## Department of Health and Human Services OFFICE OF INSPECTOR GENERAL

# MEDICARE HOSPITAL PROVIDER COMPLIANCE AUDIT: PROVIDENCE MEDICAL CENTER

Inquiries about this report may be addressed to the Office of Public Affairs at <u>Public Affairs @oig.hhs.gov</u>.



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#### **Report in Brief**

Date: December 2020 Report No. A-07-18-05113

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

#### Why OIG Did This Audit

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

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

#### **How OIG Did This Audit**

We selected for review a stratified sample of 90 inpatient and 10 outpatient claims with payments totaling \$1.1 million for our 2-year audit period (January 1, 2016, through December 31, 2017).

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

## Medicare Hospital Provider Compliance Audit: Providence Medical Center

#### What OIG Found

The Hospital complied with Medicare billing requirements for 87 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 13 claims, resulting in overpayments of \$57,800 for calendar years 2016 and 2017.

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$325,241 for the audit period.

#### **What OIG Recommends and Hospital Comments**

We recommend that the Hospital refund to the Medicare contractor \$325,241 in estimated overpayments for the audit period for claims that it incorrectly billed; based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule, and identify any of those returned overpayments as having been made in accordance with this recommendation; and strengthen controls to ensure full compliance with Medicare requirements.

The Hospital disagreed with all of our findings and our first two recommendations. The Hospital did not agree with the errors we identified and our use of extrapolation. The Hospital added that it believed that our independent medical review contractor misapplied applicable Medicare authority during the review. For our third recommendation, the Hospital described corrective actions that it had taken or planned to take to further enhance and strengthen its controls. Specifically, the Hospital stated that it was evaluating its current policies, processes, and internal review practices to identify potential opportunities for additional improvement.

To assist in the preparation of this final report, we had our independent medical review contractor review the Hospital's written comments on our draft report and the additional documentation that it provided. Based on the results of this additional medical review, we maintain that all of our findings and recommendations are valid, although we acknowledge the Hospital's right to appeal the findings.

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#### INTRODUCTION

#### WHY WE DID THIS AUDIT

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

#### **OBJECTIVE**

Our objective was to determine whether Providence Medical Center (the Hospital) complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims from January 1, 2016, through December 31, 2017.

#### **BACKGROUND**

#### **The Medicare Program**

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

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

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

#### **Hospital 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**

Our previous work at other hospitals identified these types of hospital claims, among others, that were at risk for noncompliance:

- inpatient claims billed with elective surgical procedures,
- inpatient claims billed with high-risk DRG codes,
- inpatient claims billed with high-severity-level DRG codes,
- inpatient claims billed for mechanical ventilation, and
- outpatient claims with payments greater than \$25,000.

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" (Social Security Act (the Act) § 1862(a)(1)(A)). In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§ 1815(a)).

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

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

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

<sup>&</sup>lt;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*, chapter 6, § 6.5.2). We are not constrained by the two-midnight presumption in selecting claims for medical review.

promptly (Pub. No. 100-04, chapter 1, § 80.3.2.2). The Manual states that providers must use HCPCS codes for most outpatient services (chapter 23, § 20.3).<sup>3</sup>

The Office of Inspector General (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 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>

#### **Providence Medical Center**

The Hospital is a 171-bed hospital located in Kansas City, Kansas. According to CMS's National Claims History (NCH) data, Medicare paid the Hospital approximately \$124 million for 11,128 inpatient and 53,868 outpatient claims between January 1, 2016, and December 31, 2017 (audit period).

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

Our audit covered \$4,013,165 in Medicare payments to the Hospital for 502 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 claims (90 inpatient and 10 outpatient) with payments totaling \$1,059,465. Medicare paid these 100 claims during our audit period.

We focused our audit on the risk areas identified because 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

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

<sup>&</sup>lt;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.

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 87 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 13 claims (all of which were inpatient claims), resulting in overpayments of \$57,800 for the audit period. 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 \$325,241 for the audit period.<sup>6</sup> As of the publication of this report, this amount included claims outside of the 4-year claim reopening period.

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

#### BILLING ERRORS ASSOCIATED WITH CLAIMS INCORRECTLY BILLED AS INPATIENT

The Hospital incorrectly billed Medicare for 13 of the 90 inpatient claims that we reviewed. These errors resulted in overpayments of \$57,800.

#### **Federal Requirements and Guidelines**

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)).

<sup>&</sup>lt;sup>6</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.

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)).

#### **Incorrectly Billed as Inpatient**

For 13 of the 90 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 billed as outpatient or outpatient with observation. The medical records did not support the necessity for inpatient hospital services. When we queried the Hospital regarding the causes of these incorrectly billed claims, the Hospital replied that it disputed all the findings.

As a result of these errors, the Hospital received overpayments of \$57,800.

#### **OVERALL ESTIMATE OF OVERPAYMENTS**

The combined overpayments on our sampled claims totaled \$57,800. On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$325,241 for the audit period.

#### RECOMMENDATIONS

We recommend that Providence Medical Center:

- refund to the Medicare contractor the portion of the \$325,241 in estimated overpayments for the audit period for claims that it incorrectly billed that are within the 4-year reopening period;<sup>7</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>8</sup> and identify any of those returned overpayments as having been made in accordance with this recommendation; and
- strengthen controls to ensure full compliance with Medicare requirements.

#### AUDITEE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Hospital disagreed with all of our findings and our first two recommendations. The Hospital did not agree with the errors we identified and our use of extrapolation. The Hospital added that it believed that our independent medical review contractor misapplied applicable Medicare authority in multiple respects during the review, which significantly undermined the findings. In addition, the Hospital said that it did not believe that further review outside of the audit period was appropriate at this time because it disputes the errors we identified and intends to appeal any overpayments determined by CMS to exist.

The Hospital did not expressly concur or non-concur with our third recommendation, but nonetheless described corrective actions that it had taken or planned to take to strengthen its controls. Specifically, the Hospital stated that it was evaluating its current policies, processes, and internal review practices to identify potential opportunities for additional improvement.

The Hospital's comments, from which we have removed various enclosures due to their volume and because some of them contain personally identifiable information, appear as Appendix E.

<sup>&</sup>lt;sup>7</sup> OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a Medicare administrative contractor or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

<sup>&</sup>lt;sup>8</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 on the extrapolated overpayment amount. Those overpayments are already covered in the previous recommendation.

We are providing the Hospital's comments in their entirety to CMS. The enclosures included additional claim-by-claim documentation related to the claims that our draft report had questioned, documentation which, the Hospital said, demonstrated the errors in our medical review.

To address the Hospital's concerns and to assist in our preparation of this final report, we had our independent medical review contractor review the Hospital's written comments on our draft report and the additional documentation that it provided. The contractor evaluated this additional documentation alongside the initial set of medical records to determine whether the Hospital billed the claims in compliance with selected billing requirements.

Based on the results of this additional medical review, we maintain that all of our findings and recommendations are valid, although we acknowledge the Hospital's right to appeal the findings. We believe that our independent medical review contractor reached carefully considered conclusions as to whether the services met coverage, medical necessity, and coding requirements. Below are more detailed discussions of the basis for the Hospital's disagreements with our findings and recommendations as well as our responses.

#### TWO-MIDNIGHT RULE

#### **Auditee Comments**

The Hospital did not concur with the 13 inpatient claims that we identified as incorrectly billed as inpatient; the Hospital said that "the cases at issue met the Two Midnight Rule standard and were thus appropriate for inpatient admission. Specifically, the Hospital stated that our independent medical review contractor used the absence in a medical record of a discussion of the likelihood of a two-midnight length of stay as the basis for a determination that the medical record did not support the claim. In this regard, the Hospital cited CMS guidance: "Physicians/ practitioners need not include a separate attestation of the expected length of stay; rather, this information may be inferred. . . . " (Medicare Program Integrity Manual, chapter 6, § 6.5.2; emphasis added by auditee). In addition, the Hospital stated that our independent medical review contractor appeared to misunderstand the applicable Medicare standards by failing to frame its analysis in the context of the two-midnight rule; the Hospital stated, instead, that our medical review contractor noted that "[i[npatient care is indicated when a patient can only be safely managed in an inpatient setting." The Hospital also said that our contractor "failed to evaluate medical necessity based on the information known to the treating physician based on the patient's contemporaneous clinical presentation," which did not comport with CMS guidance that the physician's expectation be based on information available at the time of the inpatient admission. The Hospital added that it appeared that our independent medical review contractor "inappropriately applied '20-20 hindsight' in violation of Medicare standards." Moreover, the Hospital stated that we should have applied the two-midnight rule presumption and deemed all alleged errors to have complied with Medicare inpatient status requirements because the admissions spanned two or more midnights. Additionally, the Hospital stated that because we found that medical records contained "adequate medical documentation to

conclude that the billed services were actually provided, were provided at the level billed, and/or were medically necessary," that the beneficiaries at issue received medically necessary care during their hospital stays.

#### Office of Inspector General Response

We acknowledge that we found that the Hospital's medical records contained "adequate medical documentation to conclude that the billed services were actually provided, were provided at the level billed, and/or were medically necessary." If there had been insufficient documentation such that our independent medical review contractor could not conclude that the billed services were actually provided, were provided at the level billed, and/or were medically necessary, we would have noted a documentation error. Instead, our medical review contractor determined that there was adequate documentation from the medical records submitted to make an informed decision that the services billed were, or in 13 cases were not, medically necessary based on Medicare coverage and payment policies.

Our independent medical review contractor did not, as the Hospital asserted, use the absence in a medical record of a discussion of the likelihood of a two-midnight length of stay as the basis for a determination that the medical record did not support the claim. In reviewing the Hospital's comments and re-reviewing the medical records, our medical review contractor revised its determination letters to clarify any misunderstanding in this regard. The Hospital was also incorrect in saying that our contractor misunderstood the applicable Medicare standards by failing to frame its analysis in the context of the two-midnight rule; instead stating that inpatient care is indicated when a patient can only be safely managed in an inpatient setting. Our medical review contractor based its medical necessity determinations on medical factors documented in medical records. That it did not use the terms "two-midnight rule," "two-midnight benchmark," or "two-midnight presumption" when reporting the results of its medical review is of no consequence. Federal regulations (42 CFR § 412.3(d)(1)) state that an inpatient admission is generally appropriate if the ordering physician expected the patient to require hospital care for a period of time that crossed two midnights. This regulation (42 CFR § 412.3(d)(1)(i)) also states that "[t]he 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." Our medical review contractor's summary of the foregoing requirements in its determination letters was imperfect, but after reviewing the Hospital's comments and rereviewing the medical records, our medical review contractor assured us that its determinations were based on the regulatory requirements. Nor did our contractor apply "20-20 hindsight" when evaluating whether the claims in question were supported by the medical records. Our medical review contractor evaluated the documented medical factors known to the admitting practitioner at the time the order to admit was furnished.

Contrary to the Hospital's assertion, it would have been improper should we have "presumed" that the inpatient admissions we audited were reasonable and necessary simply because the admissions spanned two or more midnights. As we explained in footnote 2, CMS instructs its Medicare contractors to follow the "two-midnight presumption" in order not to focus their medical review efforts on stays spanning two or more midnights after formal inpatient admission in the absence of evidence of systemic gaming, abuse, or delays in the provision of care (*Medicare Program Integrity Manual*, chapter 6, § 6.5.2). This presumption is strictly for purposes of selecting claims for medical review, and we are not bound by it under our authority to conduct audits and our independence as established by the Inspector General Act of 1978. Moreover, the presumption is not a standard of review, nor does it give hospitals a free pass to skirt medical necessity requirements and scrutiny merely because inpatient admissions are for one or more midnights.

After reviewing the results of our independent medical review contractor's additional medical review and evaluating the Hospital's written comments and its additional documentation, we maintain that our findings and recommendations are valid, although we acknowledge the Hospital's right to appeal the findings.

#### INPATIENT ADMISSION ORDERS

#### **Auditee Comments**

The Hospital disagreed with findings whose basis was that the inpatient admission order requirements were not met. Specifically, the Hospital stated that our independent medical review contractor overlooked the presence of a valid inpatient admission order in the medical records in some cases and in other cases identified "alleged technical deficiencies, such as missing signatures," that should not have been counted as errors pursuant to Medicare policy.

#### Office of Inspector General Response

Our independent medical review contractor examined all the material in the sampled medical records and the documentation submitted by the Hospital and carefully considered this information to determine whether the Hospital billed the claims in compliance with selected billing requirements. The contractor similarly evaluated the additional documentation that the Hospital provided after issuance of our draft report. As a result, our medical review contractor found valid admission orders present in the record with respect to two claims which had previously been determined to be missing valid admission orders. Moreover, neither our independent medical review contractor nor we identified any of the 13 claims in question as being in error solely because of the kind of technical deficiencies that the Hospital described in its comments. Each of these claims was also found not to be medically necessary inpatient admissions.

#### MEDICARE PART B REIMBURSEMENT

#### **Auditee Comments**

The Hospital stated that we erred in calculating the estimated overpayments because we did not account for the reimbursement that the Hospital would have been eligible to receive for outpatient services under Medicare Part B. "Accordingly, OIG's overpayment estimates are greatly overstated because they assume that [the Hospital] would have received no Part B reimbursement."

#### Office of Inspector General Response

In our audits, we cannot offset Medicare Part A overpayments with amounts that may be payable under Medicare Part B. Auditing standards do not permit us to judge the value of Part B claims that have yet to be submitted. We note that, historically, CMS has not allowed rebilling of a claim as an exception to the timely filing requirements if that claim has been denied. CMS has stated that (1) hospitals are responsible for determining whether submission of a Part A or Part B claim is appropriate within the applicable timeframe and that (2) adopting an exception to the timely filing requirements would allow hospitals to avoid the responsibility of correctly submitting claims to Medicare.

#### SAMPLING AND EXTRAPOLATION

#### **Auditee Comments**

The Hospital disputed our sampling and extrapolation approach, saying that it had concerns regarding the sample of claims selected for review and that it had not been given comprehensive information regarding the sampling and extrapolation used in this audit. The Hospital requested the underlying detail that would allow it to validate the sampling and extrapolation that we employed in our audit.

Regarding our sample selection, the Hospital stated that it appeared that our independent medical review contractor may have judgmentally selected certain claims. The Hospital also stated that 16 claims did not involve procedures and did not have any procedures coded; therefore, according to the Hospital, the selection of these 16 claims appeared to have been in error. Further, the Hospital said that it appeared that certain claims with emergency procedures were categorized as elective procedures.

The Hospital also objected to our use of extrapolation, because, it said, we did not first demonstrate either a sustained or high level of payment error or that documented educational intervention had failed to correct the payment error (42 U.S.C. § 1395dd(f)(3)). The Hospital said that it had calculated a financial error rate of 5.5 percent based on the 13 inpatient claims we identified ("which would be even lower if Part B reimbursement was taken into account"), and added that it did not believe that this error rate satisfied the "high level of payment error"

requirement conveyed in the *Medicare Program Integrity Manual*, chapter 8, § 8.4.1.4. In addition, the Hospital stated that our use of extrapolation was inappropriate, because of the highly fact-dependent nature of medical necessity determinations, and it did not concur with our decision to "pursue extrapolation in such a fact-specific review."

#### Office of Inspector General Response

We have provided the Hospital with comprehensive information regarding the sampling and extrapolation methodology we used in this audit. We describe our statistical sampling methodology and our sample results in Appendices B and C. As described in Appendix B, we used the OIG, Office of Audit Services (OAS), statistical software to calculate our estimates. This software, named RAT-STATS, is a free software package that providers can download to assist in calculating statistical estimates. Both the software and the instructions are available on the OIG website. In response to the Hospital's request for the underlying detail that would allow it to validate the sampling and extrapolation that we employed in our review, we gave the Hospital our sampling plan, sampling frame, sample items, and random number output files from our statistical software; the Hospital can use these products to recreate our sample. In addition, we provided the software input and output files necessary to replicate and validate our statistical estimate.

Regarding our sample selection, our independent medical review contractor did not, as the Hospital suggested, judgmentally select any claims for review. The OIG selected, correctly, all of the claims from high-risk categories in accordance with an approved sampling plan, and our independent medical review contractor determined whether the Hospital billed the claims in compliance with selected billing requirements. The OIG did not erroneously sample 16 claims that did not involve procedures and did not have any procedures coded. The 16 claims were selected because they had an associated inpatient claim. Concerning the Hospital's comment that certain claims with emergency procedures were categorized as elective procedures, we note that in the medical records for all of the sampled claims billed with emergency procedures that were categorized by the OIG as elective procedures, all stated that they were elective procedures. Additionally, the question of whether certain denied claims were billed with emergency or elective procedures had no bearing on these determinations, in that the contractor determined that the claims were not medically necessary, reasonable, or appropriate for the beneficiary to receive hospital services as an inpatient, because these claims as billed did not meet Medicare coverage criteria.

The requirement that a determination of a sustained or high level of payment error or documented failed educational intervention must be made before extrapolation applies only to Medicare contractors.<sup>9</sup> Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and

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<sup>&</sup>lt;sup>9</sup> The Act § 1893(f)(3) and CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 8, § 8.4 (effective January 2, 2019).

Medicaid.<sup>10</sup> This is true even when extrapolating medical necessity errors, because the Hospital has the opportunity to challenge the medical necessity determinations and extrapolation on appeal. Moreover, the legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.<sup>11</sup> We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. The statistical lower limit that we use for our recommended recovery represents a conservative estimate of the overpayment that we would have identified if we had reviewed each and every claim in the sampling frame. The conservative nature of our estimate is not changed by the nature of the errors identified in this audit.

#### **OTHER MATTERS**

For an additional 56 of the 90 selected inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays of less than two midnights, which it should have billed as outpatient or outpatient with observation. As a result of these errors, the Hospital received overpayments totaling \$408,902. None of the claims in this audit were targeted because they were short stays but rather because they fell into one of the high-risk categories discussed in the background section of this report. OIG voluntarily suspended audits of inpatient short stay claims after October 1, 2013, and the suspension was in effect while were performing this audit. As such, we are not including the number and estimated dollar amount of these errors in our overall estimate of overpayments and repayment recommendation.

In its written comments on our draft report, the Hospital "strongly" objected to inclusion in this report of mention of these 56 inpatient claims that involved beneficiary stays of less than two midnights. The Hospital stated that we "expressly recognize[d]" that this finding is outside the scope of the audit and added that these claims met the applicable two-midnight rule requirement.

<sup>&</sup>lt;sup>10</sup> See Yorktown Med. Lab., Inc. v. Perales, 948 F.2d 84 (2d Cir. 1991); Illinois Physicians Union v. Miller, 675 F.2d 151 (7th Cir. 1982); Momentum EMS, Inc. v. Sebelius, 2013 U.S. Dist. LEXIS 183591 at \*26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); Anghel v. Sebelius, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); Miniet v. Sebelius, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); Bend v. Sebelius, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

<sup>&</sup>lt;sup>11</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).

<sup>&</sup>lt;sup>12</sup> In November 2020, OIG added a new Work Plan item: a plan to audit hospital inpatient claims after the implementation of and revisions to the Two-Midnight Rule, to determine whether inpatient claims with short lengths of stay were incorrectly billed as inpatient and should have been billed as outpatient or outpatient with observation (W-00-20-35857). As part of this Work Plan item, OIG announced that "[w]hile OIG previously stated that it would not audit short stays after October 1, 2013, this serves as notification that the OIG will begin auditing short stay claims again, and when appropriate, recommend overpayment collections."

The inclusion in this report of claims that did not span two midnights is limited to the Other Matters section—for which, by policy, we do not make a recommendation—and is not reflected in our extrapolated overpayment. These claims were subjected to the same medical review process as all other claims in this report and are included in the Other Matters section for informative purposes only.

#### APPENDIX A: AUDIT SCOPE AND METHODOLOGY

#### SCOPE

Our audit covered \$4,013,165 in Medicare payments to the Hospital for 502 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 claims (90 inpatient and 10 outpatient) with payments totaling \$1,059,465. Medicare paid these 100 claims from January 1, 2016, through December 31, 2017 (audit period).

We focused our audit on the risk areas identified as a result of prior OIG audits at other hospitals. We evaluated compliance with selected billing requirements and submitted all claims to an independent medical review contractor to determine whether the claim was supported by the medical record.<sup>13</sup>

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

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

We conducted our audit work from May 2018 through August 2020.

#### **METHODOLOGY**

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Hospital's inpatient and outpatient paid claims data from CMS's NCH file 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 sample of 90 inpatient claims and 10 outpatient claims totaling \$1,059,465 for detailed review (Appendix B);

<sup>&</sup>lt;sup>13</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*, chapter 6, § 6.5.2). We are not constrained by the two-midnight presumption in selecting claims for medical review.

- obtained and reviewed billing and medical record documentation provided by the Hospital to support the selected claims;
- used an independent medical review contractor to determine whether 100 claims contained in the sample 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);
- discussed the results of our audit with Hospital officials on June 21, 2019; and
- used the independent medical review contractor to review the Hospital's written comments on our draft report and the additional documentation that it provided, and on that basis revised our findings and recommendations as discussed earlier in this report.

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

We constructed a sampling frame containing select inpatient and outpatient claims paid to the Hospital during the audit period for selected services provided to Medicare beneficiaries. The sampling frame consisted of a database of 502 claims, valued at \$4,013,165, from CMS's NCH file.<sup>14</sup>

#### **SAMPLE UNIT**

The sample unit was a Medicare paid claim.

#### SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified random sample. We stratified the sampling frame into four strata based on Medicare risk area. Elective procedure claims were in stratum 1, CERT DRG and inpatient claims billed with high-severity-level DRG codes were in stratum 2, outpatient claims paid in excess of \$25,000 were in stratum 3, and inpatient mechanical ventilation claims were in stratum 4. All claims were unduplicated, appearing in only one area and only once in the entire sampling frame. See Table 1.

**Table 1: Sample Strata** 

Stratum	Dollar Range of Frame Units	Number of Frame Units	Sample Size	Dollar Value of Frame Units
1	\$2,120.73 to \$88,751.65	248	60	\$2,582,085
2	\$450.73 to \$16,800.15	241	27	1,018,791
3	\$30,704.86 to \$47,595.22	10	10	331,500
4	\$18,563.81 to \$33,139.55	3	3	80,790
	Totals	502	100	\$4,013,165 <sup>15</sup>

#### **SAMPLE SIZE**

We randomly selected 60 unique inpatient claims from stratum 1 and 27 from stratum 2. We selected all 10 outpatient claims in stratum 3 and all 3 inpatient claims in stratum 4. Our total sample size was therefore 100 claims.

<sup>&</sup>lt;sup>14</sup> Our sampling frame excluded claims associated with (1) claims with certain discharge status and diagnosis codes, (2) all \$0 paid claims, and (3) claims associated with error codes 534 or 540 (claims that are excluded from further review, such as Recovery Audit Contractor-reviewed claims).

<sup>&</sup>lt;sup>15</sup> The overall total does not equal the sum of the stratum totals due to rounding.

#### SOURCE OF RANDOM NUMBERS

We generated the random numbers using the OIG, OAS, statistical software.

#### **METHOD OF SELECTING SAMPLE ITEMS**

We consecutively numbered the sample units in the frame from 1 to 248 for stratum 1 and from 1 to 241 for stratum 2. A statistical specialist generated 60 random numbers for stratum 1 and 27 random numbers for stratum 2. With these random numbers, we selected the corresponding frame items for review. We also selected all 10 claims in stratum 3 and all 3 claims in stratum 4.

#### **ESTIMATION METHODOLOGY**

We used the OIG, OAS, statistical software to calculate our estimates. We used the lower limit of the 90-percent confidence interval to estimate the amount of improper Medicare payments in our sampling frame during the audit period (Appendix C). 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**

#### **SAMPLE RESULTS**

**Table 2: 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	248	\$2,582,085	60	\$543,686	0	\$0
2	241	1,018,791	27	103,489	13	57,800
3	10	331,500	10	331,500	0	0
4	3	80,790	3	80,790	0	0
Total	502	\$4,013,165 <sup>16</sup>	100	\$1,059,465	13	\$57,800

#### **ESTIMATES**

**Table 3: Estimates of Overpayments in the Sampling Frame for the Audit Period**(Limits Calculated for a 90-Percent Confidence Interval)

Point Estimate	\$515,917
Lower limit	\$325,241
Upper limit	\$706,594

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 $<sup>^{16}</sup>$  The overall total does not equal the sum of the stratum totals due to rounding.

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

**Table 4: Sample Results by Risk Area** 

Risk Area	Selected Claims	Value of Selected Claims	Claims With Over- payments	Value of Overpayments
Inpatient Claims Billed With				
CERT DRG Codes	21	\$67,475	9	\$29,332
Inpatient Claims Billed With				
High Severity Level DRGs	6	36,014	4	28,468
Inpatient Elective Procedures				
Claims	60	543,686	0	0
Inpatient Mechanical				
Ventilation Claims	3	80,790	0	0
Inpatient Totals	90	\$727,965	13	\$57,800
Outpatient Claims Paid in				
Excess of \$25,000	10	\$331,500	0	\$0
Outpatient Totals	10	\$331,500	0	\$0
Inpatient and Outpatient				
Totals	100	\$1,059,465	13	\$57,800

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 audited. However, we have organized this report's findings by the types of billing errors we found at the Hospital. Because we have organized the information differently, the information in the individual risk areas in this table does not match precisely with this report's findings.

#### APPENDIX E: AUDITEE COMMENTS



November 22, 2019

#### VIA FEDERAL EXPRESS AND SECURE ELECTRONIC SUBMISSION

Department of Health and Human Services
Office of Inspector General
Office of Audit Services, Region VII
601 East 12<sup>th</sup> Street, Room 0429
Kansas City, MO 64106

Attention: Patrick J. Cogley, Regional Inspector General for Audit Services

Re: Providence Medical Center's Response to the OIG Draft Report No. A-07-18-05113

Dear Mr. Cogley:

Providence Medical Center ("Providence" or the "Hospital") appreciates the opportunity to provide a written response to the U.S. Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG") draft Report No. A-07-18-05113 titled *Medicare Hospital Provider Compliance Review: Providence Medical Center* ("Draft Report"). As requested by OIG in your September 18, 2019 correspondence accompanying the Draft Report, this letter constitutes Providence's response to the draft findings, including reasons for concurrence or nonconcurrence with each recommendation proposed by OIG.

For the reasons outlined below, Providence believes that the Draft Report should be revised prior to being finalized because the alleged errors are materially overstated due to the improper application of applicable Medicare coverage requirements, and the inappropriate use of extrapolation. As such, Providence respectfully requests that the errors outlined in this response be corrected prior to finalizing the Draft Report.

#### I. EXECUTIVE SUMMARY

OIG selected for review a sample of 100 claims, comprised of 90 inpatient and 10 outpatient claims with dates of service spanning January 1, 2016 through December 31, 2017. The 100 sample claims were divided into the following four strata, or review categories:

- 1. Inpatient elective procedure claims;
- 2. CERT DRG and inpatient claims billed with high-severity-level DRG codes;
- 3. Outpatient claims paid in excess of \$25,000; and
- 4. Inpatient mechanical ventilation claims.

However, the Draft Report alleges that Providence did not comply with Medicare billing requirements for 13 inpatient claims spanning at least two midnights ("non-Short-Stays"). For an additional 56 of the 90 selected inpatient claims, the Draft Report further alleges that the hospital incorrectly billed Medicare Part A for beneficiary stays of less than two midnights ("Short-Stays"),



which it should have billed as outpatient or outpatient with observation. However, as OIG voluntarily suspended reviews of inpatient Short-Stay claims, it concedes that the 56 alleged Short-Stay errors were outside of its review scope and thus OIG did not include the 56 alleged errors in its overall estimate of overpayments and repayment recommendation. Importantly, the Draft Report does not identify any alleged errors regarding outpatient claims. The Draft Report also does not allege any coding errors.

Providence carefully reviewed the preliminary findings included in the Draft Report and disagrees with the 13 alleged non-Short-Stay errors, as well as the additional alleged 56 Short-Stay errors not included in OIG's review scope or formal Draft Report recommendations.<sup>1</sup> Providence also disputes the sampling and extrapolation approach pursued by OIG.

As detailed below, Providence acknowledges the importance of continuous improvements to compliance efforts. To that end, Providence is evaluating potential enhancements to its policies and processes to further promote compliance with patient status requirements including the Two Midnight Rule. However, Providence disagrees with the alleged claim errors included in the Draft Report and requests that OIG revise its findings prior to issuing a final report.

#### II. PROVIDENCE'S RESPONSE TO OIG'S DRAFT FINDINGS

#### a. PATIENT STATUS FINDINGS

As noted, the OIG performed a review of 100 inpatient and outpatient claims for calendar years 2016 and 2017. Throughout the review process, Providence worked collaboratively with OIG and provided the requested information to the agency. Providence understands that OIG engaged a subcontractor, MAXIMUS, to perform the clinical review of the 100 claims. As detailed further in this response, Providence disputes the subcontractor's review approach and findings for the alleged claim errors.

OIG's Draft Report includes findings involving both non-Short-Stay and Short-Stay inpatient admissions. Specifically, for 13 non-Short-Stay claims and for 56 Short-Stay claims, the Draft Report alleges that Providence incorrectly billed Medicare Part A for inpatient stays that could have been billed as outpatient or outpatient with observation. However, only the findings with respect to the 13 alleged non-Short-Stay claim errors were included in the Draft Report overall estimate of overpayments and repayment recommendation, as the Short-Stay claims were outside of OIG's review scope.

OIG calculated the estimated overpayments for the errors attributed to the non-Short-Stay claims as \$57,800, which OIG extrapolated to an alleged overpayment of \$325,241.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Providence understands that OIG's audit recommendations do not represent final determinations by the Medicare program regarding the claims at issue and that Providence will have the opportunity to appeal any claims denials issued by CMS through the Medicare appeals process. Nothing in this response should be interpreted as limiting Providence's bases for appeal.

<sup>&</sup>lt;sup>2</sup> For the Short-Stay claims, OIG calculated an alleged overpayment of \$408,902. However, as further described below, OIG does not include this amount attributable to Short-Stay claims in its overall overpayment estimate and repayment recommendation.



As described herein, Providence does not concur with the alleged errors identified by OIG in the Draft Report.<sup>3</sup> As detailed further, OIG's medical reviewer misapplied applicable Medicare authority in multiple respects during the review, which significantly undermines the review findings. Enclosed as **Exhibit A**, Providence encloses individual clinical summaries for each of the non-Short-Stay claims denied by OIG, further supporting that OIG should revise its findings before issuing the final report.<sup>4</sup>

## b. THE REVIEW CONTRACTOR FAILED TO ACCURATELY APPLY THE TWO MIDNIGHT RULE

In accordance with 42 C.F.R. § 412.3(d) -- commonly referred to as the Two Midnight Rule -- the appropriateness of an inpatient admission turns on whether the admitting practitioner expects the patient to require medically necessary hospital services that span two midnights. Per the Centers for Medicare & Medicaid Services ("CMS") and as acknowledged in the Draft Report, "the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and outpatients, the hospital's by-laws and admission policies, and the relative appropriateness of treatment in each setting." As noted, Providence does not concur with the alleged errors identified by OIG, as the cases at issue met the Two Midnight Rule standard and were thus appropriate for inpatient admission.

In many instances (including all 13 non-Short-Stay cases denied), the review contractor alleges that the medical record did not include a "discussion of the likelihood of a two-midnight length of stay." Yet this denial rationale is flawed, as CMS explicitly states that "Physician/practitioners need not include a separate attestation of the expected length of stay; rather, this information may be inferred from the physician/practitioner's standard medical documentation, such as his or her plan of care, treatment orders, and progress notes."

Further, with respect to all denied Short-Stay and non-Short-Stay cases, the review contractor appears to misunderstand the applicable Medicare standards by failing to frame the analysis in the context of the Two Midnight Rule. Specifically, the reviewer alleges that "[i]npatient care is indicated when a patient can only be safely managed in an inpatient setting." This statement is inconsistent with the applicable Two-Midnight Rule promulgated by CMS.<sup>7</sup> In addition,

<sup>&</sup>lt;sup>3</sup> The appropriateness of the cases is not only demonstrated by the medical record documentation supporting compliance with the Two Midnight Rule requirements, but also supported in that all of the non-Short-Stay cases met Milliman screening criteria.

<sup>&</sup>lt;sup>4</sup> Providence notes that individual clinical summaries have been provided to OIG previously in connection with the review process.

<sup>&</sup>lt;sup>5</sup> Medicare Benefit Policy Manual, Chapter 1, § 10.

<sup>&</sup>lt;sup>6</sup> Medicare Program Integrity Manual, Chapter 6, § 6.5.2 (emphasis added); see also CMS, Frequently Asked Questions, 2 Midnight Inpatient Admission Guidance & Patient Status Reviews for Admissions on or after October 1, 2013, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/QAsforWebsitePosting 110413-v2-CLEAN.pdf.

<sup>&</sup>lt;sup>7</sup> Providence also notes that in certain denials, the medical reviewer appears to refer to observation services as a level of care. This demonstrates the reviewer's lack of understanding of Medicare authority, as observation services are not a level of care; instead, they are a set of services provided in the outpatient setting. Specifically, "[o]bservation



procedures on the CMS Inpatient-Only list were identified by the review contractor as inappropriate for Part A payment in sample A12, in clear contradiction to Medicare policy and again undermining the appropriateness of the review contractor's audit.

Finally, the findings in the Draft Report with respect to both non-Short-Stay and Short-Stay claims are flawed because the review contractor failed to evaluate medical necessity based on the information known to the treating physician based on the patient's contemporaneous clinical presentation. CMS has made clear that its "longstanding guidance has been that Medicare review contractors should evaluate the physician's expectation based on the information available to the admitting practitioner *at the time of the inpatient admission*." Importantly, the fact that the patient ultimately may not have required hospital services for two midnights does not alone invalidate the inpatient admission. Here, it appears that the review contractor inappropriately applied "20-20 hindsight" in violation of Medicare standards.

## c. THE REVIEW CONTRACTOR FAILED TO IDENTIFY VALID INPATIENT ADMISSION ORDERS

For certain denied claims, one of the bases of the denial was that the inpatient admission order requirements were not met. Providence disagrees with these findings, as they are contradicted by the medical record documentation. In many instances, the review contractor failed to appropriately evaluate inpatient admission orders. In other instances, including samples A03 and A10, the review contractor simply overlooked the presence of a valid inpatient admission order in the medical record, further underscoring the inadequacy of the review.

For other samples, including samples B01, B06, B15, A03 and A07, the review contractor identified alleged technical deficiencies with respect to inpatient admission orders. Again, Providence disputes many of the alleged technical deficiencies, such as missing signatures. To the extent that any technical deficiencies were present, Providence believes such alleged deficiencies should not invalidate an otherwise appropriate inpatient stay. Specifically, since the implementation of inpatient admission order requirements in 2013, providers have raised concerns regarding the demanding inpatient order technical standards that conflicted with longstanding practices. CMS recognized those concerns and issued guidance in 2014 that in cases where the "order to admit may be missing or defective" yet the intent to admit the patient as an inpatient can be clearly derived from the record, contractors have "discretion to determine that this information constructively satisfies the requirement that the hospital inpatient admission order be present in the medical record." Further, in the Fiscal Year 2019 Inpatient Prospective Payment System Final

care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital." Medicare Benefit Policy Manual, Chapter 6 § 20.6.

<sup>&</sup>lt;sup>8</sup> CMS, Frequently Asked Questions, 2 Midnight Inpatient Admission Guidance & Patient Status Reviews for Admissions on or after October 1, 2013, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/QAsforWebsitePosting\_110413-v2-CLEAN.pdf (emphasis added).

<sup>&</sup>lt;sup>9</sup> CMS, *Hospital Inpatient Admission Order and Certification*, available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/IP-Certification-and-Order-01-30-14.pdf.

Rule, CMS finalized proposed changes to eliminate its regulatory requirement that a written inpatient admission order be present in the medical record as a specific condition of Medicare Part A payment, effective October 1, 2018.<sup>10</sup> CMS explained that "it has come to our attention that some medically necessary inpatient admissions are being denied payment due to technical discrepancies with the documentation of inpatient orders" such as (but not limited to) "missing practitioner admission signatures, missing co-signatures or authentication signatures, and signatures occurring after discharge." The agency stated that it hopes its regulatory change will have the impact of focusing future medical reviews on "whether the inpatient admission was medically reasonable and necessary rather than occasional inadvertent signature documentation issues unrelated to the medical necessity of the inpatient stay." Although the regulatory changes are effective on October 1, 2018, CMS also provides insight regarding its historical perspective on the inpatient order requirement, stating that it was not the agency's intent when it finalized inpatient admission order requirements that such documentation requirements "by themselves lead to the denial of payment for medically reasonable and necessary inpatient stays." 13 As such, Providence contests any denial bases regarding alleged technical deficiencies of the inpatient admission order.

## d. THE REVIEW CONTRACTOR FAILED TO APPLY THE CMS TWO MIDNIGHT RULE PRESUMPTION TO NON-SHORT-STAY CLAIMS

CMS states that for purposes of "determining whether the admitting practitioner had a reasonable expectation of hospital care spanning 2 or more midnights at the time of admission, Medicare contractors shall take into account the time the beneficiary spent receiving contiguous outpatient services within the hospital prior to inpatient admission." Said differently, "the starting point for the 2 midnight timeframe for medical review purposes will be when the beneficiary starts receiving services following arrival at the hospital." The medical review contractor expressly concedes for all non-Short-Stay claims the record contained "adequate medical documentation to conclude that the billed services were actually provided, were provided at the level billed, and/or were medically necessary." As such, the reviewer is expressly agreeing that the beneficiaries at issue received medically necessary care during their hospital stays. All of the non-Short-Stay cases exceeded two midnights, further supporting the physician's determination that the cases were appropriate for inpatient admission.

Further, under CMS policy, hospital claims with lengths of stay of greater than two midnights after formal inpatient admission are *presumed* to be reasonable and necessary for Medicare Part A

<sup>&</sup>lt;sup>10</sup> Specifically, CMS removed the regulatory language at 42 C.F.R. § 412.3(a) stating that a physician (or other qualified practitioner) order must be present in the medical record and be supported by the physician admission and progress notes in order for the hospital to be paid for hospital inpatient services under Medicare Part A. 83 Fed. Reg. 41510.

<sup>&</sup>lt;sup>11</sup> 83 Fed. Reg. 41507.

<sup>&</sup>lt;sup>12</sup> 83 Fed. Reg. 41507.

<sup>&</sup>lt;sup>13</sup> 83 Fed. Reg. 41507.

<sup>&</sup>lt;sup>14</sup> Medicare Program Integrity Manual, Chapter 6, § 6.5.2.

<sup>&</sup>lt;sup>15</sup> CMS, Frequently Asked Questions, 2 Midnight Inpatient Admission Guidance & Patient Status Reviews for Admissions on or after October 1, 2013, updated: 3/12/2013.



payment (known as the Two Midnight Presumption). <sup>16</sup> In the Draft Report, OIG acknowledges the existence of the Two Midnight Presumption, but states that "OIG is not bound by the two-midnight presumption that might otherwise limit medical review by Medicare contractors." However, OIG's stated objective in this review was to determine whether Providence Medical Center complied with Medicare billing requirements. As such, OIG should apply the same medical review standards employed by CMS, including the Two Midnight Presumption. Indeed, all 13 of the non-Short-Stay alleged errors involved stays of *two or more* midnights after admission, and many cases exceed two midnights, such as sample CO3 where the patient received hospital services for 7 days. As such, all 13 of the non-Short-Stay alleged errors should be entitled to the Two Midnight Presumption.

#### e. SHORT-STAY CLAIMS ARE BEYOND THE SCOPE OF OIG'S AUDIT

In the Draft Report, OIG expressly recognizes that a review of Short-Stay patient status claims is beyond the scope of its audit (as OIG has suspended review of inpatient Short-Stay claims) and are not appropriate to include in its repayment recommendation. The Draft Report acknowledges that OIG suspended reviews of Short-Stays after October 1, 2013 (i.e., the implementation date of the Two Midnight Rule). Similarly, CMS has limited the review of such claims by its contractors in response to continued industry confusion.

Nevertheless, OIG states in the Draft Report that for 56 of the 90 inpatient claims reviewed, Providence incorrectly billed Medicare Part A for stays of less than two midnights that should have been billed as outpatient or outpatient with observation. Providence strongly objects to OIG including this finding in the Draft Report as OIG expressly recognizes that this finding is outside the scope of the present audit. Moreover, Providence believes that the Short-Stay claims met the applicable Two Midnight Rule requirement.

#### f. OIG FAILED TO ACCOUNT FOR MEDICARE PART B REIMBURSEMENT

Even if the claim findings in the Draft Report were accurate, which Providence disputes, OIG erred in calculating the estimated overpayments for both Short-Stay and non-Short-Stay claims. Specifically, OIG failed to account for the reimbursement Providence would have been eligible to receive for outpatient services under Medicare Part B. OIG states in its Draft Report that such claims "should have [been] billed as outpatient or outpatient with observation." As such, it is clear that OIG does not dispute that Providence provided medically necessary hospital services for which Providence could have sought Medicare Part B reimbursement. Accordingly, OIG's overpayment estimates are greatly overstated because they assume that Providence would have received no Part B reimbursement. This issue is further compounded by the fact that OIG is proposing to extrapolate its alleged overpayment estimate to a broader population of claims.

<sup>&</sup>lt;sup>16</sup> See CMS, Medicare Learning Network Matter Number SE19002 (Jan. 24, 2019), available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19002.pdf.



## g. THE REVIEW CONTRACTOR'S SAMPLING AND EXTRAPOLATION APPROACH IS FLAWED

Providence also has concerns regarding the sample of claims selected for review in this matter, further undermining the review contractor's audit. However, Providence has not been provided comprehensive information regarding the statistical sampling and extrapolation pursued in this matter. As such, Providence respectfully requests the underlying detail that would allow Providence to validate the sampling and extrapolation pursued in this review.

Selecting a statistically valid random sample of claims is a complex analysis that should be conducted by a statistical expert.<sup>17</sup> CMS, in recognition of this complexity, provides detailed requirements for the selection of a sample to be used as the basis for an overpayment extrapolation.<sup>18</sup> Although Providence has not been provided with comprehensive information regarding the process used for the sample selection for this audit, there are a number of concerning indicators with respect to the sample selection. As noted above, OIG sampled cases in four different strata for its review. It appears that the review contractor may have judgmentally selected certain claims, including claims involving chest pain and percutaneous transluminal coronary angioplasty ("PTCA"). Additionally, Providence notes that 16 claims selected in connection with Strata 1, inpatient elective procedure claims, did not involve procedures nor did these claims have any procedures coded. Accordingly, the selection of these 16 claims appears to have been in error. Further, it appears that certain emergency procedures were categorized as elective procedures, including for samples A07, A17, A28, A46, A50, A53, A54, and A56.

OIG's estimation of overpayments for the 13 alleged non-Short-Stay errors it identified was \$57,800. While OIG does not provide a financial error rate, Providence has calculated a financial error rate of only 5.5% based on the alleged 13 errors, which would be even lower if Part B reimbursement was taken into account. However, OIG seeks to extrapolate that estimated overpayment to a much larger population of claims. OIG's proposed extrapolation results in a significantly higher alleged estimated overpayment of \$325,241 for the audit period.

Congress has placed statutory limits on Medicare contractors' use of extrapolation. 42 U.S.C. § 1395dd(f)(3) prohibits the use of extrapolation by a Medicare contractor to determine overpayment amounts absent either "a sustained or high level of payment error" or "documented educational intervention has failed to correct the payment error." In its Draft Report, OIG does not allege that educational intervention has failed. Although what constitutes a "high level of payment error" is not further defined by statute, CMS's Program Integrity Manual offers additional detail about what constitutes a high error rate where extrapolation is permissible, stating that, "[f]or purposes of extrapolation, a sustained or high level of payment error shall be determined to exist through a variety of means, including, but not limited to: 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)." The 5.5% financial error rate in this case does not satisfy the "high level of

<sup>&</sup>lt;sup>17</sup> See Medicare Program Integrity Manual, Chapter 8, § 8.4.1.5.

<sup>&</sup>lt;sup>18</sup> See Medicare Program Integrity Manual, Chapter 8, § 8.4.

<sup>&</sup>lt;sup>19</sup> Medicare Program Integrity Manual, Ch. 8, Sec. 8.4.1.4 (emphasis added).



payment error" requirement. Further, Providence disputes the findings and expects succeeding in overturning the claim denials on appeal, which will further reduce any alleged error rate.

In addition, extrapolation is inappropriate in this review due to the highly fact-dependent nature of medical necessity determinations. In the Draft Report, OIG cites CMS authority which states that "the decision to admit a patient is a complex medical judgment which can only be made after the physician has considered a number of factors . . ." Federal courts have recognized that "the essence of inferential statistics is that one may confidently draw inferences about the whole from a representative sample of the whole." The appropriateness of statistical sampling turns on "the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action." As such, Providence does not concur with OIG's decision to pursue extrapolation in such a fact-specific review.

#### III. PROVIDENCE'S RESPONSE TO OIG'S RECOMMENDATIONS

Providence takes compliance with federal healthcare program requirements seriously, and to that end, is evaluating ways in which to enhance its internal processes and controls to promote compliance and minimize potential errors. Below, Providence addresses the OIG's recommendations as outlined in the Draft Report.

#### a. REFUND OF ESTIMATED OVERPAYMENT

OIG recommends that Providence refund the alleged extrapolated overpayment of \$325,241. However, Providence disagrees with this recommendation because, as outlined herein, Providence disputes both the individual alleged claim errors and OIG's use of extrapolation. Accordingly, to the extent that the alleged errors are included in the final OIG report and formally identified as an overpayment by CMS, Providence intends to appeal the alleged errors, as well as the extrapolation.<sup>22</sup>

Although OIG did not make a formal overpayment recommendation with respect to the alleged errors relating to the Short-Stay cases, Providence disagrees with OIG's findings and thus does not believe that a repayment is required at this time. In connection with its ongoing compliance efforts, Providence intends to further review these Short-Stay alleged errors.

### b. ADDITIONAL DILIGENCE IN ACCORDANCE WITH THE 60-DAY OVERPAYMENT RULE

In the Draft Report, OIG also recommends that Providence "exercise reasonable diligence to identify and return any additional similar overpayments received outside of our audit period, in accordance with the 60-day repayment rule." Again, because Providence disputes the alleged

<sup>&</sup>lt;sup>20</sup> United States v. Pena, 532 F. App'x 517, 520 (5th Cir. 2013).

<sup>&</sup>lt;sup>21</sup> Tyson Foods, Inc. v. Bouaphakeo, 136 S. Ct. 1036, 1046 (2016); see In re Chevron U.S.A., Inc., 109 F.3d 1016, 1020 (5th Cir. 1997).

<sup>&</sup>lt;sup>22</sup> As noted above, Providence understands that OIG's audit recommendations do not represent final determinations by the Medicare program regarding the claims at issue and that Providence will have the opportunity to appeal any claims denials issued by CMS through the Medicare appeals process.



errors, Providence does not believe that further review outside of the time period of the OIG audit is appropriate at this time. As such, Providence does not concur with this recommendation.

Providence takes compliance with the 60-day overpayment law and associated regulations seriously. However, Providence disputes all of the alleged claim errors and associated overpayments in this review. As such, to the extent OIG finalizes the alleged claim errors and such errors are formally identified as overpayments by CMS, Providence intends to appeal the adverse findings through the Medicare appeals process. Importantly, the CMS overpayment final rule for Medicare Part A and B provides:

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>23</sup>

Accordingly, to the extent the adverse findings are finalized, Providence intends to appeal these denials. As such, consistent with its overpayment rule obligations, Providence will evaluate any obligations under the 60-day rule once its Medicare administrative appeals have concluded.

#### c. STRENGTHENING OF CONTROLS TO ENSURE COMPLIANCE

The Draft Report recommends that Providence "strengthen controls to ensure full compliance with Medicare requirements." Providence continues to promote compliance with Medicare billing requirements, including the Two Midnight Rule.

For instance, Providence conducts concurrent and retrospective reviews of medical records for appropriate documentation and compliance with billing requirements. Providence has provided training on patient status requirements and related documentation requirements to relevant personnel including coding personnel, utilization review, and case management.

While Providence disputes the findings in the Draft Report, Providence nonetheless is evaluating its current policies, processes and internal review practices to identify potential opportunities for additional improvement.

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<sup>&</sup>lt;sup>23</sup> Medicare Program; Reporting and Returning of Overpayments, 81 Fed. Reg. 7654, 7667 (Feb. 12, 2016) (emphasis added).



#### IV. CONCLUSION

Providence greatly appreciates the opportunity to respond to OIG's Draft Report. As described in this response, Providence does not concur with OIG's findings and respectfully requests that OIG revise its findings and final report. Please do not hesitate to contact me if you would like to further discuss this matter.

Sincerely,

/s/ Karen Orr

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