

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**TOTAL SLEEP MANAGEMENT, INC.,
BILLED MEDICARE FOR UNALLOWABLE
SLEEP STUDY SERVICES**

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Office of Inspector General

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EXECUTIVE SUMMARY

Total Sleep Management, Inc., received at least \$1 million over 3 years for polysomnography services that were not allowable in accordance with Medicare requirements.

WHY WE DID THIS REVIEW

From January 1, 2011, through September 30, 2012, Medicare administrative contractors (MACs) nationwide paid freestanding facilities, facilities affiliated with hospitals, and physicians (providers) approximately \$680 million for selected polysomnography services (a type of sleep study). Previous Office of Inspector General reviews of polysomnography services found that Medicare paid for services that did not meet Medicare requirements. These reviews identified payments for services with inappropriate diagnosis codes, providers that exhibited patterns of questionable billing, and payments for services without the required supporting documentation. Furthermore, in January 2013, a provider agreed to pay \$15.3 million to settle allegations of false sleep study claims billed to Medicare and other Federal payers. The results of these reviews; increased Medicare spending on polysomnography services; and growing concerns about fraud, waste, and abuse prompted us to conduct additional reviews.

The objective of this review was to determine whether Medicare claims that Total Sleep Management, Inc. (Total Sleep), billed for polysomnography services complied with Medicare billing requirements.

BACKGROUND

Polysomnography is a type of sleep study used to diagnose a variety of sleep disorders, most commonly obstructive sleep apnea, and to evaluate a patient's response to therapies such as positive airway pressure. Providers normally perform polysomnographies at sleep disorder clinics, which may be either freestanding facilities, such as Independent Diagnostic Testing Facilities (IDTF) and provider-owned laboratories, or facilities affiliated with a hospital.

Providers report the polysomnography services administered to Medicare beneficiaries using standardized codes called Healthcare Common Procedure Coding System codes. The Centers for Medicare & Medicaid Services (CMS) pays for polysomnography services under the Outpatient Prospective Payment System when performed in a hospital outpatient department and under the Medicare Physician Fee Schedule when performed in freestanding facilities.

Total Sleep is an IDTF, based in Orlando, Florida, that operates five sleep disorder clinics throughout the State. According to CMS's National Claims History data, Medicare paid Total Sleep approximately \$1.7 million for 2,317 beneficiaries with 3,699 corresponding lines of service for selected polysomnography services provided from January 1, 2010, through December 31, 2012 (audit period).

Our audit covered \$1,657,111 in Medicare payments to Total Sleep for 2,278 beneficiaries with 3,636 corresponding lines of polysomnography service that were potentially at risk for

noncompliance with billing requirements. We reviewed a random sample of 100 beneficiaries with 149 corresponding lines of service with total payments of \$68,267 during our audit period.

WHAT WE FOUND

Total Sleep billed Medicare claims for polysomnography services that did not always comply with Medicare billing requirements. Of the 100 randomly selected beneficiaries, Total Sleep billed Medicare claims for polysomnography services that met Medicare billing requirements for 21 beneficiaries with 38 corresponding lines of service. However, Total Sleep billed Medicare claims for the remaining 79 beneficiaries with 111 corresponding lines of service that did not meet Medicare requirements, resulting in overpayments totaling \$50,700.

The 79 beneficiaries with 111 corresponding lines of service had the following deficiencies:

- for 74 beneficiaries with 106 corresponding lines of service, Total Sleep did not have the required supporting documentation, resulting in overpayments totaling \$48,293;
- for 4 beneficiaries with 4 corresponding lines of service, the attending technician or the interpreting physician lacked the proper certification, resulting in overpayments totaling \$1,878; and
- for 1 beneficiary with 1 corresponding line of service, Total Sleep billed for a service that it did not provide, resulting in an overpayment of \$529.

These errors occurred primarily because Total Sleep did not have adequate controls to ensure that it properly documented polysomnography services billed to Medicare and that its attending technicians had the proper certification.

On the basis of our sample results, we estimated that Total Sleep received overpayments of at least \$1,030,077 for the audit period. This overpayment amount includes claim payment dates outside of the 3-year recovery period. Of the total estimated overpayments, at least \$423,008 was within the 3-year recovery period and as much as \$607,069 was outside of the 3-year recovery period.

WHAT WE RECOMMEND

We recommend that Total Sleep:

- refund to the Medicare program \$423,008 in estimated overpayments for claims that it incorrectly billed that are within the 3-year recovery period;
- work with the MAC to return overpayments outside of the 3-year recovery period, which we estimate to be as much as \$607,069 for our audit period, in accordance with the 60-day repayment rule; and
- strengthen controls to ensure full compliance with Medicare requirements.

TOTAL SLEEP MANAGEMENT, INC., COMMENTS AND OUR RESPONSE

In written comments on our draft report, Total Sleep generally agreed with our findings. However, regarding 33 lines of service for which it had no documentation for the face-to-face clinical evaluation, the attending physician's orders, or the interpretation report, Total Sleep stated that, based upon its interpretation of the Local Coverage Determination (LCD), it had complied with its requirement. Total Sleep noted that the clinical information required in a face-to-face evaluation is the same for both (baseline and therapeutic positive airway pressure polysomnographies). Therefore, Total Sleep concluded that the physician's order would suffice for the latter requirement and stated that the corresponding LCD provision is ambiguous and open to interpretation.

Additionally, Total Sleep stated that it was unable to prepare a meaningful response because the report did not provide the claims-specific information for one line of service for which it did not provide supporting documentation.

Total Sleep offered no comments regarding our first and second recommendations. Regarding our third recommendation, Total Sleep provided information on corrective actions that it had taken.

After reviewing Total Sleep's comments, we maintain that all of our findings and recommendations are valid. The LCD clearly states that prior to any sleep testing, the beneficiary's treating physician must conduct a face-to-face clinical evaluation that documents the need for testing and order the study.

Additionally, we provided Total Sleep with the claims-specific information for the one line of service and allowed additional time to provide any missing documentation. However, Total Sleep did not provide the required supporting documentation for that line of service.

TABLE OF CONTENTS

INTRODUCTION	1
Why We Did This Review	1
Objective	1
Background	1
The Medicare Program	1
Polysomnography Services	2
Medicare Coverage of Polysomnography Services	2
Total Sleep Management, Inc.	3
How We Conducted This Review.....	3
FINDINGS	4
Unallowable Polysomnography Services	5
Documentation Was Incomplete or Missing.....	5
Attending Technician or Interpreting Physician Without Required Certification ...	6
Billed for a Service That Was Not Provided	6
Total Sleep Did Not Have Adequate Controls.....	6
Total Sleep Received at Least \$1 Million in Overpayments	6
RECOMMENDATIONS	7
TOTAL SLEEP MANAGEMENT, INC., COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE.....	7
Total Sleep Management, Inc., Comments.....	7
Office of Inspector General Response	7
APPENDIXES	
A: Audit Scope and Methodology	8
B: Federal Requirements Related to Medicare Administrative Contractor Payment and Provider Billing for Polysomnography Services	10
C: Sample Design and Methodology	12
D: Sample Results and Estimates	14
E: Total Sleep Management, Inc., Comments	15

INTRODUCTION

WHY WE DID THIS REVIEW

From January 1, 2011, through September 30, 2012, Medicare administrative contractors (MACs) nationwide paid freestanding facilities, facilities affiliated with hospitals, and physicians (providers) approximately \$680 million for selected polysomnography services (a type of sleep study). Previous Office of Inspector General (OIG) reviews for polysomnography services found that Medicare paid for services that did not meet Medicare requirements. These reviews identified payments for services with inappropriate diagnosis codes, providers that exhibited patterns of questionable billing,¹ and payments for services without the required supporting documentation.² Furthermore, in January 2013, a provider agreed to pay \$15.3 million to settle allegations of false sleep study claims billed to Medicare and other Federal payers.³ The results of these reviews; increased Medicare spending on polysomnography services; and growing concerns about fraud, waste, and abuse prompted us to conduct additional reviews.

OBJECTIVE

Our objective was to determine whether Medicare claims that Total Sleep Management, Inc. (Total Sleep), billed for polysomnography services complied with Medicare billing requirements.

BACKGROUND

The Medicare Program

Under Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people aged 65 and over, people with disabilities, and people with permanent kidney disease. Part B of Medicare provides supplementary medical insurance, including coverage for the cost of polysomnographies.

The Centers for Medicare & Medicaid Services (CMS) administers the Part B program and contracts with MACs to, among other things, process and pay claims, conduct reviews and audits, and safeguard against fraud and abuse.⁴ First Coast Service Options, Inc. (First Coast), was the MAC that processed and paid the Medicare claims submitted by Total Sleep.

¹ *Questionable Billing for Polysomnography Services*, OEI-05-12-00340, October 2013.

² *First Coast Service Options, Inc., Paid Some Unallowable Sleep Study Claims*, A-04-13-07039, May 2015.

³ U.S. Department of Justice, *Florida-Based American Sleep Medicine to Pay \$15.3 Million for Improperly Billing Medicare and Other Federal Healthcare Programs* (press release). Available online at: www.justice.gov. Accessed on May 6, 2015.

⁴ Section 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, required CMS to transfer the functions of fiscal intermediaries and carriers to MACs.

Polysomnography Services

Polysomnography is a type of sleep study conducted to diagnose medical conditions that affect sleep, most commonly obstructive sleep apnea (OSA), and to evaluate effectiveness of the use of positive airway pressure (PAP) devices to manage the beneficiary's condition. PAP is a common treatment used to manage sleep-related breathing disorders including OSA. During a polysomnography, the patient sleeps overnight⁵ 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 test measures the number of times that the patient either stops breathing or almost stops breathing. A sleep technician or technologist is physically present to supervise the recording during sleep time and has the ability to intervene, if needed.

If the polysomnography indicates that a patient has a sleep disorder, then the provider may conduct a PAP titration study.⁶ During a PAP titration study, providers fit and calibrate PAP devices, after which beneficiaries may receive a PAP device for home use.

In some cases, providers may perform a PAP titration study on the same night as an in-laboratory sleep study. Providers refer to this process as a split-night service because they can perform this service when they diagnose sleep apnea within the first few hours of the polysomnography. If the provider cannot make a diagnosis early in the polysomnography session, the patient usually returns another day for an additional polysomnography session to fit and calibrate the PAP device.

Providers normally perform polysomnography services at sleep disorder clinics,⁷ which may be freestanding facilities, such as Independent Diagnostic Testing Facilities (IDTF) or provider-owned laboratories, or facilities affiliated with a hospital.

Medicare Coverage of Polysomnography Services

Medicare pays for polysomnography services under the Medicare Physician Fee Schedule when performed in freestanding facilities. Providers must use standardized codes, called Healthcare Common Procedure Coding System (HCPCS)⁸ codes, to describe 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).

⁵ Most of the patients who undergo testing are not in hospital inpatient status, although they generally stay in the facility overnight.

⁶ A PAP titration study is a type of in-laboratory sleep study used to calibrate the PAP therapy. During the titration, the technician adjusts the PAP device to the appropriate pressure for the beneficiary's condition.

⁷ Polysomnography providers may also diagnose OSA for coverage of a PAP device through home sleep testing.

⁸ HCPCS is a medical code set used throughout the health care industry as a standardized system for describing and identifying health care procedures, equipment, and supplies in health care transactions.

Providers use modifier code⁹ -TC or -26, respectively, to indicate whether the billing is for the technical or professional component. If a provider does not include a modifier code on the claim, it indicates that the provider is billing for a “global service.” A provider that bills for a global service receives payment for both the technical and professional components.¹⁰

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

Prior to any sleep testing, the beneficiary’s treating physician must conduct a face-to-face clinical evaluation that documents the need for testing and write an order for the study. The face-to-face clinical evaluation must include, at a minimum: (1) the patient’s sleep history and symptoms, (2) an Epworth sleepiness scale,¹¹ and (3) a physical examination that documents body mass index, neck circumference, and a focused cardiopulmonary and upper airway evaluation. The sleep study provider is required to maintain a record of the physician’s order and face-to-face clinical evaluation (Local Coverage Determination (LCD)).¹²

Total Sleep Management, Inc.

Total Sleep is an IDTF based in Orlando, Florida, that operates five sleep disorder clinics throughout the State. According to CMS’s National Claims History (NCH) data, Medicare paid Total Sleep approximately \$1.7 million for 2,317 beneficiaries with 3,699 corresponding lines of polysomnography services with HCPCS codes 95810 and 95811 provided from January 1, 2010, through December 31, 2012 (audit period).

How We Conducted This Review

Our audit covered \$1,657,111 in Medicare payments to Total Sleep for 2,278 beneficiaries with 3,636 corresponding lines of polysomnography service that were potentially at risk for noncompliance with billing requirements. We reviewed a random sample of 100 beneficiaries

⁹ A modifier code is a two-digit code reported with a HCPCS code that provides additional information needed to process a claim.

¹⁰ The technical and professional components represent approximately 80 and 20 percent, respectively, of the total or global payment.

¹¹ The Epworth Sleepiness Scale is a scale intended to measure daytime sleepiness with a very short questionnaire. This questionnaire can help diagnose sleep disorders.

¹² LCDs are decisions published by MACs on 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. First Coast published LCD L29949 for polysomnography and sleep testing by providers in the State of Florida.

with 149 corresponding lines of service¹³ with payments totaling \$68,267 during our audit period.

We focused our review on selected polysomnography services potentially at risk for billing errors identified as a result of prior OIG reviews. We evaluated compliance with selected billing requirements but did not use medical review to determine whether the services were medically necessary. This report focuses on claims with lines of service for selected polysomnography services and does not represent an overall assessment of all claims submitted by Total Sleep for Medicare reimbursement.

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

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

FINDINGS

Total Sleep billed Medicare claims for polysomnography services that did not always comply with Medicare billing requirements. Of the 100 randomly selected beneficiaries, Total Sleep billed Medicare claims for polysomnography services that met Medicare billing requirements for 21 beneficiaries with 38 corresponding lines of service. However, Total Sleep billed Medicare claims for the remaining 79 beneficiaries with 111 corresponding lines of service that did not meet Medicare billing requirements, resulting in overpayments of \$50,700.

The 79 beneficiaries with 111 corresponding lines of service had the following deficiencies:

- for 74 beneficiaries with 106 corresponding lines of service, Total Sleep did not have the required supporting documentation, resulting in overpayments totaling \$48,293;
- for 4 beneficiaries with 4 corresponding lines of service, the attending technician or the interpreting physician lacked the proper certification, resulting in overpayments totaling \$1,878;¹⁴ and
- for 1 beneficiary with 1 corresponding line of service, Total Sleep billed for a service that it did not provide, resulting in an overpayment of \$529.

¹³ A single Medicare claim from a provider typically includes more than one line of service. In this audit, we did not review entire claims; rather, we reviewed specific lines of service billed using HCPCS codes 95810 and 95811.

¹⁴ Three of the four lines of service in this error category also had errors associated with missing or incomplete documentation.

These errors occurred primarily because Total Sleep did not have adequate controls to ensure that it properly documented polysomnography services billed to Medicare and that its attending technicians had the proper certification.

On the basis of our sample results, we estimated that Total Sleep received overpayments of at least \$1,030,077 for the audit period. This overpayment amount includes claim payment dates outside of the 3-year recovery period.¹⁵ Of the estimated overpayments, at least \$423,008 was within the 3-year recovery period and as much as \$607,069 was outside of the 3-year recovery period.

See Appendix D for our sample results and estimates.

UNALLOWABLE POLYSOMNOGRAPHY SERVICES

Documentation Was Incomplete or Missing

Section 1833(e) of the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider. Additionally, 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)). Furthermore, the LCD states that, prior to any sleep testing, the patient must have a face-to-face clinical evaluation by the treating physician that must include, among other requirements, the patient's sleep history and symptoms and a physical examination that documents body mass index, neck circumference, and a focused cardiopulmonary and upper airway evaluation.

For 74 beneficiaries with 106 corresponding lines of service, Total Sleep did not have the required supporting documentation as follows:

- For 33 lines of service, Total Sleep had no documentation for the face-to-face clinical evaluation, the attending physician's orders, or the interpretation report.
- For 72 lines of service, Total Sleep included documentation for a face-to-face clinical evaluation that was incomplete because it did not record one or more of the following requirements: patient's sleep history and symptoms, Epworth sleepiness scale, body mass index, or neck circumference.

¹⁵ Our audit report represents the results for all claims within our audit period. Section 1870(b) of the Act governs the recovery of excess payments. This section provides that excess payments identified are barred from recovery 3 years after the year in which the original payment was made. In addition, Total Sleep is responsible for reporting and returning overpayments they identified to their MAC. The 2010 Patient Protection and Affordable Care Act requires the reporting and return of Medicare overpayments along with written notice of the reason for the overpayment within 60 days after the overpayment was identified (60-day repayment rule). Failure to meet this deadline subjects providers to potential False Claims Act and Civil Monetary Penalty Law liability.

- For one line of service, Total Sleep billed for a service for which it did not provide supporting documentation.

As a result, Total Sleep received overpayments totaling \$48,293.

Attending Technician or Interpreting Physician Without Required Certification

The LCD indicates that a physician with the appropriate sleep certification, such as Diplomate of the American Board of Sleep Medicine, must review and interpret the raw data from the sleep studies. Additionally, the LCD states that sleep technicians or technologists attending polysomnography services must have appropriate training certifications, such as Registered Polysomnography Technologist or Registered Electroencephalographic Technologist.

For four beneficiaries with four corresponding lines of service, Total Sleep billed for polysomnography services for which the attending technicians (three lines of service) or the interpreting physician (one line of service) lacked the proper certifications. As a result, Total Sleep received overpayments totaling \$1,878.

Billed for a Service That Was Not Provided

Section 1862(a)(1)(A) of the Act states that Medicare payments may not be made for items and 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.” In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (the Act, § 1833(e)).

For one beneficiary (one line of service), Total Sleep billed Medicare for a polysomnography service that it did not provide. Total Sleep stated that the patient did not arrive for the sleep study appointment and that it did not perform those services for that beneficiary. Total Sleep stated that it inadvertently billed for that sleep study service that it did not provide. As a result, Total Sleep received an overpayment of \$529.

TOTAL SLEEP DID NOT HAVE ADEQUATE CONTROLS

These errors occurred primarily because Total Sleep did not have adequate controls to ensure that it properly documented polysomnography services billed to Medicare and that its attending technicians had the proper certification.

TOTAL SLEEP RECEIVED AT LEAST \$1 MILLION IN OVERPAYMENTS

As a result of Total Sleep’s incorrect billing for 111 of 149 lines of polysomnography service for 79 beneficiaries in our sample, it received overpayments of \$50,700. This overpayment amount includes claim payment dates outside of the 3-year recovery period. On the basis of our sample results, we estimated that Total Sleep received overpayments of at least \$1,030,077 for the audit period, of which \$423,008 was within the 3-year recovery period and as much as \$607,069 was outside of the 3-year recovery period.

RECOMMENDATIONS

We recommend that Total Sleep:

- refund to the Medicare program \$423,008 in estimated overpayments for claims that it incorrectly billed that are within the 3-year recovery period;
- work with the MAC to return overpayments outside of the 3-year recovery period, which we estimate to be as much as \$607,069, in accordance with the 60-day repayment rule; and
- strengthen controls to ensure full compliance with Medicare requirements.

TOTAL SLEEP MANAGEMENT, INC., COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

Total Sleep Management, Inc., Comments

In written comments on our draft report, Total Sleep generally agreed with our findings. However, regarding 33 lines of service for which it had no documentation for the face-to-face clinical evaluation, the attending physician's orders, or the interpretation report, Total Sleep stated that, based upon its interpretation of the LCD, it had complied with its requirement. Total Sleep noted that the clinical information required in a face-to-face evaluation is the same for both baseline and therapeutic PAP polysomnographies. Therefore, Total Sleep concluded that the physician's order would suffice for the latter requirement and stated that the corresponding LCD provision is ambiguous and open to interpretation.

Additionally, Total Sleep stated that it was unable to prepare a meaningful response because the report did not provide the claims-specific information for one line of service for which it did not provide supporting documentation.

Total Sleep offered no comments regarding our first and second recommendations. Regarding our third recommendation, Total Sleep provided information on corrective actions that it had taken. Total Sleep's comments are included in their entirety as Appendix E.

Office of Inspector General Response

After reviewing Total Sleep's comments, we maintain that all of our findings and recommendations are valid. The LCD clearly states that prior to any sleep testing, the beneficiary's treating physician must conduct a face-to-face clinical evaluation that documents the need for testing and order the study.

Additionally, we provided Total Sleep the claims-specific information for the one line of service and allowed additional time to provide any missing documentation. However, Total Sleep did not provide the required supporting documentation for that line of service.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$1,657,111 in Medicare payments to Total Sleep for 2,278 beneficiaries with 3,636 corresponding lines of polysomnography services that were potentially at risk for noncompliance with billing requirements. We reviewed a random sample of 100 beneficiaries with 149 corresponding lines of service with total payments of \$68,267 during our audit period.

We focused our review on polysomnography services billed with HCPCS codes 95810 and 95811 that were potentially at risk for billing errors identified during prior OIG reviews. 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 Total Sleep because our objective did not require us to do so. Rather, we limited our review to Total Sleep's internal controls to prevent incorrect billings. Our review allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's NCH file, but we did not assess the completeness of the file.

We conducted fieldwork at Total Sleep during August of 2014.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Total Sleep's paid lines of service data for polysomnography services with HCPCS codes 95810 and 95811 from CMS's NCH file for the audit period;
- created a sampling frame of 2,278 Medicare beneficiaries with 3,636 corresponding lines of service billed for HCPCS codes 95810 or 95811 during the audit period;
- selected a random sample of 100 beneficiaries (149 lines of service) totaling \$68,267 for detailed review (Appendix C);
- 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;
- reviewed the medical records and other documentation provided by Total Sleep to support the services to determine whether each line of service was billed correctly;
- calculated overpayment amounts for the lines of service requiring adjustments;

- used the results of the sample to estimate the total Medicare overpayments to Total Sleep (Appendix D);
- used the results of the sample to estimate the Medicare overpayments to Total Sleep (Appendix D) that are within the 3-year recovery period; and
- discussed the results of our review with Total Sleep 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: FEDERAL REQUIREMENTS RELATED TO MEDICARE ADMINISTRATIVE CONTRACTOR PAYMENT AND 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 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)). Medicare Part B provides coverage for outpatient diagnostic and therapeutic services provided in a hospital outpatient setting or in a freestanding facility. Diagnostic testing that is duplicative of previous testing done by the attending physician to the extent the results are still pertinent is not covered because it is not reasonable and necessary under section 1862(a)(1)(A) of the Act.

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

Chapter 15, section 70, of the *Medicare Benefit Policy Manual* (Manual), Pub. No. 100-02, indicates 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 Manual provides that all reasonable and necessary diagnostic testing for sleep disorders are covered only if the patient has symptoms or complaints such as narcolepsy, sleep apnea, impotence, or parasomnia; and 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
- the need for diagnostic testing is confirmed by medical evidence, e.g., physician examinations and laboratory tests.

The Manual also states 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.

Furthermore, the LCD published by the MAC for polysomnography and sleep testing specifies additional coverage requirements. For example, among other requirements, before any sleep testing, the patient must have a face-to-face clinical evaluation by the treating physician that must include at a minimum:

- the patient's sleep history and symptoms;
- an Epworth sleepiness scale; and
- a physical examination that documents body mass index, neck circumference, and a focused cardiopulmonary and upper airway evaluation.

The LCD also requires that sleep technicians or technologists attending polysomnography services have appropriate personnel certifications, such as Registered Polysomnography Technologist or Registered Electroencephalographic Technologist. Additionally, the LCD indicates that a physician with the appropriate sleep certification, such as Diplomate of the American Board of Sleep Medicine, must review and interpret the raw data from the sleep studies.

The *Medicare Claims Processing Manual* requires providers to complete claims accurately so that MACs may process them correctly and promptly (Pub. No. 100-04, chapter 1, section 80.3.2.2) and states that providers must use HCPCS codes for most outpatient services (chapter 23, section 20.3).

APPENDIX C: SAMPLE DESIGN AND METHODOLOGY

POPULATION

The population consisted of lines of service paid to Total Sleep for polysomnography services billed with HCPCS codes 95810 and 95811 provided to Medicare beneficiaries during our audit period.

SAMPLING FRAME

We obtained a database from CMS's NCH data containing all Part B lines of service for polysomnography services billed with HCPCS codes 95810 and 95811 performed from January 1, 2010, through December 31, 2012. This database contained 3,699 lines totaling \$1,669,661.

We further refined this database by removing:

- lines containing payments corresponding to beneficiaries under the Railroad Retirement Board system,
- \$0 paid lines,
- lines corresponding to claims under review by the Recovery Audit Contractor or other entities as of July 11, 2014, and
- all beneficiaries with total payments less than \$400 after grouping all remaining lines by beneficiary.

This resulted in a sampling frame of 2,278 Medicare beneficiaries with 3,636 corresponding lines of polysomnography services totaling \$1,657,111 from which we drew our sample.

SAMPLE UNIT

The sample unit was a Medicare beneficiary.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE SIZE

The sample consisted of 100 Medicare beneficiaries.

SOURCE OF RANDOM NUMBERS

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

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the sample units in the frame from 1 to 2,278. After generating 100 random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the total amount of Medicare overpayments paid to Total Sleep during the audit period and the amount of the overpayments paid within the 3-year recovery period. We also calculated a nonstatistical estimate of the overpayment amount outside of the 3-year recovery period. To obtain this amount, we subtracted the lower limit of the overpayments within the 3-year recovery period from the lower limit of the total estimated overpayments.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

TOTAL MEDICARE OVERPAYMENTS

Table 1: Sample Details and Results

Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Overpayments	Value of Overpayments
2,278	\$1,657,111	100	\$68,267	79	\$50,700

Table 2: Estimated Value of Overpayments
(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	\$1,154,953
Lower limit	1,030,077
Upper limit	1,279,830

MEDICARE OVERPAYMENTS WITHIN THE 3-YEAR RECOVERY PERIOD

Table 3: Sample Details and Results

Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Overpayments	Value of Overpayments
2,278	\$1,657,111	100	\$68,267	38	\$24,177

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

Point estimate	\$550,748
Lower limit	423,008
Upper limit	678,489

APPENDIX E: TOTAL SLEEP MANAGEMENT, INC., COMMENTS



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July 22, 2015

Via Federal Express and Email to Denise.Novak@oig.hhs.gov

DENISE NOVAK, AUDIT MANAGER
OFFICE OF INSPECTOR GENERAL
61 FORSYTH STREET, SW, SUITE 3T41
ATLANTA, GA 30303

RE: RESPONSE TO OIG DRAFT REPORT NO. A-04-14-07051

Dear Ms. Novak:

As you know, the Health Law Office of Anthony C. Vitale, P.A. represents Total Sleep Management (hereinafter "TSM") with regards to the OIG Draft Report (hereinafter "the Report") entitled "Total Sleep Management, Inc. Billed Medicare For Unallowable Sleep Study Services."

I. BACKGROUND OF TSM

TSM is a CMS designated 'Independent Diagnostic Testing Facility' specializing in sleep disorders, such as Obstructive Sleep Apnea Syndrome, Chronic Insomnia, Narcolepsy, Restless Leg Syndrome, etc. TSM has 5 current locations throughout the State of Florida, each individually accredited by The Joint Commission.

II. THE REPORT

The Report provides the OIG's conclusions as to TSM's sleep related disorder services and its compliance with Medicare LCD 29949 entitled "Polysomnography and Sleep Testing."

Specifically, the Report, at Page ii recommends the following actions be taken by TSM:

- Refund to the MAC \$423,008 in estimated overpayments for claims that it incorrectly billed that are within the 3-year recovery rule,
- Work with the MAC to return overpayments outside of the 3-year recovery period in accordance with the 60-day repayment rule, and
- Strengthen controls to ensure full compliance with Medicare requirements

III. OPENING COMMENTS

Upon receipt of the OIG's notice regarding the commencement of this audit, TSM fully cooperated and has been completely transparent with all OIG requests. TSM submitted all requested documentation within its possession and participated in the OIG's requested interviews and site visit. At no time has the OIG alleged that TSM is culpable of any fraudulent or deceptive billing practices.

Additionally, please note the following:

- I. All sleep disorder treatments billed to Medicare were rendered by TSM;
- II. All TSM medical records demonstrate signs and symptoms relative to the reasonableness and necessity of all sleep disorder studies performed by TSM.

IV. OIG ALLEGATIONS OF NON-COMPLIANCE

OIG CATEGORY OF NON-COMPLIANCE	ALLEGATION OF NON-COMPLIANCE	TSM REBUTTAL
<p>I. DOCUMENTATION WAS INCOMPLETE OR MISSING</p>	<p>For 74 beneficiaries with 106 corresponding lines of service, Total Sleep did not have the required supporting documentation as follows:</p> <ul style="list-style-type: none"> • For 33 lines of services, Total Sleep had no documentation for the face-to-face clinical evaluation, the attending physician's orders, or the interpretation report. 	<p>The State of Florida MAC First Coast Service option LCD L29949 requires the following for services performed on or after 07/21/2009:</p> <p>When sleep studies are performed in sleep disorder centers or laboratories or when HST is used, the following criteria must be met:</p> <ul style="list-style-type: none"> • The clinic (sleep center or laboratory) is either affiliated with a hospital or is under the direction and control of physicians. Diagnostic testing routinely performed in sleep disorder clinics (centers and laboratories) may be covered even in the absence of direct supervision by a physician. • Patients are referred to the sleep disorder clinic by their attending physicians, and the clinic (center or laboratory) maintains a record of the attending physician's orders; and • The need for diagnostic testing is confirmed by medical evidence, e.g. physician examinations and laboratory tests. Prior to any sleep testing, the patient must have a face-to-face clinical evaluation by the treating physician which must at minimum include: <ol style="list-style-type: none"> 1. Sleep history and symptoms including, but not limited to, snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches; and 2. Epworth sleepiness scale; and 3. Physical examination that documents body mass index, neck circumference and a focused cardiopulmonary and upper airway evaluation. <p>Rebuttal</p> <p>Total Sleep Management (TSM) operated within its good-faith interpretation of the FCSO LCD</p>

OIG CATEGORY OF NON-COMPLIANCE	ALLEGATION OF NON-COMPLIANCE	TSM REBUTTAL
		<p>elements above. Because the clinical information required in a face-to-face office visit is the same for a baseline polysomnography (95810) as it is for a therapeutic Positive Airway Pressure (PAP) polysomnography (95811), TSM reached the good-faith conclusion that the physician's order would suffice for the latter requirement. It was TSM's good-faith understanding, based upon its literal reading of the LCD, that it had complied with the LCD mandate.</p> <p>The OIG's allegation herein is not clearly nor explicitly stated in the LCD. The LCD provision which TSM is being held responsible for is ambiguous and clearly open to interpretation. Additional clarity is required from the MAC as to this LCD.</p>
	<ul style="list-style-type: none"> For 72 lines of services, Total Sleep included documentation for a face-to-face clinical evaluation that was incomplete because it did not record one or more of the following requirements: patient's sleep history and symptoms, Epworth sleepiness scale, body mass index, or neck circumference. 	<p>TSM took extreme effort to comply with the documentation mandates within the LCD. Every effort was made by TSM to obtain this information from various departments throughout TSM and from its ordering physicians. TSM puts immense effort into educating its ordering physicians on the proper documentation requirements. The burden of educating its referring physician's falls squarely on the shoulders of TSM. This challenge is manifested exponentially as the MAC amends its own LCD. With each change, education becomes necessary and that much more onerous on the provider.</p>
	<ul style="list-style-type: none"> For one line of service, Total Sleep billed for a service for which it did not provide supporting documentation. 	<p>Because the claims specific information was not provided in the Report, TSM I unable to prepare a meaningful response to this allegation. However, upon receipt of the claim information from the MAC with its overpayment demand, TSM will vigorously defend itself regarding these allegations.</p>
<p>II. ATTENDING TECHNICIAN OR INTERPRETING PHYSICIAN WITHOUT REQUIRED CERTIFICATION</p>	<p>For four beneficiaries with four corresponding lines of service, Total Sleep billed for polysomnography services for which the attending technicians (three lines of services) or the interpreting physician (one line service) lacked the proper certifications.</p>	<p>Every concerted effort is made to ensure proper credentialing of all TSM technicians and physicians. In these 3 isolated cases whereby an unregistered technician performed the study, it was subsequently discovered during TSM's post-audit internal investigation, that 2 particular technicians had swapped shifts without first notifying TSM corporate in advance. Both remedial and punitive Standard Operating Procedures have been established by TSM so as to avoid this issue from reoccurring.</p>

OIG CATEGORY OF NON-COMPLIANCE	ALLEGATION OF NON-COMPLIANCE	TSM REBUTTAL
III. BILLED FOR A SERVICE THAT WAS NOT PROVIDED	For one beneficiary (one line of service), Total Sleep billed Medicare for a polysomnography service that it did not provide. Total Sleep stated that the patient did not arrive for the sleep study appointment and that it did not perform those services for that beneficiary. Total Sleep stated that it inadvertently billed for that sleep study service that it did not provide.	This was an isolated incident. The billing agent responsible for this incorrect claim submission was terminated in January 2011 this DOS was billed in March 2010. All TSM billing agents are required to complete training webinars and other various on the job training modules.
IV. TOTAL SLEEP DID NOT HAVE ADEQUATE CONTROLS	These errors occurred primarily because Total Sleep did not have adequate controls to ensure that it properly documented polysomnography services billed to Medicare and that its attending technicians had the proper certification.	TSM was placed on pre-payment review by the MAC from July 2013 to February 2014. During this period, various organizational changes were implemented to attain 100% compliance with Medicare rules and regulations. TSM emerged successful from that pre-payment edit after securing a better than 90% compliance rate for all claims.

V. TSM CONCURS WITH THE OIG'S RECOMMENDATION THAT IT STRENGTHEN ITS CONTROLS TO ENSURE FULL COMPLIANCE WITH MEDICARE REQUIREMENTS

TSM concurs with this OIG recommendation. Prior to this report being published, TSM implemented the OIG's recommendation that it strengthen its controls to ensure it complies with all Medicare requirements with respect to sleep disorder services. Total Sleep has developed and implemented a Compliance Program and corresponding Code of Conduct. Its adherence to these principles is evident in its high compliance rate during the prepayment review audit.

On behalf of TSM, thank you for the OIG's time and attention to this matter. If you have any questions regarding this correspondence, please contact me at your earliest convenience.

Sincerely,

 Christopher A. Parrella, J.D., CHC, CPC, CPCO
 For the Firm