 – Medicare Contractor Medical Review Guidelines for Specific Services, see <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c06.pdf> Page 26.

<sup>26</sup> Sample numbers 77 and 79 were not denied for coding errors.

CMS regulations give deference to the admitting physician is based on two statements from the May 6, 2009, edition of the Federal Register that do not stand for the proposition the Hospital offers. It is clear on the face of the first quote—“The need for physician supervision cannot be inferred retroactively from the presence or absence of an acute medical complication during the IRF stay”—that CMS said nothing about giving deference to the admitting physician. Neither did CMS in the second quote, which simply states CMS’s justification for requiring the rehabilitation physician to sign the preadmission screening and eliminating the requirement of a post-admission evaluation period. Our medical reviewer is not required to defer to the professional judgment of the Hospital’s rehabilitation physician and made its determination after examining the original documentation.

We agree with the Hospital that one of the two claims met IDT requirements and have removed this error. The documentation supports that the physical therapist participated in the IDT meeting even though his name did not appear on the list of attendees. We maintain the other claim did not meet IDT requirements.

## **OUTPATIENT CLAIMS**

### **Hospital Comments**

The Hospital agreed with two of the three outpatient claims we found were improperly billed. For the third claim, it stated that the patient’s pain treatment was a separate service from the HCPCS/CPT code and was correctly billed with modifier 59.

### **Office of Inspector General Response**

Medicare requires accurate reporting of HCPCS codes and modifiers.<sup>27</sup> For the third claim, our medical reviewer determined that the pain management services were part of the primary procedure, not a separate service, and the claim was therefore improper.

## **STATISTICAL SAMPLING**

### **Threshold Requirement for Extrapolation**

#### *Hospital Comments*

The Hospital stated the “OIG has failed to make the findings required by statute to recommend the use of statistical sampling and extrapolate an overpayment in this case. A threshold requirement for the use of extrapolation to determine overpayment amounts is that a

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<sup>27</sup> The *Manual*, chapter 1, § 80.3.2.2

determination must be made that (1) there has been a sustained or high level of payment error, or (2) documented educational intervention has failed to correct the payment error.”<sup>28</sup> The Hospital further asserted that, “since the audit findings will be referred to the MAC, any overpayment calculation must comply with CMS guidance before repayment is pursued.”

### *Office of Inspector General Response*

The requirement that a determination of a sustained or high level of payment error must be made before extrapolation applies only to Medicare contractors, not OIG.<sup>29 30</sup> Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.<sup>31</sup> The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.<sup>32</sup> We properly executed our statistical sampling methodology by defining our sampling frame and sample unit, randomly selecting our sample, applying relevant criteria in evaluating the sample, and using statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

### **Inappropriate Use of Statistical Sampling**

#### *Hospital Comments*

The Hospital stated it is well established that the “permissibility of statistical sampling turns on the degree to which the evidence is reliable in proving or disproving the elements of the

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<sup>28</sup> 42 U.S.C. § 1395ddd(f)(3); *see also* MPIM, Chapter 8, § 8.4.1.2.

<sup>29</sup> See the Act § 1893(f)(3) and CMS, MPIM, Pub. No. 100-08, chapter 8, § 8.4.

<sup>30</sup> We also dispute the Hospital’s assertion that the Medicare contractor charged with processing any associated overpayments connected to this audit is subject to the CMS policies it cited. These policies prohibit a MAC from using extrapolation in its own audits unless there is a sustained or high level of payment error or there is a failure of documented educational interventions. The MAC is not subject to such limitations in the adjudication of an OIG audit.

<sup>31</sup> See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at \*26-28 (S.D. Tex. 2013), *adopted by* 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at \*17 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

<sup>32</sup> See *John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at \*34-35 (W.D. Pa. 2012), *aff’d* 555 F. App’x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff’d*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at \*17 (S.D. Fla. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at \*13 (S.D. Tex. 2012).

relevant cause of action.”<sup>33</sup> “Here, where the determination of medical necessity is highly subjective and fact-intensive, the use of statistical sampling to draw conclusions about the larger universe of claims is not a reliable method of determining liability (if any) for overpayments to LVHN [Lehigh Valley Health Network] over a two-year period.”<sup>34</sup> The Hospital said that “overpayment calculations should be limited to the claims OIG actually audited.”

### *Office of Inspector General Response*

We do not agree that statistical sampling is inappropriate for the claim types covered by this audit. 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.<sup>35</sup> The conservative nature of our estimate is not changed by the nature of the errors identified in this audit. Moreover, the court cases that the Hospital referenced in support of its argument are limited to the False Claims Act and inapplicable to OIG audit recommendations and CMS recoveries. Furthermore, in *Chaves County Home Health Services v. Sullivan*, 732 F. Supp. 188 (D.D.C. 1990), a provider alleged that the use of statistical sampling and extrapolation without individual review of each claim was illegal. The District Court held otherwise, and the Court of Appeals affirmed finding that the provider had the opportunity to challenge the statistical validity of both the sample and the extrapolation on appeal (*Chaves County Home Health Services v. Sullivan*, 931 F.2d 914 (D.C. Cir. 1991)). The Hospital has five levels of appeal to challenge the statistical validity of this audit.

### **Recreating the Sampling Frame**

#### *Hospital Comments*

The Hospital stated that “OIG failed to provide the target universe from which to re-recreate the sampling frame” and “despite multiple requests, OIG failed to provide the necessary information required for LVHN to evaluate the statistical sampling and extrapolation methodologies. By failing to provide this information, OIG denied LVHN of its due process rights, and as a result, the extrapolated audit result should not be used to calculate any alleged repayment amounts.”

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<sup>33</sup> *United States v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833, at \*11 (N.D. Tex. June 20, 2016) (quoting *Tyson Foods, Inc. v. Bouaphakea*, 136 S. Ct. 1036, 1046 (2016)).

<sup>34</sup> *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. CA 0:12-3466-JFA, 2015 WL 3903675, \*8 (D.S.C. June 25, 2015).

<sup>35</sup> As stated earlier in this report, 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.

## *Office of Inspector General Response*

The Hospital's claim that OIG did not provide sufficient documentation to re-create the sampling frame, the random sample, or the estimate of overpayments is incorrect. Following the exit conference, we provided the Hospital with several workpapers, including the sampling plan, the sampling frame file, the random numbers, the selected sample items, the sample results, and the RAT-STATS output file containing the point estimate and the two-sided 90 percent confidence interval. Specifically, the Hospital contends we did not provide the "target universe" however, (1) the Hospital has access to its own claims and (2) using these in conjunction with the sampling plan that we provided, which includes the definition of the target population, the Hospital can validate the sampling frame. Therefore, we maintain that the Hospital has the information necessary to re-create the sampling frame, validate the random sample, and generate statistical estimates.

### **Office of Inspector General's Calculation of Extrapolated Overpayment**

#### *Hospital Comments*

The Hospital stated the OIG's statistical methodologies are invalid because of the following reasons:

- **"The frame impermissibly excluded zero-paid claims.** The OIG failed to include denied or 'zero-paid' claims in the sampling frame. A zero-paid claim is potentially an underpaid claim, so excluding these claims from the frame causes it to be biased toward only the potential errors resulting in potential overpayments."
- **"OIG's stratified sampling plan was not statistically valid.** The construction of strata for a stratified sampling plan where the variable of interest is amounts paid and overpaid '[f]or a single item or variable  $y$ , the best characteristic is clearly the frequency distribution of  $y$  itself.'<sup>36</sup> Using amounts paid as the  $y$ , the combined frame of 6,464 claims is divided into sub-frames, which are nonoverlapping and together comprise the whole frame. OIG's six strata with respect to amounts paid are overlapping, which is an invalid stratification."

#### *Office of Inspector General Response*

OIG disagrees that it was impermissible to exclude zero-paid claims from the frame.<sup>37</sup> A valid estimate of overpayments does not need to take into consideration all claims from the Hospital within the audit period. Further, when extrapolation is used, OIG only projects to the sampling

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<sup>36</sup> Cochran, William G., *Sampling Techniques*, John Wiley & Sons, 1977, page 127.

<sup>37</sup> In Exhibit 2, the Hospital's statistical expert relied heavily on CMS's *MPIM*. As stated previously, the *MPIM* does not apply to OIG, but we note that *MPIM*, chapter 8, § 8.4.3.2 expressly allows for the exclusion of claims/claim lines that are attributable to sample units for which there was no payment.

frame from which the sample was drawn and does not extend to claims beyond the audit scope. Therefore, a valid sampling frame and estimate of overpayments does not need to include zero-paid claims.

OIG also disagrees that our stratification method was invalid. We defined each sample unit as a Medicare paid claim and stratified the sampling frame by claim type and then by paid amount. As the sampling plan states, “every claim appears only once in the sampling frame and is assigned to only one stratum,” i.e., the strata are non-overlapping and comprise all sample units in the sampling frame and therefore is a valid method of stratification.

## OTHER MATTERS

### Claims Associated with InterQual Level of Care Criteria

During our audit period, CMS required its medical review contractors to use a screening tool as part of their medical review of acute IPPS claims (*MPIM*, chapter 6, § 6.5.1). CMS did not require that the contractor use a specific tool, nor does CMS or the OIG endorse any specific tool.<sup>38</sup> During an earlier series of hospital compliance audits, in response to findings that claims did not meet Medicare inpatient admission requirements, several auditees noted that their documentation supported that the claims met the InterQual® or Milliman (the predecessor to Milliman Care Guidelines) Level of Care Criteria screening tools.<sup>39</sup>

As part of this audit, we asked our independent medical review contractor to apply clinical screening criteria to review the Hospital’s IPPS claims. This was done for informational purposes and to provide the auditee with additional information that might assist them with their compliance and utilization of review programs.

The contractor used InterQual® criteria to evaluate a sample of 65 claims. For 39 of those claims, our independent medical review contractor found that the admissions did not meet InterQual® criteria.<sup>40</sup> Although those claims do not constitute a failure to meet Medicare requirements, the results of our audit suggest that properly applying a screening tool to the Hospital’s compliance or utilization review programs would reduce inappropriately billed claims.

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<sup>38</sup> Several commercially available screening tools exist, including InterQual® Level of Care Criteria, Milliman Care Guidelines Inpatient & Surgical Care Guidelines, and other proprietary systems.

<sup>39</sup> For example, see [Medicare Hospital Provider Compliance Audit: Lake Hospital System \(A-05-19-00024\)](#), June 30, 2021, and [Medicare Hospital Provider Compliance Audit: St. Vincent Hospital \(A-05-18-00040\)](#), Nov. 27, 2019.

<sup>40</sup> Twenty-seven of the 38 claims were reported as errors for not meeting the Two-Midnight Rule.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered \$80,365,554 in Medicare payments to the Hospital for 6,464 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 claims (65 inpatient, 20 IRF, and 15 outpatient) with payments totaling \$1,255,591.<sup>41</sup> Medicare paid these 100 claims from October 1, 2020, through September 30, 2022 (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.

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

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

- Interviewed Hospital officials regarding the Hospital's internal controls for compliance with Medicare billing requirements that related to the risk areas we identified
- Reviewed the Hospital's policies and procedures for the Two-Midnight Rule, medical necessity of inpatient and outpatient services, IRF admissions and documentation requirements, billing of services provided, and inpatient and outpatient coding
- Reviewed a stratified random sample of 65 inpatient claims, 20 IRF claims, and 15 outpatient claims to determine whether claims were properly billed and reimbursed
- Discussed with Hospital officials the cause of the identified errors

We performed our audit work from January 2023 to October 2025.

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<sup>41</sup> For claim selection, CMS instructs Medicare review contractors to apply the Two-Midnight Presumption and avoid reviewing stays spanning 2 or more midnights, unless there is evidence of systemic abuse, gaming, or care delays (*MPIM*, chapter 6, § 6.5.2). The Two-Midnight Presumption is CMS guidance directing Medicare reviewers to presume that an inpatient admission is appropriate and medically necessary when a patient remains in the hospital for at least two midnights after a physician orders inpatient status, unless there is evidence of abuse. However, OIG is not constrained by the Two-Midnight Presumption for the purpose of selecting claims for review.

## METHODOLOGY

We took the following steps to accomplish our objective:

- 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
- Created a sampling frame of paid Medicare claims from selected risk areas consisting of 6,464 claims with a total paid amount of \$80,365,554
- Selected a stratified random sample of 100 claims (65 inpatient, 20 IRF, and 15 outpatient) with payments totaling \$1,255,591
- Reviewed data from the Recovery Audit Contractor Data Warehouse for the claims included in the sample to determine whether the claims had been previously reviewed
- Reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been canceled or adjusted
- Obtained from the Hospital all supporting documentation for the claims in our sample
- Used an independent medical review contractor to determine whether all claims complied with selected billing requirements
- Calculated the correct payments for those claims requiring adjustments
- Used the results of the sample review to calculate the estimated Medicare net overpayment to the Hospital in the sampling frame (Appendix C)
- Discussed the results with Hospital officials

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

## APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

### SAMPLING FRAME

Our sampling frame contained 6,464 Medicare paid claims in 10 risk areas totaling \$80,365,554 from which we selected our sample (Table 1). The sampling frame included claims:

- With only certain discharge status and diagnosis codes
- With payments greater than \$0
- Not under review by the Recovery Audit Contractor as of May 18, 2023

We assigned each claim that appeared in multiple risk areas to just one area on the basis of the following hierarchy: IRF Claims, Inpatient Short-Stay Claims of Less Than 2 Midnights, Inpatient Claims Covering Same Day Readmission, Inpatient Claims Billed with Elective Procedures, Inpatient Claims Billed with High CERT DRG Codes, Inpatient Claims Billed with High-Severity Level DRG Codes, Inpatient Claims Billed with Severe Malnutrition, Inpatient Claims Paid In Excess of Charges, Outpatient Claims Billed With Multiple Units of Surgery, and Outpatient Claims Billed with Bypass Modifiers.

**Table 1: Risk Areas**

Medicare Risk Area	Frame Size	Value of Frame
1. IRF Claims	1,211	\$29,569,764
2. Inpatient Short-Stay Claims of Less Than 2 Midnights	870	6,185,108
3. Inpatient Claims Covering Same Day Readmission	14	195,483
4. Inpatient Claims Billed with Elective Procedures	27	504,404
5. Inpatient Claims Billed with High CERT DRG Codes	1,562	14,765,426
6. Inpatient Claims Billed with High-Severity Level DRG Codes	2,271	27,748,344
7. Inpatient Claims Billed with Severe Malnutrition	36	667,809
8. Inpatient Claims Paid in Excess of Charges	8	191,765
9. Outpatient Claims Billed with Multiple Units of Surgery	31	65,482
10. Outpatient Claims Billed with Bypass Modifiers	434	471,969
<b>Total</b>	<b>6,464</b>	<b>\$80,365,554</b>

### SAMPLE UNIT

The sample unit was a Medicare paid claim.

### SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified sample. We grouped the sampling frame into strata based on risk areas in Table 1 and claim paid amount, resulting in six strata. Stratum 1 includes all claims from risk area 1; strata 2 includes all claims from risk area 2; strata 3 through 5 include claims from risk

areas 3 through 8, separated by paid amount; and stratum 6 includes all outpatient claims from risk areas 9 and 10.<sup>42</sup> All claims were unduplicated, appearing in only one risk area and only once in the entire sampling frame.

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

**Table 2: Claims by Stratum**

<b>Stratum</b>	<b>Claims Type</b>	<b>Frame Size (Claims)</b>	<b>Value of Frame</b>	<b>Sample Size</b>
1	Inpatient Risk Area 1	1,211	\$29,569,764	20
2	Inpatient Risk Area 2	870	6,185,108	15
3	Inpatient Risk Areas 3–8, High-Dollar Claims	748	17,794,966	20
4	Inpatient Risk Areas 3–8, Moderate-Dollar Claims	1,431	16,021,852	15
5	Inpatient Risk Areas 3–8, Low Dollar-Claims	1,739	10,256,413	15
6	All Outpatient Claim Risk Areas	465	537,451	15
	<b>Total</b>	<b>6,464</b>	<b>\$80,365,554</b>	<b>100</b>

#### **SOURCE OF RANDOM NUMBERS**

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

#### **METHOD FOR SELECTING SAMPLE UNITS**

We sorted the items in each stratum by a unique claim identifier, and then consecutively numbered the items in each stratum in the sampling frame. After generating the random numbers in accordance with our sample design, we selected the corresponding frame items for review.

#### **ESTIMATION METHODOLOGY**

We used the OIG/OAS statistical software to estimate the total amount of net overpayments in the sampling frame made to the Hospital at the lower limit of the two-sided 90-percent confidence interval (See Appendix C). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

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<sup>42</sup> Paid claims greater than \$15,000 are in stratum 3, paid claims greater than or equal to \$7,500 but less than or equal to \$15,000 are in stratum 4, and paid claims less than \$7,500 are in stratum 5.

**APPENDIX C: SAMPLE RESULTS AND ESTIMATES**

**Table 3: Sample Details and Results**

<b>Stratum</b>	<b>Frame Size (Claims)</b>	<b>Value of Frame</b>	<b>Sample Size</b>	<b>Value of Sample</b>	<b>Number of Incorrectly Billed Claims in Sample</b>	<b>Value of Net Overpayments in Sample</b>
1	1,211	\$29,569,764	20	\$499,836	6	\$147,967
2	870	6,185,108	15	93,607	10	65,328
3	748	17,794,966	20	385,620	7	146,397
4	1,431	16,021,852	15	174,289	5	38,550
5	1,739	10,256,413	15	85,962	7	37,193
6	465	537,451	15	16,277	3	(1,713)
<b>Total</b>	<b>6,464</b>	<b>80,365,554</b>	<b>100</b>	<b>\$1,255,591</b>	<b>38</b>	<b>\$433,723<sup>43</sup></b>

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

Point estimate	\$26,160,229
Lower limit	17,838,422
Upper limit	34,482,037

<sup>43</sup> Amounts may not add up exactly due to rounding.

**APPENDIX D: RESULTS OF AUDIT BY RISK AREA**

**Table 5: Sample Results by Risk Area\***

<b>Risk Area</b>	<b>Sample Size</b>	<b>Value of Sample</b>	<b>Number of Incorrectly Billed Claims in Sample</b>	<b>Value of Net Overpayments in Sample</b>
IRF Claims	20	\$499,836	6	\$147,967
<b>IRF Total</b>	<b>20</b>	<b>\$499,836</b>	<b>6</b>	<b>\$147,967</b>
Inpatient Short-Stay Claims of Less Than 2 Midnights	15	\$93,607	10	\$65,328
Inpatient Claims Billed with High CERT DRG Codes	28	326,592	13	143,636
Inpatient Claims Billed with High-Severity Level DRG Codes	22	319,280	6	78,505
<b>Inpatient Totals</b>	<b>65</b>	<b>\$739,479</b>	<b>29</b>	<b>\$287,469</b>
Outpatient Claims Billed With Bypass Modifiers	15	\$16,277	3	(\$1,713)
<b>Outpatient Totals</b>	<b>15</b>	<b>\$16,277</b>	<b>3</b>	<b>(\$1,713)</b>
<b>Inpatient and Outpatient Totals</b>	<b>100</b>	<b>\$1,255,592</b>	<b>38</b>	<b>\$433,723</b>

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

## APPENDIX E: HOSPITAL COMMENTS

**BASS BERRY + SIMS**<sub>PC</sub>

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December 15, 2025

**VIA KITEWORKS & FEDERAL EXPRESS**

Nicole Freda  
Regional Inspector General  
U. S. Department of Health and Human Services  
Office of Inspector General  
Office of Audit Services, Region III  
801 Market Street, Suite 8500  
Philadelphia, PA 19107-3134

**Re: Office of Audit Services Draft Report Number A-03-23-00001**

Dear Ms. Freda:

I write on behalf of Lehigh Valley Health Network (“LVHN”) to submit this response to the Draft Report Number A-03-23-00001 issued by the Office of Inspector General, Office of Audit Services (the “OIG”) on October 31, 2025 (the “Draft Report”).<sup>1</sup> In the Draft Report, OIG alleges that LVHN did not comply with Medicare billing requirements for 39 of 100 claims during the time period of October 1, 2020 through September 30, 2022 (the “Audit Period”). From this small sample, and without giving meaningful consideration to rebuttals submitted by LVHN by OIG in response to OIG’s preliminary findings, OIG’s Draft Report asserts LVHN received an overpayment of “at least \$19.2 million.”

LVHN disputes the findings in the Draft Report and does not concur with OIG’s three recommendations. The OIG’s findings largely reflect no more than a difference in medical opinion about the beneficiaries’ conditions. These differences of opinion do not provide a basis for claims denials, much less constitute systemic “errors” supporting extrapolation of the audit results. Additionally, OIG’s sampling methodology fails to meet the legal standards required to calculate an extrapolated audit result. Thus, for the reasons discussed in detail below and the referenced supporting documentation, OIG’s findings in its Draft Report should be revised to set aside the claims denials and reflect that LVHN materially complied with all Medicare payment requirements for the claims at issue.

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<sup>1</sup> Although the Report requested that LVHN provide written comments in response to the Report within 30 days, OIG confirmed a short extension of time to respond to the Draft Report until December 15, 2025.

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## I. LVHN DOES NOT CONCUR WITH OIG'S THREE RECOMMENDATIONS

As described in detail in its position papers for the denied claims, attached hereto as **Exhibit 1**,<sup>2</sup> and in the statistical expert report, attached hereto as **Exhibit 2**, LVHN disputes all but one negative claim findings contained in the Draft Report. Because the underlying findings are not supported by the beneficiaries' medical records (see **Section II**) and the sampling and extrapolation methods are likewise flawed (see **Section III**), LVHN does not concur with any of the three recommendations set forth in the Draft Report.

**OIG Recommendation #1:** Refund to the Federal government \$19.2 million in estimated net overpayments for the audit period for claims that it incorrectly billed.

**LVHN Response:** LVHN does not concur with this recommendation. OIG's findings for the audited claims are fundamentally flawed. LVHN engaged LW Consulting, Inc. ("LWCI"), a qualified, third-party expert,<sup>3</sup> to review OIG's findings. With the exception of two claims findings resulting in underpayments and a single undisputed outpatient claim,<sup>4</sup> LWCI disagreed with all OIG findings and found LVHN appropriately billed the claims based upon medical record documentation. LWCI's findings are detailed in the Position Papers specific to each claim, enclosed as **Exhibit 1**. As to the inpatient and inpatient rehabilitation ("IRF") claims, LVHN disputes all of the audit findings. The audit reflects a mere difference in clinical judgment between OIG's medical reviewer and the treating provider regarding the medical necessity of the admission and/or services that cannot render the claims invalid. As to the outpatient claims, the audit identified only minor coding errors with two claims showing an underpayment to LVHN, resulting in a net underpayment of \$11,961.69 for the sample.<sup>5</sup> Moreover, as explained in the expert report prepared by Harold Haller, Ph.D.,<sup>6</sup> enclosed as **Exhibit 2**, OIG's extrapolated overpayment from the 100 audited claims is invalid. OIG provided no documentation to support that it made the required threshold finding to use extrapolation and OIG's sampling methodology is not statistically valid and should not be used as a basis to calculate an extrapolated overpayment. Accordingly,

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<sup>2</sup> The position papers at **Exhibit 1** shall be referred to herein as "the Position Papers."

<sup>3</sup> LW Consulting, Inc. is a recognized leader in providing compliance, reimbursement, operational, and clinical consulting solutions across the full continuum of healthcare delivery. It is an Independent Review Organization ("IRO"), performing audits required under OIG Corporate Integrity Agreements, and an expert resource to providers, attorneys, and government agencies in ensuring compliance with guidelines, requirements, and statutes that regulate the delivery of healthcare services. The LW Consulting (LWCI) review was completed by experienced and qualified individuals. The reviewers include both former clinical practitioners and certified coding specialists with experience in reviewing coding and billing for IRF and hospital claims. The reviewers collectively hold a number of certifications including Psychiatric and Mental Health Nurse (PMH-BC), Nurse Executive Advanced Board Certified (NEA-BC), a National Certified Counselor (NCC), a Certified Legal Nurse Consultant (CLNC), Certified Professional Medical Auditor (CPMA), Certified Professional Compliance Officer (CPCO), Certified Documentation Expert for Outpatient (CDEO), and Certified Documentation Integrity Practitioner (CDIP).

<sup>4</sup> OIG also found one claim for inpatient services had a coding error that when corrected by OIG, resulted in an underpayment for the claim. LVHN disputes the findings related to inpatient services but agrees with the coding error change resulting in an underpayment.

<sup>5</sup> LVHN accepts the findings for Sample #98, resulting in an overpayment of \$74.96.

<sup>6</sup> Dr. Haller is an Adjunct Professor in the Department of Mathematics, Applied Mathematics, and Statistics at Case Western Reserve University. He has a PhD in Mathematics and Statistics and has been retained by Administrative Law Judges as an independent expert witness to advise on statistical sampling matters in appeals by approximately 70 healthcare providers. A copy of Dr. Haller's curriculum vitae is attached to his report.

following OIG's issuance of a final report, LVHN intends to vigorously challenge through the Medicare administrative appeals process any outstanding claims denials and the statistical sampling and extrapolation methodology used to calculate the overpayment. LVHN anticipates the alleged overpayments audited will ultimately be overturned. Therefore, any refund to the Medicare program would be inappropriate.

**OIG Recommendation #2:** Consider conducting one or more internal audits or investigations for claims after our audit period based on the risks identified by this audit to identify any similar overpayments the provider might have received and return any identified overpayments to the Medicare program.

**LVHN Response:** LVHN does not concur with this recommendation. LVHN exercised reasonable diligence in this audit by engaging a qualified outside reviewer to determine if any of the claims at issue were billed in error. LWCI's independent review of the denied claims found limited errors, ultimately resulting in an *underpayment* to LVHN for the audit. Based upon these findings, LVHN has no legal obligation to conduct further reviews outside of its routine auditing and monitoring processes already in place as part of its compliance program. Moreover, the Centers for Medicare & Medicaid Services ("CMS") has acknowledged that a provider that receives notice of a potential overpayment through an audit may reasonably determine that additional investigation of potential additional overpayments is premature during the audit appeals process.<sup>7</sup> Thus, there is no legal basis to support OIG's recommendation.

**OIG Recommendation #3:** Provide additional training to clinical and billing personnel on its policies and procedures related to:

- IRF admissions and documentation requirements;
- the two-midnight rule;
- medical necessity of inpatient and outpatient services;
- billing of services provided; and
- inpatient and outpatient coding.

**LVHN Response:** LVHN does not concur with this recommendation. As evidenced by LWCI's findings, LVHN has an effective compliance program ensuring claims are coded and billed appropriately. Thus, implementation of additional training is unnecessary; this audit proves LVHN's compliance program has been effective at ensuring accurate coding and billing practices.

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<sup>7</sup> See 81 Fed. Reg. 7654, 7667 (Feb. 12, 2016) ("If the provider appeals the contractor identified overpayment, the provider may reasonably assess that it is premature to initiate a reasonably diligent investigation into the nearly identical conduct in an additional time period until such time as the contractor identified overpayment has worked its way through the administrative appeals process.").

## II. LVHN DISPUTES THE FINDINGS THAT FORM THE BASIS OF OIG'S \$19.2 MILLION ESTIMATED OVERPAYMENT AND OTHER RECOMMENDATIONS

### A. Documentation for the IRF Claims Supports the Medical Necessity of the Services and Satisfaction of All Technical Requirements.

OIG denied seven IRF claims due to either subject reasoning or alleged failure to meet documentation requirements despite medical records refuting OIG's position. A detailed review of each of these claims found at Exhibit 1 shows the IRF services provided to the Medicare beneficiaries for these claims were for reasonable and necessary services and met all material documentation standards.

#### (1) All IRF Claims Required Supervision by a Rehabilitation Physician.

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 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 supervision by a rehabilitation physician.<sup>8</sup> The Draft Report does not dispute that requirements (1)-(3) were met in each of the 20 IRF claims reviewed.

OIG denied five claims<sup>9</sup> based on its finding that the documentation does not support that, at the time of admission, there was a reasonable expectation that the patient required supervision by a rehabilitation physician and argued the patient's recovery and care could have been overseen and managed by a non-rehabilitation physician. LVHN disputes these findings.

Regarding this requirement, Medicare guidance explains:

[T]he information in the patient's IRF medical record . . . must document a reasonable expectation that at the time of admission to the IRF the patient's medical management and rehabilitation needs require an inpatient stay and close physician involvement. . . . [T]he requirement for IRF physician supervision is intended to ensure that IRF patients receive more comprehensive assessments of their functional goals and progress, in light of their medical conditions, by a rehabilitation physician who is determined by the IRF to have specialized training and experience in inpatient rehabilitation at least 3 times per week.<sup>10</sup>

Importantly, this requirement represents a medical judgment made at the time of admission based on the physician's observations of the patient, **not** a retrospective decision made based on a cold

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<sup>8</sup> 42 C.F.R. § 412.622(a)(3)(i-iv).

<sup>9</sup> Sample ##9, 11, 15, 18, 20.

<sup>10</sup> MBPM, Chapter 1, § 110.2.4.

medical record. CMS has acknowledged that “[t]he need for physician supervision cannot be inferred retroactively from the presence or absence of an acute medical complication during the IRF stay.”<sup>11</sup> CMS further acknowledges:

[T]he importance of the professional judgment of a rehabilitation physician in the review of the preadmission screen **at the time an admission decision is made**. This information is more useful in reviewing the IRF admission decision than aspects of the IRF stay that would either be unknown or outside the control of the rehabilitation physician at the time of admission.<sup>12</sup>

In other words, CMS regulations give deference to physicians’ real-time judgment that there is a reasonable expectation the patient needs rehabilitation physician supervision.

The Draft Report demonstrates OIG has not afforded deference to physicians’ real-time judgment regarding reasonable expectation of rehabilitation physician supervision for the five IRF claims in question. For example, in explaining its rationale for why it determined this element was missing for **Sample #11**, the Report notes, “The patient had no postoperative complications [following surgery for a right hip fracture], active comorbidities, or other active issues requiring rehabilitation physician evaluation and care.” This rationale is classic post-hoc second-guessing of real-time medical decision-making; the fact that a complication did not present during the patient’s course of IRF treatment has no bearing on the ordering physician’s real-time assessment of the patient’s need for rehabilitation physician supervision during their intensive therapeutic recovery. The Draft Report continues, “The patient’s recovery, rehabilitation, and convalescence could have been overseen by a non-rehabilitation physician and did not require an IRF stay.” This rationale inappropriately grafts criteria not found in the regulations onto the fourth requirement for IRF claims to be considered reasonable and necessary. That a patient “could have” recovered in a non-IRF setting has no bearing on the ordering physician’s real-time assessment of the patient’s need for IRF care, including rehabilitation physician supervision during their stint of care.

Sample #11 is not an anomaly. OIG’s medical reviewers appear to have provided no deference to the judgment of the rehabilitation physician in any of the claims denied on this ground. Additionally, for each of the five claims, OIG fails to explain *why* the claims at issue do not meet the fourth requirement of a reasonable and necessary IRF claim. Nor does OIG appear to have considered the responses from LVHN’s outside medical reviewers.<sup>13</sup>

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<sup>11</sup> 74 Fed. Reg. 21052, 21069 (May 6, 2009).

<sup>12</sup> 74 Fed. Reg. 21052, 21070 (emphasis added).

<sup>13</sup> Additionally, prior to the Exit Conference, OIG requested LVHN to provide responses to OIG’s preliminary findings. Despite no legal requirement to do so, LVHN in good faith prepared detailed responses. During the exit conference on August 19, 2025, LVHN requested that OIG provide its medical review contractor with “all of the documentation that was provided in response to the IRF claim errors (6/20/2025), the Inpatient claim errors (8/18/25), and the outpatient claim errors (8/18/25).” OIG refused to provide this information to its reviewers, in doing so mischaracterizing the IRF documentation as “just a summary of the documentation LVHN provided to us on 4/30/24.” LVNH renewed its request to provide its reviewers with all information LVNH has provided to OIG on August 28, 2025. OIG ignored this request and, to LVNH’s knowledge, has never provided LVNH’s responses to OIG’s medical reviewers, despite demanding more than \$19 million related to its reviewers’ limited and erroneous findings. LVHN

## (2) Denials Based Upon IDT Meeting Documentation Are Refuted By Documentation Within The Patient's Medical Record

The Draft Report also denied two claims<sup>14</sup> due to alleged technical documentation errors related to interdisciplinary team ("IDT") meetings to assert a net overpayment of \$74,526. CMS does not require a specific form to document IDT meetings. An IRF may use a particular form, or notes in the patients general medical record to document these meetings. Despite this, OIG denied claims where a patient was missing a specific IDT form, even when the medical record itself made clear that the IDT met and documented their assessment of the patient.

IRF patients require an interdisciplinary team approach to care, as evidenced by documentation in the patients' medical record of weekly interdisciplinary team ("IDT") meetings.<sup>15</sup> IDT meetings must include a rehabilitation physician; a registered nurse; a social worker or case manager (or both); and a licensed or certified therapist from each therapy discipline involved in treating the patient.<sup>16</sup> IDT meetings must be held at least once per week during the patient's stay to: implement appropriate treatment services; review the patient's progress toward stated rehabilitation goals; identify any problems that could impede progress towards those goals; and, where necessary, reassess previously established goals in light of impediments, revise the treatment plan in light of new goals, and monitor continued progress toward those goals.<sup>17</sup> In setting out these requirements, the regulations do not prescribe a specific form for the documentation of these meetings. Rather, the patient's entire medical record, as opposed to an individual form, should be considered in assessing whether the IDT meetings occurred.

Regarding specific claims, OIG found documentation did not support that IDT meetings occurred once per week for one claim (**Sample #16**). While a Team Conference Summary was not included in the patient's medical record for one week of the patient stay, there is sufficient documentation in the medical record to evidence an IDT meeting and IDT involvement in the patient's care occurred that week. This documentation included comprehensive team conference scores assessing the patient's functional abilities for self-care and mobility performance; team goals entered by IDT members; and physiatrist's progress notes referencing the IDT Team Notes. This documentation illustrated that the IDT assessed the patient's status, coordinated and evaluated the patient's treatment plan and rehabilitation goals, and communicated amongst the IDT members as required by the IRF standards. The patient's entire medical record, as opposed to a hospital form not required by Medicare, should be considered in assessing whether the IDT meetings occurred. Based upon this documentation, OIG's denial should be set aside.

OIG also denied one claim (**Sample #10**) due to the alleged failure of the physical therapist to attend one – and only one – IDT meeting. For the IDT meeting in question, there is sufficient contemporaneous evidence to support the physical therapist's attendance. The team conference

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again renews its request that LVNH's rebuttals submitted on June 20, 2025 and August 18, 2025 along with the Position Paper be submitted to OIG's medical reviewers for consideration prior to the issuance of OIG's final report.

<sup>14</sup> Sample #10, 16.

<sup>15</sup> 42 C.F.R. § 412.622(a)(5).

<sup>16</sup> 42 C.F.R. § 412.622(a)(5)(i).

<sup>17</sup> 42 C.F.R. § 412.622(a)(5)(ii).

summary includes information from the physical therapist, and other contemporaneous documentation by the physical therapist. Similar to the other technical denial, OIG should withdraw this denial before finalizing the Draft Report.

**B. The Inpatient Claims Under Review Were Appropriately Billed As Inpatient Services.**

OIG found that twenty-nine inpatient claims were non-compliant based on a lack of medical necessity and coding errors. LVHN disputes each of these findings.

**(1) The Denied Inpatient Claims were Reasonable and Necessary.**

OIG found that for twenty-seven of the inpatient claims reviewed,<sup>18</sup> documentation did not support that it was reasonable for the admitting physician, at the time the inpatient order was written, to have expected that hospital care was required for a period that crosses two or more midnights. As described in more detail below, LVHN disputes these findings. The medical records for each of these claims reflect that the admitting physician reasonably expected, at the time of the admission order, that the hospital stay would cross two midnights as required by the applicable legal standards.

**General Background on Two-Midnight Rule.** Under what is commonly referred to as the “two-midnight rule,” inpatient admission generally is appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights.<sup>19</sup> Medicare regulations and guidance recognize that this is a medical judgment based on complex medical factors such as:

- Patient history and comorbidities;
- Severity of the patient’s signs and symptoms;
- Patient’s current medical needs;
- Risk of the patient experiencing an adverse event;
- Need for diagnostic studies; and
- Availability of diagnostic procedures.<sup>20</sup>

The expectation for a stay that crosses two midnights is inferred from the record—no separate attestation of the expected length of stay is required.<sup>21</sup> Importantly, the inpatient admission is generally payable if the medical record supports the admitting physician’s judgment was *reasonable*.<sup>22</sup>

<sup>18</sup> Sample ##22, 24, 26, 28, 29, 30, 31, 33, 34, 35, 36, 37, 40, 44, 45, 47, 53, 56, 58, 60, 62, 71, 77, 79, 81, 83, and 85.

<sup>19</sup> 42 C.F.R. § 412.3(d)(1).

<sup>20</sup> 42 C.F.R. § 412.3(d)(1)(i); MBPM, Chapter 1, § 10.

<sup>21</sup> Medicare Program Integrity Manual (Pub. 100-08) (hereinafter “MPIM”), Chapter 6, § 6.5.2.

<sup>22</sup> *Id.* While LVHN recognizes this guidance is applicable to Medicare contractors, OIG likewise should not use its post-hoc review of the medical record to question the medical judgment of its admitting physicians (made at the time of services based on personal observations of the patient’s then-current presenting signs and symptoms) without similar evidence of systematic gaming, abuse, or delays.

Whether the admitting physician's judgment was reasonable requires consideration of the medical evidence available *at the time* the admission decision was made. Post-admission information can only be used to support a finding that admission was appropriate. In providing guidance for reviews of hospital admissions to Quality Improvement Organizations ("QIOs"), CMS explained:

Under original Medicare, the [QIO], for each hospital is responsible for deciding, during review of inpatient admissions on a case-by-case basis, whether the admission was medically necessary.... In making these judgments, however, QIOs consider only the medical evidence which was available to the physician at the time an admission decision had to be made. They do not take into account other information (e.g., test results) which became available only after admission, *except in cases where considering the post-admission information would support a finding that an admission was medically necessary.*<sup>23</sup>

Stated differently, clinical information available post-admission is only relevant to the extent it supports the medical reasonableness and necessity of admission. As explained in more detail below and in the Position Papers, OIG's medical reviewers failed to consider post-admission information that supported the reasonableness and necessity of the claims at issue. More fundamentally, OIG can point to no evidence that would rebut the presumption that these were medically necessary admissions.

Multiple of OIG's inpatient findings reveal that its reviewers ignored clear indicia on the face of admission orders of the physician's expectation of a stay spanning at least two midnights, which is supported by surrounding medical record documentation. In one glaring example (**Sample #36**), the 75-year-old patient with comorbidities including morbid obesity and hypertension, was admitted for elective laminectomy due to symptomatic lumbar stenosis. Even before addressing a complicated operative course, it was reasonable for the physician to expect the patient to require hospital care that crosses two or more midnights. In another example (**Sample #37**), the admission order clearly indicates an anticipated discharge date that would cross two midnights, and the patient's documented signs and symptoms underscore the reasonableness of the admitting physician's determination.

Similarly (**Sample #45**), the patient's H&P notes clearly indicate the anticipation of the patient's stay crossing two midnights. This determination is supported by the 63-year-old patient's documented signs, symptoms, and medical history upon presentation to the hospital. In particular, the patient had been sent home from another emergency department with an orthopedic follow-up but did not manage well overnight. During an office visit, the surgeon directed the patient to immediately transfer to the emergency department for immediate admission to undergo an open reduction and internal fixation. The patient was complaining of severe pain and inability to utilize crutches in her home. Prior to surgery, the patient was grimacing and moaning in pain. As a smoker, the patient's risks for cardiovascular and respiratory problems, reduced healing, and

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<sup>23</sup> MBPM, Chapter 1, § 10 (emphasis added).

infection were higher, including a significantly higher risk of pulmonary embolism. The patient also had been diagnosed with hypertension and pulmonary hypertension. The patient had multiple risk factors for developing deep vein thrombosis (“DVT”) or a PE. The patient was diagnosed with a PE after a previous surgery. A previous PE significantly increases the likelihood of experiencing another PE. The patient was also obese with mobility deficits due to the fracture. Appropriate DVT prophylaxis was required. This course provides overwhelming support for an inpatient hospital stay, and this example along with the other claims demonstrate the flaws in OIG’s review of the inpatient claims, and all claims should be allowed.

## **(2) OIG Improperly Denied Three Claims Due to Coding Issues**

OIG also denied four claims<sup>24</sup> for various coding errors. For one of these four findings (**Sample #70**), LVHN agrees with the determination that the appropriate code would be E43 and not E46. Notably, this coding change reflects an *underpayment* rather than an overpayment. As supported by the Position Papers, LVHN disputes the remaining three inpatient findings because the claims are properly coded and the relevant codes are supported.

### **C. Denied Outpatient Claims Resulted In Underpayment, Demonstrating LVHN’s Processes Did Not Result in Overbilling of Medicare.**

OIG found three outpatient claims<sup>25</sup> were non-compliant based on coding issues, resulting in a net underpayment for this category of claim. As noted previously, LVHN does not dispute the error findings for Sample #88, resulting in an overpayment of \$74.96, which is more than offset by OIG’s finding of an underpayment for Sample #98.

## **III. OIG’s Sampling Methodology to Calculate the Alleged Overpayment Is Not Supported.**

As explained in more detail below and in Dr. Haller’s Report at **Exhibit 2**, OIG’s extrapolated overpayment calculation is flawed and does not follow applicable legal requirements. First, OIG does not establish the necessary grounds for using statistical sampling and extrapolation. Any overpayment referred to the Medicare Administrative Contractor must comply with CMS requirements before repayment is pursued. Second, using extrapolation here is especially problematic because the denials are based on subjective, patient-specific medical necessity decisions that cannot be reliably generalized. This approach risks penalizing providers for legitimate differences in clinical judgment. Third, OIG failed to provide the data needed to review or test the sampling and extrapolation, which undermines LVHN’s due process rights. Finally, flaws in OIG’s sampling make the extrapolated estimate unreliable. For these reasons, any recommendation related to repayment should be limited to the audited claims rather than the flawed extrapolated overpayment estimate.

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<sup>24</sup> Sample ## 70, 72, 77, 79.

<sup>25</sup> Sample ## 86, 88, 98. For the reasons detailed in the Position Paper, LVHN disputes the denial for Sample #86.

#### A. **OIG Did Not Make the Threshold Finding to Justify the Use of Extrapolation**

OIG has failed to make the findings required by statute to recommend the use of statistical sampling and extrapolate an overpayment in this case. A threshold requirement for the use of extrapolation to determine overpayment amounts is that a determination must be made that (1) there has been a sustained or high level of payment error, or (2) documented educational intervention has failed to correct the payment error.<sup>26</sup>

OIG has provided no evidence that it made this threshold finding. In its July 3, 2023 Audit Notification Letter, OIG informed LVHN that it would utilize statistical sampling and extrapolation, stating “[r]esults from statistically sampled claims may be projected to all claims in the sampling frame.” The Audit Notification Letter made no mention of LVHN having a sustained or high level of payment error or any educational interventions that may have failed. It was not until the August 19, 2025 Exit Conference that OIG explained why LVHN was selected for this audit: “because it had a number of claims submitted in areas OIG designated as high-risk.” This explanation is divorced from any evidence of payment errors by LVHN or lack of improvement despite education. In fact, in its Report, OIG acknowledges: “[s]ubmitting claims at-risk for noncompliance does not by itself mean the claims were noncompliant.” Instead, OIG targeted LVHN because it is a large hospital that treated a large number of patients. This is not only an unjust reason to select LVHN for the audit, but also an insufficient basis to justify the use of extrapolation.

Furthermore, even if OIG could use this audit as a basis to justify the use of extrapolation, which LVHN disputes,<sup>27</sup> the error rate is too low to establish a sustained or high level of payment error. The Medicare guidance in effect during the Audit Period defined a high error rate as “greater than or equal to 50 percent from a previous pre- or post-payment review.” OIG’s inflated claims error rate of 39% does not reach this threshold level.

Regardless of OIG’s position on the statutory threshold’s applicability to its audit, since the audit findings will be referred to the Medicare Administrative Contractor, any overpayment calculation must comply with CMS guidance before repayment is pursued. OIG acknowledges the Medicare Administrative Contractor’s authority in the Draft Report: “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*.”<sup>28</sup> The Draft Report repeatedly emphasizes that its findings are merely recommendations for CMS, yet fails to explain why its recommendations would be based on anything other than CMS’ policies and procedures. Although OIG’s Draft Report states it conducted this audit “in accordance with generally accepted government auditing standards,” OIG does not explain *which* standards it used nor why, in an audit of Medicare claims, OIG deems it appropriate to disregard CMS’ key threshold inquiry for statistical sampling and extrapolation. For this reason alone, the recommendation to refund the extrapolated overpayment using statistical sampling and extrapolation should be revised to a recommendation related to the audited claims only.

<sup>26</sup> 42 U.S.C. § 1395ddd(f)(3); *see also* MPIM, Chapter 8, § 8.4.1.2.

<sup>27</sup> See Section III.B below.

<sup>28</sup> Draft Report at 10, n.17 (emphasis added).

**B. OIG’s Apparent Use of this Audit as a Basis for the Threshold Finding is Inappropriate**

The use of extrapolation here appears to suggest the required threshold finding is satisfied if there has been a sustained or high level of payment error *within* the audit at issue or where education has been provided in connection with this audit. This is incorrect. This determination must be made prior to the audit. Medicare guidance explains that “*before* using extrapolation . . . there must be a determination of sustained or high level of payment error, or documentation that educational intervention has failed to correct the payment error.”<sup>29</sup> (emphasis added). It goes on to explain that after the provider is selected for the audit, the contractor and statistical expert will determine the timeframe for which sampling units will be reviewed. The scope of the review is based on factors such as how long the pattern of sustained or high level of payment error is believed to have existed.<sup>30</sup> If the scope of the audit is determined by how long a high or sustained level of payment error has existed, it logically follows that this determination must be made *before* the contractor conducts the audit.

The fact that the requirements for determining when statistical sampling may be used are included within the procedures for initiating the audit (e.g. Section 8.4.1 – Introduction [to Use of Statistical Sampling for Overpayment Estimation] and Section 8.4.3 – Selection of Period to be Reviewed and Composition of Universe) further underscores that the threshold findings must be made at the beginning, not the end, of the audit.

Moreover, upon receipt of supplemental information from LVHN, OIG overturned four of its findings (one inpatient, three outpatient), before releasing the Draft Report. LVHN’s success in reversing several of the claim denials upon which this Report is based further undermines the ability to rely on any alleged finding of a sustained or high payment error. Accordingly, the use of extrapolation here to calculate the recommended overpayment amount is not permissible.

**C. Use of Statistical Sampling For Claims Denials Based Upon Medical Necessity Is Inappropriate**

Most of the claims denials in the Draft Report relate to the medical necessity and appropriateness of inpatient admissions or services rendered. This rationale underpins in whole or part the majority of OIG’s denied claims. The use of statistical sampling to extrapolate the overpayment amount across the claims universe in the context of these subjective determinations of medical necessity is inappropriate.

It is well established that the “permissibility of statistical sampling turns on ‘the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action.’”<sup>31</sup> Here, where the determination of medical necessity is highly subjective and fact-intensive, the use of statistical sampling to draw conclusions about the larger universe of claims is

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<sup>29</sup> MPIM, Chapter 8, § 8.4.1.2.

<sup>30</sup> MPIM, Chapter 8, § 8.4.3.1.

<sup>31</sup> *United States v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833, at \*11 (N.D. Tex. June 20, 2016) (quoting *Tyson Foods, Inc. v. Bouaphakea*, 136 S. Ct. 1036, 1046 (2016)).

not a reliable method of determining liability (if any) for overpayments to LVNH over a two-year period. In determining whether to permit statistical sampling in a case involving medical necessity, one court held:

Distilled to its essence, each claim asserted here presents the question of whether certain services . . . were medically necessary. Answering that question for each of the patients involved in the action is highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient. As the Court has acknowledged, some cases are suited for statistical sampling and, indeed, in many cases that method is the only way that damages may be proved. This civil action, however, is not such a case.<sup>32</sup>

Given the highly individualized assessment of medical necessity, and the outsized number of claims in this audit where the findings rely on post-hoc second-guessing of real-time medical decision-making by qualified physicians, the overpayment calculations should be limited to the claims OIG actually audited.

**D. LVHN Has Not Been Provided the Required Information to Conduct a Complete Statistical Analysis.**

Despite multiple requests, OIG failed to provide the necessary information required for LVHN to evaluate the statistical sampling and extrapolation methodologies. By failing to provide this information, OIG denied LVHN of its due process rights, and as a result, the extrapolated audit result should not be used to calculate any alleged repayment amounts.

It is well established that “[a] provider can . . . challenge the statistical validity of both the sample and the extrapolation.”<sup>33</sup> Providers are entitled to sufficient statistical data needed to rebut the validity of the statistical sampling and extrapolation.<sup>34</sup> Therefore, failure to provide the information needed to perform this statistical analysis denies providers of their due process rights and may constitute independent grounds for invalidating an overpayment extrapolation.<sup>35</sup>

Medicare guidance for contractors utilizing statistical sampling and extrapolation makes it abundantly clear that for each step it takes in the statistical sampling process—from identifying the provider to estimating the overpayment—the contractor is required to provide “**complete and clear documentation** sufficient to explain the action(s) taken in the step **and to replicate, if**

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<sup>32</sup> *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. CA 0:12-3466-JFA, 2015 WL 3903675, \*8 (D.S.C. June 25, 2015).

<sup>33</sup> *Chaves County Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 916 (D.C. Cir. 1991).

<sup>34</sup> See *Maxmed Healthcare, Inc. v. Price*, 860 F.3d 335, 344 (5th Cir. 2017) (“No doubt, 42 U.S.C. § 1395ddd(f)(3) and 42 C.F.R. § 405.371 require the Secretary to disclose information about the review and statistical sampling that was followed to calculate an overpayment.” (internal quotation marks omitted)).

<sup>35</sup> See *Global Home Care, Inc.*, M-11-116 (H.H.S. Jan. 11, 2011); *Podiatric Medical Associates*, M-10-230 (H.H.S. June 22, 2010).

**needed, the statistical sampling.**<sup>36</sup> The “complete documentation” of the sampling methodology must include, at minimum, the following:

- Statistician-approved sampling methodology, universe, sampling frame and formal worksheets;
- An explicit statement of how the universe is defined and elements included;
- Sampling frame and specific details as to the period covered;
- List of all sampling units in the sampling frame;
- Definition of the sampling unit(s);
- All the universe elements that are incorporated into those sampling units;
- Identifiers for the sampling units (e.g., claim numbers, carrier control numbers);
- Dates of service and source; and
- Any random numbers used in the sample and an explanation of how they were selected.<sup>37</sup>

Despite multiple requests, OIG failed to provide the target universe from which to re-recreate the sampling frame. As noted by Dr. Haller in his report, because OIG failed to provide sufficient information to recreate and verify that the sampling frame was valid, it was impossible to verify that the sample drawn from the frame was a statistically valid random sample. The failure to provide such information to enable LVHN to challenge the overpayment calculation violates LVHN’s due process rights, and OIG’s calculations of an extrapolated overpayment should not be considered by the Medicare Administrative Contractor.

#### **E. The Statistical Methodologies Employed to Calculate the Extrapolated Overpayment are Invalid and Should be Set Aside.**

OIG’s statistical methodologies also are invalid because:

- **The frame impermissibly excluded zero-paid claims.** The OIG failed to include denied or “zero-paid” claims in the sampling frame. A zero-paid claim is potentially an underpaid claim, so excluding these claims from the frame causes it to be biased toward only the potential errors resulting in potential overpayments.
- **OIG’s stratified sampling plan was not statistically valid.** The construction of strata for a stratified sampling plan where the variable of interest is amounts paid and overpaid “[f]or a single item or variable *y*, the best characteristic is clearly the frequency distribution of *y* itself.”<sup>38</sup> Using amounts paid as the *y*, the combined frame of 6,464 claims is divided into sub-frames, which are nonoverlapping and together

<sup>36</sup> MPIM, Chapter 8, § 8.4.1.3 (emphasis added); *see also* MPIM, Chapter 8, § 8.4.3.2 (“All information needed to recreate the sampling frame and sample shall be included in the case documentation.”); MPIM, Chapter 8, § 8.4.4.2 (“The contractor shall document all steps taken in the random selection process *exactly as done* to ensure that the necessary information is available for anyone attempting to replicate the sample selection.” (emphasis added)); MPIM, Chapter 8, § 8.4.4.4.1 (“Documentation shall be kept in sufficient detail so that the sampling frame can be re-created should the methodology be challenged.”).

<sup>37</sup> MPIM, Chapter 8, § 8.4.4.4.1; 8.4.4.5

<sup>38</sup> Cochran, William G., *Sampling Techniques*, John Wiley & Sons, 1977, page 127.

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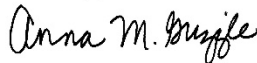
comprise the whole frame. OIG's six strata with respect to amounts paid are overlapping, which is an invalid stratification.

Based upon these findings, OIG's report should be revised to limit any alleged overpayment to the audited claims only rather than the flawed extrapolated overpayment estimate.

#### IV. CONCLUSION

LVHN understands and takes seriously its obligations to bill Medicare appropriately for the services rendered to program beneficiaries, and it appreciates the opportunity to comment on OIG's findings before the Draft Report is finalized. For the reasons discussed herein, OIG's findings as set forth in the Draft Report are flawed. LVHN understands it will have the opportunity to challenge the Report's findings on appeal and is confident that those findings will be overturned. Nonetheless, LVHN should not be forced to incur the time and expense of an appeal given the numerous deficiencies in the Draft Report. LVHN requests OIG withdraw the disputed findings discussed above without the need for an appeal.

Sincerely,



Anna M. Grizzle

Enclosures

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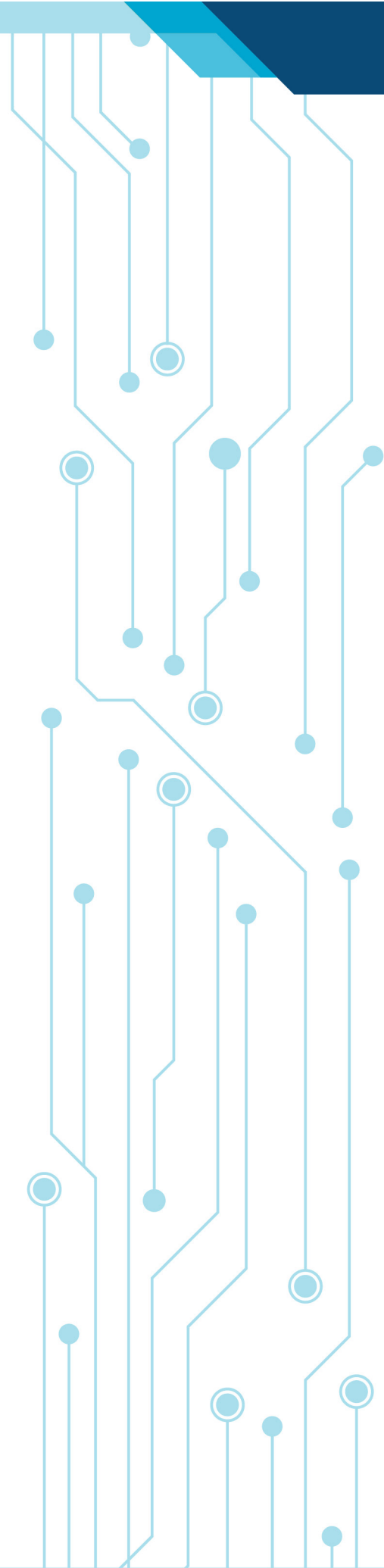
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