

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE HOSPITAL PROVIDER  
COMPLIANCE AUDIT: ALTA BATES  
SUMMIT MEDICAL CENTER**

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## Report in Brief

Date: September 2020  
Report No. A-04-19-08071

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



### Why OIG Did This Audit

This audit is part of a series of hospital compliance audits. Using computer matching, data mining, and data analysis techniques, we identified hospital claims that were at risk for noncompliance with Medicare billing requirements. For calendar year 2018, Medicare paid hospitals \$179 billion, which represents 47 percent of all fee-for-service payments for the year.

Our objective was to determine whether Alta Bates Summit Medical Center (the Hospital) complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims.

### How OIG Did This Audit

Our audit covered about \$31 million in Medicare payments to the Hospital for 1,072 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 85 inpatient and 15 outpatient claims with payments totaling \$4 million for our 2-year audit period (January 1, 2017, through December 31, 2018).

We focused our audit on the risk areas that we identified as a result of prior OIG audits at other hospitals. We evaluated compliance with selected billing requirements.

## Medicare Hospital Provider Compliance Audit: Alta Bates Summit Medical Center

### What OIG Found

The Hospital complied with Medicare billing requirements for 54 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 46 claims, resulting in overpayments of \$1.6 million for the audit period. Specifically, 45 inpatient claims and 1 outpatient claim had billing errors.

On the basis of our sample results, we estimated that the Hospital received overpayments of approximately \$16.4 million for the audit period. During the course of our audit, the Hospital submitted four of these claims for reprocessing, and we verified those claims as correctly reprocessed. Accordingly, we have reduced the recommended refund by \$49,118.

### What OIG Recommends and Hospital Comments

We recommend that the Hospital refund to the Medicare contractor \$16.3 million (\$16.4 million less \$49,118 that the Hospital has already repaid) in estimated overpayments for the audit period for claims that it incorrectly billed; exercise reasonable diligence to identify and return any additional similar overpayments received outside of our audit period, in accordance with the 60-day rule; and strengthen controls to ensure full compliance with Medicare requirements.

In written comments on our draft report, the Hospital disagreed with most of our findings and recommendations. The Hospital disagreed with the inpatient rehabilitation facility claims that we identified as incorrectly billed, highlighting the claims that were documentation errors. In addition, the Hospital disagreed with OIG's extrapolation, audit timing, and methodology. Furthermore, the Hospital disagreed with the application of the 60-day rule.

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

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## **INTRODUCTION**

### **WHY WE DID THIS AUDIT**

This audit is part of a series of hospital compliance audits. Using computer matching, data mining, and other data analysis techniques, we identified hospital claims that were at risk for noncompliance with Medicare billing requirements. For calendar year (CY) 2018, Medicare paid hospitals \$179 billion, which represents 47 percent of all fee-for-service payments; accordingly, it is important to ensure that hospital payments comply with requirements.

### **OBJECTIVE**

Our objective was to determine whether Alta Bates Summit Medical Center (the Hospital) complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims from January 1, 2017, through December 31, 2018.

### **BACKGROUND**

#### **The Medicare Program**

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

#### **Hospital Inpatient Prospective Payment System**

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

#### **Hospital Inpatient Rehabilitation Facility Prospective Payment System**

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

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

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

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

### **Hospital Claims at Risk for Incorrect Billing**

Previous Office of Inspector General (OIG) audits at other hospitals identified types of claims at risk for noncompliance. Out of the areas identified as being at risk, we focused our audit on the following:

- inpatient rehabilitation facility (IRF) claims,
- inpatient comprehensive error rate testing (CERT) DRG codes,
- inpatient high-severity level DRG codes,
- inpatient mechanical ventilation,
- inpatient claims paid in excess of charges,
- inpatient claims paid in excess of \$25,000,
- inpatient elective procedures,
- outpatient bypass modifiers,
- outpatient claims paid in excess of charges,
- outpatient claims paid in excess of \$25,000, and
- outpatient skilled nursing facility (SNF) consolidated billing.

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



For the purposes of this report, we refer to these areas at risk for incorrect billing as “risk areas.” We reviewed these risk areas as part of this audit.<sup>2</sup>

## **Medicare Requirements for Hospital Claims and Payments**

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

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

Claims must be filed on forms prescribed by CMS in accordance with CMS instructions (42 CFR § 424.32(a)(1)). The *Medicare Claims Processing Manual*, Pub. No. 100-04 (the Manual), chapter 1, section 80.3.2.2, requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly. The Manual states that providers must use HCPCS codes for most outpatient services (chapter 23 § 20.3).<sup>3</sup>

OIG believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers must report and return any identified overpayments by the later of (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.<sup>4</sup>

The 6-year lookback period is not limited by OIG’s audit period or restrictions on the Government’s ability to reopen claims or cost reports. To report and return overpayments

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<sup>2</sup> For purposes of selecting claims for medical review, CMS instructs its Medicare contractors to follow the “two-midnight presumption” in order not to focus their medical review efforts on stays spanning two or more midnights after formal inpatient admission in the absence of evidence of systemic gaming, abuse, or delays in the provision of care (*Medicare Program Integrity Manual*, ch. 6, § 6.5.2). We are not constrained by the two-midnight presumption in selecting claims for medical review.

<sup>3</sup> “Under the hospital outpatient prospective payment system, predetermined amounts are paid for designated services furnished to Medicare beneficiaries. These services are identified by codes established under the Centers for Medicare & Medicaid Services Common Procedure Coding System (HCPCS)” 42 CFR § 419.2(a). Moreover, claims must be filed on forms prescribed by CMS in accordance with CMS instructions (42 CFR § 424.32(a)(1)).

<sup>4</sup> The Act § 1128J(d); 42 CFR §§ 401.301–401.305; and 81 Fed. Reg. 7654 (Feb. 12, 2016).

under the 60-day rule, providers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.<sup>5</sup>

### **Alta Bates Summit Medical Center**

The Hospital is a 354-bed short-term, acute care, nonprofit hospital, located in Oakland, California. According to CMS's National Claims History (NCH) data, Medicare paid the Hospital approximately \$241 million for 10,279 inpatient and 61,146 outpatient claims from January 1, 2017, through December 31, 2018 (audit period).

### **HOW WE CONDUCTED THIS AUDIT**

Our audit covered about \$31 million<sup>6</sup> in Medicare payments to the Hospital for 1,072 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 claims (85 inpatient and 15 outpatient) with payments totaling \$4.1 million.<sup>7</sup> Medicare paid these 100 claims during our 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 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 scope and methodology.

### **FINDINGS**

The Hospital complied with Medicare billing requirements for 54 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 46 claims, resulting in overpayments of \$1,571,741 for the audit period. Specifically, 45 inpatient claims had billing errors, resulting in overpayments

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<sup>5</sup> 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, Provider Reimbursement Manual—Part 1, Pub. No. 15-1, § 2931.2; and 81 Fed. Reg. at 7670.

<sup>6</sup> The total Medicare payments were \$31,012,633.

<sup>7</sup> The total paid was \$4,064,777.

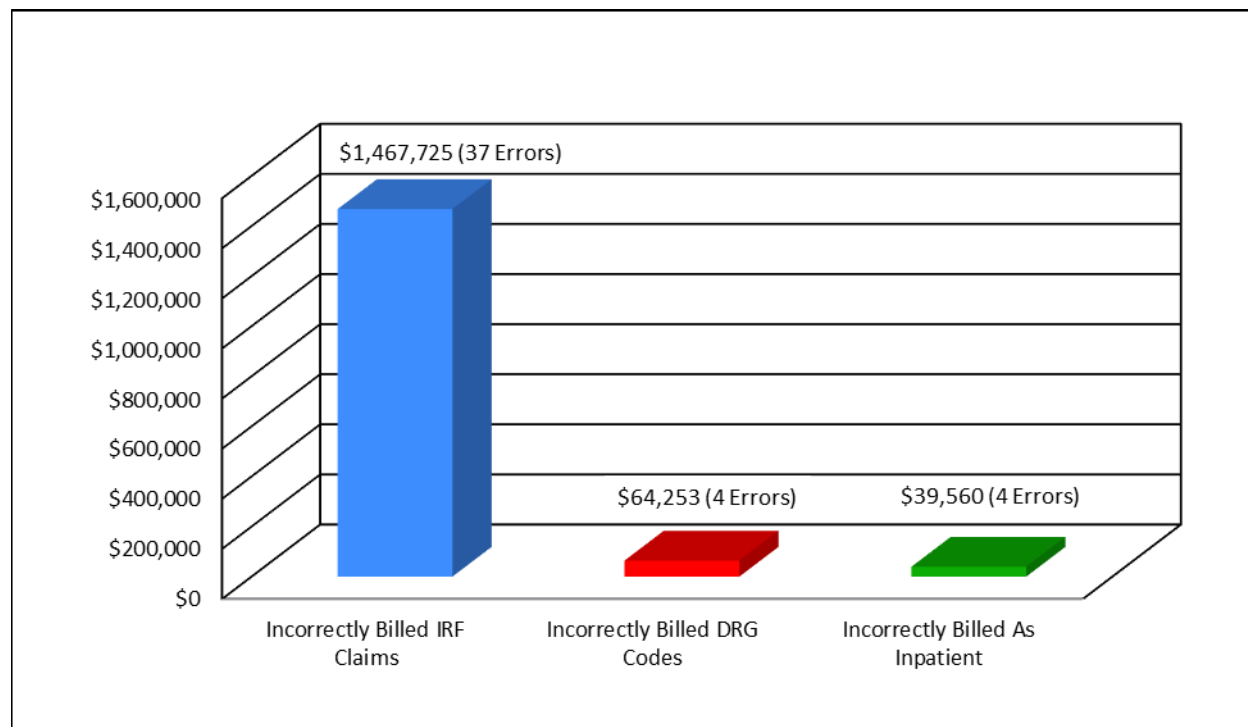
of \$1,571,538, and 1 outpatient claim had a billing error, resulting in an overpayment of \$203. These errors occurred primarily because the Hospital did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$16,395,489 for the audit period.<sup>8</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.

### BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 45 of the 85 inpatient claims that we reviewed. These errors resulted in overpayments of \$1,571,538, as shown in the figure.

**Figure: Inpatient Billing Errors**



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

## **Incorrectly Billed Inpatient Rehabilitation Facility Claims**

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

For an IRF claim to be considered reasonable and necessary, Federal regulations require that there be a reasonable expectation that, at the time of admission, the patient (1) requires the active and ongoing therapeutic intervention of multiple therapy disciplines; (2) generally requires and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program; (3) is sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation program; and (4) requires physician supervision by a rehabilitation physician (42 CFR § 412.622(a)(3)(i-iv)).<sup>9</sup>

Federal regulations require that the patient’s medical record must contain certain documentation to ensure that the IRF coverage requirements are met. The record must include (1) a comprehensive preadmission screening that is completed within the 48 hours preceding the admission, (2) a post-admission physician evaluation that is completed within 24 hours of admission and documents the patient’s status on admission to the IRF, and includes a comparison with the information in the preadmission screening, and (3) an individualized overall plan of care that is completed within 4 days of admission to the IRF (42 CFR § 412.622(a)(4)(i-iii)).

According to Federal regulations, the patient must require an interdisciplinary team approach to care, as evidenced by documentation in the medical record of weekly interdisciplinary team meetings. The meetings must be led by a rehabilitation physician, and further consist of a registered nurse, a social worker or case manager, and a licensed or certified therapist from each therapy discipline involved in treating the patient (42 CFR § 412.622(a)(5)(A)).<sup>10</sup>

For 37 of the 85 selected inpatient claims, the Hospital incorrectly billed IRF services. Specifically, for 22 of these 37 claims, the Hospital incorrectly billed IRF claims that did not comply with Medicare documentation requirements. The 22 claims consisted of 1 or more of the following errors:

- for 21 claims, the documentation did not show that all required team members were present at the interdisciplinary team meetings;

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<sup>9</sup> 42 CFR § 412.622(a)(3)(iv) was amended effective October 1, 2018, to provide that the post-admission physician evaluation described in 42 CFR § 412.622(a)(4)(ii) may count as one of the face-to-face visits (83 Fed. Reg. 38514, 38573 (Aug. 6, 2018)).

<sup>10</sup> 42 CFR § 412.622(a)(5)(A) was redesignated as § 412.622(a)(5)(i) and amended effective October 1, 2018, to provide that the rehabilitation physician may lead the interdisciplinary team meeting remotely (83 Fed. Reg. 38514, 38573 (Aug. 6, 2018)).

- for 7 claims, the individualized overall plan of care was not completed within 4 days of the patient's admission to the IRF;
- for 4 claims, the post-admission physician evaluation was either not completed within 24 hours of the patient's admission to the IRF or did not include a comparison to the information in the preadmission screening; and
- for 1 claim, the pre-admission screening was not completed within the 48 hours preceding the patient's admission to the IRF.

For 15 of the 37 claims, the hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for acute inpatient rehabilitation. IRF services for these beneficiaries were not reasonable and necessary because these beneficiaries did not require the active and ongoing therapeutic intervention of multiple therapy disciplines; generally did not require and could not reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program; were not sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation program; or did not require supervision by a rehabilitation physician. In addition, 10 of the 15 claims also did not comply with Medicare documentation requirements.<sup>11</sup>

Hospital officials stated that the documentation errors related to the weekly interdisciplinary team meetings occurred because internal controls were not effective in ensuring attendance of the required team members. For all other errors, Hospital officials did not provide a cause because they generally contended that these claims met Medicare requirements. However, Hospital officials did not provide any additional information that would impact our finding.

As a result of these errors, the Hospital received overpayments of \$1,467,725.

### **Incorrectly Billed Diagnosis-Related Group Codes**

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

For 4 of the 85 selected inpatient claims, the Hospital submitted claims to Medicare that were incorrectly coded, resulting in incorrect DRG payments to the Hospital. Specifically, certain procedure or diagnosis codes were not supported by the medical records. Hospital officials stated that these errors occurred because of human error in the application of coding guidelines. In addition, Hospital officials stated the Hospital's coding quality reviews are

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<sup>11</sup> These claims were only counted as one error each for purposes of our statistical estimates.

conducted on a sample basis and may not identify all possible errors relating to the appropriate DRG assignments.

As a result of these errors, the Hospital received overpayments of \$64,253. For three of these claims, the Hospital refunded \$48,915 of the overpayments after the start of our audit.

### **Incorrectly Billed as Inpatient**

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

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

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

For 4 of the 85 selected inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for inpatient status that should have been billed as outpatient or outpatient with observation. The medical records did not support the necessity for inpatient hospital services. Hospital officials stated that one of these errors occurred because the Hospital’s review process was not completed on a timely basis when observation status was initiated or when the patient’s status changed to an inpatient level of care. The Hospital did not provide a cause for the remaining errors because its officials generally contended that these claims met Medicare requirements. Furthermore, Hospital officials did not provide any additional information that would impact our finding.

As a result of these errors, the Hospital received overpayments of \$39,560.

## **BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS**

The Hospital incorrectly billed Medicare for 1 of the 15 outpatient claims that we reviewed. This error resulted in an overpayment of \$203.

### **Incorrectly Billed Modifiers**

The Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§§ 1815(a) and 1833(e)). Claims must be filed on forms prescribed by CMS in accordance with CMS instructions (42 CFR § 424.32(a)(1)). Acute care hospitals are required to report HCPCS codes, of which CPT codes are a subset, on outpatient claims (the Manual, ch. 4, § 20.1),<sup>12</sup> and providers are required to complete claims accurately so that Medicare contractors may process them correctly and promptly (the Manual, ch. 1, § 80.3.2.2).

“The ‘59’ modifier is used to indicate a distinct procedural service. This may represent a different session or patient encounter, different procedure or surgery, different site or organ system, separate incision/excision, or separate injury (or area of injury in extensive injuries)” (the Manual, ch. 23, § 20.9.1.1(B)).<sup>13</sup>

Effective January 1, 2015, CMS established four new HCPCS modifiers to define subsets of the “59” modifier. The four new HCPCS modifiers to selectively identify subsets of Distinct Procedural Services are: Modifier XE-Separate Encounter, Modifier XS-Separate Structure, Modifier XP-Separate Practitioner, and Modifier XU-Unusual Non-Overlapping Service. CMS will continue to recognize the “59” modifier, but providers should use one of the more descriptive modifiers when it is appropriate (Pub 100-20, “One Time Notification,” Transmittal 1422 Aug. 15, 2014).

For 1 of 15 selected outpatient claims, the Hospital incorrectly billed Medicare Part B for a HCPCS code appended with an XU modifier that was not separate from other services or procedures billed on the same claim. Hospital officials stated that human error by a newly certified coder caused this error.

As a result of this error, the Hospital received an overpayment of \$203. For this claim, the Hospital refunded the \$203 overpayment after the start of our audit.

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<sup>12</sup> “Under the hospital outpatient prospective payment system, predetermined amounts are paid for designated services furnished to Medicare beneficiaries. These services are identified by codes established under the Centers for Medicare & Medicaid Services Common Procedure Coding System (HCPCS)” (42 CFR § 419.2(a)).

<sup>13</sup> This manual provision was revised after our audit period by Change Request 10868, dated December 28, 2018, and effective January 30, 2019.

## OVERALL ESTIMATE OF OVERPAYMENTS

The combined overpayments on the 46 sampled claims that did not fully comply with Medicare billing requirements totaled \$1,571,741. On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$16,395,489 for the audit period. During the course of our audit, the Hospital submitted for reprocessing four of the claims that did not fully comply, and we verified those claims as correctly reprocessed. Accordingly, we have reduced the recommended refund by \$49,118.

## RECOMMENDATIONS

We recommend that Alta Bates Summit Medical Center:

- refund to the Medicare contractor \$16,346,371 (\$16,395,489 less \$49,118 that the Hospital has already repaid) in estimated overpayments for the audit period for claims that it incorrectly billed;<sup>14</sup>
- based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule,<sup>15</sup> and identify any of those returned overpayments as having been made in accordance with this recommendation; and
- strengthen controls to ensure that:
  - all IRF beneficiaries meet Medicare criteria for acute inpatient rehabilitation and all required documentation is included in the medical records,
  - procedure and diagnosis codes are supported in the medical records and staff are properly trained,
  - all inpatient beneficiaries meet Medicare requirements for inpatient hospital services,

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<sup>14</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>15</sup> This recommendation does not apply to any overpayments that are both within our sampling frame (i.e., the population from which we selected our statistical sample) and refunded based upon the extrapolated overpayment amount. Those overpayments are already covered in the previous recommendation.



- the use of bypass modifiers is supported in the medical records, and
- staff are properly trained.

## **OTHER MATTERS**

Of the 85 inpatient claims in our sample, the Hospital incorrectly billed Medicare Part A for 9 beneficiary stays of less than two midnights (known as “inpatient short stays”), which it should have billed as outpatient or outpatient with observation. Because the medical records did not support the necessity for inpatient hospital services, the services should have been provided at a lower level of care. As a result of these errors, the Hospital received overpayments totaling \$147,536.<sup>16</sup>

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

## **HOSPITAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, the Hospital disagreed with almost all of our findings and recommendations. We summarized the Hospital’s agreements, disagreements, and objections below.<sup>17</sup> After review and consideration of the Hospital’s comments, we maintain that our findings and recommendations, as revised, are correct.

## **SELECTION OF THE HOSPITAL FOR AUDIT**

### **Hospital Comments**

The Hospital contends that our audit of its IRF claims submitted during CYs 2017 and 2018 nullifies and disregards the Hospital’s successful completion of a Targeted Probe and Educate (TPE) program in October 2018. The Hospital further contends that the OIG suspended provider specific IRF audits (concentrating on the requirements set forth in 42 CFR § 412.622(a)(4)) in 2013. Moreover, the Hospital contends that the OIG’s audit of the Hospital undermined the integrity of the TPE process. Specifically, our 2018 report recommended that CMS “educate IRF clinical and billing personnel on Medicare coverage and documentation

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<sup>16</sup> The Hospital has reprocessed and repaid 2 of these claims totaling \$26,372.

<sup>17</sup> We list the Hospital’s agreements, disagreements, and objections by subject matter rather than following the bullet point list in the Executive Summary of the Hospital’s comments because the Hospital touched on several topics across several headings. We have responded to the Hospital’s comments within each topic area.

requirements,” so CMS subsequently approved the Medicare Administrative Contractor (MAC) reviews of IRF claims under the TPE program.<sup>18</sup>

## **Office of Inspector General Response**

The Hospital is incorrect in its assertion that the OIG suspended provider specific audits of IRF claims in 2013. We have continued to undertake such audits from 2013 to the present.<sup>19</sup> These audits included determining compliance with 42 CFR sections 412.622(a)(3) and (a)(4). The Hospital states that our current audit undermines the integrity of the TPE process, but it never states how, and we find no support for its assertion.<sup>20</sup> Our continuation of provider-specific audits of hospitals (including Alta Bates) that included review of IRF claims following our recommendation in the 2018 report<sup>21</sup> and CMS’s pledge to have MACs perform reviews of IRF claims under the TPE program does not undermine the integrity of the TPE process. The TPE process is meant to identify providers’ common errors and help providers quickly correct them. The same holds true of the Hospital’s successful completion of a TPE program in October 2018, for which we commend the Hospital. The Hospital was not improperly targeted but selected for audit following our standard practice.

## **COMPLIANCE WITH 42 CFR SECTION 412.622(A)(4)**

### **Hospital Comments**

The Hospital states that our review of compliance with 42 CFR section 412.622(a)(4), which it refers to as the “Documentation Standards,” elevates form over substance. In addition, the Hospital states that any recoupment based solely on documentation standards would be improper as a matter of law. The Hospital contends that compliance with 42 CFR section 412.622(a)(4) does not establish medical necessity and that an IRF claim is payable if it is

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<sup>18</sup> OIG, *Many Inpatient Rehabilitation Stays Did Not Meet Medicare Coverage and Documentation Requirements* (A-01-15-00500, Sept. 2018).

<sup>19</sup> For example: *Medicare Compliance Review of Abbott Northwestern Hospital for 2013 and 2014* (A-05-15-00043, December 2016); *Medicare Compliance Review of NorthShore University Health System for 2013 and 2014* (A-05-15-00044, December 2016); *Medicare Compliance Review of Parkridge Medical Center, Inc., for 2014 and 2015* (A-04-16-08048, August 2017); *Medicare Compliance Review of Memorial University Medical Center* (A-04-17-08055, February 2018); *Medicare Hospital Provider Compliance Audit: Forbes Hospital* (A-03-18-00005, March 2020).

<sup>20</sup> At any given time, we have numerous outstanding recommendations to CMS regarding the Medicare program, none of which precludes us from continuing to do additional, similar work.

<sup>21</sup> OIG, *Many Inpatient Rehabilitation Stays Did Not Meet Medicare Coverage and Documentation Requirements* (A-01-15-00500, Sept. 2018). In addition to the recommendation contained in this OIG report that CMS “educate IRF clinical and billing personnel on Medicare coverage and documentation requirements . . .”, the report also contained a recommendation that CMS “increase oversight activities of IRFs, such as postpayment medical review, to determine compliance with coverage and documentation requirements . . .”

medically necessary, even if it fails to comply with 42 CFR section 412.622(a)(4).<sup>22</sup>

Furthermore, the Hospital contends that the Medicare Benefit Policy Manual, ch. 1, section 110 supports its assertion that IRF claims can be paid despite violations of 42 CFR section 412.622(a)(4).

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

The Hospital is incorrect that recoupment based solely on 42 CFR section 412.622(a)(4) would be improper as a matter of law. Section 412.622 sets forth Medicare coverage requirements for IRF claims. Furthermore, section 412.622(a)(3) states that there must be a reasonable expectation that the patient meets all four listed requirements at the time of admission to the IRF “to be considered reasonable and necessary under section 1862(a)(1) of the Act.” Finally, section 412.622(a)(4) states that the patient’s medical record must contain all of the listed documentation, along with all of the required information, to document that each patient for whom the IRF seeks payment is reasonably expected to “meet all of the requirements in paragraph (a)(3).” As the Hospital noted in its comments, CMS promulgated these coverage rules in 2009, effective January 1, 2010.<sup>23</sup>

CMS regarded 42 CFR sections 412.622(a)(3), (a)(4), and (a)(5) as “coverage” requirements.<sup>24</sup> The Hospital’s repeated isolation and characterization of 42 CFR section 412.622(a)(4) as “Documentation Standards” is erroneous. As conditions of coverage, 42 CFR sections 412.622(a)(3), (a)(4), and (a)(5) all must be met for an IRF service to be covered by Medicare. The Hospital also is mistaken that the *Medicare Benefit Policy Manual* supports its assertion that IRF claims can be paid despite violations of 42 CFR section 412.622(a)(4). The *Medicare Benefit Policy Manual*, ch. 1, section 110 states, “IRF care is only considered by Medicare to be reasonable and necessary under 1862(a)(1)(A) of the Social Security Act if the patient meets *all* of the requirements outlined in 42 CFR sections 412.622(a)(3), (4), and (5) . . .” (emphasis added).

## **STATISTICAL SAMPLING AND EXTRAPOLATION**

### **Hospital Comments**

The Hospital asserts that, pursuant to section 1893(f)(3) of the Social Security Act and chapter 8, section 8.4.1.4 of the *Medicare Program Integrity Manual* (MPIM), we lacked authority to use statistical sampling and to extrapolate an overpayment without finding a sustained or high rate

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<sup>22</sup> Forty-five of the sample items that we reviewed were IRF claims. Of those, we determined 37 to be improperly paid. Of those determined to be improperly paid, 22 were improperly paid solely on the basis of inadequate documentation.

<sup>23</sup> 74 Fed. Reg. 39762 (Aug. 7, 2009).

<sup>24</sup> 74 Fed. Reg. at 39788-39789.

of error or documented failed educational intervention. The Hospital also asserts that we used a statistically invalid methodology that did not agree with the MPIM to extrapolate the alleged overpayment and MACs are precluded from acting on OIG recommendations for recovery of overpayments if we do not comply with the statistical sampling and extrapolation requirements applicable to MACs. In addition, the Hospital contends that certain beneficiaries showed up more than once in our sample frame, thus invalidating our sample approach and extrapolations. Furthermore, the Hospital raises additional concerns that we did not include IRF claims from after the period of its TPE, implying that we specifically excluded these claims to create a higher error rate or, alternatively, by not reviewing these claims, our results overestimate the number and dollar value of claims in error. Finally, the Hospital requests that we remove from the extrapolation the outpatient modifier claim found to be in error because it is not statistically significant. The Hospital also contends that we provided it with insufficient detail to be able to recreate the sample.

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

The requirement that a determination must be made of a sustained or high level of payment error or documented failed educational intervention before extrapolation applies only to extrapolations by Medicare contractors.<sup>25</sup> Moreover, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.<sup>26</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>27</sup> We properly executed our statistical sampling methodology because we defined our sampling frame and sampling unit, selected a sample of claims at random from each stratum, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. We provided the Hospital with all of the information necessary to replicate the sample from the sampling frame and to recalculate

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<sup>25</sup> See Social Security Act § 1893(f)(3) and CMS Medicare Program Integrity Manual, Pub. No. 100-08, ch. 8.4, § (effective January 2, 2019).

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

<sup>27</sup> See John Balko & Assoc. v. Sebelius, 2012 WL 6738246 at \*12 (W.D. Pa. 2012), aff'd 555 F. App'x 188 (3d Cir. 2014); Maxmed Healthcare, Inc. v. Burwell, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), aff'd, 860 F.3d 335 (5th Cir. 2017); Anghel v. Sebelius, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); Transyd Enters., LLC v. Sebelius, 2012 U.S. Dist. LEXIS 42491 at \*13 (S.D. Tex. 2012).

the estimated overpayment amount.<sup>28</sup> In addition, the Hospital has direct access to its own claims information, which it can use to validate the sampling frame.

The Hospital's contention that certain beneficiaries showed up more than once in our sample frame, thus invalidating our sample approach and extrapolations holds no merit.<sup>29</sup> Our statistical sampling methodology and our sample results are described in Appendices B and C of this report. As described in Appendix B, the sample unit for this audit is a Medicare claim, not a beneficiary. Each Medicare claim in our sample frame is unique and has the same chance of being selected within each stratum. More generally, our methods do not make any assumptions about the presence or absence of dependencies between items within the sampling frame.<sup>30</sup>

The Hospital's concern that we did not include IRF claims from after the period of its TPE, implying that we specifically excluded these claims to create a higher error rate or, alternatively, by not reviewing these claims, our results overestimate the number and dollar value of claims in error, is inaccurate. We developed our sample frame from claims that CMS had cleared as final action, paid claims, as of the date we drew down the data from CMS's records. As explained in Appendix B, we drew our sample items from the sample frame and extrapolated all results back to the sample frame. We acknowledge that CMS may have paid additional claims to the Hospital after we drew our data, but our report can make no assertion about the accuracy of these claims because they are outside of our sample frame.

The Hospital argues that the outpatient claim with the bypass modifier error is not statistically significant and should be removed from the sample. Statistical significance refers to whether an observed result is due to the randomness of the underlying statistical process. By recommending recovery at the lower limit, we accounted for the randomness of the sampling process in a manner that generally favors the Hospital.

## **MEDICAL NECESSITY**

### **Hospital Comments**

The Hospital states that the medical experts that it hired to respond to our report determined that all sample claims were reasonable and necessary and any inconsistencies with 42 CFR

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<sup>28</sup> We provided the Hospital with the sampling plan, the numbered sampling frame, the random seed, the output of software used to generate the random numbers, the sample results file, and the estimation input and output files. Under standard statistical definitions, the universe is either the set of items from which a sample is pulled or to which an estimate is calculated. The sampling frame, which we provided, meets both of these definitions.

<sup>29</sup> Notably, this argument about claim dependence has been previously rejected by the Department Appeal Board. See *MaxMed Healthcare, Inc.*, DAB No. 2978, at 18 (2014).

<sup>30</sup> See e.g., Cochran, William G. 1977. *Sampling Techniques*, 3rd edition. The text provides the detailed proofs underlying design-based sampling methods for stratified and simple random sampling that are used by the OIG. The type of independence cited by the Hospital is not referenced in any of these proofs.

section 412.622(a)(4) were immaterial to medical necessity. The Hospital said that its medical experts found that we: “(i) focused heavily on technical supporting documentation considerations, and (ii) applied IRF medical necessity requirements inconsistently.”

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

We disagree with the Hospital’s claim that our medical experts: “(i) focused heavily on technical supporting documentation considerations and (ii) applied IRF medical necessity requirements inconsistently.” We obtained an independent medical review for all claims in our sample. We submitted the claims to a contractor that reviewed the medical records in their entirety to determine whether the services were medically necessary and provided in accordance with Medicare requirements. We worked with the medical reviewers to ensure that they applied the correct Medicare criteria and that they used professionals with appropriate medical expertise, including physicians with training and expertise in rehabilitation. We appropriately assessed the medical record documentation to determine whether it supported the Medicare payments. The medical reviewers considered each patient’s entire clinical picture, including other medical needs and co-morbid conditions, and found that these beneficiaries: (1) did not require the active and ongoing therapeutic intervention of multiple therapy disciplines; (2) generally did not require and could not reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program; (3) were not sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation program; or (4) did not require supervision by a rehabilitation physician.

### **60-DAY RULE**

#### **Hospital Comments**

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

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

With respect to the Hospital’s intention to appeal our recommendations and assertion that the audit report is not credible information of a patient overpayment (within or outside our audit period) as a result, we refer the Hospital and other readers to this sentence from footnote 14 of this report: “The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal.” That is no reason, however, to withdraw or modify our recommendation. With regard to the Hospital’s argument that completion of a TPE program means that our report does not constitute credible information of

a potential overpayment from completion of the TPE program to the present, we note that determining whether information is sufficiently credible to merit an investigation is a “fact-specific determination” 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016). The Hospital should consider all relevant facts.

Moreover, the Hospital’s argument that the 60-Day Rule does not obligate it to report and return overpayments without actual knowledge is incorrect. The UnitedHealthcare Ins. Co. v. Azar, 330 F.Supp.3d 173 (D.C.D.C. 2018) decision relied upon by the Hospital is inapplicable because it is a False Claims Act case and states that a False Claims Act action for failure to return overpayments requires actual knowledge, reckless disregard, or deliberate ignorance. This audit is not a False Claims Act action. We continue to believe that this audit report constitutes credible information of potential overpayments.

## **PREVIOUSLY REFUNDED CLAIMS**

### **Hospital Comments**

The Hospital contends that we did not give it credit for previously reprocessed and refunded claims thus inflating the amount in overpayments currently outstanding to the Hospital.

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

We make every effort to give the Hospital credit for claims that had been reprocessed at the time of our draft report. The additional six claims the Hospital indicated were reimbursed but not accounted for were not reported as errors for our recommended recovery. However, errors for two of the six claims were reported in the Other Matters section of this report. The Hospital has repaid these claims, and we are not requesting recovery; therefore, we have no need to indicate how much the Hospital has refunded. For the remaining four claims, we did not consider these claims errors and, therefore, did not report any overpayment related to them. We updated the Other Matters section of the report to reflect repaid overpayments by the Hospital.

## **ACUTE INPATIENT ADMISSIONS**

### **Hospital Comments**

The Hospital disagreed that two of the four inpatient hospital admissions that did not comply with requirements were errors. The Hospital stated that, at the time of admission, the patients had signs and symptoms of such severity that the predictability of an adverse medical outcome was high.

## **Office of Inspector General Response**

We disagree with the Hospital's assertion that two of the four inpatient hospital admissions that did not comply with requirements were not errors because, at the time of admission, the patients had signs and symptoms of such severity that the predictability of an adverse medical outcome was high. Based on our independent medical review, neither patient had the signs and symptoms at the time of admission that were considered severe, and the medical predictability of an adverse outcome was not high.

## **INCORRECTLY BILLED DIAGNOSIS RELATED GROUP CODES**

### **Hospital Comments**

The Hospital disagreed with one of the four claims that used an incorrect DRG code, but it did not provide a reason why.

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

We disagree with the Hospital that one of the four claims that used an incorrect DRG code was correct. Based on our independent medical review, Hyperkalemia was not substantiated as the primary diagnosis, which resulted in a DRG change from 981 to 252 and an overpayment.

## **INCORRECTLY BILLED BYPASS MODIFIERS**

The Hospital concurred with our finding that one outpatient claim used an incorrect modifier.

See Appendix E for the Hospital's comments on our draft report. We did not include some attachments to the Hospital's comments because they contained protected information.



## **APPENDIX A: AUDIT SCOPE AND METHODOLOGY**

### **SCOPE**

Our audit covered \$31,012,633 in Medicare payments to the Hospital for 1,072 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 claims (85 inpatient and 15 outpatient) with payments totaling \$4,064,777. Medicare paid these 100 claims from January 1, 2017, through December 31, 2018 (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.

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

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

### **METHODOLOGY**

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Hospital's inpatient and outpatient paid claims data from CMS's NCH database for the audit period;
- used computer matching, data mining, and analysis techniques to identify claims potentially at risk for noncompliance with selected Medicare billing requirements;
- selected a stratified random sample of 85 inpatient claims and 15 outpatient claims totaling \$4,064,777 for detailed review (Appendix B);
- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been cancelled or adjusted;
- reviewed the itemized bills and medical record documentation provided by the Hospital to support the sampled claims;

- requested that the Hospital conduct its own review of the sampled claims to determine whether the services were billed correctly;
- reviewed the Hospital's procedures for assigning DRG and admission status codes for Medicare claims;
- used an independent medical review contractor to determine whether all claims complied with selected billing requirements;
- discussed the incorrectly billed claims with Hospital personnel to determine the underlying causes of noncompliance with Medicare requirements;
- calculated the correct payments for those claims requiring adjustments;
- used the results of the sample review to calculate the estimated Medicare overpayment to the Hospital (Appendix C); and
- discussed the results of our audit with Hospital officials.

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

## APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

### SAMPLING FRAME

According to CMS's NCH database, Medicare paid the Hospital \$241 million for 10,279 inpatient and 61,146 outpatient claims during the audit period.

We obtained a database of claims from the NCH data totaling \$83 million for 3,201 inpatient and 22,216 outpatient claims in 29 risk areas. From these 29 areas, we selected 11 consisting of 14,151 claims totaling \$36,287,479 for further review.

We performed data filtering and analysis of the claims within each of the 11 high-risk areas. The specific filtering and analysis steps performed varied depending on the Medicare issue but included such procedures as removing:

- claims with certain discharge status and diagnosis codes,
- paid claims less than \$0, and
- claims under review by the Recovery Audit Contractor as of June 27, 2018.

We assigned each claim that appeared in multiple risk areas to just one area on the basis of the following hierarchy: IRF Claims, Inpatient Claims Billed with CERT DRG Codes, Inpatient Claims Billed with High-Severity Level DRG Codes, Inpatient Mechanical Ventilation Claims, Inpatient Claims Paid in Excess of Charges, Inpatient Claims Paid in Excess of \$25,000, Inpatient Elective Procedures, Outpatient Claims with Bypass Modifiers, Outpatient Claims Paid in Excess of Charges, Outpatient Claims in Excess of \$25,000, and Outpatient SNF Consolidated Billing Claims. This resulted in a sample frame of 1,072 Medicare paid claims in 11 high-risk areas totaling \$31,012,633 from which we drew our sample (Table 1).

**Table 1: Risk Areas**

| <b>Medicare Risk Area</b>                                | <b>Frame Size</b> | <b>Value of Frame</b> |
|--|-------------------|-----------------------|
| 1. IRF Claims  | 621               | \$21,729,176          |
| 2. Inpatient Claims Billed with CERT DRG Codes           | 93                | 655,508               |
| 3. Inpatient Claims Billed with High Severity Level DRGs | 98                | 1,355,561             |
| 4. Inpatient Mechanical Ventilation Claims               | 2                 | 104,286               |
| 5. Inpatient Claims Paid in Excess of Charges            | 8                 | 223,728               |
| 6. Inpatient Claims Paid in Excess of \$25,000           | 9                 | 1,620,951             |
| 7. Inpatient Elective Procedures Claims                  | 107               | 2,742,185             |
| 8. Outpatient Claims with Bypass Modifiers               | 51                | 50,526                |
| 9. Outpatient Claims Paid in Excess of Charges           | 1                 | 3,237                 |
| 10. Outpatient Claims Paid in Excess of \$25,000         | 66                | 2,519,365             |
| 11. Outpatient SNF Consolidated Billing Claims           | 16                | 8,110                 |
| <b>Total</b>   | <b>1,072</b>      | <b>\$31,012,633</b>   |

**SAMPLE UNIT**

The sample unit was a Medicare paid claim.

**SAMPLE DESIGN AND SAMPLE SIZE**

We used a stratified random sample. We stratified the sampling frame into five strata on the basis of claim type, relative risk of improper payment based on previous OIG audit work and claims paid amount. Strata 1 and 2 include risk areas 1 and 2 from Table 1 separated by paid amount;<sup>31</sup> strata 3 and 4 include risk areas 3 through 7 from Table 1 separated by paid amount,<sup>32</sup> and stratum 5 includes all outpatient claims from risk areas 8 through 11 from Table 1. All claims were unduplicated, appearing in only one area and only once in the entire sampling frame.

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

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<sup>31</sup> Paid claims less than \$35,870 are in stratum 1 and paid claims \$35,870 or greater are in stratum 2.

<sup>32</sup> Paid claims less than \$47,127 are in stratum 3 and paid claims \$47,127 or greater are in stratum 4.

**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 Areas 1-2, Low Dollar Claims  | 472                        | \$10,728,420          | 25                 |
| 2              | Inpatient Risk Areas 1-2, High Dollar Claims | 242                        | 11,656,264            | 25                 |
| 3              | Inpatient Risk Areas 3-7, Low Dollar Claims  | 191                        | 3,050,291             | 20                 |
| 4              | Inpatient Risk Areas 3-7, High Dollar Claims | 33                         | 2,996,419             | 15                 |
| 5              | All Outpatient Claims                        | 134                        | 2,581,239             | 15                 |
|                | <b>Total</b>                                 | <b>1,072</b>               | <b>\$31,012,633</b>   | <b>100</b>         |

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

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

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

We consecutively numbered the claims within strata 1 through 5. After generating the random numbers, we selected the corresponding claims in each stratum.

#### **ESTIMATION METHODOLOGY**

We used the OIG/OAS statistical software to calculate our estimates. To be conservative, we used the lower-limit of the two-sided 90-percent confidence interval to estimate the amount of improper Medicare payments in our sampling frame during the audit period. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

## APPENDIX C: SAMPLE RESULTS AND ESTIMATES

**Table 3: Sample Results**

| Stratum      | Frame Size (Claims) | Value of Frame      | Sample Size | Value of Sample    | Number of Incorrectly Billed Claims in Sample | Value of Overpayments in Sample |
|--------------|---------------------|---------------------|-------------|--------------------|---|---------------------------------|
| 1            | 472                 | \$10,728,420        | 25          | \$592,912          | 18  | \$476,928                       |
| 2            | 242                 | 11,656,264          | 25          | 1,237,792          | 20  | 997,432                         |
| 3            | 191                 | 3,050,291           | 20          | 342,363            | 4   | 49,783                          |
| 4            | 33                  | 2,996,419           | 15          | 1,546,442          | 3   | 47,395                          |
| 5            | 134                 | 2,581,239           | 15          | 327,268            | 1   | 203                             |
| <b>Total</b> | <b>1,072</b>        | <b>\$31,012,633</b> | <b>100</b>  | <b>\$4,046,777</b> | <b>46</b>                                     | <b>\$1,571,741</b>              |

### ESTIMATES

**Table 4: Estimates of Overpayments for the Audit Period**

*Limits Calculated for a 90-Percent Confidence Interval*

|                |              |
|----------------|--------------|
| Point estimate | \$19,241,056 |
| Lower limit    | 16,395,489   |
| Upper limit    | 22,086,622   |

## APPENDIX D: RESULTS OF AUDIT BY RISK AREA

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

| <b>Risk Area</b>   | <b>Selected Claims</b> | <b>Value of Selected Claims</b> | <b>Claims With Over Payments</b> | <b>Value of Overpayments</b> |
|--|------------------------|---------------------------------|----------------------------------|------------------------------|
| IRF Claims   | 45                     | \$1,799,527                     | 37                               | \$1,467,725                  |
| Inpatient Claims Billed With CERT DRG Codes                | 5                      | 31,177                          | 1                                | 6,635                        |
| Inpatient Claims Billed With High-Severity Level DRG Codes | 9                      | 211,806                         | 4                                | 51,465                       |
| Inpatient Mechanical Ventilation Claims                    | 1                      | 49,514                          | -                                | -                            |
| Inpatient Claims Paid in Excess of Charges                 | 3                      | 111,710                         | 1                                | 15,339                       |
| Inpatient Claims Paid in Excess of \$25,000                | 5                      | 989,708                         | -                                | -                            |
| Inpatient Elective Procedures Claims                       | 17                     | 544,067                         | 2                                | 30,374                       |
| <b>Inpatient Totals</b>                                    | <b>85</b>              | <b>\$3,737,509</b>              | <b>45</b>                        | <b>\$1,571,538</b>           |
|  |                        |                                 |                                  |                              |
| Outpatient Claims With Bypass Modifiers                    | 5                      | 4,627                           | 1                                | 203                          |
| Outpatient Claims Paid in Excess of \$25,000               | 9                      | 322,021                         | -                                | -                            |
| Outpatient SNF Consolidated Billing Claims                 | 1                      | 620                             | -                                | -                            |
| <b>Outpatient Totals</b>                                   | <b>15</b>              | <b>\$327,268</b>                | <b>1</b>                         | <b>\$203</b>                 |
|  |                        |                                 |                                  |                              |
| <b>Inpatient and Outpatient Totals</b>                     | <b>100</b>             | <b>\$4,064,777</b>              | <b>46</b>                        | <b>\$1,571,741</b>           |

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



June 4, 2020

Lori S. Pilcher  
Regional Inspector General for Audit Services  
Office of Inspector General  
Department of Health and Human Services  
Office of Audit Services, Region IV  
61 Forsyth Street, SW, Suite 3T41  
Atlanta, GA 30303

RE: Medicare Hospital Provider Compliance Audit: Alta Bates Summit Medical Center  
Draft Report No. A-04-19-08071

Dear Ms. Pilcher,

Alta Bates Summit Medical Center (“Alta Bates”) respectfully submits this letter in response to OIG Draft Report No. A-04-19-08071, *Medicare Hospital Provider Compliance Audit: Alta Bates Summit Medical Center*, dated March 2020 (the “Draft Report”). As discussed below, Alta Bates believes the Draft Report contains legal and factual errors with respect to the claims that were subject to review. Alta Bates urges the OIG to make the changes described herein before finalizing the Draft Report.

### **I. Summary of Draft Report**

The Draft Report summarizes a hospital audit undertaken by the OIG to determine Alta Bates’s compliance with Medicare requirements for billing inpatient and outpatient services. The audit involved Medicare claims paid during a two-year audit period (January 1, 2017 through December 31, 2018) (“Audit Period”) and focused on 11 risk areas identified by the OIG. The OIG selected for review a stratified random sample of 100 claims (85 inpatient; 15 outpatient). The OIG submitted the claims to an independent review contractor to determine whether each claim was supported by the medical record.



The OIG found that a total of 46 claims (45 inpatient; 1 outpatient) did not comply with Medicare billing requirements, leading to an alleged overpayment of \$1,571,741. The Draft Report describes three categories of alleged errors associated with inpatient claims:

- **Inpatient Rehabilitation Facility (IRF) Claims:** 37 claims for IRF services were billed incorrectly. Specifically, 22 claims did not meet the documentation standards set forth at 42 C.F.R. § 412.622(a)(4) (the “Documentation Standards”). Another 15 claims did not meet Medicare’s reasonable and necessary coverage criteria, and 10 of those claims also did not meet the Documentation Standards.
- **Diagnosis-Related (DRG) Codes:** 4 inpatient claims were incorrectly coded. Specifically, certain procedure or diagnosis codes were not supported by the medical records.
- **Incorrectly Billed as Inpatient:** 4 inpatient claims were incorrect because they did not meet criteria for inpatient status and should have been billed as outpatient or outpatient with observation.

After extrapolating based on the sample results, the OIG recommended Alta Bates refund to the Medicare contractor \$16,346,371. This amount accounts for a subset of claims that Alta Bates submitted for reprocessing during the audit.

## **II. Executive Summary of Alta Bates’s Response**

Alta Bates strongly disagrees with the OIG’s review, findings, and recommendations. Our objections fall into the following categories:

- **The OIG’s audit of IRF claims improperly elevates form over substance and disregards the hospital’s successful completion of a prior educational program.** The Medicare program has long struggled with the Documentation Standards. The OIG has encouraged CMS to address this vulnerability by engaging providers in collaborative educational programs. Following this advice, CMS has since worked with providers through various vehicles, including the Targeted Probe and Educate (TPE) Program, which Alta Bates successfully completed *on these very issues* in 2018. The OIG’s decision to audit Alta Bates’s compliance with the Documentation Standards during a time period that predates the TPE review is a complete about-face that effectively nullifies the results of Alta Bates’s TPE review.
- **Compliance with the Documentation Standards was never intended to be the exclusive means of assessing the medical necessity of IRF services.** The Medicare program must pay claims for medically necessary IRF services regardless of technical inconsistencies with the Documentation Standards. Payment for IRF services turns on whether the services meet applicable medical necessity criteria, not a particular element of the Documentation Standards. If a medical reviewer (whether a MAC or other auditor) determines a claim for payment for IRF services is supported by medical necessity, then the claim is payable without regard to the Documentation Standards.

- **The OIG lacks authority to use statistical sampling and extrapolate an overpayment without finding a sustained or high rate of error.** There are limited circumstances in which Medicare contractors may use statistical sampling and extrapolation to estimate an overpayment. The Draft Report fails to demonstrate that an extrapolation is appropriate here. Further, the OIG cannot recommend that a Medicare contractor recoup an alleged overpayment that was calculated inconsistently with the Medicare Program Integrity Manual, which MACs must follow in order to initiate a recoupment.
- **The OIG used a statistically invalid methodology to extrapolate the alleged overpayment.** The OIG’s review violates applicable law and CMS policy in numerous ways that render its conclusions invalid and any extrapolation and recoupment unlawful. The OIG failed to provide adequate documentation to permit Alta Bates to replicate and review the audit, and also failed to satisfy key statistical requirements necessary for an extrapolation. These deficiencies make the alleged overpayment statistically invalid and unreliable.
- **The audited IRF claims met Medicare’s coverage requirements and all material Documentation Standards.** A detailed review by an expert consultant shows all the audited IRF claims were for reasonable and necessary services and any inconsistencies with the Documentation Standards were immaterial to the medical necessity of the admissions.
- **The Medicare 60-day rule does not obligate Alta Bates to review IRF claims outside the Audit Period and uses a legally invalid constructive knowledge standard.** Alta Bates disputes OIG’s findings and intends to appeal any effort by a MAC to recoup payments on any of the bases contained in the Draft Report. Accordingly, the Draft Report is not credible information of a potential overpayment for claims outside the Audit Period. Additionally, based on a recent opinion issued by a federal district court, the Medicare 60-day rule cannot make a provider liable for failing to report and return an overpayment unless the provider does so with actual knowledge. Alta Bates lacks the requisite actual knowledge of an overpayment, and thus lacks an obligation to report and return any overpayment to the Medicare program.

### III. Accounting for Previously Refunded Claims

The Draft Report does not account for a certain number of previously refunded claims. The Draft Report states that during OIG’s audit, Alta Bates correctly submitted four claims for reprocessing, thereby refunding \$49,118. That figure is underinclusive. As of the date of this letter, Alta Bates has submitted 10 claims for reprocessing, resulting in a total repayment of \$84,017.<sup>1</sup> Accordingly, the OIG should reduce the recommended refund amount to reflect the entire amount that Alta Bates has already repaid.

<sup>1</sup> Exhibit A (“Summary of Reprocessed Claims”).

#### **IV. Claims for IRF Services**

##### **A. It was improper for the OIG to target Alta Bates for an audit that elevates form over substance.**

This report appears to mark the first time in nearly a decade that the OIG has focused a hospital audit on compliance with the Documentation Standards. The only comparable review – which the OIG purportedly described as a “pilot” audit of the Documentation Standards – ended with disastrous results. In the 2013 audit of Norwalk Hospital, the OIG examined IRF claims for calendar year (CY) 2010 and found that 98 percent did not meet Documentation Standards.<sup>2</sup> Based solely on those deficiencies, the OIG estimated that Norwalk was overpaid by nearly \$8 million in a single year.

Following the Norwalk audit, the OIG appeared to suspend further provider-specific audits of compliance with the IRF Documentation Standards. In a 2018 report, the OIG instead conducted a nationwide audit of claims from 164 IRFs and found almost 80 percent of those claims did not meet the Documentation Standards.<sup>3</sup> The OIG attributed those errors not merely to IRF documentation practices, but also to certain programmatic shortcomings on the part of the Medicare program. The OIG observed that CMS’s educational efforts and post-payment reviews had not been effective in controlling the rate of improper payments.<sup>4</sup> The OIG made several recommendations to CMS, including that the agency “educate IRF clinical and billing personnel on Medicare coverage and documentation requirements and work with providers to identify, develop, and share compliance best practices that may lead to improved internal controls.”<sup>5</sup> In written comments, CMS concurred with OIG’s recommendations and described several educational interventions designed to prevent overpayments, including the Targeted Probe and Educate (TPE) Program:

CMS has approved the Medicare Administrative Contractors to perform reviews of inpatient rehabilitation providers under its [TPE] Program. This program includes one-on-one education to reduce claim errors and denials for providers who have high denial rates or unusual billing practices. The level of educational intervention increases depending on the claim denial rates.<sup>6</sup>

The OIG highlighted the TPE Program in its final report: “These actions, together with actions taken in response to our recommendations, may significantly reduce the number and amount of improper payments to IRFs.”<sup>7</sup>

<sup>2</sup> OIG, “Norwalk Hospital Did Not Comply with Medicare Inpatient Rehabilitation Facility Documentation Requirements,” No. A-01-11-00531 (Feb. 2013).

<sup>3</sup> OIG, “Many Inpatient Rehabilitation Facility Stays Did Not Meet Medicare Coverage and Documentation Requirements,” No. A-01-15-00500 (Sept. 2018).

<sup>4</sup> *Id.* at p. 6.

<sup>5</sup> *Id.* at p. 12.

<sup>6</sup> *Id.* at 30.

<sup>7</sup> *Id.* at 13.

The conclusion OIG reached in September 2018 is clear: The Documentation Standards are not universally implemented among providers and further education is necessary to improve performance. Not surprisingly, then, Alta Bates was subject to and successfully completed a TPE review *on these very issues* only one month later in October 2018.

The OIG’s decision to now audit providers for compliance with the Documentation Standards for a period of time when the OIG conceded additional provider education was necessary contradicts the agency’s prior views and significantly undermines the integrity of the TPE process. The Draft Report purports to review 11 risk areas, but approximately 58 percent of the sample frame consists of IRF claims. A review of this nature – and a recommended recoupment of \$16 million – is exactly the wrong way to address the problems the OIG noted in its September 2018 report. Had the OIG wanted to apply such a harsh policy, it could have continued provider-specific audits after the Norwalk Hospital review. But the OIG instead chose to spotlight the Documentation Standards as an issue ripe for broader and more collaborative education with the provider community. By the OIG’s own admission, the TPE Program is a more appropriate vehicle to address this issue, and Alta Bates participated in that very process immediately thereafter.

Alta Bates’s experience is the perfect example of what CMS and the OIG had envisioned in September 2018. The OIG’s decision to resume provider-specific audits on this issue during this time period is a complete about-face that effectively nullifies the results of Alta Bates’s TPE review. We therefore encourage the agency to reaffirm its prior support of the TPE process and remove from the Draft Report all claims denied for alleged noncompliance with the Documentation Standards.

#### **B. The audit’s timing and sampling methodology disregards the successful results of Alta Bates’s recent TPE review.**

According to the OIG’s sampling plan, the target population was limited to “inpatient and outpatient Medicare claims paid to the [Alta Bates] during [CY] 2017 and 2018, for selected services provided to Medicare beneficiaries.”<sup>8</sup> The sampling frame was further selected from 11 risk areas as identified by the OIG. The OIG then performed “data filtering and analyses of the claims within each risk area” and removed certain claims, including “claims under review by the Recovery Audit Contractor.” For CY 2018, the sample frame did not include any IRF claims paid after March 2018. Indeed, all claims within the audit’s sample were for services that Alta Bates furnished in CY 2016 and 2017. But in CY 2018, Alta Bates participated in a pre-payment TPE review focused on IRF claims and ultimately achieved *a zero percent error rate* (the “TPE Review”). Unsurprisingly, this TPE Review took place after the OIG’s calculation of a 98-percent error rate for Norwalk Hospital in 2013. TPEs by their very nature are intended to focus on common shortcomings in provider documentation that can be corrected prospectively with provider education. Alta Bates passed its TPE Review with the best possible results, yet the OIG makes no attempt to credit that performance. Indeed, the OIG’s failure to review claims for services billed *after* the TPE Review – but within the Audit Period – overstates the overall error rate and undermines the purpose of the TPE Program.

<sup>8</sup> The sampling plan acknowledges: “Claims paid during this period may include services provided prior to 2017.”

**Background.** Reviews under the TPE Program are administered by MACs and may include up to three rounds or phases. Each phase “typically involves the review of 20-40 claims, per provider/supplier, per service/item, and corresponding education.”<sup>9</sup> As part of the TPE intra-probe educational process, “[t]he MAC may identify errors in the claim(s) that can be easily resolved during the course of provider’s/supplier’s probe reviews.”<sup>10</sup> Such “easily curable errors include . . . missing documentation that can be resolved through the submission of additional documentation.”<sup>11</sup> The MAC will “discontinue the process if/when providers/suppliers become compliant.”<sup>12</sup> The provider/supplier will be referred to CMS if noncompliance remains after three phases.<sup>13</sup> Providers that are removed from the TPE Program after demonstrating low error rates or sufficient improvement in error rates are generally not subject to further review on the same topic for at least one year.<sup>14</sup>

Alta Bates’s TPE Review began on January 29, 2018 and spanned two phases. In Phase 1, Noridian reviewed 25 IRF claims for complete and timely documentation of the preadmission screening, the post admission physician evaluation, the plan of care, the patient assessment instrument, and the interdisciplinary team conference. Noridian identified errors in 14 of the 25 claims, equaling a 56 percent error rate. A copy of Noridian’s Phase 1 summary is attached as Exhibit B. The top trending errors were documentation of all required team members attendance at the interdisciplinary team conference and one claim involving untimely physician documentation, post admission physician evaluation (PAPE), and plan of care. In response to these findings, Alta Bates designed and implemented an appropriate plan of correction.

Alta Bates made extraordinary improvements during Phase 2 of the review, which began on June 25, 2018. In a letter dated October 22, 2018, Noridian announced that it had accepted all 25 claims the MAC audited. In other words, *Alta Bates had not committed any documentation errors, thus achieving a perfect score.*<sup>15</sup> Noridian promptly closed Alta Bates’s audit file based on this outcome. Only one month earlier, in the OIG’s 2018 report, the agency had predicted this exact process would “reduce the number” of claims missing elements of the Documentation Standards. Alta Bates had reduced its number to zero. The TPE Program had achieved its objectives and served both the provider and the Medicare program.

***It was improper for the OIG to exclude claims billed by Alta Bates following the TPE Review.*** As noted above, the Draft Report establishes an error rate for IRF claims based on a target population of claims paid during CY 2017 and 2018, but only audited claims for services furnished in CY 2016 and 2017 – prior to the TPE Review. The OIG then extrapolated that error rate to determine an overpayment covering the entire Audit Period, *which includes periods after Alta Bates implemented its Plan of Correction and achieved its perfect TPE Review score.* The error rate and corresponding overpayment are inaccurate because they are based on a dataset

<sup>9</sup> MPIM (Pub. No. 100-08), Ch. 3, § 3.2.5.

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> CMS, Targeted Probe and Educate (TPE) (“If compliant, you will not be reviewed again for at least 1 year on the selected topic.”), <https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-ffs-compliance-programs/medical-review/targeted-probe-and-educatetpe>.

<sup>15</sup> Exhibit C.

designed to inflate Alta Bates's alleged noncompliance and potential extrapolation. Had the OIG reviewed claims billed after the TPE Review, it would have determined a significantly lower error rate.

***The OIG's choice to audit claims billed prior to the TPE Review undermines the TPE Program.*** The TPE Program is intended to be educational, collaborative, and to decrease burden on providers, MACs, and the Medicare program. Providers have the opportunity to work one-on-one with MAC educators and are not referred to CMS unless they fail to cooperate or improve. As noted above, part of the benefit to providers for participating is the understanding that successful providers will not be reviewed for the same issue for at least one year. OIG's choice to audit Alta Bates's pre-TPE claims effectively end runs the review program.

**C. Compliance with the Documentation Standards was never intended to be the exclusive means of assessing the medical necessity of IRF services.**

Even if Alta Bates had shown no improvement in its documentation practices, any recoupment based solely on the Documentation Standards would be improper as a matter of law. A study of the relevant regulatory history and CMS guidance shows that CMS and MACs must pay claims for medically necessary IRF services regardless of technical inconsistencies with the Documentation Standards. CMS's requirements for coverage of medically necessary IRF services are currently located at 42 C.F.R. § 412.622(a)(3) (the "Coverage Requirements"). In 2009, CMS established separate Documentation Standards at 42 C.F.R. § 412.622(a)(4) (the "IRF Final Rule").<sup>16</sup> At that time, CMS issued corresponding revisions to section 110 of the Medicare Benefit Policy Manual (MBPM) to implement the new regulations. In explaining the scope of the changes to the MBPM, the agency observed: "The revised manual provisions will not contain substantive requirements beyond those that are in the regulations."<sup>17</sup>

The Documentation Standards are intended to evidence that each patient for whom the IRF seeks payment is reasonably expected at the time of admission to meet all the Coverage Requirements.<sup>18</sup> The Documentation Standards do not independently establish medical necessity; the Coverage Requirements do. The Documentation Standards, while helpful to that determination, are not the exclusive means of determining compliance with the Coverage Requirements if the patient's medical record otherwise demonstrates the medical necessity of the admission.

The Documentation Standards serve an evidentiary function in that they are intended to aid a MAC in determining whether IRF services are medically necessary. In implementing the IRF Final Rule through the MBPM, CMS explained the Documentation Standards as follows:

<sup>16</sup> 74 Fed. Reg. 39762, 39788 (Aug. 7, 2009).

<sup>17</sup> *Id.* at 39789.

<sup>18</sup> 42 C.F.R. § 412.622(a)(4).

A/B MACs (A) must *consider* the documentation contained in a patient’s IRF medical record when determining whether an IRF admission was reasonable and necessary, specifically focusing on the preadmission screening, the post-admission physician evaluation, the overall plan of care, and the admission orders.<sup>19</sup>

This explanation underscores that payment for IRF services turns on whether the services meet the Coverage Requirements, not a particular element of the Documentation Standards. Notably, this MBPM passage does not authorize MACs to deny medically necessary claims solely because the provider did not meet each and every technical Documentation Standard. Instead, this passage instructs MACs to “consider,” or take into account, the medical record documentation as a factor in determining whether the IRF services were reasonable and necessary. This is a sensible directive, since requiring MACs to deny payment for otherwise documented medically necessary services due to technical shortcomings would elevate form over substance and impose new conditions of payment not found in the Coverage Requirements.

CMS has elsewhere made clear that MACs may not deny claims for medically necessary IRF services due solely to imperfect or incomplete documentation. In a guidance document that CMS issued while implementing the IRF Final Rule and MBPM updates, CMS indicated that documentation deficiencies *may* lead to claim denials – but only when there is no other support in the medical record to demonstrate medical necessity:

**Clarification regarding whether an IRF claim could be denied because a preadmission screening contains missing or conflicting information.**

*We expect that IRFs would make every effort possible to include the basic information that we are requesting in the medical record so that medical reviewers can determine the appropriateness of the admission.* The information should sufficiently describe the services furnished and the medical need for these services. If missing or conflicting information *is not reasonably explained* in the appropriate document in the IRF medical record, then the IRF claim *could be* subject to denial.<sup>20</sup>

The agency responded similarly to a question about deficiencies in the post-admission physician evaluation:

**Clarification regarding whether an IRF claim *may be* subject to denial if the postadmission physician evaluation was not completed within the 24 hours immediately following the IRF admission, even though the patient’s medical and functional status appeared to warrant an IRF admission.**

<sup>19</sup> Medicare Benefit Policy Manual (MBPM), Pub. No. 100-02, ch. 1, § 110.1 (emphasis added).

<sup>20</sup> CMS, Clarifications for the IRF Coverage Requirements, available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/Complete-List-of-IRF-Clarifications-Final-Document.pdf> (emphasis added).

Yes, an IRF claim is subject *to* denial if the documentation requirements are not met. *However, we expect that IRFs would make every effort possible to include the basic information that we are requesting in the medical record so that medical reviewers can determine the appropriateness of the IRF admission.*<sup>21</sup>

The agency's careful, consistent word choice is instructive. CMS indicated that if a claim did not meet the Documentation Standards with respect to the preadmission screening, "then the claim *could be* subject denial." The word "could" conveys a possibility, not a compulsory outcome. If CMS intended to deny payment for claims that did not meet the Documentation Standards, then the agency would have used clearer, more concrete language – or incorporated the Documentation Standards into the Coverage Requirements. CMS also gives providers the opportunity to demonstrate that the claim met the Coverage Requirements even if a particular Documentation Standard was not met. While CMS says it "expect[s]" the Documentation Standards to be met, they do not form the basis of payment for the claim. If an element is absent, the provider has the opportunity to "reasonably explain[]" in the medical record why the claim is otherwise payable. If payment were based on satisfying every Documentation Standard, there would be no opportunity for providers to provide such an explanation. But CMS's regulation is clear that payment is based on compliance with the Coverage Requirements using the totality of the medical record. CMS established the Documentation Standards to facilitate determinations about whether the services at issue met the Coverage Requirements, but the Documentation Standards were never intended to trump all other information in the medical record demonstrating medical necessity.

If a medical reviewer (whether a MAC or other auditor) determines a claim for payment for IRF services is supported by medical necessity, then the claim is payable without regard to the Documentation Standards. Yet, in the Draft Report, the OIG concluded that 22 claims did not meet Medicare's billing requirements solely because they "did not comply with Medicare documentation requirements."<sup>22</sup> The OIG also determined a second set of 15 claims were incorrectly billed because they did not comply with the Coverage Requirements, and further noted that 10 of those claims also failed to comply with the Documentation Standards. In other words, the OIG reviewed *each* IRF claim for compliance with both the Documentation Standards *and* the Coverage Requirements. Once the OIG found that the referenced 22 claims met the Coverage Requirements, there was no reason to continue examining the Documentation Standards. The OIG's recommendation that Alta Bates refund payments received for medically necessary services solely due to documentation inconsistencies is improper and should be revised.

<sup>21</sup> *Id.*

<sup>22</sup> Draft Report, p. 6.



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

*There are limited circumstances in which Medicare auditors may use statistical sampling and extrapolation to estimate an overpayment.* The Draft Report does not demonstrate that an extrapolation of any alleged errors is appropriate. In 2003, Congress passed the Medicare Modernization Act (“MMA”), which establishes the following limitation on the use of extrapolation:

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

- (A) there is a sustained or high level of payment error; or
- (B) documented educational intervention has failed to correct the payment error.<sup>23</sup>

In the Medicare Program Integrity Manual (MPIM), CMS emphasizes the MMA establishes the *exclusive* grounds for extrapolation:

The [MMA], mandates that before using extrapolation (i.e., projection, extension, or expansion of known data) to determine overpayment amounts to be recovered by recoupment, offset, or otherwise, *there must be* a determination of sustained or high level of payment error, *or* documentation that educational intervention has failed to correct the payment error.<sup>24</sup>

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

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

The MPIM also provides a non-exhaustive list of methods Medicare auditors may use to identify the type of “sustained or high level of payment error” necessary “[f]or purposes of extrapolation,” including “high error rate determinations by the contractor or by other medical reviews (i.e., greater than or equal to 50 percent from a previous pre- or post-payment review).”<sup>25</sup>

The Draft Report’s use of statistical sampling and extrapolation is not supported by either of the bases established under the MMA. The Draft Report does not suggest the alleged payment errors are the result of failed educational interventions. To the contrary, educational interventions were clearly successful: Alta Bates achieved a perfect score in Phase 2 of the 2018 TPE Review. Not

<sup>23</sup> 42 U.S.C. § 1395ddd(f)(3).

<sup>24</sup> MPIM (Pub. 100-08), Ch. 8, § 8.4.1.2 (emphasis added).

<sup>25</sup> *Id.* at 8.4.1.4.

surprisingly, the Draft Report neither alleges nor cites any evidence that Alta Bates had the type of sustained or high level error rate necessary to justify sampling and extrapolation. Instead, the OIG’s audit of Alta Bates was driven by its experience with *other hospitals*. At several points, the Draft Report acknowledges, “We focused our audit on the risk areas identified as a result of prior OIG audits at *other hospitals*.”<sup>26</sup>

Apart from the audit findings – which do not meet the 50 percent error rate threshold established in the MPIM – the Draft Report provides no other bases for the use of extrapolation. Alta Bates’s expert consultant and statistician (further discussed below) determined the alleged claims error rate to be only 46 percent with an error rate of 38.7 percent of the dollars paid. Thus, the Draft Report recommends the MAC recoup an alleged overpayment that was calculated using statistical sampling and extrapolation methodologies that violate applicable law and CMS guidance.

***A MAC may not recoup an alleged overpayment that was calculated inconsistently with applicable law.*** The OIG has previously argued that the MMA and the MPIM apply only to Medicare contractors, and not the OIG.<sup>27</sup> This position ignores the fact that the Draft Report constitutes a mere recommendation to recoup the alleged overpayment. As the Draft Report acknowledges, “CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments *consistent with its policies and procedures*.”<sup>28</sup> If MACs are bound by the limits imposed by the MMA and MPIM, then the OIG cannot recommend that a MAC recoup an alleged overpayment calculated using a methodology that violates those authorities. The OIG must conduct its review consistent with these policies and procedures in order for the MAC to initiate a lawful recoupment.

#### **E. The OIG used a statistically invalid methodology to extrapolate the alleged overpayment amount.**

The OIG’s review violates the MMA and MPIM in numerous ways that render its conclusions invalid and any extrapolation and recoupment unlawful. When it received the Draft Report, Alta Bates engaged (through outside legal counsel) PYA, P.C., a nationally recognized healthcare consultant, to (i) perform a comprehensive billing, coding, and medical necessity assessment of the IRF claims identified as erroneous by the OIG; and (ii) review whether the documentation provided by the OIG supports proper statistical calculations and methodology. PYA and its statistician, Dr. Pat Maykuth (collectively, “PYA”) reviewed that information and provided the attached report at Exhibit D (the “PYA Report”).

In reviewing the statistical validity of the Draft Report, PYA applied the standards set forth in the MPIM, Chapter 8 (8.4) (Use of Statistical Sampling for Overpayment Estimation). As noted above, these provisions apply to the OIG insofar as it recommends that a MAC recoup amounts

<sup>26</sup> Draft Report, p. 4 (emphasis added). *See also* p. 2 (“Previous [OIG] audits at other hospitals identified types of claims at risk for noncompliance. Out of the areas identified as being at risk, we focused our audit on the following: . . .”).

<sup>27</sup> *See, e.g.*, OIG Report No. A-02-17-01016, p. 16 (“We also note that the MPIM applies to Medicare contractors—not the OIG.”)

<sup>28</sup> Draft Report, n.9 (emphasis added).

based on its findings. When the OIG uses statistical sampling and extrapolation to calculate an alleged overpayment, the OIG must comply with the MPIM or else it will be directing the MAC to violate applicable law. Applying the MPIM standards, PYA found the OIG committed errors that fall into the two categories described below.

***First, the OIG failed to provide adequate documentation to permit Alta Bates to replicate and review the audit.*** This issue is much more significant than a mere technical debate over the rules governing which materials must be provided to a provider during an audit. Rather, an essential component of a valid statistical analysis is that the methods of sampling and extrapolation must be fully documented so that there is a complete audit trail that would enable an independent reviewer to replicate, test, and verify the auditor’s methodology. For this reason, the MPIM repeatedly requires Medicare contractors to document their methodologies with full transparency:

- “The contractor *shall identify* the sampling methodology to be followed.”<sup>29</sup>
- “The contractor *shall maintain complete documentation* of the sampling methodology that was followed.”<sup>30</sup>
- “An explicit statement of how the universe is defined and elements included *shall be made and maintained in writing*.”<sup>31</sup>
- “The contractor *shall maintain all documentation* pertinent to the calculation of an estimated overpayment including but not limited to the statistician-approved sampling methodology, universe, sample frame and formal worksheets. The documentation must be sufficient to allow for any future replication and/or validation by an administrative or judicial body.”<sup>32</sup>

The OIG failed to meet the MPIM’s transparency requirements because – despite Alta Bates’s requests – the agency did not provide (i) the documentation necessary to replicate the audit (i.e., the universe of claims<sup>33</sup> or the sample procedure), and (ii) a proper statement of the methodology used to calculate the overpayment. For example, the sampling plan that the OIG provided to Alta Bates:

- lacks the specific claims data (i.e., codes, modifiers, etc.) necessary to permit replication of the sample;
- does not identify the discharge status codes and revenue codes that the OIG purports to have removed from the claims universe; and
- lacks the detailed characteristics, descriptions, or criteria used to define each OIG-identified risk area.

<sup>29</sup> MPIM (Pub. No. 100-08), Ch. 8, § 8.4.4.1 (emphasis added).

<sup>30</sup> *Id.* at § 8.4.4.4 (emphasis added).

<sup>31</sup> *Id.* at § 8.4.4.4.1 (emphasis added).

<sup>32</sup> *Id.* at § 8.4.4.5 (emphasis added).

<sup>33</sup> The OIG denied Alta Bates’s request for the universe of claims, explaining: “Regarding the Universe of Claims – We do not provide any claims outside the sampling frame without a formal FOIA request.” Email from Scott Perry (OIG) (May 1, 2020). We elected against submitting a FOIA request due to the timeline for responding to the OIG’s Draft Report, and the unlikelihood that we would receive – and have sufficient time to analyze – the requested information.

These issues are not about technical or academic minutia. These are material shortcomings that invalidate the entire review. Alta Bates will appeal any claims recouped by the MAC pursuant to these findings and will be able to demonstrate that the OIG has not provided documentation “sufficient to allow ... validation by an administrative or judicial body.” The OIG cannot proceed on this basis and expect its recommendations to result in a valid and enforceable recoupment.

***Second, the OIG failed to meet the minimum requirements for a valid statistical extrapolation.***

The MPIM requires Medicare contractors to “follow a procedure that results in a probability sample”<sup>34</sup> and provides a set of instructions to ensure that a “probability sample drawn from the sampling frame of the target population yields a valid estimate of an overpayment in the target population.”<sup>35</sup> If an auditor does not meet key requirements for a probability sample, then any subsequent extrapolation is statistically invalid and unreliable.

The OIG did not follow a procedure that resulted in a statistically valid probability sample, making the Draft Report’s use of an extrapolated overpayment statistically invalid. The MPIM lists six minimum requirements that must be present for a probability sample;<sup>36</sup> the OIG’s work does not meet five of those elements. While the PYA Report describes each shortcoming in detail, here are a few examples of the Draft Report’s deficiencies:

- The OIG did not use sampling units that had an equal chance of selection. There were multiple beneficiaries who appear in multiple frame strata, and beneficiaries with associated claims have a different chance of those claims being paid in error than non-associated claims.
- The OIG failed to use proper randomization for dependent data. The OIG’s methodology failed to address the existence of overlapping beneficiaries between the strata.
- The OIG failed to accurately measure overpayments in the frame. As noted above, the OIG extrapolated on an error rate below 50 percent contrary to MPIM guidance. This is problematic because low error rates lead to inaccurate measurement and tend to inflate the repayment amount.

Again, these deficiencies are not about trivial technical issues. Rather, the requirements imposed by the MPIM are intended to ensure any extrapolation accurately represents the actual overpayment amount. The OIG’s extrapolation falls far short of meeting the MPIM’s important requirements.

<sup>34</sup> *Id.* at § 8.4.2.

<sup>35</sup> *Id.* at § 8.4.1.1.

<sup>36</sup> *Id.* at §8.4.2 (“If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample or that the resulting estimates are ‘not statistically valid’ cannot legitimately be made.”).

## **F. The audited IRF claims met Medicare's Coverage Requirements and all material Documentation Standards.**

Notwithstanding the numerous legal and procedural deficiencies that undermine the statistical validity and reliability of the findings in the Draft Report, all of the audited IRF claims were nonetheless for reasonable and necessary services.<sup>37</sup> As indicated above, PYA performed a detailed medical record review of the 37 IRF claims that the OIG alleged were incorrectly paid. Overall, PYA found the OIG (i) focused heavily on technical supporting documentation considerations, and (ii) applied IRF medical necessity criteria inconsistently. With respect to the 22 claims where the OIG identified inconsistencies with the Documentation Standards, PYA determined each claim met all Coverage Requirements and all material Documentation Standards. PYA found that all denials based on the Documentation Standards were improper because any errors were immaterial to the medical necessity of the IRF admissions and care provided by Alta Bates during the inpatient stays and otherwise documented in the patient's medical record. Each claim met the Coverage Requirements for a reasonable and necessary admission. Indeed, PYA found that a number of these 22 claims *in fact met all the Documentation Standards*, despite the OIG's assertions to the contrary. As such, PYA concluded the admissions should not be denied based solely on documentation technicalities.

The PYA Report explains in detail why the documentation issues identified by the OIG are insufficient to warrant the denial of the claims at issue. The OIG medical reviewer appears to have taken a rote checklist approach to the audit without examining the entire medical record of each sampled claim. The OIG proposes to deny these claims based on technical documentation requirements even though the services were clearly furnished and medically necessary. Examples of specific bases for the denials include:

- ***Denials Based on the Absence of a Team Member at a Meeting.*** The OIG proposes denying 21 claims because the medical record documentation does not show that all required team members were present at all interdisciplinary team (IDT) meetings. However, PYA confirmed that in each case the medical record documentation supports that services were provided by an IDT approach to the delivery of rehabilitation care and that the team met weekly in a coordinated effort to benefit the patient. Beyond the weekly IDT meeting, the medical records contain frequently documented communications among disciplines to establish, prioritize, and achieve treatment goals.

For example, in Sample #4, a 92-year old patient was admitted following a neurological event. The services she received during her 13-day admission included 1,770 minutes of physical and occupational therapy. The OIG denied the entire admission based on a finding that the registered nurse (RN) did not participate in one – and only one – IDT meeting. Yet, the nursing notes from the same day show the RN updated the plan of care (POC) and communicated with the social worker, and that all updates were communicated to and approved by the rehabilitation physician who lead the IDT meeting.

<sup>37</sup> Earlier, in response to OIG's Internal Controls Questionnaire, Alta Bates expressed disagreement with the OIG's findings for samples #14, #19, #20, #23, #29, #33, and #46, but concurred with the OIG's remaining findings about the IRF claims. We wish to clarify that, upon further review, Alta Bates believes all of the audited IRF claims met all of the Coverage Requirements and material Documentation Standards.

Further, the RN participated in an earlier IDT meeting and updated the nursing plan twice daily throughout the entire admission. There can be little doubt the RN in question was part of the team that actively provided care to the patient during her stay.

In another case, Sample #24, a 72-year old patient was admitted following a stroke. During her 14-day admission she received a range of services, including 2,220 minutes of physical, occupational, and speech therapy. The OIG denied the entire admission based on a finding that the social worker did not attend one – and only one – IDT meeting. However, the social worker had already performed an evaluation upon admission and determined that the patient would not have any social or discharge needs. The social worker's evaluation was then incorporated in the POC and discussed at the IDT meeting, where it was approved by the rehabilitation physician. The documentation fully supports that the services were medically necessary, the patient benefited from those services, and Alta Bates discharged the patient within a reasonable period of time.

- ***Denials Based on the Timing of the Plan of Care.*** The OIG proposes denying seven claims based on findings that the POC was not completed within four days of admission. The OIG reached this incorrect conclusion by assuming the POC was established on the date of the first IDT meeting. Yet, in each case the POC was established prior to the first IDT meeting and within four days of admission. There is no requirement that the POC must be established at, or subsequent to, the first meeting. For example, in Sample #44, a 57-year-old patient was admitted following a stroke. He received a range of services during his 20-day admission, including 2,760 minutes of physical, occupational, and speech therapy. The OIG denied the entire admission based on the timing of the POC. The POC was documented on the same day that the patient was admitted. The OIG erred by focusing on the date of the first IDT meeting, which did not occur until later, and disregarding the scope of care the patient received pursuant to the POC that the physician and IDT carried out.
- ***Denials Based on the Timing of the Post-Admission Physician Evaluations (PAPE):*** The OIG proposes denying two claims based on findings that the PAPE was not completed within 24 hours of the patient's admission. In Sample #3, a 70-year-old patient was admitted after she sustained a pelvic fracture and an elbow fracture. During her 10-day admission she received a range of intensive interdisciplinary services, including 1,440 minutes of physical and occupational therapy. The OIG denied the entire admission based on an observation that the PAPE was documented 24 hours and 59 minutes after the patient's admission. The physician documented the PAPE, the admission history and physical (H&P) and POC at the same time. Performing and documenting the PAPE, H&P, and POC is a significant undertaking that requires more than 59 minutes. It is reasonable to conclude based on the information in the medical record that the PAPE, which involves a face-to-face visit and evaluation, was performed prior to completing the documentation and within the 24-hour timeframe. More fundamentally, it would be unreasonable for the OIG to deny a claim for a 10-day admission based solely on a brief potential delay where there is no question whether the services the patient received were medically necessary.

With respect to the 15 claims that the OIG determined did not meet the Coverage Requirements, PYA found the OIG applied an inappropriate standard of review and that each claim met the necessary criteria at the time of admission.<sup>38</sup> According to the OIG’s determination letters, the agency’s the primary justification for denying these claims was, “at the time of admission, there was no reason to think that an intensive rehabilitation therapy program would significantly impact the patient’s condition.” This standard is found nowhere in the Coverage Requirements and is instead an arbitrary and subjective opinion by one medical reviewer. Indeed, this standard is contrary to the standard established in the MBPM, which requires only that the admission be of practical value to improve the patient’s condition. Each claim contains medical record documentation demonstrating a reasonable expectation that the patients would make a measurable improvement of practical value to improve their functional capacity and/or to adapt to their impairments. The OIG’s conclusion to the contrary is based on a pseudo standard lacking any legal or factual basis and thus must be set aside.

#### **G. The Medicare 60-day rule does not obligate Alta Bates to review IRF claims outside the Audit Period.**

The Draft Report recommends that Alta Bates “exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule,”<sup>39</sup> including overpayments relating to IRF claims. The Draft Report further advises that the 60-day rule’s 6-year lookback period “is not limited by OIG’s audit period or restrictions on the Government’s ability to reopen claims or cost reports.”<sup>40</sup> The OIG should omit this recommendation because it is premature to say whether the Draft Report constitutes credible information of potential overpayment. Alta Bates disputes the OIG’s findings and intends to appeal through the MAC appeal process should a recoupment occur. And even if the findings of the Draft Report constitute “credible information”—and they do not—there is no credible information that IRF claims billed *after* Alta Bates implemented its Plan of Correction during the TPE Review are likely to contain any of the same issues described in the Draft Report since Alta Bates concluded its TPE Review with a perfect score. Any such issues, however immaterial, were corrected in 2018 and Alta Bates has no reason to believe they persisted beyond that time period.

**Legal Standard.** Under the Affordable Care Act (ACA), a person who has received an overpayment must “report and return the overpayment” by “the date which is 60 days after the date on which the overpayment was *identified*,” or by the date the corresponding cost report is due, whichever is later (the “Overpayment Statute”).<sup>41</sup> Under the regulations governing the Medicare fee-for-service program (collectively the “FFS 60-Day Rule”), an overpayment may be “identified” through actual or constructive knowledge. Specifically, the regulations provide:

<sup>38</sup> PYA found that for one claim (sample #7), the discharge process should have begun earlier. However, that delay is attributable to documented patient unwillingness/inability to participate in the rehabilitation therapy program.

<sup>39</sup> Draft Report, 10.

<sup>40</sup> *Id.* at 3.

<sup>41</sup> 42 U.S.C. § 1320a-7k(d) (emphasis added).

A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise *reasonable diligence* and the person in fact received an overpayment.<sup>42</sup>

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

“Reasonable diligence” includes both proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments and investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining *credible information* of a potential overpayment.<sup>43</sup>

Neither the Overpayment Statute nor the FFS 60-Day Rule use the term “credible information.” However, CMS indicated in the preamble that the “credible information” standard is central to understanding when providers must engage in reactive investigations. Specifically, CMS explained, “credible information includes information that supports a reasonable belief that an overpayment may have been received.”<sup>44</sup> The agency also acknowledged: “Determining whether information is sufficiently credible to merit an investigation is a fact-specific determination.”<sup>45</sup>

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

If the provider appeals the contractor identified overpayment, the provider may reasonably assess that it is premature to initiate a reasonably diligent investigation into the nearly identical conduct in an additional time period until such time as the contractor identified overpayment has worked its way through the administrative appeals process.<sup>46</sup>

Even if the provider’s appeal is unsuccessful, contractor or government audit findings only constitute “credible information of receiving a potential overpayment beyond the scope of the audit if the practice that resulted in the overpayment also occurred outside the audited timeframe.”<sup>47</sup> In other words, if a provider has a reasonable basis to believe it resolved the

<sup>42</sup> 42 C.F. R. § 401.305(a)(2) (emphasis added).

<sup>43</sup> 81 Fed. Reg. 7654, 7661 (Feb. 12, 2016) (emphasis added).

<sup>44</sup> *Id.* at 7662.

<sup>45</sup> *Id.* at 7663.

<sup>46</sup> *Id.* at 7667.

<sup>47</sup> *Id.*



practice underlying an overpayment identified in an audit report, then the report may not be credible information that the provider was overpaid on claims billed after implementing the corrective action. Absent credible information of an overpayment for claims billed following the corrective action, the provider would not have a duty under the FFS 60-Day Rule to undertake a reactive investigation.

***The Audit Report is not credible information of a potential overpayment for claims outside the Audit Period.*** As detailed above, Alta Bates disputes the findings in the Draft Report and intends to exercise its right to appeal any determination by the MAC to recoup Medicare payments on any of the bases contained in the Draft Report. Indeed, the Draft Report clearly acknowledges the preliminary nature of the OIG's determinations:

OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures.<sup>48</sup>

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

Even if Alta Bates accepted the OIG's findings, which it does not, the Draft Report still does not constitute the type of credible information that would compel the hospital to investigate IRF claims billed during a significant part of the 6-year lookback period. Specifically, the successful outcome of Alta Bates's TPE Review is strong evidence that IRF claims billed on or after the Phase 2 commencement date, June 25, 2018, are unlikely to be afflicted by the issues described in the Draft Report. By that date, Alta Bates had fully implemented an appropriate Plan of Correction that enabled the hospital to achieve a perfect score. The hospital has maintained consistent IRF billing practices since Noridian closed the hospital's TPE file. Thus, even if the Draft Report is considered credible information of a potential overpayment for claims outside the Audit Period, Alta Bates has a strong basis to conclude it is not required to investigate IRF claims billed on or after June 25, 2018.

#### **H. The FFS 60-Day Rule's use of a negligence-based constructive knowledge standard is not valid.**

A federal district court recently vacated the 60-Day rule that applies to the Medicare Advantage (MA) program after finding, *inter alia*, that CMS exceeded its authority by applying a negligence standard of liability that extends the reach of the federal False Claims Act (FCA). The FFS 60-Day Rule is invalid for the same reason and may not impose liability beyond what is otherwise permitted by the FCA. In other words, the FFS 60-Day Rule cannot make a provider liable for failing to report and return an overpayment unless the provider does so with actual knowledge.

<sup>48</sup> *Id.* at n.9.

Thus, if Alta Bates lacks the requisite actual knowledge, then the hospital has no obligation under the FFS 60-Day Rule to report and return any overpayment to the Medicare program.

***The FFS and MA 60-Day Rules use the same negligence-based constructive knowledge standard.*** CMS has promulgated regulations implementing the Overpayment Statute as to Medicare Parts A, B, C, and D.<sup>49</sup> The FFS 60-Day Rule, which applies to Parts A and B, is discussed above. The regulations that apply to the MA program (the “MA 60-Day Rule”) are—in all respects material to the present matter—identical to the FFS 60-Day Rule. CMS finalized the MA 60-Day Rule in May 2014,<sup>50</sup> and the FFS 60-Day Rule in a separate rulemaking in February 2016.<sup>51</sup>

With respect to the actual and constructive knowledge requirements, the relevant, corresponding language of the FFS and MA rules is provided below:

| MA 60-Day Rule   | FFS 60-Day Rule   |
|--|---|
| The MA organization has identified an overpayment when the MA organization has determined, <i>or should have determined through the exercise of reasonable diligence</i> , that the MA organization has received an overpayment. <sup>52</sup> | A person has identified an overpayment when the person has, <i>or should have through the exercise of reasonable diligence</i> , determined that the person has received an overpayment and quantified the amount of the overpayment. <sup>53</sup> |

Like the FFS 60-Day Rule,<sup>54</sup> the MA 60-Day Rule provides: “Any overpayment retained by an MA organization is an obligation” for purposes of the FCA if not returned in accordance with the overpayment regulation.<sup>55</sup>

***The MA 60-Day Rule was vacated on grounds that are equally applicable to the FFS 60-Day Rule.*** In *UnitedHealthcare Ins. Co. v. Azar* (“*United*”),<sup>56</sup> the U.S. District Court for the District of Columbia vacated the MA 60-Day Rule. Critically, the court held CMS lacked authority to impose a negligence standard on MA insurers to identify and report overpayments, as that standard is plainly inconsistent with the standards of the FCA. As shown above, the FFS 60-Day Rule applies the *same* negligence standard, and there is no reason to believe that regulation would fare differently if challenged before the same court.

The *United* case concerned a statutory actuarial standard that applies to the MA program. MA insurers are required to provide, at a minimum, the same level of benefits provided by traditional Medicare. The Medicare statute requires CMS to pay MA insurers in a manner that ensures “actuarial equivalence” between payments for healthcare under traditional Medicare and MA

<sup>49</sup> 42 C.F.R. §§ 422.305 (Parts A and B), 422.326 (Part C) and 423.360 (Part D).

<sup>50</sup> 79 Fed. Reg. 29843 (May 23, 2014).

<sup>51</sup> 81 Fed. Reg. 7653 (Feb. 12, 2016).

<sup>52</sup> 42 C.F.R. § 422.326(c) (emphasis added).

<sup>53</sup> 42 C.F.R. § 401.305(a)(2) (emphasis added).

<sup>54</sup> See 42 C.F.R. § 401.305(e).

<sup>55</sup> 42 C.F.R. § 422.326(e).

<sup>56</sup> 330 F.Supp.3d 173 (D.D.C. 2018), *appeal filed*, Case No. 18-5326 (D.C. Cir.).

plans. United challenged the MA 60-Day Rule, alleging it failed to satisfy the mandate of actuarial equivalence. Most critical for the present purposes, United also argued the MA 60-Day rule imposed a negligence standard that unlawfully departed from the FCA's standard of liability.<sup>57</sup>

The *United* court vacated the MA 60-Day Rule on several independent grounds, including that CMS lacked authority to expand the FCA's reach through applying a regulatory negligence standard. In analyzing the standard imposed by the MA 60-Day Rule, the court underscored CMS' explanation of "reasonable diligence" in the preamble to the final rule:

In the preamble to the 2014 Overpayment Rule, CMS explained that such reasonable diligence "at a minimum ... would include proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments." Failure to do so could place a [MA] insurer at risk of liability under the [FCA].<sup>58</sup>

The court contrasted the MA 60-Day Rule with the FCA, which imposes liability for "knowingly" submitting false claims. After noting how the FCA defines "knowingly," the court explained, "the FCA and the ACA require actual knowledge, deliberate ignorance, or reckless disregard before liability can be found."<sup>59</sup> Upon distinguishing between the foregoing standards of liability, the court concluded, "the [MA 60-Day] Rule extends far beyond the [FCA] and, by extension, the [ACA]. Not being Congress, CMS had no legislative authority to impose FCA consequences through regulation."<sup>60</sup>

Although *United* vacated the MA 60-Day Rule, alone, the FFS 60-Day Rule is invalid for the same reason. To reiterate, the FFS and MA 60-Day Rule apply the same negligence standard. Further, a comparison between the preambles to the final rules clearly shows the term "reasonable diligence," as used in both rules, has the same meaning. Thus, in the wake of *United*, the FFS 60-Day Rule should be interpreted as requiring actual knowledge for an overpayment to constitute an obligation for purposes of the FCA.

## **V. Other Claims**

### **A. Incorrectly Billed Inpatient Claims**

Alta Bates disagrees with the OIG findings on 2 of the 4 errors the OIG identified and classifies as 4 inpatient Medicare Part A claims that should have been billed as outpatient or outpatient with observation. Specifically, we disagree with the findings for samples #12 and 57. In both cases, at the time of admission, the patients had signs and symptoms of such severity that the predictability of an adverse medical outcome was high. Physicians and other clinical personnel must determine medical necessity based on information present at the time of admission. For this

<sup>57</sup> *Id.* at 182.

<sup>58</sup> *Id.* at 190 (quoting 79 Fed. Reg. 29843, 29923 (May 23, 2014)).

<sup>59</sup> *Id.* at 190 - 91.

<sup>60</sup> *Id.* at 191.

reason, the MBPM recognizes that, in reviewing determining whether an admission was medically necessary, reviewers should

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>61</sup>

Below is a brief summary of the justifications for the inpatient admissions, as observed at the time admission and as documented in the patients' medical records:

- Sample #12 involved a 90-year-old patient with a history of dementia, hypertension, diverticulitis with diverting colostomy, CKD, hyperlipidemia, and anemia who was emergently admitted to inpatient care for evaluation and management of syncope (i.e., a loss in consciousness due to a fall in blood pressure). The OIG's medical reviewer found there was no documentation in the record to justify an order for inpatient level of care at the time of admission; yet, the patient's symptoms of unsteadiness were persistent in the emergency department despite treatment with intravenous fluids. This placed the patient at a notably increased risk for falls and subsequent injury, especially if she would have been discharged back to her home alone. Further, the etiology of her syncope was unclear and a workup for cardiac etiology ensued at the time of admission. The unwitnessed episode of syncope resulted in head trauma including ecchymosis of the right cheek and left medial eyebrow. Head injury in patients of advanced age significantly increases the risks for subarachnoid and subdural hematomas that are often not clinically identifiable soon after the incident. Additionally, the patient's medication to treat dementia had to be held due to its propensity to cause bradycardia, as a cardiac etiology including dysrhythmia had not yet been ruled out. This put the patient at risk for increased confusion and posed a safety risk.
- Sample #57 involved a 63-year-old patient who presented with sepsis, acute gangrenous cholecystitis, and poorly controlled diabetes. The patient also had hyperglycemia, hyponatremia, hypokalemia. In view of the significant risk that sepsis in patients with gangrenous cholecystitis and multiple comorbidities can lead to rapid deterioration and death, the attending physician elected to admit the patient of an emergent laparoscopic cholecystectomy, which was ultimately successful in relieving the patient's symptoms.

Based on the above, we strongly disagree with the OIG's findings and ask the agency to remove these two samples from the error list.

<sup>61</sup> MBPM, Pub. No. 100-02, ch. 1, § 10.

## **B. Incorrectly Billed Diagnosis-Related Group Codes**

Alta Bates concurs with 3 of 4 OIG findings. We determined that random coding errors with partial reimbursement impact occurred in 4 out of 85 inpatient claims. A corrected claim was promptly submitted and corrected reimbursement was subsequently received for samples #63, 74, and 83. We dispute and intend to exercise our right to appeal sample #84.

Given the extremely low underlying payment error rate, coupled with the particular nature of the errors at issue, we do not believe the discovery of 2 errors over a 2-year period constitutes "credible information" of the existence of a "potential overpayment." As a result, we do not believe Alta Bates is obligated under the FFS 60-Day Rule to review claims outside the Audit Period.

## **C. Incorrectly Billed Bypass Modifiers**

The OIG identified 1 error (i.e., one outpatient claim with an incorrect bypass modifier) out of 15 outpatient claims resulting in an overpayment of \$203. Alta Bates concurred with this finding and promptly submitted a corrected claim. We believe the inclusion of an incorrect bypass modifier was the result of human error.

Alta Bates requests that the OIG remove this claim from the extrapolation calculation because it is not statistically significant. Further, Sutter Health has a robust compliance program and strong controls and charge router rules built within the EMR that prevents unauthorized users from adding modifier 59 or the EPSU modifiers. Claim edits are built within the EMR to trigger National Correct Coding Initiative (NCCI) edits. Additionally, Sutter Health's Ethics and Compliance Services provides periodic monitoring and the Revenue Integrity Service Line Specialist provides regular education to the teams. These protections make it very unlikely that other outpatient claims might be afflicted by similar errors.

Given the extremely low underlying payment error rate, coupled with the particular nature of the errors at issue, we do not believe that the discovery of 1 coding error over a 2-year period constitutes "credible information" of the existence of a "potential overpayment." Therefore, we do not believe Alta Bates is obligated under the FFS 60-Day Rule to review claims outside the Audit Period.

\* \* \* \* \*

Thank you for considering our comments to the Draft Report. If you have further questions pertaining to the responses in this letter, please contact Nathan Perumal at (510) 204-1288 or via email at [peruman@sutterhealth.org](mailto:peruman@sutterhealth.org).

Sincerely,

*/David Clark/*

David Clark  
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