

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE COMPLIANCE
REVIEW OF ABBOTT
NORTHWESTERN HOSPITAL
FOR 2013 AND 2014**

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Office of Inspector General

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EXECUTIVE SUMMARY

Abbott Northwestern Hospital did not fully comply with Medicare requirements for billing inpatient and outpatient services, resulting in estimated overpayments of at least \$8 million over 2 years.

WHY WE DID THIS REVIEW

This review is part of a series of hospital compliance reviews. Using computer matching, data mining, and data analysis techniques, we identified certain types of hospital claims that are at risk for noncompliance with Medicare billing requirements. For calendar year (CY) 2014, Medicare paid hospitals \$159 billion, which represents 46 percent of all fee-for-service payments; therefore, the Office of Inspector General (OIG) must provide continual and adequate oversight of Medicare payments to hospitals.

The objective of this review was to determine whether Abbott Northwestern Hospital (the Hospital) complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) pays inpatient 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. CMS pays inpatient rehabilitation services at a predetermined rate according to the distinct case-mix group (CMG). The CMG is based on the beneficiary's clinical characteristics and expected resource needs. CMS pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification.

Under section 1128J(d) of the Social Security Act and 42 CFR Part 401 Subpart D (the 60-day rule), upon receiving credible information of a potential overpayment, providers must: (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify the overpayment amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments. (42 CFR 401.305(a)(2), (f) and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016)). OIG believes that this audit report constitutes credible information of potential overpayments.

The Hospital is a 952-bed not-for-profit hospital located in Minneapolis, Minnesota. Medicare paid the Hospital approximately \$410 million for 25,190 inpatient and 328,174 outpatient claims for services provided to beneficiaries during CYs 2013 and 2014 based on CMS's National Claims History data.

Our audit covered \$27,637,086 in Medicare payments to the Hospital for 2,225 claims that were potentially at risk for billing errors. These claims consisted of inpatient and outpatient claims

paid to the Hospital for services provided to Medicare beneficiaries during CYs 2013 or 2014 (audit period). We selected a stratified random sample of 162 claims with payments totaling \$2,519,417 for review. These 162 claims had dates of service during the audit period and consisted of 108 inpatient and 54 outpatient claims.

WHAT WE FOUND

The Hospital complied with Medicare billing requirements for 88 of the 162 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 74 claims, resulting in overpayments of \$933,991 for the audit period. Specifically, 55 inpatient claims had billing errors, resulting in overpayments of \$903,237, and 19 outpatient claims had billing errors, resulting in overpayments of \$30,754. 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 \$8,038,356 for the audit period.

WHAT WE RECOMMEND

We recommend that the Hospital:

- refund to the Medicare contractor \$8,038,356 (of which \$933,991 was overpayments identified in our sample) in estimated overpayments for incorrectly billed services;
- exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having being made in accordance with this recommendation; and
- strengthen controls to ensure full compliance with Medicare requirements.

ABBOTT NORTHWESTERN HOSPITAL COMMENTS AND OUR RESPONSE

In written comments on our draft report, the Hospital generally disagreed with our findings and recommendations and described corrective actions that it has taken in response to our third recommendation.

After considering the Hospital's comments, we continue to recommend that the Hospital refund to the Medicare contractor \$8,038,356 in estimated overpayments and strengthen controls to ensure full compliance with Medicare requirements.

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INTRODUCTION

WHY WE DID THIS REVIEW

This review is part of a series of hospital compliance reviews. Using computer matching, data mining, and data analysis techniques, we identified certain types of hospital claims that are at risk for noncompliance with Medicare billing requirements. For calendar year (CY) 2014, Medicare paid hospitals \$159 billion, which represents 46 percent of all fee-for-service payments; therefore, the Office of Inspector General (OIG) must provide continual and adequate oversight of Medicare payments to hospitals.

OBJECTIVE

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

BACKGROUND

The Medicare Program

Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge, and Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

CMS contracts with Medicare administrative contractors (MACs) to, among other things, process and pay claims submitted by hospitals.

Hospital Inpatient Prospective Payment System

CMS pays hospital costs at predetermined rates for patient discharges under the inpatient prospective payment system (IPPS). 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.

Hospital Inpatient Rehabilitation Facility Prospective Payment System

Inpatient rehabilitation facilities (IRFs) provide rehabilitation for patients who require a hospital level of care, including a relatively intense rehabilitation program and an interdisciplinary, coordinated team approach to improve their ability to function. Section 1886(j) of the Social Security Act (the Act) established a Medicare prospective payment system for inpatient rehabilitation facilities. CMS implemented the payment system for cost-reporting periods beginning on or after January 1, 2002. Under the payment system, CMS established a Federal

prospective payment rate for each of the distinct case-mix groups (CMGs). The assignment to a CMG is based on the beneficiary's clinical characteristics and expected resource needs.

Hospital Outpatient Prospective Payment System

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

Hospital Claims at Risk for Incorrect Billing

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

- inpatient rehabilitation,
- inpatient claims billed with high-severity-level DRG codes,
- inpatient claims paid in excess of charges,
- inpatient and outpatient manufacturer credits for replaced medical devices, and
- outpatient claims billed with modifier -59.

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 review.

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 (§ 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)).

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

The *Medicare Claims Processing Manual* (the Manual) requires providers to complete claims accurately so that Medicare contractors may process them correctly and 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).

Under section 1128J(d) of the Social Security Act and 42 CFR Part 401 Subpart D (the 60-day rule), upon receiving credible information of a potential overpayment, providers must: (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify the overpayment amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments. (42 CFR 401.305(a)(2), (f) and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016)). OIG believes that this audit report constitutes credible information of potential overpayments.

Abbott Northwestern Hospital

The Hospital, which is part of Allina Health, is a 952-bed not-for-profit hospital located in Minneapolis, Minnesota. Medicare paid the Hospital approximately \$410 million for 25,190 inpatient and 328,174 outpatient claims for services provided to beneficiaries during CYs 2013 and 2014 based on CMS's National Claims History data.

HOW WE CONDUCTED THIS REVIEW

Our audit covered \$27,637,086 in Medicare payments to the Hospital for 2,225 claims that were potentially at risk for billing errors. These claims consisted of inpatient and outpatient claims paid to the Hospital for services provided to Medicare beneficiaries during CYs 2013 or 2014 (audit period).² We selected a stratified random sample of 162 claims with payments totaling \$2,519,417 for review. These 162 claims had dates of service during the audit period and consisted of 108 inpatient and 54 outpatient claims.

We focused our review on the risk areas that we had identified as a result of prior OIG reviews at other hospitals. We evaluated compliance with selected billing requirements and submitted 120 claims to focused medical review to determine whether the services met medical necessity and coding requirements. This report focuses on selected risk areas and does not represent an overall assessment of all claims submitted by the Hospital for Medicare reimbursement.

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

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

² Of the 2,225 claims, 165 had dates of service in CY 2012 but had payment dates in CY 2013.

FINDINGS

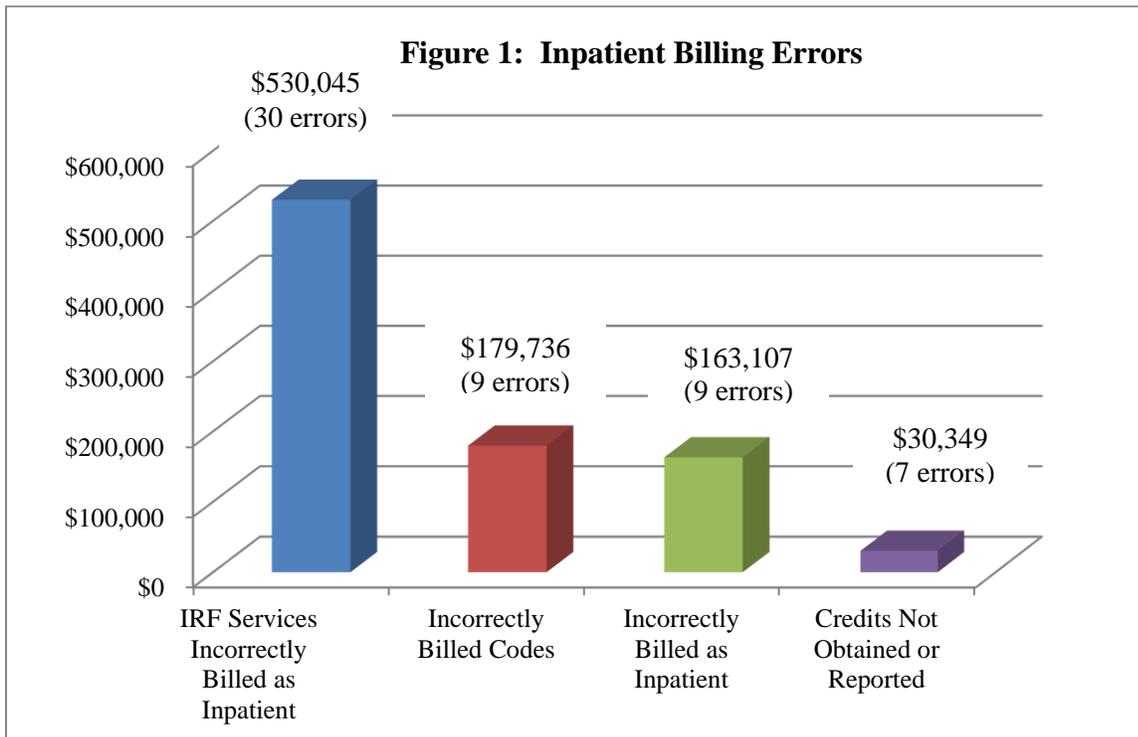
The Hospital complied with Medicare billing requirements for 88 of the 162 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 74 claims, resulting in overpayments of \$933,991 for the audit period. Specifically, 55 inpatient claims had billing errors, resulting in overpayments of \$903,237, and 19 outpatient claims had billing errors, resulting in overpayments of \$30,754. 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 \$8,038,356 for the audit period.

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

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 55 of 108 sampled inpatient claims, which resulted in overpayments of \$903,237, as shown in Figure 1.



Inpatient Rehabilitation Facility Services Incorrectly Billed as Inpatient

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

The *Medicare Benefit Policy Manual* states that the IRF benefit is designed to provide intensive rehabilitation therapy in a resource intensive inpatient hospital environment for patients who, due to the complexity of their nursing, medical management, and rehabilitation needs, require and can reasonably be expected to benefit from an inpatient stay and an interdisciplinary team approach to the delivery of rehabilitation care (Pub. No. 100-02, chapter 1, § 110).

In addition, the *Medicare Benefit Policy Manual* states that for IRF care to be considered reasonable and necessary, the documentation in the patient’s IRF medical record must demonstrate a reasonable expectation that at the time of admission to the IRF the patient (1) required the active and ongoing therapeutic intervention of multiple therapy disciplines; (2) generally required an intensive rehabilitation therapy program; (3) actively participated in, and benefited significantly from, the intensive rehabilitation therapy program; (4) required physician supervision by a rehabilitation physician; and (5) required an intensive and coordinated interdisciplinary approach to providing rehabilitation (Pub. No. 100-02, chapter 1, § 110.2).

Furthermore, the *Medicare Benefit Policy Manual* states that a primary distinction between the IRF environment and other rehabilitation settings is the intensity of rehabilitation therapy services provided in an IRF. For this reason, the information in the patient’s IRF medical record must document a reasonable expectation that at the time of admission to the IRF the patient generally required the intensive rehabilitation therapy services that are uniquely provided in IRFs (Pub. No. 100-02, chapter 1, § 110.2.2).

For 30 of the 108 sampled inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for acute inpatient rehabilitation services. The Hospital disagreed that 25 of the 30 claims were incorrectly billed.³ For the remaining five claims, the Hospital stated that the errors occurred because of human error.

As a result of these errors, the Hospital received overpayments of \$530,045.⁴

³ After the conclusion of our medical review, the Hospital requested that certain records from patients’ acute inpatient stays be reconsidered by medical review in determining medical necessity for acute inpatient rehabilitation. We reviewed the documentation and concluded that most of the exhibits were duplicative (i.e., they were already included in the original submission sent for medical review). For the remaining documentation, it was unclear whether the records were (1) part of the permanent IRF chart and (2) available to clinicians during the IRF preadmission screening or IRF stay.

⁴ The Hospital may be able to bill Medicare Part B for all services (except for services that specifically require an outpatient status). Until these Medicare Part B services are billed by the hospital and adjudicated by the MAC, we do not have enough information to determine the effect on the overpayment amount. The Hospital should contact its MAC for rebilling instructions.

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)). In addition, the Manual states: “In order to be processed correctly and promptly, a bill must be completed accurately” (chapter 1, § 80.3.2.2).

For 9 of the 108 sampled inpatient claims, the Hospital billed Medicare with incorrect DRG codes. The Hospital disagreed that one of the nine claims was incorrectly billed. For four of the remaining eight claims, the Hospital attributed the errors to human error that could be further mitigated by additional training related to determining the severity level of a patient’s congestive heart failure. For the other four claims, the Hospital attributed the errors to human error in the form of incorrectly assigned procedure or diagnosis codes for three claims and a typographical error for one claim.

As a result of these errors, the Hospital received overpayments of \$179,736.

Incorrectly Billed as Inpatient or Without a Valid Physician Order

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)). Section 1815(a) of the Act precludes payment to any provider without information necessary to determine the amount due the provider.

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 state that Medicare Part A pays for inpatient hospital services only if a physician certifies and recertifies, among other things, the reasons for continued hospitalization (42 CFR § 424.13(a)).

For 6 of the 108 sampled inpatient claims, the Hospital billed Medicare for a beneficiary whose level of care and services provided should have been billed as outpatient or outpatient with observation services. For 3 of the 108 sampled inpatient claims, the Hospital incorrectly billed for inpatient services when the medical record did not contain a valid physician’s order to admit. The Hospital stated that the errors occurred because of a lack of controls in place at the time the claims were processed, which did not completely eliminate the risk of human error.

As a result of these errors, the Hospital received overpayments of \$163,107.⁵

⁵ The Hospital may be able to bill Medicare Part B for all services (except for services that specifically require an outpatient status) that would have been reasonable and necessary had the beneficiary been treated as a hospital outpatient rather than admitted as an inpatient. Until these Medicare Part B services are billed by the hospital and adjudicated by the MAC, we do not have enough information to determine the effect on the overpayment amount. The Hospital should contact its MAC for rebilling instructions.

Manufacturer Credits for Replaced Medical Devices Not Obtained or Reported

Federal regulations require reductions in the IPPS payments for the replacement of an implanted device if (1) the device is replaced without cost to the provider or the beneficiary, (2) the provider receives full credit for the cost of the replaced device, or (3) the provider receives partial credit equal to or greater than 50 percent of the cost of the device (42 CFR § 412.89).

Federal regulations state: “All payments to providers of services must be based on the reasonable cost of services...” (42 CFR § 413.9). The CMS *Provider Reimbursement Manual* (PRM) reinforces these requirements in additional detail (Pub. No. 15-1). The PRM states: “Implicit in the intention that actual costs be paid to the extent they are reasonable is the expectation that the provider seeks to minimize its costs and that its actual costs do not exceed what a prudent and cost conscious buyer pays for a given item or service. If costs are determined to exceed the level that such buyers incur, in the absence of clear evidence that the higher costs were unavoidable, the excess costs are not reimbursable under the program” (part I, § 2102.1).

The PRM further defines prudent buyer principles and states that Medicare providers are expected to pursue free replacements or reduced charges under warranties (part I, § 2103.A). The PRM provides the following example: “Provider B purchases cardiac pacemakers or their components for use in replacing malfunctioning or obsolete equipment, without asking the supplier/manufacture for full or partial credits available under the terms of the warranty covering the replaced equipment. The credits or payments that could have been obtained must be reflected as a reduction of the cost of the equipment” (part I, § 2103.C.4).

The Manual states that to bill correctly for a replacement device that was provided with a credit or no cost, the hospital must code its Medicare claims with a combination of condition code 49 or 50 along with value code “FD” (chapter 3, § 100.8).

For 7 of the 108 sampled inpatient claims, the Hospital incorrectly billed Medicare for medical devices that were under warranty.

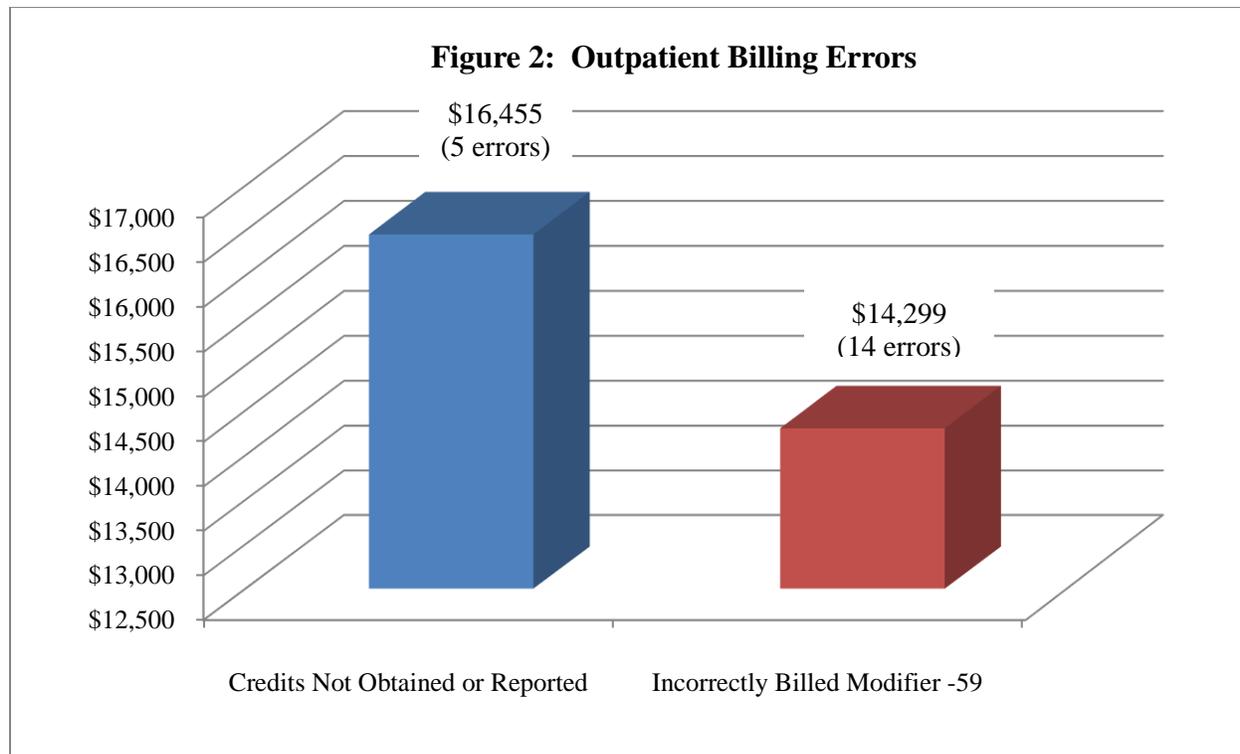
- For five claims, the Hospital received a reportable credit from a manufacturer for a replaced device but did not adjust its inpatient claim with the proper condition and value code to reduce payment as required.
- For two claims, the Hospital did not obtain the credit for a replaced medical device for which a credit was available under the terms of the manufacturer’s warranty.

Hospital officials stated that these errors occurred because they relied on the device manufacturer’s representative to initiate the warranty process and provide notice of credit eligibility.

As a result of these errors, the Hospital received overpayments of \$30,349, which the Hospital had not refunded by the beginning of our audit. The Hospital subsequently refunded \$10,236 prior to our report.

BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 19 of 54 sampled outpatient claims, which resulted in overpayments of \$30,754, as shown in Figure 2.



Manufacturer Credits for Replaced Medical Devices Not Obtained or Reported

Federal regulations require a reduction in the OPPS payment for the replacement of an implanted device if (1) the device is replaced without cost to the provider or the beneficiary, (2) the provider receives full credit for the cost of the replaced device, or (3) the provider receives partial credit equal to or greater than 50 percent of the cost of the replacement device (42 CFR § 419.45(a)).

Federal regulations state: “All payments to providers of services must be based on the reasonable cost of services ...” (42 CFR § 413.9). The PRM reinforces these requirements in additional detail (Pub. No. 15-1). The PRM states: “Implicit in the intention that actual costs be paid to the extent they are reasonable is the expectation that the provider seeks to minimize its costs and that its actual costs do not exceed what a prudent and cost conscious buyer pays for a given item or service. If costs are determined to exceed the level that such buyers incur, in the absence of clear evidence that the higher costs were unavoidable, the excess costs are not reimbursable under the program” (part I, § 2102.1).

The PRM further defines prudent buyer principles and states that Medicare providers are expected to pursue free replacements or reduced charges under warranties (part I, § 2103.A). The PRM provides the following example: “Provider B purchases cardiac pacemakers or their

components for use in replacing malfunctioning or obsolete equipment, without asking the supplier/manufacturer for full or partial credits available under the terms of the warranty covering the replaced equipment. The credits or payments that could have been obtained must be reflected as a reduction of the cost of the equipment” (part I, § 2103.C.4).

For services furnished on or after January 1, 2007, CMS requires the provider to report the modifier “FB” and reduced charges on an outpatient claim that includes a procedure code for the insertion of a replacement device if the provider incurs no cost or receives full credit for the replaced device.⁶

Specific procedure codes reported with value code “FD” reduce the Medicare payment by the amount of the device credit. For services furnished on or after January 1, 2014, the Manual states that, when a hospital furnishes a replacement device received without cost or with a credit of 50 percent or more of the cost of a replacement because of a warranty, recall, or field action, the hospital must report the amount of the device credit in the amount portion for value code “FD” and report either condition code 49 or 50 (CMS Transmittal 2903, dated March 11, 2014, and the Manual, chapter 4, § 61.3).

For 5 of the 54 sampled outpatient claims, the Hospital incorrectly billed Medicare for medical devices that were under warranty.

- For four claims, the Hospital received full credit for replaced devices but did not report the “FB” modifier and reduced charges on its claims or report value code “FD” indicating that it received a full warranty.
- For one claim, the Hospital did not obtain the credit for a replaced medical device for which a credit was available under the terms of the manufacturer’s warranty.

Hospital officials stated that these errors occurred because they relied on the device manufacturer’s representative to initiate the warranty process and provide notice of credit eligibility.

As a result of these errors, the Hospital received overpayments of \$16,455, which the Hospital had not refunded by the beginning of our audit. The Hospital subsequently refunded \$6,946 prior to our report.

Incorrectly Billed Outpatient Services With Modifier -59

The Manual states: “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)” (chapter 23, § 20.9.1.1). In addition, the Manual states: “In order to be processed correctly and promptly, a bill must be completed accurately” (chapter 1, § 80.3.2.2).

⁶ CMS provides guidance on how a provider should report no-cost and reduced-cost devices under the OPPTS (CMS Transmittal 1103, dated November 3, 2006, and the Manual, chapter 4, § 61.3). If the provider receives a replacement device without cost from the manufacturer, the provider must report a charge of no more than \$1 for the device.

For 14 of the 54 sampled outpatient claims, the Hospital incorrectly billed Medicare for HCPCS codes that had been appended with modifier -59 and already included in the payments for other services billed on the same claim or that did not require modifier -59. The Hospital disagreed that 4 of the 14 claims were incorrectly billed. For the remaining 10 claims, the Hospital stated that its key controls did not prevent the incorrect code assignment because of human error.

As a result of these errors, the Hospital received overpayments of \$14,299.

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that the Hospital received overpayments totaling at least \$8,038,356 for the audit period.

RECOMMENDATIONS

We recommend that the Hospital:

- refund to the Medicare contractor \$8,038,356 (of which \$933,991 was overpayments identified in our sample) in estimated overpayments for incorrectly billed services;
- exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having being made in accordance with this recommendation; and
- strengthen controls to ensure full compliance with Medicare requirements.

ABBOTT NORTHWESTERN HOSPITAL COMMENTS

In written comments on our draft report, the Hospital generally disagreed with our findings and recommendations and described corrective actions that it has taken in response to our third recommendation.

The Hospital agreed that 35 of the 74 claims identified in our draft report were improperly billed and said that it plans on reprocessing the claims and refunding Medicare. The Hospital disagreed with our determination that it did not correctly bill the remaining 39 claims. For 28 inpatient claims, the Hospital maintained that the inpatient admissions were appropriate and met Medicare criteria. For four inpatient and seven outpatient claims, the Hospital stated that the medical record documentation appropriately supports the services provided. Finally, the Hospital disagreed with our statistical extrapolation methodology.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

In response to the Hospital's comments, we maintain that all of our findings and the associated recommendations are valid. For 30 of the 39 contested claims, we subjected these claims to a

focused medical review to determine whether the services met medical necessity and coding requirements. Each claim that was denied was reviewed by two clinicians, including a physician. We stand by those determinations. The Hospital is within its rights to appeal the recommended disallowances through the Medicare appeals process.

Regarding the Hospital's objections to our statistical sampling and extrapolation methodology, 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.⁷ 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 sampling software to apply the correct formulas for the extrapolation.

⁷ See *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enter., LLC, v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$27,637,086 in Medicare payments to the Hospital for 2,225 claims that were potentially at risk for billing errors. These claims consisted of inpatient and outpatient claims paid to the Hospital for services provided to Medicare beneficiaries during the audit period.⁸ We selected a stratified random sample of 162 claims with payments totaling \$2,519,417 for review. These claims consisted of 108 inpatient and 54 outpatient claims.

We focused our review on the risk areas that we had identified as a result of prior OIG reviews at other hospitals. We evaluated compliance with selected billing requirements and submitted 120 claims to focused medical review to determine whether the services met medical necessity and coding requirements.

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

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

We conducted our fieldwork from October 2015 through September 2016.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Hospital's inpatient and outpatient paid claim data from CMS's National Claims History file for the audit period;
- obtained information on known credits for replaced cardiac medical devices from the device manufacturers 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 162 claims (108 inpatient and 54 outpatient) totaling \$2,519,417 for detailed review (Appendix B and C);

⁸ Of the 2,225 claims, 165 had dates of service in CY 2012 but had paid dates in CY 2013.

- reviewed available data from CMS’s Common Working File for the sampled claims to determine whether the claims had been cancelled or adjusted;
- reviewed the itemized bills and medical record documentation provided by the Hospital to support the sampled claims;
- requested that the Hospital conduct its own review of the sampled claims to determine whether the services were billed correctly;
- reviewed the Hospital’s procedures for submitting Medicare claims;
- used an independent medical review contractor to determine whether 120 sampled claims met medical necessity and coding requirements;
- discussed the incorrectly billed claims with Hospital personnel to determine the underlying causes of noncompliance with Medicare requirements;
- calculated the correct payments for those claims requiring adjustments;
- used the results of the sample review to calculate the estimated Medicare overpayments to the Hospital (Appendix C); and
- discussed the results of our review 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

POPULATION

The population contained inpatient and outpatient claims paid to the Hospital for services provided to Medicare beneficiaries during the audit period.

SAMPLING FRAME

Medicare paid the Hospital approximately \$410 million for 25,190 inpatient and 328,174 outpatient claims for services provided to beneficiaries during CYs 2013 and 2014 based on CMS's National Claims History data.

We downloaded a database of claims from CMS's National Claims History database totaling \$286,602,133 for 14,798 inpatient and 48,594 outpatient claims in 26 risk areas. From these 26 areas, we selected 6 consisting of 37,617 claims totaling \$192,901,038 for further review.

We performed data analysis of the claims within each of the six risk areas. For risk area one, we removed claims with payment amounts less than \$3,000. For risk area three, we removed claims with claim lines containing Modifier -59 with payment amounts less than \$500.

We then removed the following:

- all \$0 paid claims,
- all claims under review by the Recovery Audit Contractor, and
- all duplicated claims within individual risk areas.

We assigned each claim that appeared in multiple high risk categories to just one category based on the following hierarchy: Inpatient Claims Paid in Excess of Charges, Inpatient Medical Devices, Inpatient MCC/CC, Inpatient Rehabilitation, Outpatient Medical Devices, and then Outpatient Claims Billed with Modifier 59. This resulting database contained 2,225 unique Medicare claims in 6 risk areas totaling \$27,637,086 from which we drew our sample.

Table 1: Risk Area Sampled

Risk Area	Number of Claims	Amount of Payments
Inpatient Claims Billed With High-Severity-Level DRG Codes	864	\$12,023,333
Inpatient Rehabilitation	525	10,430,163
Outpatient Claims Billed with Modifier -59	794	4,260,414
Inpatient Claims Paid in Excess of Charges	9	377,218
Inpatient Manufacturer Credits for Replaced Medical Devices	19	395,123
Outpatient Manufacturer Credits for Replaced Medical Devices	14	150,835
Total	2,225	\$27,637,086

SAMPLE UNIT

The sample unit was a Medicare paid claim.

SAMPLE DESIGN

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

SAMPLE SIZE

We selected 162 claims for review as follows:

Table 2: Sampled Claims by Stratum

Stratum	Risk Area	Claims in Sampling Frame	Claims in Sample
1	Inpatient Claims Billed With High-Severity-Level DRG Codes	864	40
2	Inpatient Rehabilitation	525	40
3	Outpatient Claims Billed with Modifier -59	794	40
4	Inpatient Claims Paid in Excess of Charges	9	9
5	Inpatient Manufacturer Credits for Replaced Medical Devices	19	19
6	Outpatient Manufacturer Credits for Replaced Medical Devices	14	14
	Total	2,225	162

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the claims within strata one through three. After generating the random numbers for these strata, we selected the corresponding frame items. We selected all claims in strata four through six.

ESTIMATION METHODOLOGY

We used the OAS statistical software to estimate the total amount of overpayments paid to the hospital during the audit period.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 3: Sample Results

Stratum	Frame Size (Claims)	Value of Frame	Sample Size	Total Value of Sample	Number of Incorrectly Billed Claims in Sample	Value of Over-payments in Sample
1	864	\$12,023,333	40	\$593,573	13	\$119,003
2	525	10,430,163	40	825,767	30	530,045
3	794	4,260,414	40	176,901	14	14,299
4*	9	377,218	9	377,218	5	223,840
5*	19	395,123	19	395,123	7	30,349
6*	14	150,835	14	150,835	5	16,455
Total	2,225	\$27,637,086	162	\$2,519,417	74	\$933,991

*We reviewed all claims in this stratum.

ESTIMATES

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

Point Estimate	\$10,081,781
Lower Limit	8,038,356
Upper Limit	12,125,206

APPENDIX D: RESULTS OF REVIEW BY RISK AREA

Risk Area	Sampled Claims	Value of Sampled Claims	Claims With Over-payments	Value of Over-payments
Inpatient				
Rehabilitation	40**	\$825,767	30	\$530,045
Claims Paid in Excess of Charges	9	377,218	5	223,840
Claims Billed With High-Severity-Level Diagnosis-Related-Group Codes	40**	593,573	13	119,003
Manufacturer Credits for Replaced Medical Devices	19	395,123	7	30,349
Inpatient Totals	108	\$2,191,681	55	\$903,237
Outpatient				
Manufacturer Credits for Replaced Medical Devices	14	\$150,835	5	16,455
Claims Billed with Modifier -59	40**	176,901	14	14,299
Outpatient Totals	54	\$327,736	19	\$30,754
Inpatient and Outpatient Totals	162	\$2,519,417	74	\$933,991

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

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

APPENDIX E: ABBOTT NORTHWESTERN HOSPITAL COMMENTS



November 21, 2016

Brian Ritchie
Assistant Inspector General for Audit Services
Office of Inspector General
Department of Health and Human Services
Office of Audit Services, Region V
233 North Michigan, Suite 1360
Chicago, IL 60601

Re: Allina Health's Response to the OIG Draft Report A-05-15-00043 (Medicare Compliance Review of Abbott Northwestern Hospital for 2013 and 2014)

Dear Mr. Ritchie:

We appreciate the opportunity to submit this response to the Office of Inspector General (OIG) draft report A-05-15-00043 (*Medicare Compliance Review of Abbott Northwestern Hospital for 2013 and 2014*)¹ (Draft Audit Report), dated October 11, 2016.

I. Introduction

The Draft Audit Report summarizes the OIG's findings from its review of 2,225 claims for which Medicare made payment to Allina Health in calendar years 2013, 2014 and 2015, which the OIG identified as claims potentially at risk for billing errors. In our view, the Draft Audit Report reflects numerous factual and legal errors that combine to overstate significantly the amount of overpayments that Medicare made to Allina Health over the audit period. As explained in detail below, the OIG has violated its own auditing standards by refusing to consider relevant evidence or to account for relevant factors in its calculations; misunderstood and mischaracterized Medicare billing rules and guidelines; extrapolated an inflated overpayment amount from a flawed sample of claims using an equally flawed methodology; and overstepped its role with respect to the "60-day rule" governing reporting and returning overpayments. We urge the OIG to revise the Draft Audit Report to correct the many serious errors identified in this response.

II. The OIG's Recommendations

The Draft Audit Report includes three recommendations. Allina Health responds as follows to each recommendation.

- a. *OIG Recommendation: We recommend that the Hospital refund to the Medicare contractor \$8,038,356 (of which \$933,991 was overpayments identified in our sample) in estimated overpayments for incorrectly billed services.*

¹ Although the Draft Audit Report states that the claims the OIG reviewed had payment dates in calendar years 2013 and 2014, the individual claims that the OIG provided to Allina Health included some claims with payment dates in 2015.

We do not concur with this recommendation because the recommended refund amount vastly overstates the amount of overpayments made to Allina Health. The OIG misidentified a large number of validly billed and paid claims as overpayments, and then inappropriately extrapolated from those mistakenly identified payments to arrive at a significantly inflated estimated overpayment for the audit period. Should Allina Health receive a demand for repayment of this amount from the Centers for Medicare & Medicaid Services (CMS) or one of its contractors, we would expect to appeal the denial of these claims, and likely would be successful in reversing a large number of the claim denials. We do agree that Medicare made certain overpayments to Allina Health, as discussed in detail below, and we will work with the Medicare contractor to refund those overpayments through the contractor's ordinary process. However, any request for repayment by the contractor based on the OIG's extrapolation from those limited overpayments would be statistically invalid and an unlawful end-run around congressional limitations on extrapolation by contractors. And, in any case, the OIG's actual extrapolation methodology suffers from multiple serious flaws. Accordingly, we do not agree that any part of the recommended refund amount calculated by extrapolation constitutes an overpayment.

- b. *OIG Recommendation: We recommend that the Hospital exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period in accordance with the 60-day rule. When returning overpayments, payments should be identified as being made in accordance with this recommendation.*

We do not concur with this recommendation to the extent it assumes that each of the claims identified in the Draft Audit Report was in fact an overpayment. That assumption results in a significantly broader repayment obligation than actually exists based on our review of the claims the OIG identified as overpayments. As explained below, there are certain limited areas where we acknowledge that the Draft Audit Report correctly identifies overpayments to Allina Health, and we will exercise reasonable diligence based on this information to identify and return any similar overpayments outside of the audit period. In exercising such reasonable diligence, we will act in accordance with the requirements of Social Security Act (SSA) § 1128J(d) and implementing regulations and guidance published by CMS, as well as all other applicable laws and regulations.

- c. *OIG Recommendation: We recommend that the Hospital strengthen controls to ensure full compliance with Medicare requirements.*

We do not concur with this recommendation to the extent it assumes a significantly higher rate of billing errors and overpayments than actually occurred. As explained in detail below, to the extent that Allina Health submitted Medicare claims that did not comply fully with Medicare requirements, we have taken reasonable steps to review and strengthen our controls with respect to the relevant requirements, and we will continue our efforts to do so. Allina Health also will continue to review our existing processes more generally, as we do routinely through our compliance program, in search of opportunities to improve and enhance our policies, procedures, and training.

III. Allina Health's Responses to the OIG's Assignments of Error

We have reviewed carefully the Draft Audit Report and the OIG's findings with respect to alleged billing errors made by Allina Health, including the specific claims identified by the OIG as incorrectly billed. We also have reviewed the OIG's methodology for sampling the 162 claims that it reviewed

out of the 2,225 identified in the OIG's sampling frame, as well as the OIG's methodology for extrapolating from the \$933,931 in alleged overpayments for that sample to the recommended refund amount of \$8,038,356.

a. Inpatient Rehabilitation Services

The Draft Audit Report states that Allina Health incorrectly billed Medicare Part A for 30 inpatient claims (out of 40 claims reviewed for this potential error) because these stays did not meet Medicare criteria for acute inpatient rehabilitation services. The OIG states that Allina Health received overpayments of \$530,045 as a result of these errors. Allina Health responds as follows.

1. *The large majority of inpatient rehabilitation claims that the OIG reviewed (35 out of 40) were correctly billed and paid and do not constitute overpayments, and the relevant medical records contain information supporting the medical necessity of admission on an inpatient basis for each of these claims. Moreover, the OIG improperly refused to consider some of this evidence.*

Based on our review of the claims identified as inaccurate by the OIG, we believe that 25 of these inpatient admissions are supported by evidence in the medical record that demonstrates all Medicare criteria were met. We have provided this evidence to the OIG and highlighted the information that we believe supported inpatient admission. Moreover, our conclusion is corroborated by the findings of the Medicare contractor responsible for administering Allina Health's inpatient rehabilitation claims, which conducts annual reviews of these claims to assess whether Allina Health is meeting Medicare requirements. Medicare rules require providers to pass this review as a condition of billing for inpatient rehabilitation services under the Inpatient Rehabilitation Facility Prospective Payment System. In the annual reviews of Allina Health's claims, including for reviews performed on claims during the audit period, the Medicare contractor routinely found that Allina Health's performance far exceeded the threshold for passage and that more than 80% of the claims reviewed met the Medicare inpatient rehabilitation compliance requirements. These findings are difficult to square with the OIG's conclusion that Allina Health got 75% of its inpatient rehabilitation claims wrong. Indeed, the contractor's repeated favorable findings are consistent with Allina Health's conclusion, based on our review, that more than 80% of the claims that the OIG reviewed were properly billed.

In addition, the OIG failed to conduct an adequate and complete review of the majority of these 25 claims due to the OIG's refusal to consider all of the relevant evidence submitted by Allina Health. As previously discussed with the OIG on multiple occasions, we continue to object to the OIG's refusal to conduct a full medical review of additional documents provided by Allina Health, which bolster the conclusion that inpatient admission was medically necessary for these claims. Until the OIG completes the required review, there can be no valid basis to conclude that these claims were improperly billed or that they constituted overpayments.

On August 5, 2016, Allina Health submitted additional medical record documentation to the OIG for most of the 25 claims at issue. On August 5, August 8, and again by letter dated August 11, 2016, [REDACTED] Allina Health requested that the OIG perform medical review of this additional documentation. The OIG denied the request to engage its medical review team to review the additional documentation.

The OIG's failure to consider relevant evidence of medical necessity is inconsistent with the laws and rules that govern OIG's audits and renders invalid the OIG's findings with respect to these claims.² As the OIG acknowledges in the Draft Audit Report, the Medicare billing guidelines for inpatient rehabilitation services require the determination of whether an inpatient admission was reasonable and necessary to be based on the supporting evidence in the medical record. The OIG cannot accurately determine whether there was any error in billing for an inpatient admission unless it reviews the full and complete medical record, but it has outright refused to do so.

Even as the OIG refuses to perform medical review of the additional evidence submitted by Allina Health, it also contends, paradoxically, that this additional evidence is duplicative of records that the OIG already reviewed. The OIG states in footnote 3 to the Draft Audit Report, "We reviewed the documentation and concluded that most of the exhibits were duplicative (i.e. were already included in the original submission sent for medical review)." While the OIG may have given the additional records a cursory administrative review, the OIG's mischaracterization of these records shows that it cannot have performed the full and complete medical review that is required by the Medicare billing guidelines and by the OIG's own auditing standards. For the majority of the 25 contested claims, Allina Health's August 5 submission included newly-submitted medical records that further support the medical necessity of inpatient admission, and the OIG's contention that these records are duplicative is simply inaccurate. For the remainder of the 25 contested claims, Allina Health resubmitted selected records with additional annotations to show exactly where in the records medical necessity was demonstrated. This was intended to be for the OIG's convenience, as we explained in our cover sheet to the exhibits. Whether it reviews the selected resubmitted documents or not, the OIG's statement that most of the additional records are duplicative is inaccurate and indicates that the OIG simply has chosen not to review the *new* information that Allina Health provided. This is inconsistent with the OIG's obligation to consider all of the relevant evidence.

The OIG also misunderstands and misstates the role and importance of these additional records in demonstrating the medical necessity of inpatient admission. In footnote 3 of the Draft Audit Report, the OIG states: "For the remaining documentation [i.e., records other than those the OIG inaccurately determined to be duplicative], it was unclear whether the records were (1) part of the permanent IRF chart, and (2) available to clinicians during the IRF pre-admission screening or IRF stay." This is inaccurate. As Allina Health previously explained to the OIG on an August 8, 2016, telephone call and in the August 11, 2016, letter referenced above, the additional medical record documentation from the acute inpatient stay is part of the patient's permanent electronic medical record and is available to and relied upon by clinicians both during the IRF pre-admission screening *and* subsequent IRF stay. Contrary to the OIG's suggestion, these records are essential to demonstrating that Allina Health properly assessed and documented the medical necessity for inpatient admission.

For all of the reasons above, we strongly dispute the OIG's conclusion that there was any overpayment for 25 of the 30 claims identified in the Draft Audit Report. Indeed, Allina Health has provided evidence sufficient for the OIG or any adjudicator to conclude that each of these claims was properly billed and paid under Medicare rules.

² See, e.g., Gov't Accountability Off., Government Auditing Standards ¶ 6.03 (2011) (requiring auditors conducting performance audits to "obtain reasonable assurance that the evidence is sufficient and appropriate to support the auditors' findings and conclusions in relation to the audit objectives"); *id.* ¶ 6.56 (requiring auditors to "obtain sufficient, appropriate evidence to provide a reasonable basis for their findings and conclusions").

2. *With respect to 5 of the 30 claims, we agree that the relevant medical records do not support admission on an inpatient basis.*

Allina Health will work with the contractor to refund the amounts incorrectly billed for these 5 claims under the contractor's ordinary process.

In addition, through our further review of these claims, we have identified the need for and undertaken the following corrective actions. In response to the OIG audit, Allina Health is reevaluating current controls, procedures, and documentation for inpatient admissions to determine whether changes are warranted. To the extent that this reevaluation identifies process improvements that Allina Health can make to promote even greater consistency and compliance with Medicare rules on inpatient admissions, we will implement those changes. In addition, Allina Health has reviewed and will continue routinely to review the performance of individual employees and contractors to ensure that they are complying with all applicable rules and internal policies, and will make any changes necessary to promote Allina Health's ongoing compliance efforts.

3. *We disagree that any amounts extrapolated from the sample of 40 inpatient rehabilitation claims constitute overpayments. The OIG's extrapolation from its flawed assessment of the sample claims is improper and methodologically unsound, and the extrapolation artificially and inaccurately inflates the recommended repayment amount with little recourse for Allina Health.*

The 40 inpatient rehabilitation claims that the OIG reviewed represented only a subset of the 525 total claims that the OIG identified as part of the sampling frame. After determining that 30 of the 40 sample claims were in error and calculating an overpayment amount due to these alleged errors, the OIG extrapolated from the sample to arrive at an estimated overpayment amount for the full 525 claims. As explained above, the OIG errs in concluding that a large portion of the sample inpatient rehabilitation claims were unsupported by the medical record – and by turning a blind eye to evidence supporting the validity of those claims. The OIG then compounds these errors by extrapolating the alleged overpayments to establish a much larger overpayment estimate for the full audit period. This extrapolation is improper for a number of reasons.

First, the OIG's extrapolation methodology is fundamentally flawed and the estimated overpayment amount based on that methodology cannot stand. Among other things, the OIG errs by extrapolating from a sample that is too small to be statistically valid and failing to account for (1) Medicare Part B payment for the affected inpatient stays and (2) the limitation on a provider's liability under SSA § 1879.

The number of claims eventually acknowledged or determined by an adjudicator to be improperly billed as inpatient stays is likely to be quite small in comparison to the sampling frame – too small, in fact, to constitute a statistically valid sample from which the OIG can properly extrapolate. At present, we believe that number is 5 claims, which is only 12.5% of the sample of 40 inpatient rehabilitation claims that the OIG reviewed. In cases where the OIG found similar error rates, the OIG appropriately declined to extrapolate.³ While some of the other claims identified by the OIG

³ See, e.g., OIG, Medicare Compliance Review of Medical University of South Carolina for the Period January 1, 2011 Through June 30, 2012, at 14 (Jan. 2014).

eventually may be found to be overpayments if the Medicare contractor reopens and denies them and an adjudicator upholds the denial, we do not expect the number of actual overpayments to rise to a statistically valid level. The OIG should follow its precedent and should not extrapolate from a small sample of errors.

The OIG also has failed to take account of two offsetting factors in calculating the extrapolated overpayment. First, the OIG has failed to offset from the alleged overpayment the amount of the Medicare payment that the hospital is entitled to receive for those services – in this case, the Part B payment that Allina Health is entitled to receive for the services that it provided. For each of the 30 claims identified as overpayments, the OIG does not contest that Allina Health provided treatment that was medically necessary and for which Allina Health legitimately and lawfully could seek payment from Medicare. Yet the OIG fails to offset the alleged overpayments by the amount the OIG says Allina Health should have received, even though offsetting this amount will dramatically reduce not only the amount of the overpayment based upon the claims that were reviewed, but also the extrapolated amount. The OIG acknowledges in footnote 4 of the Draft Audit Report that such a reduction in the overpayment associated with the identified claims is possible, but declines to reduce the alleged extrapolated overpayment, saying that it does “not have enough information to determine the effect on the overpayment amount.” If that is true, then the OIG does not have sufficient evidence to extrapolate an overpayment estimate fairly under its own auditing standards,⁴ and the OIG should not extrapolate at all from the individual inpatient rehabilitation claims.⁵

Second, even if Allina Health concedes (or a claims adjudicator determines) that a particular inpatient admission was not reasonable and necessary, SSA § 1879 provides that Allina Health is nonetheless entitled to receive Part A payment if Allina Health and the Medicare beneficiary did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under Part A. In such cases, Allina Health is not liable for the excess payment and no overpayment exists. Allina Health continues to believe that the contested inpatient claims meet medical necessity. At a minimum, however, there is sufficient ambiguity in the inpatient admission rules that Allina Health cannot reasonably have been expected to know that payment would not be made for these items or services under Part A, and therefore is entitled to receive Part A payment under section 1879.

Even if the OIG had extrapolated using a proper methodology, any repayment demand by the contractor based on this extrapolated overpayment amount (as opposed to the contractor’s *own* determination of an extrapolated overpayment amount) would violate the Medicare statute. SSA § 1893(f) prohibits contractors from using extrapolation unless the Secretary determines that “there

⁴ See GAO, *supra* n.2.

⁵ In the past, the OIG has suggested that it could not offset Part A overpayments by Part B payment amounts because the Inspector General Act of 1978, which established the OIG in the Department of Health and Human Services, prohibits the Secretary from transferring program operating responsibilities to the Inspector General. But nothing about offsetting Part A overpayments by Part B payments would entail the OIG exercising program operating responsibilities: CMS has changed its policy and now provides that hospitals may be paid under Part B where a Part A stay is denied because the beneficiary could have been treated on an outpatient basis. Thus, in offsetting Part A overpayments by payments under Part B, the OIG would be engaged in its usual application of Medicare rules to the claims being audited. Nothing in the Social Security Act requires or authorizes the OIG to publish estimated overpayment amounts that the OIG knows are incorrect; it would be absurd to suggest otherwise.

is a sustained or high level of payment error” or “documented educational intervention has failed to correct the payment error.”⁶ The OIG’s findings do not rise to that level, nor do we believe that the contractor would have a basis to make such a finding. Indeed, given the multiple errors in the OIG’s audit findings, we would hope that CMS would not permit its contractor to collect the majority of the OIG’s estimated overpayments from Allina Health. However, if the contractor were to issue a demand for repayment by using the OIG’s flawed extrapolation as the contractor’s own estimate, it would be an unlawful end-run around the statute. We understand that this is exactly what CMS and its contractors have done in similar cases.

Such action by a contractor also would result in a fundamental unfairness to Allina Health. If the contractor demanded repayment of the full extrapolated amount, it would have to do so by denying each of the individual claims identified by the OIG as an overpayment. As the OIG knows, the process for appealing such denials is costly and afflicted by extremely long delays. Because of the overall burden of these delays and costs, as compared to the claim value, we ordinarily might opt not to pursue such appeals, even though we believe 25 of the 30 inpatient admissions are supported by the medical record and that a denial of those claims by the contractor would be reversed upon appeal, extinguishing any demand for repayment of those individual claims as well as any extrapolated amount based on those claims. But with a significantly larger amount of alleged overpayments at stake due to extrapolation, and no means of challenging the extrapolation other than to challenge each individual claim on which the extrapolation is based, we likely would have no reasonable choice but to divert valuable resources to appeal each of these properly billed and paid claims that were subsequently denied through a faulty review. It is unreasonable and improper for the OIG, or by extension the contractor, to use extrapolation when these are the consequences.

For all of the reasons above, extrapolation from the inpatient rehabilitation sample is improper. Allina Health strongly disputes that any part of the estimated repayment amount based on extrapolation from that sample constitutes an overpayment.

b. Diagnosis-Related Groups

The Draft Audit Report states that Allina Health incorrectly billed Medicare for 9 inpatient claims (out of 108 reviewed) because Allina Health billed for these stays using the incorrect Diagnosis-Related Group (DRG) code. The OIG states that Allina Health received overpayments of \$179,736 as a result of these errors. Allina Health responds as follows.

1. *The DRG was correctly assigned for 1 of the 9 claims that the OIG views as incorrectly billed.*

Allina Health continues to dispute the OIG’s determination that Claim A4 was incorrectly billed because it was assigned to MS-DRG 483 (Major joint and limb reattachment procedure of upper extremity with CC/MCC). The medical record clearly supports a secondary diagnosis of major depression, which in turn supports the billing of MS-DRG 483. We have provided the OIG with specific examples and citations to the relevant pages of the medical record.

2. *With respect to 8 of the 9 claims, we agree that the relevant medical records do not support billing under the DRG code that was originally selected.*

We will work with the contractor to refund the amounts incorrectly billed for these claims under the contractor's ordinary process. In addition, through our further review of these claims, we have identified the need for and undertaken the following corrective actions:

4 of the 8 claims (A5, A17, A20, A30) involved patients with a historic or current primary or secondary cardiac-related diagnosis. This is a very specialized and medically complex area. Allina Health provides both general training on diagnosis and procedure codes as part of its coding program, as well as Clinical Significance Education sessions that provide more detailed and diagnosis-specific guidance focused on translating complex clinical diagnoses and procedures into code assignments. In response to this audit, Allina Health:

- Provided additional acute heart failure coder education with specific treatment criteria;
- Facilitated a Clinical Significance Education session on congestive heart failure for all inpatient coding staff;
- Implemented clinical significance criteria for acute heart failure and coding workflow for acute heart failure review when not meeting set clinical significance criteria;
- Created a clinical validity coding clarification request template to query providers when documentation is not clear if diagnosis is appropriate; and
- Implemented acute heart failure as a secondary diagnosis auto hold of claims to review appropriateness of coding prior to submission.

In addition, in lieu of further training on the defunct ICD-9 codes and in preparation for the transition to ICD-10, Allina Health provided comprehensive training to all coding staff on ICD-10, which included competency testing. As this is still a relatively new coding system, Allina Health continues to hold ICD-10 education sessions for coders. Allina Health will continue to reinforce to all coding staff the importance of close attention to detail in code assignment.

c. Inpatient Admission Where Outpatient Treatment Was Appropriate or with No Physician Order

The Draft Audit Report states that Allina Health incorrectly billed Medicare for 6 inpatient claims (out of 108 reviewed) because the beneficiary's level of care and services provided should have been billed as outpatient or outpatient with observation services. The Draft Audit Report also states that Allina Health incorrectly billed Medicare for 3 inpatient claims (out of 108 reviewed) because the medical record did not contain a physician's order to admit as an inpatient. The OIG states that Allina Health received overpayments of \$163,107 as a result of these errors. Allina Health responds as follows.

1. *With respect to the 3 claims for which there was no physician's order to admit, there was no overpayment because the regulation in effect at the time that required such an order was unlawful.*

In support of its conclusion that Allina Health improperly billed for 3 inpatient stays when the medical record did not contain a valid physician's order to admit, the Draft Audit Report cites section 1814(a)(3) of the SSA, which provides that Medicare will pay for inpatient hospital services "which are furnished over a period of time" only if "a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment." The Draft Audit Report also cites federal regulations at 42 C.F.R. § 424.13(a) for the proposition that "Medicare Part A pays for

inpatient hospital services only if a physician certifies and recertifies, among other things, the reasons for continued hospitalization.” However, this regulatory provision took effect on January 1, 2015, and thus was not in effect in 2014, when the services at issue in the Draft Audit Report were furnished. And the physician order rule that was in effect in 2014 was unlawful because the rule was not limited to longer inpatient stays as required by section 1814(a)(3).

Section 1814(a)(3) does not apply to short-term, acute-care inpatient stays like those identified as errors by the OIG because the statute requires a certification only for inpatient hospital services “which are furnished over a period of time.” For the same reason, section 1814(a)(3) renders invalid the regulation in effect in 2014 that required physician certification even for short-term inpatient stays.

The legislative history of section 1814(a)(3) confirms that neither the statute nor the regulation provides any basis for the OIG’s finding of error. When Medicare was enacted in 1965, section 1814(a) stated that an eligible provider could be paid for inpatient hospital services only if a physician certifies that “such services are or were required to be given on an inpatient basis[.]”⁷ Two years later, however, Congress amended the statute and struck the quoted language, replacing it with the current paragraph (3), which limits the certification requirement by adding the “over a period of time” qualifier.⁸ And the legislative reports on that amendment explained, in no uncertain terms, why Congress made this change: to *eliminate* the requirement that a physician order appear in the files in every case.⁹ Both the House and Senate reports state that the effect of the change was to “*eliminate the hospital insurance program requirement that there be a physician’s certification of medical necessity with respect to each admission to a general hospital, and to require such a certification only in cases of hospital stays of extended duration[.]*”¹⁰ This history makes unmistakably clear that the language “furnished over a period of time” limits the physician-order requirement to extended inpatient stays. And that means the physician order rule in effect in 2014—a rule that re-established the very requirement Congress deleted — failed at step one of *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*¹¹ “[A]t step one, a court must ‘exhaust the traditional tools of statutory construction to determine whether Congress has spoken to the precise question at issue. The traditional tools include examination of the statute’s text, legislative history, and structure, as well as its purpose.’”¹² And here, the “text” and “legislative history” foreclose CMS’s interpretation so clearly that they almost seem written for the occasion. The rule accordingly was invalid during the audit period and always has been invalid. As the D.C. Circuit has put it, the agency’s interpretation must be invalidated where it is “contrary to congressional intent as expressed in the plain language and legislative history” of the Medicare Act.¹³ That is particularly obvious where, as here, “Congress has so explicitly and deliberately considered, and then rejected, a more

⁷ Pub. L. No. 89-97, § 102(a), 79 Stat. 286, 294.

⁸ See Pub. L. No. 90-248, § 126(a), 81 Stat. 921, 846.

⁹ See H.R. Rep. No. 90-544, at 149 (1967); S. Rep. No. 90-744, at 239 (1967).

¹⁰ *Id.* (emphasis added).

¹¹ 467 U.S. 837 (1984).

¹² *Petit v. U.S. Dept. of Educ.*, 675 F.3d 769, 781 (D.C. Cir. 2012) (citation omitted).

¹³ *Washington Hosp. Ctr. v. Bowen*, 795 F.2d 139, 141 (D.C. Cir. 1986); accord *Georgetown University Hospital v. Bowen*, 821 F.2d 750, 758 (D.C. Cir. 1987) *aff’d*, 488 U.S. 204 (1988) (Secretary’s actions were barred where it was “clear from the terms and the legislative history of the Medicare Act that Congress did *not* intend to empower the Secretary to promulgate retroactive cost-limit rules.”).

expansive requirement.”¹⁴ In such cases “it is not for the agency to exceed the statutory limits under the guise of ‘interpretation.’”¹⁵

In addition, the physician-order rule in effect in 2014 was arbitrary and capricious because CMS did not provide any justification for creating this new condition of payment after more than half a century of contrary policy. That failure to justify is a textbook Administrative Procedure Act violation.¹⁶ The failure to provide an explanation is unsurprising given that the rule does not serve to protect patient health or safety or to avoid a lack of clarity in record-keeping because regulations already require (as a condition of a hospital’s participation in Medicare) that the inpatient admission decision be made upon the “recommendation” of a physician,¹⁷ and that the patient’s medical record “contain information to justify admission and continued hospitalization.”¹⁸

Although CMS did not acknowledge the legal vulnerabilities of its rule requiring physician certification for inpatient hospital services, CMS’s subsequent actions spoke louder than its words. In 2014, after the physician certification requirement was challenged in federal court, CMS proposed a different rule to be effective January 1, 2015.¹⁹ CMS based this rule requiring a physician order for inpatient hospital services on the agency’s general rulemaking authority in section 1871 of the Social Security Act. In our view, the 2015 physician order rule is unlawful for many of the same reasons as its predecessor. But in any event, the rule in effect at the time, on which the OIG relies in identifying these 3 claims as overpayments, is unlawful. As a result, we disagree with the OIG’s findings and recommendations regarding these 3 claims and dispute that any extrapolated amount based on these claims constitutes an overpayment.

2. *With respect to the 6 claims that the OIG believes should have been billed as outpatient services, we agree that the relevant medical records do not support billing for an inpatient admission.*

We will work with the contractor to refund the amounts incorrectly billed for these claims under the contractor’s ordinary process. Our further review of these claims resulted in the following conclusions with respect to corrective action:

- Although Allina Health has a concurrent review process in which certain claims are reviewed for proper patient status classification while the patient is still at the hospital, 4 of the 6 claims were not reviewed through this concurrent review process and errors made in the admission status were not subsequently identified (i.e., were not identified through any other monitoring and oversight).
 - In December 2015, Allina Health’s Corporate Compliance Department, Utilization Management (UM) leadership and Abbott Northwestern leadership created a focused

¹⁴ *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1578 (D.C. Cir. 1984).

¹⁵ *Id.*

¹⁶ *See, e.g., Am. Petroleum*, 541 F. Supp. 2d at 182 (explaining that the *State Farm* requirement of agency explanation “includes an obligation to explain a decision to depart from a ‘settled course of behavior.’”) (quoting *Int’l Ladies’ Garment Workers’ Union v. Donovan*, 722 F.2d 795, 813-15 (D.C. Cir. 1983)).

¹⁷ 42 C.F.R. § 482.12(c)(2).

¹⁸ *Id.* § 482.24(c).

¹⁹ The plaintiffs in that lawsuit voluntarily dismissed their challenge after CMS changed the physician certification rule and two-midnights rule. However, Allina Health is prepared to challenge the certification rule in effect in 2014 if the claims identified by the OIG are reopened and denied by the contractor.

workgroup to evaluate the process for determining cases subject to the concurrent review process.

- o This workgroup developed a plan to enhance provider education with respect to inpatient admissions and to enhance tracking of inpatient admissions.
- 2 of the 6 claims were concurrently reviewed by the UM Department and, under Allina Health's established UM procedures, those claims likely would have been identified and corrected. However, the claims were not referred for secondary physician review as a result of human error, and errors made in the admission status were not subsequently identified (i.e., were not identified through any other monitoring and oversight). Allina Health has reviewed and will continue routinely to review the performance of individual employees and contractors to ensure that they are complying with all applicable rules and internal policies, and will make any changes necessary to promote Allina Health's ongoing compliance efforts.

d. Use of Modifier -59

The Draft Audit Report states that Allina Health incorrectly billed Medicare for 14 outpatient claims (out of 54 reviewed) because Allina Health billed these claims with Healthcare Common Procedure Coding System (HCPCS) codes appended using modifier -59 where the services billed were already included in the payments or the services did not require modifier -59. The OIG states that Allina Health received overpayments of \$14,299 as a result of these errors. Allina Health responds as follows.

1. *With respect to 4 of the 14 claims, modifier -59 was used correctly and there was no overpayment.*

Allina Health continues to dispute the OIG's determination that Claims C21, C23, C24, and C32 were incorrectly billed with modifier -59. The medical record for each of these claims supports use of a separate billing code with modifier -59. We have provided the OIG with detailed descriptions of Allina Health's rationale for billing these additional codes with modifier -59 based on the coding guidance available at the time.

2. *With respect to 10 of the 14 claims, we agree that modifier -59 should not have been used.*

We will work with the contractor to refund the amounts incorrectly billed for these claims under the contractor's ordinary process.

In addition, through our further review of these claims, we have identified the need for and undertaken the following corrective actions:

- **Misapplication of CPT Assistant (C16, C18, C19, C20, C22, C28 and C40):** Before Allina Health received notice of this OIG audit, we already had identified an inaccurate coding practice that led to these errors and put an end to that practice through retraining of all outpatient coding staff. In addition, Allina Health's Compliance Department annual review plan for 2017 will include a review of various billing codes where Modifier -59 is appended. The results of this review will determine what, if any, further remedial action needs to occur.

- **Miscoded and Misapplication of Modifier -59 (C2, C36 and C39):** Allina Health identified no commonality in the procedures for these patients or the coder performing the coding. Individual education was provided in June 2016 to the coders who performed the coding for these 3 claims.

e. Manufacturer Warranty Credits

The Draft Audit Report states that Allina Health incorrectly billed Medicare for 7 inpatient claims (out of 108 reviewed) and 5 outpatient claims (out of 54 reviewed) because Allina Health failed to obtain and/or failed to report manufacturer credits for replaced devices where a credit was available under the manufacturer's warranty. The OIG states that Allina Health received overpayments of \$30,349 (for inpatient claims) and \$16,455 (for outpatient claims) as a result of these errors. Allina Health responds as follows.

1. *With respect to 6 of the 12 claims, Allina Health did not receive an overpayment because Medicare rules do not require (or enable) providers to report no-cost or reduced-cost devices other than through the limited use of modifier codes for credits that the provider has received at the time of billing. With respect to 2 of these 6 claims, Allina Health voluntarily refunded the contractor for the amount of the credit and, for that reason as well, those amounts should not be included in the recommended overpayment amount.*

The Draft Audit Report cites certain Medicare manual provisions to support the OIG's conclusion that Allina Health received overpayments for inpatient and outpatient claims where Allina Health failed to report or obtain manufacturer credits for replaced medical devices. None of these provisions applies to these 6 claims, and they are not overpayments.

The prudent buyer principles laid out in the Provider Reimbursement Manual address situations where providers are paid on the basis of their reported costs. But payment under either the Medicare Inpatient Prospective Payment System or Outpatient Prospective Payment System is a far cry from payment based directly on reported costs. Under these prospective payment systems, providers' reported costs are incorporated in payment amounts only over time and along with many other factors, and may have a barely perceptible impact on actual reimbursement. Providers may be required to include on their cost report warranty credits that they obtained or might have obtained, and a CMS contractor may account for these credits at reconciliation or disallow the cost of a device included on a cost report where the provider could have received the device for free. But the provider's Medicare *claim* does not include costs, and the rules for claim submission simply do not contemplate reducing charges at all. Again, this is consistent with the principles of prospective payment, as opposed to the cost-based reimbursement principles on which the Provider Reimbursement Manual provision is based.

Apart from accounting for their costs (and reductions to those costs) in proper and complete cost reports, providers are required by the Medicare manuals to append modifier codes to claims for inpatient and outpatient hospital services to account for receiving a device at no cost or for full or partial credit that they have actually received.²⁰ However, these rules cannot be read to require providers – either as a general matter or with respect to replacement devices in particular – to

²⁰ See Medicare Claims Processing Manual, ch. 3, § 100.8 (inpatient setting); *id.* ch. 4, § 61.3.

reduce *charges* on their claims. As noted above, there is simply no requirement for providers to do this, and no way to account separately for warranty credits on the claim form so that the charges and the credits are accurately reported. Moreover, as the OIG acknowledges, even the requirement to append a modifier is limited to cases where the provider is billing for replacement of a device that was in fact provided with a credit or at no cost. There is no such rule requiring a provider to append a modifier when the provider could receive or could have received a credit, either in the inpatient or in the outpatient setting.

For the reasons above, the OIG should modify its report to remove the following 6 claims: E4, E9, E16, F1, F8, F13.

Although the cited regulations do not impose upon Allina Health any obligation to seek or obtain warranty credits or to report available but unobtained credits with its claims, Allina Health observes prudent buyer principles and has taken the following voluntary steps to facilitate claiming and obtaining manufacturer warranty credits in the future:

- Allina Health convened a workgroup of department leadership to assess the existing workflow for explant procedures.
- Based on the findings of that workgroup, Allina Health revised its process for seeking manufacturer device warranty credits. Among other things, Allina Health now will initiate the process for seeking and obtaining device credits at the time the patient's explant procedure is scheduled, rather than when an explanted device is identified as being credit-eligible. Under the revised process, all explanted device replacements are reviewed for credit eligibility.
- Allina Health also instituted monitoring of the revised process to ensure that it is working properly to identify available warranty credits earlier in time.

2. With respect to 6 of the 12 claims, Allina Health received a credit prior to billing for the procedure and should have appended the appropriate modifier to the claim.

We will work with the contractor to refund the amounts incorrectly billed for 5 of these 6 claims (E6, E8, E12, E17, F2) under the contractor's ordinary process. As described below, for 1 of the 6 claims (F14), Allina Health already has refunded the contractor for the overpayment amount. In addition, we have adopted the corrective action steps identified above to facilitate appropriate reporting of manufacturer warranty credits that Allina Health has obtained at the time of billing.

3. With respect to 3 of the 12 claims, Allina Health already has refunded the contractor for the credits and those amounts should not be included in the recommended overpayment amount.

Regardless of whether payment to Allina Health should have been reduced by the amount of an available warranty credit, Allina Health in fact has already refunded the contractor for the amount of the credit for 3 of the 12 claims identified by the OIG (E4, F13, F14). The total amount of these refunded credits (\$17,181.72) should be subtracted from the recommended overpayment amount.

In Allina Health's February 26, 2016, responses to the OIG's Repricing Summaries for Risk Area E – Inpatient Medical Devices and Risk Area F – Outpatient Medical Devices, Allina Health disagreed with including Claim Overpayment Amounts for Samples E4, F13 and F14. While Allina Health

acknowledged it had not refunded the overpayments for these 3 claims to its Medicare contractor at the time it received the OIG's notice of review, it subsequently refunded these overpayments for a total of \$17,181.72. In its March 21, 2016, response to Allina Health, the OIG stated: "Although the claim is now considered adjusted, this claim is included in the scope of our review and was corrected after you received our audit notification letter on 8/18/15. As such, it will be included in our total findings for this risk area."

Allina Health strongly disagrees with the OIG's decision to include these amounts in the recommended overpayment amount of \$8,038,356. If the OIG agrees that the three claims have been adjusted, then the refunded amount should be subtracted from the recommended overpayment amount. Otherwise, the OIG is knowingly recommending that Allina Health repay more than it actually owes. Allina Health also recommends adding a clarifying statement that of the overpayments identified in the OIG's sample, Allina Health has already refunded \$17,181.72.

IV. Claims Outside the Audit Period

The Draft Audit Report recommends that Allina Health "exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period in accordance with the 60-day rule." The Draft Audit Report also states, without supporting legal analysis, that the "OIG believes that this audit report constitutes credible information of potential overpayments." Allina Health will comply fully with its obligations under all applicable laws and regulations, including but not limited to those cited in the Draft Audit Report. In that regard, we will review claims outside the audit period to the extent such review is consistent with our legal obligations and/or our internal policies. However, for the reasons below, we do not agree that the Draft Audit Report as a whole constitutes "credible information of potential overpayments," including with respect to claims outside the audit period, although certain overpayments that we have acknowledged above may give rise to an obligation to exercise reasonable diligence with respect to further investigation in those specific areas. Moreover, we do not agree that the OIG has the authority to determine unilaterally whether such "credible information" exists – under the law, this is squarely the provider's obligation. We will carefully review the final audit report, as we do all information about potential compliance issues that we receive, and determine whether further diligence is warranted to meet our obligations under the law.

By way of background, SSA § 1128J(d), sometimes known as the "60-day rule" or "overpayment rule," provides that, "[i]f a person has received an overpayment, the person shall—(A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address" The statute goes on to provide that an overpayment must be reported and returned by the later of the date 60 days after the overpayment was identified or the date any corresponding cost report is due, if applicable. "Any overpayment retained by a person after the deadline for reporting and returning the overpayment" becomes an "obligation" as defined under the federal False Claims Act, 31 U.S.C. § 3729. Notably, section 1128J(d) provides that, "[i]n this subsection [i.e., with respect to section 1128J(d) itself] . . . [t]he term 'overpayment' means any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title." (Emphasis added.)

CMS has promulgated regulations at 42 C.F.R. part 401, subpart D, to implement section 1128J(d), which restate the statutory requirements laid out above. The regulations also provide that 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 he or she 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.”²¹ The obligation to exercise reasonable diligence is not unlimited, however; the regulations also establish that an overpayment must be reported and returned only if a person identifies the overpayment within six years of the date the overpayment was received.²²

It is likely that the majority of the OIG’s final audit report will not provide Allina Health with information that triggers a duty to exercise reasonable diligence in identifying and quantifying potential overpayments outside the audit period, for the following reasons.

First, many of the alleged billing errors identified by the OIG in the Draft Audit Report were not, in fact, billing errors, as explained in detail above. As CMS has explained, if a provider reviews claims identified as erroneous by a government audit and concludes that the claims were validly billed and paid, then the provider’s duty under section 1128J(d) is at an end.²³

Second, even if certain overpayments identified in the Draft Audit Report are acknowledged by Allina Health or are later affirmed as overpayments by an adjudicator following an appeal, those overpayments may not give rise to a statistically valid inference that there may be other overpayments outside the audit period. As explained in detail above, it is inappropriate to extrapolate from such a small error rate within the audit period. It would be similarly inappropriate to infer an obligation to investigate outside the audit period based on a tiny sample of errors, and section 1128J(d) imposes no such obligation.

Likewise, the limited set of acknowledged or affirmed overpayments may not reveal a pattern of errors coherent enough to give rise to an inference that similar overpayments occurred outside the audit period. Allina Health regularly performs internal audits, monitoring, and other compliance reviews intended to detect, correct, and prevent billing errors and overpayments by the Medicare program. Despite these proactive efforts to detect, correct, and prevent billing errors and overpayments, Allina Health is not immune from good-faith mistakes in billing. But, if the only thing that the confirmed overpayments reveal is that Allina Health occasionally made such mistakes, for example, when we bill for inpatient stays for rehabilitation or when we bill using modifier -59, then we would know nothing more than we did before receiving the audit report. Moreover, we would have no reason to believe that the error rate in these particular sets of claims amounts to a pattern of conduct or otherwise creates credible evidence of additional overpayments that would trigger an obligation beyond our ordinary obligation to maintain an effective compliance program, to perform regular claim reviews as part of that compliance program, and to return any identified overpayments. Thus, whether section 1128J(d) requires Allina Health to perform additional review of past claims depends in part on whether we are able to identify, based on the information we receive, a pattern of conduct that was inconsistent with applicable laws and regulations. If we are not able to do so, for example, because the errors acknowledged by Allina Health or affirmed by an adjudicator consist of a limited number of independent human errors or independent ambiguities in the billing rules, then

²¹ 42 C.F.R. § 401.305(a)(2).

²² *Id.* § 401.305(f).

²³ 81 Fed. Reg. 7654, 7667 (Feb. 12, 2016) (explaining that the duty to exercise reasonable diligence to investigate potential overpayments based on a government audit is limited to the “issues that the contractor or government audited” and the “limited time period” covered by the audit, unless the provider or supplier “confirms the audit’s findings”).

our duty of reasonable diligence for claims outside the audit period is satisfied by our regular, proactive compliance reviews.

Third, the obligation to exercise reasonable diligence in investigating overpayments outside the audit period is limited in time, both under section 1128J(d) itself and under other potentially applicable laws. Such provisions are intended to allow providers and others to have a measure of finality with respect to very old claims, at least where there is no evidence of fraud or other intentional misconduct. As noted above, the section 1128J(d) regulations require providers to report and return overpayments only if the overpayment is “identified” within six years of the date the overpayment was received. If a claim was paid more than six years before we “identify” the claim as an overpayment by confirming the OIG’s finding that we erred in billing that claim, then section 1128J(d) does not apply and Allina Health has no obligation to investigate such claims.

Other laws may also limit the scope of our obligation to investigate potential overpayments outside the audit period as well. For example, SSA § 1870(c) provides that there shall be “no recovery” in any case where the government determines that an incorrect payment was made, but this determination occurs subsequent to the fifth year after the year in which payment is made, unless there is evidence that the provider committed fraud or otherwise was not “without fault.” For example, if a contractor were to determine in 2017 that Allina Health made an overpayment in 2011, that determination would be subsequent to the fifth year (2016) after the year in which payment was made (2011), and section 1870 would bar recovery, assuming no fault. Importantly, this is entirely in harmony with the new and distinct requirements of section 1128J(d), which defines an “overpayment” as any funds that a person receives or retains under title XVIII or XIX to which the person “is not entitled under such title.” This is so because a provider is “entitled” under title XVIII to retain overpayments for which recovery is barred under section 1870, and, indeed, any suggestion to the contrary (which would purport to require reporting and returning overpayments even if recovery is barred under section 1870(c)), would render section 1870(c) a nullity, which fundamental principles of statutory interpretation instruct us to avoid. This harmonization also explains Congress’s decision to extend the period of permissible recovery under section 1870(c) in 2013,²⁴ well after enactment of section 1128J(d) in 2010,²⁵ which would have been pointless if Congress intended for section 1128J(d) to supplant section 1870(c) altogether. In sum, because overpayments for which section 1870(c) bars recovery are not “overpayments” at all under section 1128J(d), Allina Health has no obligation to investigate potential overpayments in those periods for which recovery would be barred under section 1870(c).

Finally, we dispute the OIG’s suggestion that it has the authority to determine whether Allina Health has “credible information of overpayments,” particularly to the extent that this statement is intended as support for the OIG’s recommendation that Allina Health “exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period.” As CMS makes clear in the regulations and preamble discussion implementing section 1128J(d), it is the provider’s responsibility to determine whether the provider has received sufficient information to trigger a duty to exercise reasonable diligence in investigating potential overpayments, and what that reasonable

²⁴ American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 638(a), 126 Stat. 2313, 2357 (2013).

²⁵ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402(a), 124 Stat. 119, 755-56 (2010).

diligence should include.²⁶ Nowhere in the regulation or preamble discussion does CMS suggest that the OIG or another third party can or should make this determination for the provider. Indeed, CMS suggests that one purpose of defining “identified” claims based in part on the exercise of reasonable diligence is to incentivize providers themselves to think carefully about whether potential overpayments may exist and, if so, how to find them.²⁷ While we do not dispute that there are certain overpayments identified in the Draft Audit Report and that we must consider carefully whether the information we have received constitutes credible information of potential overpayments outside the audit period, the OIG’s categorical statement is overbroad and inconsistent with regulations that say it is for the *provider* to determine what constitutes credible information and what steps to take in response. In that regard, Allina Health has carefully reviewed the OIG’s communications to date and will carefully review the final audit report, and will take all appropriate steps to meet its obligations under the law.

* * *

Allina Health appreciates the opportunity to submit this response to the Draft Audit Report. We urge the OIG to amend the Draft Audit Report and reduce the estimated overpayment amount to address the serious errors identified above. Please do not hesitate to contact me if you would like to discuss this matter further at (612) 262-4905 or katherine.tarvestad@allina.com.

Sincerely,



Katherine C. Tarvestad
Senior Vice President and Chief Compliance Officer
Allina Health

²⁶ See, e.g., 81 Fed. Reg. at 7667 (“[P]roviders and suppliers will need to review the specific facts and circumstances, including the billing and coverage rules, to determine the required scope of their reasonable diligence.”).

²⁷ See *id.* at 7659.