Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

UNIVERSITY OF MICHIGAN HEALTH SYSTEM: AUDIT OF MEDICARE PAYMENTS FOR POLYSOMNOGRAPHY SERVICES

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Office of Inspector General

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Report in Brief
Date: June 2021
Report No. A-04-20-07088

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

University of Michigan Health System: Audit of Medicare Payments for Polysomnography Services

Why OIG Did This Audit

Medicare administrative contractors nationwide paid approximately $885 million for selected polysomnography (a type of sleep study) services provided to Medicare beneficiaries during January 1, 2017, through December 31, 2018 (audit period). Previous OIG audits of polysomnography services found that Medicare paid for some services that did not meet Medicare requirements. These audits identified payments for services with inappropriate diagnosis codes, without the required supporting documentation, and to providers that exhibited questionable billing patterns. After analyzing Medicare claim data, we selected for audit University of Michigan Health System (University of Michigan), a hospital provider located in Ann Arbor, Michigan.

Our objective was to determine whether Medicare claims that University of Michigan submitted for polysomnography services complied with Medicare requirements.

How OIG Did This Audit

Our audit covered $1.9 million in Medicare payments to University of Michigan for 1,931 beneficiaries associated with 2,826 lines of polysomnography service billed using Current Procedural Terminology codes 95810 and 95811. We reviewed a stratified random sample of 100 beneficiaries who received polysomnography services (166 lines of service) with payments totaling $112,147 during our audit period.

What OIG Found

University of Michigan submitted Medicare claims for some polysomnography services that did not comply with Medicare billing requirements. Of the 100 randomly selected beneficiaries in our sample, University of Michigan submitted Medicare claims for polysomnography services that complied with Medicare billing requirements for 96 beneficiaries associated with 161 lines of service. However, University of Michigan submitted Medicare claims for the remaining four beneficiaries associated with five lines of service that did not comply with Medicare requirements, resulting in overpayments of $3,127.

On the basis of our sample results, we estimated that University of Michigan received overpayments of at least $12,520 for polysomnography services during our audit period.

The errors occurred because University of Michigan's policies and procedures did not address the processing of Medicare claims for polysomnography services to ensure that services billed to Medicare were adequately documented and coded correctly.

What OIG Recommends and University of Michigan Comments

We recommend that University of Michigan (1) refund to the Medicare program the estimated $12,520 overpayment for claims that it incorrectly billed that are within the 4-year reopening period; (2) based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule; and (3) implement policies and procedures to ensure that Medicare claims for polysomnography services comply with Medicare requirements.

In written comments on our draft report, University of Michigan disagreed with our findings associated with four lines of service billed with incomplete medical record documentation. Additionally, University of Michigan asserted that our findings do not support extrapolation.

We disagree with University of Michigan's assertion that the medical record documentation supported the need for testing. For three beneficiaries (four lines of service), the face-to-face evaluation from the treating physician did not indicate that the physical examination was focused on sleep related disorders nor did it recommend sleep testing as part of the treatment plan for the patient. The physician's progress notes in the face-to-face evaluations did not attribute the patient's symptoms or complaints to sleep-related disorders.

Therefore, we maintain that our findings and recommendations are valid.

TABLE OF CONTENTS

INTRODUCTION

WHY WE DID THIS AUDIT

Medicare administrative contractors (MACs) nationwide paid freestanding facilities, facilities affiliated with hospitals, and physicians (collectively referred to as "providers") approximately $885 million for selected polysomnography (a type of sleep study) services provided to Medicare beneficiaries from January 1, 2017, through December 31, 2018 (audit period).[1] Previous Office of Inspector General (OIG) audits[2] of polysomnography services found that Medicare paid for some services that did not comply with Medicare requirements. These audits identified payments for services with inappropriate diagnosis codes, without the required supporting documentation, and to providers that exhibited questionable billing patterns. The results of these previous audits—combined with increased Medicare spending on polysomnography services and growing concerns about fraud, waste, and abuse—prompted us to conduct additional audits.

After analyzing Medicare claim data for our audit period, we selected several providers for audit based on Medicare Part B payments to the providers. This report covers one of those providers, University of Michigan Health System (University of Michigan), a hospital provider located in Ann Arbor, Michigan.

OBJECTIVE

Our objective was to determine whether Medicare claims that University of Michigan submitted for polysomnography services complied with Medicare requirements.

BACKGROUND

The Medicare Program

Title XVIII of the Social Security Act (the Act) established the Medicare program, which provides health insurance to people aged 65 and over, people with disabilities, and people with end-stage renal disease. Part B of the Medicare program provides supplementary medical insurance for medical and other health services, including polysomnography services and associated medical supplies. Medicare covers polysomnography services when they are reasonable and medically necessary.

The Centers for Medicare & Medicaid Services (CMS) administers Medicare and contracts with MACs to, among other things, process and pay Medicare Part B claims, conduct reviews and

[1] These were the most current data available when we began our audit.

[2] Appendix B contains a list of related OIG reports.

audits, safeguard against fraud and abuse, and educate providers on Medicare billing requirements.

Polysomnography Services

Medicare coverage for polysomnography services includes a diagnostic sleep study and, depending on a beneficiary's diagnosis, may include a positive airway pressure (PAP) titration study. Providers conduct a diagnostic sleep study to diagnose medical conditions that affect sleep, most commonly obstructive sleep apnea (OSA), and to evaluate how effectively PAP devices[3] manage the beneficiary's condition. During a diagnostic sleep study, the patient sleeps overnight[4] while connected to sensors that measure and record parameters of sleep, such as brain waves, blood oxygen levels, heart rate, breathing, and eye and leg movements. Primarily, the diagnostic sleep study measures the number of times that a patient either stops breathing or almost stops breathing. A sleep technician or technologist is physically present to supervise the recording during sleep time and can intervene, if needed.

If the diagnostic sleep study indicates that a patient has a sleep disorder, then the provider may conduct a PAP titration study.[5] Providers use a PAP titration study to calibrate the PAP therapy. In some cases, providers may perform a PAP titration study on the same night as a diagnostic sleep study. Providers refer to this process as a split-night service because they can conduct a PAP titration study when they diagnose OSA within the first few hours of the diagnostic sleep study. If the provider cannot make a diagnosis in the first few hours of the diagnostic sleep study, the beneficiary usually returns another day for a PAP titration study to fit and calibrate the PAP device.

Providers normally perform polysomnography services at sleep disorder clinics,[6] which may be either freestanding facilities, such as Independent Diagnostic Testing Facilities or provider-owned laboratories, or facilities affiliated with a hospital.

Medicare Coverage of Polysomnography Services

Medicare Part B covers outpatient diagnostic and therapeutic services provided in a hospital outpatient setting or in a freestanding facility. Medicare pays for polysomnography services under the Medicare Physician Fee Schedule when performed in freestanding facilities and

[3] PAP devices are common treatments used to manage sleep-related breathing disorders such as OSA.

[4] Most of the patients who undergo testing are not in hospital inpatient status, although they generally stay in a facility overnight.

[5] During a PAP titration study, providers adjust the PAP device to the appropriate pressure for the beneficiary's condition and fit the PAP for home use.

[6] Polysomnography providers may also diagnose OSA through sleep testing in the patient's home. Home sleep tests are a type of sleep study used for diagnostic purposes; however, they are not a type of polysomnography service and, therefore, were not included within the scope of our review.

under the Outpatient Prospective Payment System when performed in a hospital outpatient department. Providers must use standardized codes, called Current Procedural Terminology (CPT)[7] codes, to identify the polysomnography service.

All polysomnography services consist of two components: the administration of the test (technical component) and the provider's interpretation of the test (professional component). Providers generally bill separately for the technical and professional components when each is performed by a different provider; some providers may perform only one component of the service. Hospital outpatient departments can receive payment only for the technical component.

When submitting claims to the MAC, providers most commonly bill using CPT code 95810 for sleep disorder diagnostic services. For both full-night PAP titration and split-night services, providers commonly bill using CPT code 95811.

Medicare covers diagnostic tests, including polysomnography, only when ordered by the physician treating the beneficiary (42 CFR § 410.32(a)). The provider performing the polysomnography service must retain documentation of the order (42 CFR § 410.32(d)(3)(i) as well as sufficient information to determine whether payment is due and the amount of payment (42 CFR § 424.5(a)(6)).

Furthermore, most MACs have published local coverage determinations (LCDs)[8] that specify coverage requirements for polysomnography. LCDs L34535 and L36839, in effect in Michigan during our audit period,[9] say that Medicare covers all reasonable and necessary diagnostic tests

[7] The five character codes and descriptions included in this report are obtained from Current Procedural Terminology (CPT®), copyright 2017–2018 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of CPT outside of this report should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.

[8] LCDs are decisions that the MACs publish regarding whether to cover a particular item or service within their jurisdictions. LCDs specify under what clinical circumstances an item or service is reasonable and necessary. They contain information to assist providers in submitting correct claims for payment and to provide guidance to the public and medical community within their jurisdictions.

[9] Wisconsin Physicians Service Insurance Corporation, the MAC for Jurisdiction 8, published two LCDs regarding polysomnographies and sleep studies that were effective during our audit period. The final version of LCD 34535 was in effect from before the beginning of our audit period through February 15, 2017. Five consecutive versions of LCD L36839, which covered most of our audit period, were in effect from February 16, 2017, through the end of our audit period. The LCDs were substantively the same for our purposes. Accessed at https://localcoverage.cms.gov/mcd_archive/ on April 6, 2020.

given for sleep disorders only if the patient has symptoms or complaints of narcolepsy, OSA, impotence,[10] or parasomnia.

The LCDs also specify that, for coverage of services, medical evidence, such as physician examinations and laboratory tests, must support the medical necessity of the services performed and the provider must maintain the attending physician's order.

OIG believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers must report and return any identified overpayments by the later of (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.[11]

The 6-year lookback period is not limited by OIG's audit period or restrictions on the Government's ability to reopen claims or cost reports. To report and return overpayments under the 60-day rule, providers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.[12]

University of Michigan Health System

University of Michigan is a hospital provider located in Ann Arbor, Michigan. Wisconsin Physicians Service Insurance Corporation, its MAC, paid University of Michigan approximately $1.9 million[13] for 1,931 beneficiaries associated with 2,826 lines of polysomnography services billed using CPT codes 95810 and 95811 provided in calendar years (CYs) 2017 and 2018 on the basis of CMS's National Claims History (NCH) data.

HOW WE CONDUCTED THIS AUDIT

Our audit covered approximately $1.9 million in Medicare payments to University of Michigan for 1,931 beneficiaries associated with 2,826 lines of polysomnography service billed using CPT

[10] All versions of the LCDs in effect during our audit period list impotence as a medical condition for which testing is covered, but state that coverage of impotence is addressed in the Medicare Benefit Policy Manual, ch. 15, § 70, not the LCD.

[11] The Act § 1128J(d); 42 CFR §§ 401.301–401.305; 81 Fed. Reg. 7654 (Feb. 12, 2016).

[12] 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, Provider Reimbursement Manual—Part 1, Pub. No. 15-1, § 2931.2; 81 Fed. Reg. at 7670.

[13] Actual payments were $1,907,355.

codes 95810 and 95811.[14] We reviewed a stratified random sample of 100 beneficiaries who received polysomnography services (166 lines of service) with payments totaling $112,147 during our audit period.

We focused our audit on CPT codes 95810 and 95811 because of billing errors identified during prior OIG audits. We evaluated compliance with selected billing requirements but did not use medical review to determine whether the services were medically necessary.

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

See Appendix A for the details of our scope and methodology, Appendix C for Federal requirements related to provider billing for polysomnography services, and Appendix D for the statistical sampling methodology.

FINDINGS

University of Michigan submitted Medicare claims for some polysomnography services that did not comply with Medicare billing requirements. Of the 100 randomly selected beneficiaries in our sample, University of Michigan submitted Medicare claims for polysomnography services that complied with Medicare billing requirements for 96 beneficiaries associated with 161 lines of service. However, University of Michigan submitted Medicare claims for the remaining four beneficiaries associated with five lines of service that did not comply with Medicare requirements, resulting in overpayments of $3,127. Table 1 lists the types of errors corresponding to those four beneficiaries.

Table 1: Errors in Sample Items

Type of Error	Number of Sample Items*
Incomplete Medical Record Documentation	3 (4 lines of service)
Incorrectly Coded Lines of Service	1 (1 line of service)
* A sample item is a Medicare beneficiary.	

[14] A single Medicare claim from a provider typically includes more than one line of service.

On the basis of our sample results, we estimated that University of Michigan received overpayments of at least $12,520 for polysomnography services provided during our audit period. (See Appendix E for our sample results and estimates.)

The errors occurred because University of Michigan's policies and procedures did not address the processing of Medicare claims for polysomnography services to ensure that services billed to Medicare were adequately documented and coded correctly.

UNIVERSITY OF MICHIGAN SUBMITTED CLAIMS FOR SOME POLYSOMNOGRAPHY SERVICES THAT DID NOT COMPLY WITH MEDICARE REQUIREMENTS

Of the 100 randomly selected beneficiaries in our sample, University of Michigan submitted Medicare claims for polysomnography services for four beneficiaries associated with five lines of service that did not comply with Medicare requirements.

Medical Record Documentation Was Incomplete

The LCDs provide that Medicare will cover all reasonable and necessary diagnostic testing for sleep disorders only if the patient has symptoms or complaints of narcolepsy, OSA, impotence, or parasomnia and all of the following criteria are met:

- the clinic is either affiliated with a hospital or is under the direction and control of physicians;
- patients are referred to the sleep disorder clinic by their attending physicians, and the clinic maintains a record of the attending physician's orders; and
- medical evidence confirms the need for diagnostic testing, e.g., physician examinations and laboratory tests.

For three beneficiaries (four lines of service), University of Michigan was unable to provide us with the medical evidence that supported the need for testing. As a result, University of Michigan received overpayments of $2,789.

Services Were Incorrectly Coded

The LCDs require providers to complete claims with CPT codes that describe the services performed. The HCPCS and CPT Codebook directs providers to use modifier code[15] -52 if the test was terminated prior to recording at least 6 hours of sleep or in cases of reduced services, as appropriate.

[15] A modifier code is a two-digit code reported with a CPT code that provides additional information about the service.

For one beneficiary (one line of service), University of Michigan incorrectly billed without using the required modifier code -52. The medical record indicated that the attending technician stopped the titration study after less than 4 hours of sleep recording. The patient felt claustrophobic and had a difficult time exhaling. Therefore, he requested to end the study prematurely. As a result of this error, University of Michigan received an overpayment of $338.

UNIVERSITY OF MICHIGAN DID NOT HAVE POLICIES AND PROCEDURES FOR POLYSOMNOGRAPHY SERVICES

Although University of Michigan had some policies and procedures, they did not address the processing of Medicare claims for polysomnography services to ensure that services billed to Medicare were adequately documented and coded correctly.

ESTIMATE OF OVERPAYMENTS

Of the 100 randomly selected beneficiaries in our sample, University of Michigan submitted Medicare claims for polysomnography services for four beneficiaries associated with five lines of service that did not comply with Medicare requirements, resulting in overpayments of $3,127. On the basis of our sample results, we estimated that University of Michigan received overpayments of at least $12,520 for polysomnography services during our audit period.

RECOMMENDATIONS

We recommend that University of Michigan Health System:

- refund to the Medicare program the estimated $12,520 overpayment for claims that it incorrectly billed that are within the 4-year reopening period;[16]

- based upon the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule[17] and identify any of those returned overpayments as having been made in accordance with this recommendation; and

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

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

- implement policies and procedures to ensure that Medicare claims for polysomnography services comply with Medicare requirements.

UNIVERSITY OF MICHIGAN COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

University of Michigan Comments

In written comments on our draft report, University of Michigan disagreed with our findings associated with four lines of service billed with incomplete medical record documentation. It stated that the documentation supported the clinical indication for the sleep studies and that, in each instance, the patient had symptoms, complaints, or conditions for which sleep studies are indicated.

Additionally, University of Michigan asserted that our findings do not support extrapolation. University of Michigan asserted that the OIG cannot use extrapolation to determine overpayment amounts unless there is a (1) sustained or high level of payment error or (2) failure of documented educational interventions, as stated in the Medicare Program Integrity Manual (PIM). University of Michigan also stated that the use of extrapolation is also unfounded because the findings relate to medical necessity issues and noted that, in cases related to potential False Claims Act liability, courts have rejected the application of extrapolation to medical necessity issues.[18]

University of Michigan agreed with the finding associated with one line of service that it coded incorrectly and described actions that it had taken to address this finding. University of Michigan's comments appear as Appendix F.

Office of Inspector General Response

We disagree with University of Michigan's assertion that the medical record documentation supported the need for testing. For three beneficiaries (four lines of service), the face-to-face evaluation from the treating physician did not indicate that the physical examination was focused on sleep related disorders nor did it recommend sleep testing as part of the treatment plan for the patient. The physician's progress notes in the face-to-face evaluations did not attribute the patient's symptoms or complaints to sleep-related disorders.

Additionally, the requirement that a determination of a sustained or high level of payment error or documented failed educational intervention must be made before extrapolation applies only to Medicare contractors.[19] The PIM and the statutory provisions upon which the

[18] United States ex rel. Misty Wall v. Vista Hospice Care, Inc., 2016 WL 3449833, at *12 (N.D. Tex. 2016); United States v. Medco Phys. Unlimited, No. 98-C-1622, 2000 U.S. Dist. LEXIS 5843, at *23 (N.D. Ill. Mar. 15, 2000).

[19] Social Security Act § 1893(f)(3) and CMS Medicare Program Integrity Manual, Pub. No. 100-08, chapter 8, § 8.4 (effective January 2, 2019).

PIM guidelines are based do not prohibit CMS from accepting and acting upon our monetary recommendation.

Furthermore, we disagree with University of Michigan's assertion that, when the findings relate to medical necessity issues, courts have rejected the use of extrapolation. The cases cited by University of Michigan to support this assertion rejected the use of extrapolation to establish liability in False Claims Act cases, not the use of extrapolation for purposes of post-payment medical review of Medicare claims. Moreover, in Chaves County Home Health Services v. Sullivan, 732 F. Supp. 188 (D.C.D.C. 1990), a provider alleged that the use of statistical sampling and extrapolation without individual review of each claim was illegal. The District Court held otherwise, and the Court of Appeals affirmed the finding that the provider had the opportunity to challenge the statistical validity of both the sample and the extrapolation on appeal (Chaves County Home Health Services v. Sullivan, 931 F.2d 914 (DC Cir. 1991)). University of Michigan has appeals rights to challenge the statistical validity of both the sample and the extrapolation.

Therefore, we maintain that our findings and recommendations are valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $1,907,355 in Medicare payments to University of Michigan for 1,931 beneficiaries associated with 2,826 lines of polysomnography service billed using CPT codes 95810 and 95811[20] with dates of service from January 1, 2017, through December 31, 2018 (audit period). We reviewed a stratified random sample of 100 beneficiaries who received polysomnography services (166 lines of service) with total payments of $112,147 during our audit period.

We focused our audit on CPT codes 95810 and 95811 because of billing errors identified during prior OIG audits. We evaluated compliance with selected billing requirements but did not use medical review to determine whether the services were medically necessary.

We did not review the overall internal control structure of University of Michigan because our objective did not require us to do so. Rather, we limited our review to University of Michigan's internal controls to prevent incorrect billings for polysomnography services. Our review allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's National Claims History (NCH) file, but we did not assess the completeness of the file.

We conducted our audit from October 2019 through October 2020.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted all lines of service data for polysomnography services with CPT codes 95810 and 95811 from CMS's NCH file for our audit period;
- created a sampling frame of 1,931 Medicare beneficiaries associated with 2,826 lines of service billed for CPT codes 95810 or 95811 during our audit period;

[20] The five character codes and descriptions included in this report are obtained from Current Procedural Terminology (CPT®), copyright 2017–2018 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of CPT outside of this report should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.

- selected for detailed review a stratified random sample of 100 beneficiaries who received polysomnography services (166 lines of service) with payments totaling $112,147 (Appendix D);

- reviewed available data from CMS's Common Working File for the lines of service associated with our sampled beneficiaries to determine whether the lines had been canceled or adjusted;

- obtained and reviewed University of Michigan's supporting documentation to determine whether each line of service was billed correctly;

- calculated overpayment amounts for those lines of service that were in error and required adjustment;

- used our sample results to estimate the total Medicare overpayments to University of Michigan for polysomnography services for our audit period (Appendix E); and

- discussed the results of our audit with University of Michigan 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: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
North Mississippi Medical Center: Audit of Medicare Payments for Polysomnography Services	A-04-19-07086	3/17/2021
Peninsula Regional Medical Center: Audit of Medicare Payments for Polysomnography Services	A-04-19-07087	3/4/2021
Medicare Payments To Providers for Polysomnography Services Did Not Always Meet Medicare Billing Requirements	A-04-17-07069	6/7/2019
Sleep Health Center Billed Medicare For Some Unallowable Sleep Study Services	A-04-14-07053	9/27/2016
International Institute of Sleep, Inc., Billed Medicare for Unallowable Sleep Study Services	A-04-14-07052	6/21/2016
Total Sleep Management, Inc., Billed Medicare For Unallowable Sleep Study Services	A-04-14-07051	10/14/2015
First Coast Service Options, Inc., Paid Some Unallowable Sleep Study Claims	A-04-13-07039	5/14/2015
Questionable Billing for Polysomnography Services	OEI-05-12-00340	10/8/2013

APPENDIX C: FEDERAL REQUIREMENTS RELATED TO PROVIDER BILLING FOR POLYSOMNOGRAPHY SERVICES

FEDERAL LAW AND REGULATIONS

Section 1862(a)(1)(A) of the Act requires that, to be paid by Medicare, a service or an item must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. In addition, the Act precludes payment to any provider of services or other person who fails to furnish information necessary to determine the amount due the provider (the Act, § 1833(e)).

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

CENTERS FOR MEDICARE & MEDICAID SERVICES REQUIREMENTS

LCDs L34535 and L36839[21] published by the MAC specify coverage requirements regarding polysomnography. The LCDs say that sleep disorder clinics are facilities in which certain conditions are diagnosed through the study of sleep. These clinics may be affiliated with a hospital or a freestanding facility and may provide some diagnostic or therapeutic services, which are covered under Medicare.

The LCDs also provide that Medicare will cover all reasonable and necessary diagnostic tests given for sleep disorders only if the patient has symptoms or complaints of narcolepsy, OSA, impotence,[22] or parasomnia, and all of the following criteria are met:

- the clinic is either affiliated with a hospital or is under the direction and control of physicians;
- patients are referred to the sleep disorder clinic by their attending physicians, and the clinic maintains a record of the attending physician's orders; and
- medical evidence confirms the need for diagnostic testing, e.g., physician examinations and laboratory tests.

[21] Wisconsin Physicians Service Insurance Corporation, the MAC for Jurisdiction 8, published two LCDs regarding polysomnography and sleep studies that were effective during our audit period. The final version of LCD 34535 was in effect from before the beginning of our audit period through February 15, 2017. Five consecutive versions of LCD L36839, which covered most of our audit period, were in effect from February 16, 2017, through the end of our audit period. They were substantively the same for our purposes. Accessed at https://localcoverage.cms.gov/mcd_archive/ on April 6, 2020.

[22] All versions of the LCDs in effect during our audit period list impotence as a medical condition for which testing is covered, but state that coverage of impotence is addressed in the Medicare Benefit Policy Manual, ch. 15, § 70, not the LCD.

Medicare does not cover diagnostic testing that duplicates previous testing done by an attending physician, to the extent the results are still pertinent, because such testing is not reasonable and necessary under section 1862 (a)(1)(A) of the Act.

The LCDs state that Medicare may cover therapeutic services for sleep disorders in a hospital outpatient setting or freestanding facility when reasonable and necessary for the patient and when performed under the direct supervision of a physician.

The LCDs also state that sleep technicians or technologists attending polysomnography services must have appropriate training certifications, such as Registered Polysomnography Technologist or Registered Sleep Technologist.

The LCDs further specify that documentation in the patient's medical record must support the medical necessity of services performed. When the documentation does not meet the criteria for the service rendered or establish the medical necessity of the services, MACs will deny the services as not reasonable and necessary. Additionally, the provider must submit CPT codes that describe the services performed.

The HCPCS and CPT Codebook directs providers to use modifier code -52 if the test was terminated prior to recording at least 6 hours of sleep or in cases of reduced services, as appropriate.

APPENDIX D: STATISTICAL SAMPLING METHODOLOGY

TARGET POPULATION

The target population consisted of lines of service paid to University of Michigan for polysomnography services provided to Medicare beneficiaries and billed with CPT codes 95810 and 95811 during our audit period.

SAMPLING FRAME

We obtained a database from CMS's NCH data containing outpatient lines of service for polysomnography services billed with CPT codes 95810 and 95811 and performed during CYs 2017 and 2018. This database contained 2,826 lines totaling $1,907,355.

We then compared all of the lines of service to the claims in the Recovery Audit Contractor (RAC) Data Warehouse and found that none of the lines of service were on any claims that were selected for review by another contractor or had been previously excluded from the RAC Data Warehouse.

We grouped these lines by beneficiary (using corresponding Health Insurance Claim Numbers) which resulted in a sampling frame of 1,931 Medicare beneficiaries composed of 2,826 lines of polysomnography service with a total paid amount of $1,907,355 from which we drew our sample.

SAMPLE UNIT

The sample unit was a Medicare beneficiary.

SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified random sample of 100 Medicare beneficiaries, as follows:

Table 2: Sample Design

Stratum	Description	Beneficiary Count	Total Payments	Sample Size
1	Beneficiaries with two or more polysomnography services	753	$1,117,862	59
2	Beneficiaries with one polysomnography service	1,178	789,493	41
Total		**1,931**	**$1,907,355**	**100**

SOURCE OF RANDOM NUMBERS

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

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the sample units within each stratum, and, after generating the random numbers for each stratum, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the total amount of overpayments paid to University of Michigan during our audit period. This analysis resulted in a point estimate and a two-sided 90-percent confidence interval.

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

APPENDIX E: SAMPLE RESULTS AND ESTIMATES

Table 3: Sample Results

Stratum	Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Sample Items Containing Errors	Value of Overpayments
1	753	$1,117,862	59	$84,643	1	$1,410
2	1,178	789,493	41	27,504	3	1,717
Total	**1,931**	**$1,907,355**	**100**	**$112,147**	**4**	**$3,127**

Table 4: Estimated Value of Overpayments in the Sampling Frame
(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	$67,330
Lower limit	12,520
Upper limit	$122,140

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March 24, 2021

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

RE: OIG Report No. A-04-20-07088

Dear Ms. Pilcher,

The University of Michigan Health System (UMHS) is submitting this letter in response to the preliminary findings of the Department of Health and Human Services Office of Inspector General ("OIG") related to an audit of 2017-2018 UMHS hospital claims. OIG's audit was focused on Medicare payments for polysomnography services. This audit was not triggered by any particular concerns with UMHS. OIG's preliminary findings are in its draft report, dated January 2021 ("Draft Audit Report").

The principal findings in the Draft Audit Report are as follows:

1. UMHS complied with 161 of the 166 lines of service reviewed.
2. 5 lines of service did not completely comply with applicable billing rules, resulting in a claim-based overpayment calculation of $3,127:
    a. 4 of the 5 lines relate to incomplete medical record documentation.
    b. 1 of the 5 lines relates to an incorrectly coded line of service.

Based on these findings, the Draft Audit Report proposes the following recommendations:

- UMHS should refund the Medicare program the estimated $3,127 for claims that were overpaid, plus $9,393 related to extrapolation.
- UMHS should exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation.
- UMHS should implement policies and procedures to ensure that Medicare claims for polysomnography services comply with Medicare requirements.

As discussed below, UMHS disagrees with finding (2)(a); agrees with finding (2)(b) and asserts that based on these findings, extrapolation is not warranted.

UMHS RESPONSE TO OIG'S FINDINGS

Incomplete Medical Record Documentation (3 claims; 4 service lines)

For 3 claims (4 service lines), UMHS disagrees with the OIG finding that they lack sufficient clinical evidence of the medical necessity of the services in question. For each of the 4 service lines, there is documentation supporting the clinical indication for the sleep studies. In each instance, the patient had symptoms, complaints or conditions for which sleep studies are indicated.[1]

As UMHS does not agree with the OIG's findings related to these 4 service lines, it does not plan further action to address these findings.

Incorrectly Coded Line of Service (1 service line)

UMHS agrees with the finding regarding an incorrectly coded line of service for 1 line of service in the sample. UMHS's root cause analysis indicates this was a result of a human error. Although it is well known by UMHS sleep study coding staff that 6 hours of total recorded time are required in order to bill for a completed sleep study, the time appears to have been inadvertently miscalculated in this instance, resulting in the failure to add Modifier 52 to this claim.

In response to this finding, UMHS has, or is doing, the following:

1. Re-educate the sleep study coders as to the required addition of Modifier 52, when the recorded time is less than 6 hours.
2. Ongoing exploration of whether there is an "automated" or "forcing function" that can be implemented so that when the recorded time is less than 6 hours, the Modifier 52 is automatically applied (thus eliminating the human element).
3. Perform a quarterly audit of all studies with less than 6 hours of recorded time until an "automated or "forcing function" can be implemented for applying the Modifier 52.
4. Perform a probe review to determine if this was an isolated occurrence (which it appears to be based on the root cause identified above), or if it is more pervasive. If the probe sample reveals additional problems, then UMHS will proceed in accordance with 42 CFR Subpart D – Reporting and Returning of Overpayments.
5. Refund the portion of the payment that should have been reduced by application of Modifier 52.

UMHS RESPONSE TO OIG'S RECOMMENDATIONS

Refund to the Medicare program the estimated $12,520 for claims that it billed incorrectly

As noted above, because UMHS disagrees with the findings associated with 4 service lines pertaining to medical necessity, UMHS declines to repay those claims. As for the service line associated with the incorrect coding (i.e., lack of use of Modifier 52), UMHS will refund the amount received for the claim that would have been reduced by application of the modifier.

The amount requested to be paid back includes an extrapolated amount of $9,393. UMHS asserts that the OIG's findings do not support extrapolation.

The Social Security Act, § 1893(f)(3), states that Medicare contractors "may not use extrapolations to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that" either (1) there is a sustained or high level of payment error; or (2) there is a failure of documented education interventions." UMHS challenges the extrapolation on the grounds that the judgmental sample reviewed by OIG is not representative of the larger universe of sleep study claims.

In accordance with the Medicare Program Integrity Manual (PIM)[2], for purposes of extrapolation, a sustained or high level of payment error shall be determined to exist through a variety of means, including, but not limited to:

- high error rate determinations by the contractor or by other medical reviews (i.e., greater than or equal to 50 percent from a previous pre- or post-payment review);
- provider/supplier history (i.e., prior history of non-compliance for the same or similar billing issues, or historical pattern of non-compliant billing practices);
- CMS approval provided in connection to a payment suspension;
- information from law enforcement investigations
- allegations of wrongdoing by current or former employees of a provider/supplier; and/or
- audits or evaluations conducted by the OIG.

The error rate here does not meet the 50 percent standard. Moreover, there is no historical evidence that the Medicare contractor has found a high level of payment error with respect to sleep study claims in reference to either the stated error of incorrect medical record documentation or the stated error of an incorrectly coded service. The OIG's recommendation that extrapolation be applied in this instance is not warranted.

Additionally, with respect to the OIG's assertion that 3 claim lines are either incomplete or lack sufficient medical record documentation, extrapolation is also unfounded, as the OIG's findings relate to medical necessity questions. In analogous circumstances related to potential false claims act liability, courts have noted, with respect to the application of extrapolation to medical necessity questions:

> *Because "each and every claim at issue" [is] "fact-dependent and wholly unrelated to each and every other claim," and determining eligibility for "each of the patients involved a highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient," …the case [is] not "suited for statistical sampling."*[3]

UMHS does not agree to the OIG's assertion of extrapolation on the 4 claim lines.

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UMHS thanks the OIG for the opportunity to provide feedback on the Draft Audit Report and appreciates the professionalism and cooperative spirit of its auditors, as well as the information furnished through the audit process. UMHS takes it compliance efforts very seriously. As indicated above, we agree with OIG's assessment of an opportunity for improvement and we appreciate this matter having been brought to our attention. As to those areas where we are not in agreement, we request that OIG reconsider its initial findings, and in any event, we request that OIG not extrapolate any medical necessity findings.

Sincerely,

Jeanne Strickland
Chief Compliance Officer

[1] Social Security Act section 1862(a)(1)(A); https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=56903&ver=4&keyword=sleep%20studies&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3; https://www.wpsgha.com/wps/portal/mac/site/policies/guides-and-resources/credentialing-sleep-studies-polysomnography/!ut/p/z1/jZFBT8MwDIV_C4ce25hWTBW3ggYVagWXQckFZa2XBqVxlKSrxq8n0k5IUOabre_ZT8-Ms45xI45KiqDICB37d775eKnrTX1dQvOctwBV-_BabMvmDrY5e1sBCngsGL9ED39UBZfpVwC-vv7pvwMxgdy1961k3IowpsociHVyVgP6VJghdehpdj161vUOBzRBCa2MTL1GtKkP86AiakmfPE2GpBN2PEXjfOX0OboL

zEtN-_OfKrMvyujS4QEdumx2cTyGYP1tAgksy5JJIqkx62lK4DfJSD6w7ifJ7LTbdV9NDZ83-thUV9-xjEnC/dz/d5/L2dBISEvZ0FBIS9nQSEh/#. Accessed on February 25, 2021.

[2] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R828PI.pdf

[3] United States *ex rel*. Misty Wall v. Vista Hospice Care, Inc., 2016 WL 3449833, at *12 (N.D. Tex 2016.); United States v. Medco Phys. Unlimited, No. 98-C-1622, 2000 U.S. Dist. LEXIS 5843, at *23 (N.D. Ill. Mar. 15, 2000)