

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**SLEEP HEALTH CENTER BILLED  
MEDICARE FOR SOME UNALLOWABLE  
SLEEP STUDY SERVICES**

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# *Office of Inspector General*

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## EXECUTIVE SUMMARY

*Sleep Health Center received at least \$486,932 over 3 years for some 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 Sleep Health Center (Sleep Health) 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 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.

Sleep Health is based in Fort Myers, Florida, and it operates two sleep disorder clinics in the State. According to CMS's National Claims History data, Medicare paid Sleep Health approximately \$1.1 million for 1,192 beneficiaries with 3,419 corresponding lines of service for selected polysomnography services provided from January 1, 2010, through December 31, 2012 (audit period).

Our audit covered \$1,087,087 in Medicare payments to Sleep Health for 1,158 beneficiaries with 3,346 corresponding lines of polysomnography service that were potentially at risk for

noncompliance with billing requirements. We reviewed a random sample of 100 beneficiaries with 286 corresponding lines of service with total payments of \$92,613 during our audit period.

## **WHAT WE FOUND**

Sleep Health billed Medicare claims for polysomnography services that did not always comply with Medicare billing requirements. Of the 100 randomly selected beneficiaries, Sleep Health billed Medicare claims for polysomnography services that met Medicare billing requirements for 36 beneficiaries with 137 corresponding lines of service. However, Sleep Health billed Medicare claims for the remaining 64 beneficiaries with 149 corresponding lines of service that did not meet Medicare billing requirements, resulting in net overpayments of \$48,934.

The 64 beneficiaries with 149 corresponding lines of service had the following deficiencies:

- for 63 beneficiaries with 145 corresponding lines of service, Sleep Health did not have the required supporting documentation, resulting in net overpayments totaling \$47,639 and
- for 1 beneficiary with 4 corresponding lines of service, Sleep Health received duplicate Medicare payments for the same polysomnography services for which it previously received payment from the MAC, resulting in overpayments totaling \$1,295.

These errors occurred primarily because Sleep Health did not have adequate controls to ensure that it properly documented polysomnography services billed to Medicare.

On the basis of our sample results, we estimated that Sleep Health received overpayments of at least \$486,932 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 \$141,339 was within the 3-year recovery period and as much as \$345,593 was outside of the 3-year recovery period.

## **WHAT WE RECOMMEND**

We recommend that Sleep Health:

- refund to the Medicare program \$141,339 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 \$345,593 for our audit period, in accordance with the 60-day repayment rule; and
- strengthen controls to ensure full compliance with Medicare requirements.



## **SLEEP HEALTH CENTER COMMENTS AND OUR RESPONSE**

In written comments on our draft report, Sleep Health did not concur with our recommendations or with most of our findings.

Primarily, Sleep Health did not concur that it received overpayments because of incomplete documentation and contended that its MAC implemented requirements for payments beyond the applicable National Coverage Determination and that other MACs did not impose these same requirements.

After reviewing Sleep Health's comments, we maintain that most of our findings and recommendations are correct. However, to provide a conservative estimate, we accepted that the face-to-face clinical evaluations and orders, which Sleep Health's own physicians documented, fulfilled the documentation requirements of the Local Coverage Determination (LCD). Based on our acceptance of the documentation of the evaluations conducted by Sleep Health's own physicians, we revised our findings to disallow 149, instead of 225, lines of service and adjusted our first and second recommendations to reflect the reductions in the total estimated overpayments.

Additionally, CMS has given each MAC authority to develop LCDs for items and services within their jurisdictions. All of our findings are instances in which Sleep Health did not follow the requirements of the LCDs or other applicable criteria.

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## 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,<sup>1</sup> and payments for services without the required supporting documentation.<sup>2</sup> 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.<sup>3</sup> 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 Sleep Health Center (Sleep Health) 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.<sup>4</sup> First Coast Service Options, Inc. (First Coast), was the MAC that processed and paid the Medicare claims submitted by Sleep Health.

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

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

<sup>3</sup> 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 <http://www.justice.gov>. Accessed on May 6, 2015.

<sup>4</sup> 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 overnight<sup>5</sup> 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.<sup>6</sup> 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,<sup>7</sup> which may be freestanding facilities, such as Independent Diagnostic Testing Facilities 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)<sup>8</sup> 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).

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

<sup>6</sup> 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.

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

<sup>8</sup> 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 code<sup>9</sup> -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.<sup>10</sup>

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.

According to Local Coverage Determination (LCD) L29949, 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.<sup>11</sup> The face-to-face clinical evaluation must include, at a minimum: (1) the patient’s sleep history and symptoms; (2) an Epworth sleepiness scale;<sup>12</sup> 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 attending physician’s order and the face-to-face clinical evaluation.

## **Sleep Health Center**

Sleep Health is based in Fort Myers, Florida, and it operates two sleep disorder clinics in the State. According to CMS’s National Claims History (NCH) data, Medicare paid Sleep Health approximately \$1.1 million for 1,192 beneficiaries with 3,419 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 \$1,087,087 in Medicare payments to Sleep Health for 1,158 beneficiaries with 3,346 corresponding lines of polysomnography service that were potentially at risk for noncompliance with billing requirements. We reviewed a random sample of 100 beneficiaries

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

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

<sup>11</sup> 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. First Coast published LCD L29949 for polysomnography and sleep testing by providers in the State of Florida.

<sup>12</sup> The Epworth Sleepiness Scale is a scale intended to measure daytime sleepiness with a very short questionnaire. This questionnaire can help diagnose sleep disorders.

with 286 corresponding lines of service<sup>13</sup> with payments totaling \$92,613 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 Sleep Health 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 provider billing for polysomnography services, and Appendix C for the statistical sampling methodology.

## FINDINGS

Sleep Health billed Medicare claims for polysomnography services that did not always comply with Medicare billing requirements. Of the 100 randomly selected beneficiaries, Sleep Health billed Medicare claims for polysomnography services that met Medicare billing requirements for 36 beneficiaries with 137 corresponding lines of service. However, Sleep Health billed Medicare claims for the remaining 64 beneficiaries with 149 corresponding lines of service that did not meet Medicare billing requirements, resulting in net overpayments of \$48,934.

These errors occurred primarily because Sleep Health did not have adequate controls to ensure that it properly documented polysomnography services billed to Medicare.

On the basis of our sample results, we estimated that Sleep Health received overpayments of at least \$486,932 for the audit period. This overpayment amount includes claim payment dates outside of the 3-year recovery period.<sup>14</sup> Of the estimated overpayments, at least \$141,339 was within the 3-year recovery period and as much as \$345,593 was outside of the 3-year recovery period.

See Appendix D for our sample results and estimates.

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<sup>13</sup> 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.

<sup>14</sup> Section 1870(b) of the Act.

## **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 63 beneficiaries<sup>15</sup> with 143 corresponding lines of service, Sleep Health did not have the required supporting documentation as follows:

- For 27 lines of service, Sleep Health had no documentation for the face-to-face clinical evaluation, the attending physician's orders, or the technician's report.
- For 116 lines of service, Sleep Health included documentation for the 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.

As a result, Sleep Health received net overpayments of \$47,639.

### **Sleep Health Received Duplicate Payments for the Same Services**

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 with four corresponding lines of service, Sleep Health received duplicate Medicare payments for the same polysomnography services for which it previously received payment from the MAC. As a result, Sleep Health received overpayments totaling \$1,295.

## **SLEEP HEALTH DID NOT HAVE ADEQUATE CONTROLS**

These errors occurred primarily because Sleep Health did not have adequate controls to ensure that it properly documented polysomnography services billed to Medicare.

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<sup>15</sup> For 1 of these 63 beneficiaries, Sleep Health billed Medicare 2 additional lines of service with incorrect HCPCS codes that resulted in underpayments totaling \$37.29 for a total of 145 lines billed incorrectly.



## **SLEEP HEALTH RECEIVED THOUSANDS IN OVERPAYMENTS**

As a result of Sleep Health incorrectly billing for 149 of 286 lines of polysomnography services for 64 beneficiaries in our sample, it received net overpayments of \$48,934. On the basis of our sample results, we estimated that Sleep Health received overpayments of at least \$486,932 for the audit period, of which \$141,339 was within the 3-year recovery period and as much as \$345,593 was outside of the 3-year recovery period.

### **RECOMMENDATIONS**

We recommend that Sleep Health:

- refund to the Medicare program \$141,339 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 \$345,593 for our audit period, in accordance with the 60-day repayment rule,<sup>16</sup> and
- strengthen controls to ensure full compliance with Medicare requirements.

### **SLEEP HEALTH CENTER COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

#### **SLEEP HEALTH CENTER COMMENTS**

In written comments on our draft report, Sleep Health disagreed with our recommendations or with most of our findings.

Sleep Health did not concur that it received net overpayments of \$48,934 for services in our audit sample or \$486,932 for the audit period because of incomplete documentation. Sleep Health stated that it had provided the following documentation:

- Regarding the lines of service for which we found Sleep Health had no documentation of a face-to-face evaluation by a treating physician, a Sleep Health physician conducted a face-to-face evaluation before performing “most” of the services.
- Regarding the lines of service for which we found Sleep Health had no order from an attending physician, a Sleep Health physician ordered the testing for “most” of the services.
- Regarding the lines of service for which we found the face-to-face evaluation by the treating physician did not document certain coverage requirements set forth in the LCD

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<sup>16</sup> Section 1128J(d) of the Act and 42 CFR § 401 Subpart D.

(e.g., an Epworth sleepiness scale), a Sleep Health physician documented the requirements in “almost all cases.”

Sleep Health concurred that some claims in the audit sample did not meet all documentation requirements of the LCD; nevertheless, Sleep Health asserted that the documentation obtained prior to any diagnostic testing was sufficient to establish medical necessity for polysomnography testing.

Additionally, Sleep Health contended that its MAC implemented requirements for payment beyond the applicable National Coverage Determination (NCD) and that other MACs did not impose these same requirements. Therefore, Sleep Health stated that we determined that it failed to comply with selected billing requirements solely on the basis of its geographic location.

Finally, Sleep Health did not concur that additional controls were necessary to ensure full compliance with Medicare requirements because the prepayment review that the MAC completed after our audit period confirmed Sleep Health’s compliance.

Sleep Health’s comments are included in their entirety as Appendix E.

## **OFFICE OF INSPECTOR GENERAL RESPONSE**

After reviewing Sleep Health’s comments, we maintain that most of our findings and recommendations are correct.

However, to provide a conservative estimate, we accepted that the face-to-face clinical evaluations and orders, which Sleep Health’s own physicians documented, fulfilled the documentation requirements of the LCD. As previously noted, Sleep Center stated that, to meet the requirements of the LCD to document face-to-face clinical evaluations performed by treating physicians, Sleep Health’s physicians performed additional evaluation and management services<sup>17</sup> that they billed to Medicare. It was outside the scope of our audit to determine whether Medicare payments were appropriate for these evaluation and management services. Additionally, we did not determine whether the beneficiary’s condition warranted the services of more than one physician on an attending basis or whether the individual services each physician provided were reasonable and necessary in accordance with the *Medicare Benefit Policy Manual* (Pub. No. 100-02, chapter 15, section 30) because it was outside of the scope of our audit. Based on our acceptance of the documentation of the evaluations conducted by Sleep Health’s own physicians, we revised our findings to disallow 149, instead of 225, lines of service and adjusted our first and second recommendations to reflect the reductions in the total estimated overpayments.

In response to Sleep Health’s assertions that its MAC implemented requirements for payments beyond the applicable NCD and that other MACs did not impose these same requirements, the *Medicare Program Integrity Manual* (PIM), ch. 13, § 13.1.1, states that NCDs are developed by CMS to describe circumstances for Medicare coverage nationwide for an item or service. The

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<sup>17</sup> Sleep Health billed Medicare for these additional services using related evaluation and management services HCPCS codes.

PIM (ch. 13, § 13.1.2) also states that coverage provisions in interpretative manuals are instructions that are used to further define when and under what circumstances items or services may be covered. Moreover, the Foreword to chapter 1 of the *Medicare National Coverage Determinations Manual* states that coverage-related instructions are located in other manuals, including the *Medicare Benefit Policy Manual* and the *Medicare Claims Processing Manual*.

The PIM (ch. 13, § 13.1.3) states that 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 in communicating guidance to the public and medical communities within their jurisdictions.

MACs develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, and public and provider community comments (PIM, ch. 13, § 13.1.3). Additionally, the use of LCDs helps avoid situations in which claims are paid or denied without a provider having a full understanding of the basis for payment or denial (§ 13.4). LCDs are to be clear, concise, and properly formatted, and should not restrict or conflict with NCDs or coverage provisions in interpretative manuals (§ 13.5).

The NCD for Sleep Testing for Obstructive Sleep Apnea (*Medicare National Coverage Determinations Manual*, Pub. No. 100-03, chapter 1, section 240.4.1) only identifies the type of sleep tests that Medicare will cover and states that Medicare covers these tests for beneficiaries who have signs and symptoms indicative of OSA. The *Medicare Benefit Policy Manual* (ch. 15, § 70) states that the need for diagnostic sleep testing must be confirmed by medical evidence, e.g., physician examinations and laboratory tests. Rather than restrict these requirements, the LCD specifically explains what signs and symptoms and medical evidence are required to confirm the need for testing.

Additionally, CMS has given each MAC authority to develop LCDs for items and services within their jurisdictions. Each MAC has the authority to specify under what clinical circumstances an item or service is reasonable and necessary under 1862(a)(1)(A) of the Act. Moreover, the LCD lists “Sources of Information and Basis for Decision” and mentions several Advisory Committee meetings regarding the development of the LCD.

We listed the requirements of the LCD both in the report above and in Appendix B below. All of our findings are instances in which Sleep Health did not follow the requirements of the LCDs or other applicable criteria.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered \$1,087,087 in Medicare payments to Sleep Health for 1,158 beneficiaries with 3,346 corresponding lines of polysomnography services that were potentially at risk for noncompliance with billing requirements. We reviewed a random sample of 100 beneficiaries with 286 corresponding lines of service with total payments of \$92,613 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 Sleep Health because our objective did not require us to do so. Rather, we limited our review to Sleep Health'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 Sleep Health during September of 2014.

### METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted Sleep Health'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 1,158 Medicare beneficiaries with 3,346 corresponding lines of service billed for HCPCS codes 95810 or 95811 during the audit period;
- selected a random sample of 100 beneficiaries (286 lines of service) totaling \$92,613 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 Sleep Health 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 Sleep Health (Appendix D);
- used the results of the sample to estimate the Medicare overpayments to Sleep Health (Appendix D) that are within the 3-year recovery period; and
- discussed the results of our review with Sleep Health 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 indicates that, ordinarily, a single polysomnography session is sufficient either to diagnose OSA or to calibrate PAP therapy. If a provider claims more than one polysomnography diagnostic testing session, the LCD requires persuasive medical evidence justifying the medical necessity for the additional tests. Further, the LCD does not consider routine use of more than one polysomnography session to calibrate PAP therapy as reasonable and necessary.

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: STATISTICAL SAMPLING METHODOLOGY**

### **POPULATION**

The population consisted of lines of service paid to Sleep Health 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 3,419 lines totaling \$1,103,632.

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 9, 2014, and
- all beneficiaries with total payments less than \$400 after grouping all remaining lines by beneficiary.

This resulted in a sampling frame of 1,158 Medicare beneficiaries with 3,346 corresponding lines of polysomnography services totaling \$1,087,087 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 1,158. 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 Sleep Health during the audit period and the amount of the overpayments paid within the 3-year recovery period. We also calculated a non-statistical estimate of the overpayment amount outside 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 Results**

<b>Frame Size</b>	<b>Value of Frame</b>	<b>Sample Size</b>	<b>Value of Sample</b>	<b>Number of Overpayments</b>	<b>Value of Overpayments</b>
1,158	\$1,087,087	100	\$92,613	64	\$48,934

**ESTIMATES**

**Table 2: Estimated Value of Overpayments**

*(Limits Calculated for a 90-Percent Confidence Interval)*

Point estimate	\$566,650
Lower limit	486,932
Upper limit	646,368

**MEDICARE OVERPAYMENTS WITHIN THE 3-YEAR RECOVERY PERIOD**

**Table 3: Sample Results**

<b>Frame Size</b>	<b>Value of Frame</b>	<b>Sample Size</b>	<b>Value of Sample</b>	<b>Number of Overpayments</b>	<b>Value of Overpayments</b>
1,158	\$1,087,087	100	\$92,613	26	\$17,188

**ESTIMATES**

**Table 4: Estimated Value of Overpayments**

*(Limits Calculated for a 90-Percent Confidence Interval)*

Point estimate	\$199,036
Lower limit	141,339
Upper limit	256,734



# Sleep Health Center

*Medical Director*  
Julio Conrado, M.D., F.C.C.P.

*Diagnosis & Treatment of Sleep Related Pulmonary & Neurological Disorders*

September 1, 2015

RE: Report Number: A-04-14-07053

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Regional Inspector General for Audit Services  
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## **Comments of Vision Health Care Group, Inc. d/b/a Sleep Health Center**

Vision Health Care Group, Inc. d/b/a Sleep Health Center (“SHC”) hereby submits its response and written comments to the June 2015 HHS/OIG draft report titled “Sleep Health Center Billed Medicare for Unallowable Sleep Study Services” (the “Draft Report”).

1. SHC does not concur with the Draft Report’s conclusion that it received net overpayments of \$71,450 due to incomplete documentation.
2. SHC responds that it did in fact maintain complete documentation for many of the claims in the sample that were flagged as unallowable by the auditors. However, SHC concurs that some claims in the audit sample did not meet all the documentation requirements of the Local Coverage Determination (“LCD”) issued by the MAC, First Coast Service Options, Inc. (“First Coast”), but contends that the documentation obtained and maintained by SHC prior to any diagnostic testing was sufficient to establish medical necessity for polysomnography testing (“PSG”).
3. SHC concurs that it received \$1,295 in error on account of the inadvertent resubmission of a single claim. SHC will work with the MAC to repay those funds.
4. SHC does not concur that it received overpayments of \$182,818 within the three year recovery period or that it received \$767,003 in overpayments for the audit period and has not identified claims outside the three year period that were overpayments.
5. SHC does not concur that additional controls are necessary to ensure full compliance with Medicare requirements, as SHC has been in full compliance with First Coast’s



interpretation of its LCD 29949<sup>1</sup> (and its updates) since first learning that First Coast considered SHC's documentation to be incomplete or insufficient—even though SHC continues to believe that First Coast's application of the LCD goes beyond national coverage requirements as well as the requirements of the LCD itself. SHC's compliance was confirmed by a prepayment review by First Coast in 2013 and early 2014 that determined that SHC's error rate was within an acceptable range.

6. SHC does not concur that additional repayment is appropriate. As the Draft Report makes clear, the OIG audit did not examine the touchstone question of whether the diagnostic tests performed by SHC were medically necessary. No review by First Coast or any other contractor has raised any significant question about the medical necessity for services provided by SHC under HCPCS Codes 95810 or 95811. The efficacy of SHC's ongoing efforts to ensure that the PSG tests it conducts are medically necessary is borne out by the results of those tests. Between 2010 and 2012, SHC conducted approximately 2,557 baseline PSG studies. Of those studies, 2,366 – or 92.5% – were positive for a diagnosis of obstructive sleep apnea (“OSA”). It cannot be said that there is a pattern of abuse or that the documentation issues identified in the Draft Report resulted in a significant error rate or overpayment, or suggested any pattern of fraud or abuse. Under the Medicare Integrity Manual, “provider education” was the proper remedial measure—especially where there are no questions about medical necessity. Compliance issues unique to the MAC should be handled in this fashion rather than by recoupment outside of the CMS claims review and appeal process. Here, SHC fully complied with First Coast's interpretation of the LCD following provider education, much of which was at the initiation of SHC.
7. As is set forth more fully below, SHC fully complied with the applicable National Coverage Determination requirements. The only issues the OIG found (with the exception of a single claim erroneously submitted twice) arise from First Coast's LCD guidelines. First Coast has imposed requirements for payment beyond the applicable National Coverage Determination. Those requirements are not imposed by other MACs. Thus, the OIG's determination that SHC failed to comply with selected billing requirements turns solely on the geographic location of SHC. In 49 other states, SHC would have been fully compliant with coverage requirements.

### **Medicare Coverage of Polysomnography Services**

Effective July 10, 2009, CMS issued a National Coverage Determination (“NCD”) mandating that all carriers (“MACs”), FIs, QIOs, QICs, the Medicare appeals council, and ALJs cover testing for polysomnography services. *See* Publication 100-3, Section 240.4.1. The NCD stated that effective March 3, 2009, Medicare would cover Type I PSG “when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.” Carriers were instructed to post a provider education article on their websites and to include information about the NCD in a listserv message within one week

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<sup>1</sup> References to LCD 29949 or the “First Coast LCD” in these Comments encompass related First Coast LCDs regarding coverage of diagnostic testing for sleep disorders, including L29905, L29907, and L29951.



of its availability. That letter contained the same language as the NCD and no additional requirements for coverage. See MLN Matters No. MM6534.

The Medicare Policy Benefit Manual was amended to include coverage of PSG where “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.” Diagnostic testing is covered 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. Diagnostic testing routinely performed in sleep disorder clinics 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 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.

See Chapter 15, section 70, of the *Medicare Benefit Policy Manual*, Pub. No.100-02.

First Coast issued an LCD for Polysomnography and Sleep Testing, effective June 30, 2009. See L29905. That LCD imposed the following additional restrictions on coverage under the NCD:

Prior to any sleep testing, the patient must have a face-to-face clinical evaluation by the treating physician which must at minimum include:

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.

First Coast’s additional restrictions do not appear in the Medicare National Coverage Determinations Manual or the Medicare Benefit Policy Manual. A review of the other current MAC LCDs covering PSG reveals that *only First Coast* has issued any LCD with these additional coverage restrictions. All other MACs covering the 49 states other than Florida *do not* appear to have these specific restrictions.<sup>2</sup>

<sup>2</sup> See L31718 (Palmetto GBA); L24350, L33483 and L33663 (Noridian Healthcare Solutions); L31082 (Wisconsin Physicians Service Insurance); L2753 and L32711 (Novitas Solutions, Inc.); and L31846 (CGS Administrators).



The scientific literature indicates that any of the additional three requirements imposed by First Coast's LCD can yield information that is useful in determining whether PSG is necessary to confirm or exclude a diagnosis of OSA. The NCD contains a review of studies regarding the diagnostic efficacy of the three types of information required by the LCD, but First Coast has not provided any guidance or standards as to how those measures and evaluations implicate medical necessity for PSG testing.

### **The 2013 OIG Audit of Billing for Polysomnography Services**

In 2013, the OIG issued a report titled *Questionable Billing for Polysomnography Services* (October 2013 OEI-05-12-00340). The "2013 Report" noted that

Medicare paid nearly \$17 million for polysomnography services that did not meet one or more of three Medicare requirements. Payments for services with inappropriate diagnosis codes composed a majority of these payments. Eighty-five percent of claims with inappropriate diagnosis codes came from hospital outpatient departments. Inappropriate payments might have been averted with effective electronic edits that automatically deny claims or suspend them for manual review.

Further, 180 providers exhibited patterns of questionable billing for polysomnography services. Most of these providers submitted an unusually high percentage of claims for beneficiaries with another polysomnography claim on the same day, which is questionable because beneficiaries can undergo only one polysomnography service in a day, as the process requires an overnight stay.

The OIG identified three measures of "questionable billing" – inappropriate diagnosis codes, same day duplicate claims, and use of an invalid NPI – that it used to estimate the amount of inappropriate payments. Despite finding only a 3.41% error rate, generated mostly by 180 providers (3% of the providers in the sample)<sup>3</sup>, the 2013 Report generated additional reviews of MACs and providers, including First Coast and SHC. However, SHC is not a hospital outpatient center and there is no suggestion that SHC used inappropriate diagnosis codes, submitted a high percentage of claims for multiple PSG tests on the same day, or used invalid NPI numbers.

The 2013 Report asserted that

An in-person evaluation is required to determine whether polysomnography services are warranted; according to sleep medicine professionals, polysomnography should be performed within a year after the in-person evaluation. Given this, these providers may be performing polysomnography services for which they do not have valid orders, and that therefore are not medically necessary."

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<sup>3</sup> 85% of the claims with inappropriate diagnosis codes came from hospital based providers, which made up only 53% of providers audited.

(p. 19). As is more fully detailed below, in-person evaluations were conducted prior to testing by SHC and SHC had valid physician orders either from referring physicians or from the SHC physician who performed an in-person evaluation and reviewed the data required by the First Coast LCD.

### **The 2015 OIG Audit of First Coast's Payment of Claims for Polysomnography Services**

In May 2015, the OIG issued a report titled *FIRST COAST SERVICE OPTIONS, INC., PAID SOME UNALLOWABLE SLEEP STUDY CLAIMS* (A-04-13-07039). The "First Coast Report" stated:

[P]rior OIG survey work of polysomnography services found that First Coast Service Options, Inc. (First Coast), the MAC for Jurisdiction 9 [Florida, Puerto Rico, and the U.S. Virgin Islands], paid providers for services that did not comply with Medicare reimbursement requirements. The results of the survey; increased Medicare spending on polysomnography services; and growing concerns about fraud, waste, and abuse prompted us to conduct this review.

The objective of this review was to determine whether payments that First Coast made to providers for polysomnography services were in accordance with Medicare reimbursement requirements.

See p. 4. The OIG found that during the audit period (January 1, 2011 through September 30, 2012), First Coast paid inappropriate claims for 61 of 100 sampled beneficiaries, resulting in estimated overpayments of \$15.6 million. For all but two of the 61 beneficiaries, the provider did not have sufficient documentation. The OIG opined that:

These errors occurred because First Coast did not have adequate claim-processing edits in place to prevent the incorrect payment of Medicare claims **or because providers did not understand the Medicare requirements when billing for the services**. Furthermore, the Common Working File, the Fiscal Intermediary Standard System, and the Multi-Carrier System had insufficient edits in place to prevent or detect the overpayments.

See page 5 (emphasis added). The "Medicare requirements" referenced above appear to be exclusively the additional restrictions imposed by the First Coast LCD.

The OIG recommended that First Coast (1) recover the identified overpayments for the 61 beneficiaries, (2) strengthen internal controls, and (3) use the results of the First Coast Report in provider education activities. Notwithstanding recommendation three and its own recognition that providers in First Coast's jurisdiction may not have understood the requirement of the LCD, the OIG almost immediately posted the SHC Draft Report recommending that SHC repay at least \$767,000 to the MAC—without considering that medical necessity was demonstrated in over 90% of the subject claims, not including other claims where PSG testing was necessary to exclude OSA as a diagnosis for patient conditions.



## First Coast LCD 22905

As noted above, the coverage requirements for PSG are that 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. Diagnostic testing routinely performed in sleep disorder clinics 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 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.

See Chapter 15, section 70, of the *Medicare Benefit Policy Manual*, Pub. No.100-02.

These requirements, along with use of the appropriate diagnostic codes, comprise the substance of all LCDs, with the singular exception of First Coast's LCD.<sup>4</sup> SHC notes that the First Coast Report states in Appendix B that Local Coverage Determinations by the MACs specify additional coverage requirements, such as:

[B]efore 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.

It appears that only First Coast's LCD includes these additional requirements. The relevant NCD (publication 100-3, Section 240.4.1) states only that "Type I PSG is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility." The provider education letter that CMS required the MACs to post and publicize did not contain any requirements beyond those in the NCD.

The First Coast LCD restricts the coverage afforded by the NCD and the Medicare Benefit Policy Manual beyond any restriction imposed in the other 49 states by requiring a face-to-face

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<sup>4</sup> The 2013 Report noted that only 9 of the 15 MAC jurisdictions issued LCDs regarding PSG performed by non-hospital providers.

clinical evaluation “by the treating physician” and requiring specific clinical measures that may or may not be indicative of OSA<sup>5</sup>. As noted above, the Medicare Benefit Policy Manual only requires “the need for diagnostic testing [be] confirmed by medical evidence, e.g., physician examinations and laboratory tests” and that the sleep center maintain copies of orders from the “attending” physician. It does not require that the need for testing be confirmed only in the course of a face-to-face evaluation with the *referring* physician.

This raises questions as to whether First Coast exceeded its authority by imposing the additional restrictions in the LCD that are inconsistent with national policy.

According to the Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations:

The LCDs specify under what clinical circumstances an item or service is considered to be reasonable and necessary. *They are administrative and educational tools to assist providers in submitting correct claims for payment.* Contractors publish LCDs to *provide guidance* to the public and medical community within their jurisdictions. Contractors develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community.

The contractor should adopt LCDs that have been developed individually or *collaboratively with other contractors*. The contractor shall ensure that all LCDs are *consistent with all statutes, rulings, regulations, and national coverage, payment and coding policies*.

See section 13.1.3 - Local Coverage Determinations (LCDs) (emphasis supplied). Additionally:

The LCD shall be clear, concise, properly formatted and *not restrict or conflict with NCDs or coverage provisions in interpretive manuals*. If an NCD or coverage provision in an interpretive manual states that a given item is “covered for diagnoses/conditions A, B and C,” contractors should not use that as a basis to develop LCD to cover only “diagnoses/conditions A, B and C.”

See section 13.5 - Content of an LCD (emphasis supplied). By imposing additional requirements not contained in the NCD, First Coast’s LCD improperly restricts the NCD.

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<sup>5</sup> A “treating physician” is a physician, as defined in §1861(r) of the Social Security Act (the Act), who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results of a diagnostic test in the management of the beneficiary’s specific medical problem. Medicare Benefit Policy Manual, Chapt.15, 80.6.1.



## SHC's Efforts to Comply with the First Coast LCD

While there were some instances where the documentation of one or two elements required by the LCD might have been missing from a claim file when the audit was conducted, it is SHC's position that its policies, practices, and controls were consistent with Medicare's requirements and a good faith interpretation of the LCD.

Following First Coast's issuance of LCD 29949 in 2009, SHC obtained accreditation by the American Academy of Sleep Medicine and ensured that all of its professionals were appropriately credentialed. SHC promptly began educating referring physicians on the documentation requirements contained in the LCD and began using a referral form that sought specific documentation of the factors indicating that the patient might have OSA, including height, weight, BMI, neck circumference, and an Epworth Sleepiness Scale Score, as well as a detailed section for recording specific medical history. SHC's form advised referring physicians as follows:

To order Baseline Polysomnography or Home Sleep Testing (HST) directly, we must receive clinical evaluation and documentation which includes the above and a focused cardiopulmonary and upper airway evaluation. If documentation is not received, the patient will be scheduled as soon as possible for a consult prior to testing to ensure/document Medical Necessity.

Consistent with this policy, it was SHC's practice to gather missing information not supplied by the referring physician prior to any testing and to perform clinical evaluations prior to testing when such evaluations were not sufficiently documented with the referral. In such cases, SHC, in effect, became both the referring and attending physician and made an independent determination of medical necessity prior to the PSG testing.

In some cases, an SHC physician actually ordered the test rather than the original referring physician. In such cases, a referral for SHC to evaluate the patient is not treated by SHC as the effective "order" for diagnostic testing. Where the referring physician was not a qualified sleep specialist, SHC always required a consult with its own physician to review medical necessity and perform the evaluations required by the LCD. In both scenarios, "the need for diagnostic testing [was] confirmed by medical evidence, e.g., physician examinations and laboratory tests" as required for coverage under the Medicare Benefit Policy Manual. *See* Chapter 15, section 70.

The Medicare Benefit Policy Manual does not restrict confirming medical evidence to the elements required by the First Coast LCD, nor does it disallow claims where (1) confirmation of the need for testing is made through an examination by a consulting physician at the sleep center or (2) where appropriate laboratory tests are conducted by the sleep center prior to diagnostic testing. Further, the First Coast LCD does not define the term "*treating physician*" and just prior to using that term the LCD states that "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..." (emphasis added). Thus, under the LCD, where an SHC physician orders the diagnostic testing rather than the referring physician, the SHC physician acts as a "treating physician." When the SHC physician evaluates the patient's need for diagnostic sleep testing, including the review of laboratory tests and measures by SHC and/or the referring physician, the



PSG should be covered under the NCD, the Policy Benefit Manual, and the LCD. The Draft Report shows that the auditors failed to take this into account, resulting in the erroneous designation of a majority of the claims in the sample as improperly paid.

As noted above, SHC's compliance with the NCD, LCD, and Benefit Policy Manual was highly effective. Of the PSG tests conducted between 2010 and 2012, 92.5% yielded a positive diagnosis of OSA. Further, that does not mean that the remaining 7.5% were medically unnecessary, as the exclusion of OSA is medically necessary in the course of treating some patients. It simply cannot be said that SHC improperly billed for medically unnecessary tests at any significant level.

Since first learning in 2013 that First Coast did not consider SHC to be compliant with its LCD, SHC made good faith attempts to obtain clarification, guidance, and education from the MAC, which was not always forthcoming. Since that time, SHC has been in full compliance with First Coast's more restrictive interpretation of the LCD. Notwithstanding SHC's disagreement with First Coast's restrictive interpretation of the NCD, SHC has worked diligently with First Coast to comply with that carrier's unique requirements.

For example, First Coast took the position that an additional face-to-face evaluation and additional measurements had to be taken after a positive PSG before a CPAP titration study could be covered. That interpretation of the LCD is unreasonable in that it requires repetition of an evaluation that was the threshold for ordering the PSG study. Such a requirement is particularly unworkable where a split-night PSG/CPAP titration study is appropriate. As a result, SHC can no longer offer Medicare the cost savings of such a procedure. The SHC physician (who is the referring, treating and attending physician for purposes of a titration study following an SHC administered PSG) now conducts a second in-person evaluation of the patient prior to the titration study. This practice generates additional cost to Medicare and cost and inconvenience to the patient and provider. SHC does not know whether other MACs are imposing similar restrictions on titration studies.

To ensure that there is no question about compliance with the First Coast LCD, SHC now also independently performs an in-person evaluation of each patient prior to testing, including a face-to-face encounter with an SHC physician. In the course of that process, SHC also independently collects all information required by the LCD prior to testing, even when the referring physician has provided evidence of medical necessity for PSG testing. The PSG test is ordered by the SHC physician or by an ARNP at the SHC physician's direction. Thus, the SHC physician is the "treating physician" under the LCD and the Medicare Benefit Policy Manual, and the documentation required by the LCD is in the file prior to testing.

### **Analysis of OIG Claim Review**

As noted above, SHC does not concur with the amounts of overpayment estimated in the Draft Report. There is a fundamental misunderstanding underlying the negative review of most of the claims in the audit sample—that only a "referring physician" can perform a qualifying in-person evaluation or collect the documentation required by the LCD. As explained above, where SHC acted as a "treating physician" by performing its own in-person evaluation and documenting the information required by the LCD prior to testing, the requirements for coverage were met. This error was a factor in almost every disallowed claim in the sample.



The following are general categories of claims in the audit that SHC believes were erroneously found to be overpayments:

- 1. Claims disallowed because “referring physician” did not include ESS, BMI, neck circumference, sleep history, and/or symptoms or for incomplete face-to-face clinical evaluation:** The files for almost all these claims included all information required by the LCD prior to testing. In almost all cases where the referring physician did not submit all the information required by the LCD, SHC performed an independent evaluation and gathered that information prior to testing. Some files included patient height and weight but did not include the corresponding calculation of BMI. The OIG reviewers accepted this in lieu of BMI for some claims but not for others. If those claims are treated as having complied with the substance of the BMI requirement, then most of the claims in the audit sample contained all information required by the LCD prior to testing.
- 2. Missing face-to-face clinical evaluation from referring physician:** In all cases where the referring physician did not submit all the information required by the LCD, SHC performed an independent evaluation and gathered that information prior to testing (except in a few instances where documentation of a single element was inadvertently not recorded). In most cases, this included a face-to-face encounter with an SHC physician in addition to the encounter with the referring physician. For most claims where the OIG reviewers determined that the “referring physician” did not document a face-to-face encounter, there was a face-to-face physician encounter with the SHC physician who actually ordered the PSG prior to the study. There were a few claims where the ARNP completing the documentation failed to document the physician’s encounter with the patient even though it occurred.
- 3. Missing order from referring physician:** For most, if not all, of these claims, SHC ordered the diagnostic testing, not the referring physician.

SHC concurs that a limited number of claims did not have documentation of all the information required by the LCD. SHC will address these issues with First Coast.

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Respectfully submitted,

/Cynthia L. Bledsoe/

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