

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**International Institute of  
Sleep, Inc., Billed Medicare  
for Unallowable Sleep Study  
Services**

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# *Office of Inspector General*

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## EXECUTIVE SUMMARY

*International Institute of Sleep, 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; especially a 39 percent increase in Medicare spending for polysomnography services from 2005 through 2011 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 International Institute of Sleep, Inc. (the Institute), 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.

The Institute is an IDTF based in Deerfield Beach, Florida, that operates three sleep disorder clinics in the State. According to CMS's National Claims History data, Medicare paid the Institute approximately \$1.2 million for 1,430 beneficiaries with 1,951 corresponding lines of service for selected polysomnography services provided from January 1, 2010, through December 31, 2012 (audit period).

Our audit covered \$1,136,592 in Medicare payments to the Institute for 1,383 beneficiaries with 1,888 corresponding lines of polysomnography service that were potentially at risk for noncompliance with billing requirements. We reviewed a random sample of 100 beneficiaries with 130 corresponding lines of service with total payments of \$78,441 during our audit period.

## **WHAT WE FOUND**

The Institute billed Medicare for polysomnography services that did not comply with Medicare billing requirements for all 100 randomly selected beneficiaries with 130 corresponding lines of service, resulting in overpayments of \$78,441.

These errors occurred primarily because the Institute 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 the Institute received overpayments of at least \$1,013,882 for the audit period. This overpayment amount includes claim payment dates outside of the 3-year recovery period. Of the estimated overpayments, at least \$333,905 was within the 3-year recovery period and as much as \$679,977 was outside of the 3-year recovery period.

## **WHAT WE RECOMMEND**

We recommend that the Institute:

- refund to the Medicare program \$333,905 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 \$679,977 for our audit period, in accordance with the 60-day repayment rule; and
- strengthen controls to ensure full compliance with Medicare requirements.

## **THE INSTITUTE COMMENTS AND OUR RESPONSE**

In written comments on our draft report, the Institute did not agree with our first and second recommendations. In regard to our third recommendation, the Institute described steps it has taken to strengthen controls to comply with Medicare requirements.

Primarily, the Institute stated that its MAC should disregard the Local Coverage Determination requirements because they exceed national standards and are arbitrary and that it billed polysomnography services correctly.

After reviewing the Institute's comments, we maintain that our findings and recommendations are correct.

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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; especially a 39 percent increase in Medicare spending for polysomnography services from 2005 through 2011 and growing concerns about fraud, waste, and abuse; prompted us to conduct additional reviews.

### OBJECTIVE

Our objective was to determine whether Medicare claims that International Institute of Sleep, Inc. (the Institute), 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 the Institute.

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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: [www.justice.gov](http://www.justice.gov). Accessed on June 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 (IDTF) or provider-owned laboratories, or facilities affiliated with a hospital.

## **Medicare Coverage of Polysomnography Services**

Medicare 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. Providers must use standardized codes, called Healthcare Common Procedure Coding System (HCPCS)<sup>8</sup> codes, to describe the polysomnography service.

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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.



All polysomnography services consist of two components: the administration of the test (technical component) and the provider's interpretation of the test (professional component). Providers 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.

Before 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;<sup>11</sup> and (3) a physical examination that documents body mass index, neck circumference, and a focused cardiopulmonary and upper airway evaluation. The Local Coverage Determination (LCD)<sup>12</sup> requires that the sleep study provider maintain a record of the physician's order and face-to-face clinical evaluation.

### **International Institute of Sleep, Inc.**

The Institute is an IDTF based in Deerfield Beach, Florida, that operates three sleep disorder clinics in the State. According to CMS's National Claims History (NCH) data, Medicare paid the Institute approximately \$1.2 million for 1,430 beneficiaries with 1,951 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 \$1,136,592 in Medicare payments to the Institute for 1,383 beneficiaries with 1,888 corresponding lines of polysomnography service that were potentially at risk for

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

<sup>12</sup> 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.

noncompliance with billing requirements. We reviewed a random sample of 100 beneficiaries with 130 corresponding lines of service<sup>13</sup> with payments of \$78,441 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 the Institute 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

The Institute billed Medicare for polysomnography services that did not comply with Medicare billing requirements for all 100 randomly selected beneficiaries with 130 corresponding lines of service, resulting in overpayments of \$78,441.

These errors occurred primarily because the Institute 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 the Institute received overpayments of at least \$1,013,882 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 \$333,905 was within the 3-year recovery period and as much as \$679,977 was outside of the 3-year recovery period.

See Appendix D for our sample results and estimates.

## INCOMPLETE OR MISSING DOCUMENTATION FOR POLYSOMNOGRAPHY SERVICES

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

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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.

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, before 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 all 100 beneficiaries with 130 corresponding lines of service in our sample, the Institute did not have the required supporting documentation as follows:

- For 50 lines of service,<sup>15</sup> the Institute had no documentation for the face-to-face clinical evaluation, attending physician's orders, technician's report, or interpretation report.
- For 80 lines of service, the Institute 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, the Institute received overpayments of \$78,441.

### **THE INSTITUTE DID NOT HAVE ADEQUATE CONTROLS**

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

### **THE INSTITUTE RECEIVED AT LEAST \$1 MILLION IN OVERPAYMENTS**

As a result of the Institute incorrectly billing for 130 lines of polysomnography services for 100 beneficiaries in our sample, it received overpayments of \$78,441. On the basis of our sample results, we estimated that the Institute received overpayments of at least \$1,013,882 for the audit period, of which \$333,905 was within the 3-year recovery period and as much as \$679,977 was outside of the 3-year recovery period.

### **RECOMMENDATIONS**

We recommend that the Institute:

- refund to the Medicare program \$333,905 in estimated overpayments for claims that it incorrectly billed that are within the 3-year recovery period;

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<sup>15</sup> For 20 of these 50 lines of service, the Institute also included incomplete documentation for the face-to-face evaluation.

- work with the MAC to return overpayments outside of the 3-year recovery period, which we estimate to be as much as \$679,977 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.

## **THE INSTITUTE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

### **THE INSTITUTE COMMENTS**

In written comments on our draft report, the Institute did not agree with our first or second recommendations. In regard to our third recommendation, the Institute described steps it has taken to strengthen controls to comply with Medicare requirements.

The Institute stated that the LCD issued by its MAC includes requirements that exceed the requirements of the National Coverage Determination (NCD) for Sleep Testing for OSA, are inconsistent with the LCDs of all other MACs, and contain documentation requirements that are arbitrary and do not assist in determining whether a sleep test is reasonable and necessary. Therefore, the Institute contended that its MAC should disregard some of the requirements of the LCD.

The Institute also maintained that it billed correctly for polysomnography services. The Institute agreed that the LCD requires a patient to have a face-to-face clinical evaluation before any sleep testing. However, it contended that, although the LCD requires the sleep disorder clinic to maintain a record of the attending physician's order for the test, it does not require the clinic to maintain a record of the physician's face-to-face evaluation. Additionally, the absence of a face-to-face evaluation from the medical record included with the claim does not mean that the physician failed to perform the evaluation. The Institute contends that only a review of the physician's file for the patient could accurately reveal whether the physician conducted the required face-to-face evaluation.

Furthermore, the Institute maintained that the LCD requires that the physician perform an evaluation, but it does not require that the physician record the clinical elements such as the patient's sleep history and symptoms, an Epworth sleepiness scale, or a physical examination that documents body mass index, neck circumference, and cardiopulmonary and upper airway condition.

Finally, the Institute stated that the LCD does not require a separate face-to-face evaluation before the performance of a PAP titration. It also stated that the OIG misinterpreted the LCD by requiring a face-to-face evaluation when the Institute performed a PAP titration on a different date than the diagnostic polysomnography.

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

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

## OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the Institute's comments, we maintain that all of our findings and recommendations are valid. Regarding the Institute's assertion that the LCD exceeds the requirements of the NCD, to the extent the Institute may be asserting that local coverage determinations relate to only national coverage determinations, we note that local coverage determinations relate to coverage requirements set forth in the Act, regulations, manual provisions, or NCDs, not just NCDs. Insofar as the Institute asserts that the LCD exceeds controlling national requirements, we note that the LCD is consistent with the NCD and relevant manual provisions.

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 *PIM* (ch. 13, § 13.1.2) also states that coverage provisions in interpretive 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) provides 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 interpretive manuals (§ 13.5).

The NCD for Sleep Testing for OSA (*Medicare National Coverage Determinations Manual*, ch. 1, § 240.4.1) identifies the type of sleep tests that Medicare will cover and states that these tests are covered 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.

In response to the Institute's assertions that the LCD is inconsistent with the LCDs of all other MACs and that it contains requirements that are arbitrary and do not assist in determining whether a sleep test is reasonable and necessary, 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 several “Sources of Information and Basis for Decision” and mentions several Advisory Committee meetings regarding the development of the LCD.

Regarding the Institute’s comment that the LCD does not require the clinic to maintain a record of the physician’s face-to-face evaluation, section 1833(e) of 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. 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)).

The Institute contested that the LCD does not require that the physician record the clinical elements in the face-to-face clinical evaluation. The LCD specifically states that the face-to-face clinical evaluation must include these elements (LCD L29949, p. 3, par. 8).

In response to the Institute’s assertion that the LCD does not require a separate face-to-face evaluation before the performance of a PAP titration, the LCD clearly states that, before 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. The face-to-face clinical evaluation must include clinical elements used to determine whether polysomnography testing is reasonable and necessary (LCD L29949, p. 3, par. 8).

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

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered \$1,136,592 in Medicare payments to the Institute for 1,383 beneficiaries with 1,888 corresponding lines of polysomnography services that were potentially at risk for noncompliance with billing requirements. We reviewed a random sample of 100 beneficiaries with 130 corresponding lines of service with total payments totaling \$78,441 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 the Institute because our objective did not require us to do so. Rather, we limited our review to the Institute'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 the Institute during August of 2014.

### METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Institute'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 1,383 Medicare beneficiaries with 1,888 corresponding lines of service billed for HCPCS codes 95810 or 95811 during the audit period;
- selected a random sample of 100 beneficiaries (130 lines of service) with total payments of \$78,441 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 the Institute 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 the Institute (Appendix D);
- used the results of the sample to estimate the Medicare overpayments to the Institute (Appendix D) that are within the 3-year recovery period; and
- discussed the results of our review with Institute 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, i.e., 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, LCD L29949, published by the MAC for polysomnography and sleep testing, specifies additional coverage requirements. For example, among other requirements,

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;
2. Epworth sleepiness scale; and
3. Physical examination that documents body mass index, neck circumference and a focused cardiopulmonary and upper airway evaluation.

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 the Institute 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 1,951 lines totaling \$1,161,077.

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 1,383 Medicare beneficiaries with 1,888 corresponding lines of polysomnography services totaling \$1,136,592 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 1,383. 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 the Institute 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 Details and 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>
1,383	\$1,136,592	100	\$78,441	100	\$78,441

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

Point estimate	\$1,084,842
Lower limit	1,013,882
Upper limit	1,155,802

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

**Table 3: Sample Details and 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>
1,383	\$1,136,592	100	\$78,441	42	\$30,716

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

Point estimate	\$424,803
Lower limit	333,905
Upper limit	515,701

## APPENDIX E: THE INSTITUTE COMMENTS

# Holland & Knight

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October 2, 2015

*Via E-mail [Lori.Pilcher@oig.hhs.gov]  
Via First Class Mail*

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

Re: International Institute of Sleep, Inc., Billed Medicare for Unallowable Sleep Study Services, Report Number A-04-14-07052

Dear Inspector General Pilcher:

Holland & Knight has been retained by International Institute of Sleep, Inc. (“IIS”) to represent it in connection with its response to the draft report issued by the U.S. Department of Health and Human Services, Office of Inspector General (“OIG”) entitled “*International Institute of Sleep, Inc., Billed Medicare for Unallowable Sleep Study Services*” (Report Number A-04-14-07052) (the “Draft Report”).

In the Draft Report, the OIG recommends that IIS:

1. refund to the Medicare Administrative Contractor (“MAC”) \$333,905 in estimated overpayments for claims that it incorrectly billed that are within the 3-year recovery period,
2. work with the MAC to return overpayments outside of the 3-year recovery period, and
3. strengthen controls to ensure full compliance with Medicare requirements.

IIS welcomes the opportunity to comment on the Draft Report. For the reasons outlined below, IIS does not concur with the Draft Report’s first and second recommendations, both relating to the return of overpayments. Specifically, the local coverage determination requirements should be disregarded because they exceed national standards and are arbitrary, and the services were billed correctly. IIS concurs with the third recommendation and has already taken several steps to improve controls.

Anchorage | Atlanta | Austin | Boston | Chicago | Dallas | Denver | Fort Lauderdale | Houston | Jacksonville | Lakeland | Los Angeles  
Miami | New York | Northern Virginia | Orlando | Portland | San Francisco | Tallahassee | Tampa | Washington, D.C. | West Palm Beach

## I. General Comments

IIS is an Independent Diagnostic Testing Facility that provides polysomnography services in its three sleep disorder clinics in the State of Florida. Approximately 20% of its patients are Medicare beneficiaries. In establishing Medicare coverage for polysomnography in March 1990, the Centers for Medicare & Medicaid Services (“CMS”) found that the use of such sleep studies demonstrates improved health outcomes in Medicare beneficiaries who have obstructive sleep apnea (“OSA”) and receive the appropriate treatment. For more than a decade, IIS has treated and helped tens of thousands of patients suffering from sleep disorders, including OSA.

IIS and its President and CEO, Mr. Glenn Becker, are committed to excellence in patient care and have made it a priority to be compliant with federal and state regulations, while also following the best clinical practices and meeting national quality standards. IIS is accredited by the Joint Commission in the both the Ambulatory Care and Home Care Programs. IIS was re-accredited on June 4, 2014. Mr. Becker has also served on the Joint Commission’s Ambulatory Health Care Advisory Council since April 2009, further demonstrating Mr. Becker’s commitment to quality and care. Additionally, IIS received its most recent Medicare re-validation in 2012.

Importantly, the Draft Report does not find that IIS engaged in any fraudulent or unethical behavior, or that beneficiaries did not receive the critical treatment for which Medicare was billed. There is no similarity between the findings of the Draft Report and the \$15.3 million false claims settlement made by another provider of sleep diagnostic studies that was fraudulently submitting claims to Medicare for sleep studies conducted by unqualified technicians.<sup>1</sup>

It is also important to note that the Draft Report covers Medicare claims for polysomnography services from the period January 2010 to December 2012. The OIG in the Draft Report finds that IIS did not have the required supporting documentation for Medicare claims based on the requirements of the LCD for polysomnography and sleep studies by providers in the State of Florida, LCD L29949. However, since the effective date of the LCD, June 30, 2009, IIS has diligently attempted to comply with the LCD’s documentation requirements despite the arbitrary nature of some of the LCD’s requirements. IIS’ compliance has been hindered by its encountering significant -- but understandable -- resistance by physicians who refer beneficiaries to IIS for sleep studies. In fact, a recent OIG audit of the State of Florida’s MAC, First Coast Service Options, Inc. (“First Coast”), which issued LCD L29949, recognized that one of the causes of incorrect Medicare payments it made to providers of polysomnography services pursuant to LCD L29949 was “because providers did not understand the Medicare requirements when billing for these services.” (*First Coast Service Options, Inc. Paid Some Unallowable Sleep Study Claims*, Report No. A-04-13-0739). In that audit report, the OIG recommended that

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<sup>1</sup> See *United States ex rel. Daniel Purnell v. American Sleep Medicine LLC*, no. 3:07-cv-12-S (W.D. Ky.).

First Coast engage in provider education activities.<sup>2</sup> Despite these challenges, IIS' improved controls and its efforts to educate referring physicians has resulted in more complete documentation since the period covered by the Draft Report. For the reasons outlined more fully below, collection of overpayments for this particular LCD is not warranted.

## II. IIS' Response

### A. The LCD Requirements Should be Disregarded.

The Draft Report finds that IIS did not comply with Medicare billing requirements as set forth in First Coast's LCD for polysomnography and sleep studies by providers in the State of Florida, LCD L29949. However, LCD L29949 should be disregarded since it goes well beyond the requirements of the national coverage determination ("NCD") for sleep testing for OSA<sup>3</sup>, is inconsistent with the LCDs in all other MAC jurisdictions, and fails to appropriately specify what clinical circumstances make the polysomnography services reasonable and necessary.

Furthermore, neither a MAC, nor an Administrative Law Judge is bound by LCDs.<sup>4</sup> First Coast has declined to be bound by its own LCD L29949, evidenced by its practice of reimbursing for polysomnography services without enforcing the LCD's strict documentation requirements.<sup>5</sup>

Based on the flawed nature of LCD L29949 as outlined below, the OIG should recommend to First Coast that it disregard the sections of the LCD that are inconsistent with the NCD and that impose arbitrary documentation requirements on physicians who refer patients to IIS for sleep studies.

#### 1. The LCD exceeds the requirements of the NCD and all other MACs.

An NCD provides higher level policy and direction than an LCD. NCDs are developed by CMS "to describe the circumstances for Medicare coverage nationwide for an item or service. NCDs generally outline the conditions for which an item or service is considered to be covered (or not covered)..." *Medicare Program Integrity Manual ("MPIM"), Chapter 13.1.1*. The NCD for Sleep Testing for OSA requires only that "beneficiaries have clinical signs and symptoms indicative of OSA" to qualify for a sleep study.

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<sup>2</sup> Physicians would also benefit from education from First Coast. Mr. Becker reports he regularly encounters physicians who are not aware of their obligations to perform face-to-face evaluations according to the requirements contained in LCD L29949.

<sup>3</sup> NCD § 240.4.1.

<sup>4</sup> See 42 C.F.R. § 405.1062(a) (stating "[Administrative Law Judges ("ALJ")] and the MAC are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.) If an ALJ or MAC declines to follow an LCD, the "ALJ or MAC decision must explain the reasons why the policy was not followed." 42 C.F.R. § 405.1062(b).

<sup>5</sup> See "First Coast Service Options, Inc. Paid Some Unallowable Sleep Study Claims," Report No. A-04-13-0739.



The Draft Report, consistent with Section 1869(f)(2)(B) of Title XVIII of the Social Security Act<sup>6</sup> and Chapter 13 of the *MPIM*<sup>7</sup>, recognizes in footnote 12 the role an LCD should play:

LCDs are decisions published by MACs on whether to cover a particular item or service within their jurisdiction. LCDs specify under what clinical circumstances an item 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.

Section 13.1.3 of the *MPIM* also requires MACs to ensure that “all LCDs are consistent with all statutes, rulings, regulations, and national coverage, payment, and coding policies.”

The relevant language of the NCD for Sleep Testing for OSA provides:

Effective for claims with dates of service on and after March 3, 2009, the Centers for Medicare & Medicaid Services finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary’s treating physician to diagnose OSA, that the use of such sleep testing technologies demonstrates improved health outcomes in Medicare beneficiaries who have OSA and receive the appropriate treatment, and that these tests are thus reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act.

1. 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 relevant language of LCD L29949 requires that prior to a sleep study being performed, the following criteria must be met:

- 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 a minimum include:

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<sup>6</sup> Section 1869(f)(2)(B) of Title XVIII of the Social Security defines a “local coverage determination” as “a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary–or carrier–wide basis under such parts, in accordance with section 1862(a)(1)(A).”

<sup>7</sup> Section 13. 1.3 of the Medicare Program Integrity Manual states: 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.

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.

The LCD's requirement for an evaluation of a patient's sleep history and symptoms (as set forth in #1 above) is consistent with the NCD's requirement that beneficiaries have clinical signs and symptoms indicative of OSA. The requirements set forth in #2 and #3, however, are a list of risk factors that must be documented, regardless of whether they are clinically relevant. By requiring this additional documentation, the LCD is much more than an "administrative and educational tool to assist providers in submitting correct claims for payment," but is instead a list of arbitrary measurements that must be documented regardless of clinical relevance.

Another reason that LCD L29949 should be disregarded is First Coast is the only MAC that requires a physician perform the requirements set forth in #2 and #3 of the LCD.<sup>8</sup> One MAC, CGS Administrators, LLC<sup>9</sup>, requires an initial evaluation that "may" include elements such as symptoms, Epworth sleepiness scale, body mass index, and neck circumference. That LCD specifically states that not every element has to be addressed in every evaluation. In fact, the Decision Memo for the NCD contemplates that other measurement tools, other than the Epworth Sleepiness Scale, may be useful to evaluate the presence of OSA.<sup>10</sup> This would appear to be more consistent with the requirements of the NCD. That is, to provide evidence of the beneficiaries having clinical signs and symptoms of OSA, without dictating the exact measurements to be included; especially in the absence of actual parameters on the measurements to enable them to be clinically relevant.

Since LCD L29949 is inconsistent with the applicable NCD (as required by Chapter 13 of the *MPIM*) and other similar LCDs in other jurisdictions, a strict interpretation of the LCD's documentation requirements should be disregarded by the OIG.

**2. The LCD's requirements are arbitrary and do not assist in determining whether a sleep test is "reasonable and necessary."**

In addition to exceeding the NCD and being inconsistent with the LCDs of other MACs, LCD L29949 contains documentation requirements that are arbitrary and do not assist in determining

<sup>8</sup> See CGS Administrators, LLC's LCD L31846; Noridian Healthcare Solutions, LLC's LCDs L24350, L33483, and L33663; Palmetto GBA's LCD L31718; and Wisconsin Physician Services Insurance Corporation's LCD L31082.

<sup>9</sup> CGS Administrators, LLC is the Part B MAC for Kentucky and Ohio.

<sup>10</sup> The NCD's Decision Memo set forth the clinical evidence CMS found sufficient to determine that sleep studies can be used by a beneficiary's physician to diagnose OSA. In the Decision Memo's background, CMS listed alternative methods to diagnose OSA, including questionnaires such as the Epworth Sleepiness Scale or the Sleep Apnea Clinical Scores.

whether a sleep test is “reasonable and necessary.” By using the conjunctive “and” after #1 of the LCD, First Coast has imposed a large, and meaningless burden on attending physicians and made it difficult for IIS to comply with the LCD. Without parameters, #2 and #3 in LCD 29949 do not aid in a determination of whether a sleep study is reasonable and necessary.

For example, while a patient’s neck size could be a clinical sign of OSA, the LCD does not establish what neck size would be diagnostically significant, it only requires that the measurement be recorded. As a result, a patient who snores and has daytime sleepiness, plus has recorded measurements that are within a normal clinical range for the risk factors listed in #2 and #3 of the LCD, would qualify for a sleep study. However, a patient that snores and has daytime sleepiness, an extremely high body mass index, an Epworth sleepiness scale score greater than 10, airway blockages, and a pulmonary condition would be denied coverage by Medicare for a sleep study if the referring physician’s documentation did not include a neck circumference measurement.

In addition to not providing any diagnostic value, these additional coverage requirements have the potential to delay necessary treatment and increase costs to the Medicare program. For example, the current scheme requires a patient who is clearly suffering from symptoms of OSA, but whose attending physician did not document his or her neck circumference, to make another appointment for that measurement to be taken, documented, and sent to the sleep clinic. This delay could negatively impact the patient’s health and increase costs to the Medicare program for the extra office visit. In striving for compliance, IIS routinely encounters physicians who are reluctant to take their time to document unnecessary information.

The list of indicators in the current LCD is also not complete. As reflected in the background section of Decision Memo for NCD § 240.4.1, patients who also suffer from such diseases as congestive heart failure, hypertension, obesity accompanied with excessive daytime drowsiness, or witnessed apneas, should also be eligible to have Medicare cover sleep tests.<sup>11</sup> Diagnosing and treating OSA in these patients could result in a decrease to the corresponding health care costs for the co-morbid diseases. Yet, the current LCD does not take into consideration these risk factors when determining whether the patient suffers from clinical signs and symptoms indicative of OSA to support the performance of a sleep study.

To help address First Coast’s flawed LCD, on July 24, 2015, IIS’ President and CEO, Mr. Glenn Becker, responded to requests for comments on a revised polysomnography LCD (DL33405) as LCD L29949 expired on September 30, 2015. Mr. Becker’s proposal would require more meaningful documentation from the attending physician to help identify those patients who would benefit from a sleep study. Hopefully, First Coast will give careful consideration to his suggestions and the reference materials he provided in support of his recommendations. In the meantime, the current LCD should be disregarded.

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<sup>11</sup> In the background portion of the Decision Memo, CMS recognized that these diseases are common clinical indicators of OSA.

**B. Polysomnography services were billed correctly.**

The OIG in the Draft Report finds that each sample it examined did not comply with Medicare billing requirements because the claims' records were missing documentation required by LCD L29949. It concluded that these errors occurred primarily because IIS "did not have adequate controls to ensure that it properly documented polysomnography services billed to Medicare." However, as further explained below, the OIG misinterpreted the requirements of the LCD by requiring documentation to be in either the physician's evaluation notes or IIS' claim records. Furthermore, the OIG disregarded important information that was present in the claim records that supported the patients had clinical signs and symptoms indicative of OSA to support the performance of a sleep study.

**1. The Report overstates the number of claims missing face-to-face evaluations.**

During the course of the audit, the OIG provided to IIS a chart itemizing the specific elements it designated as missing for each service line. The OIG's chart specified for 33 claims that the face-to-face evaluation was missing from the documentation.

A careful review of the patients' records reveals there are actually 19 claims where the physician's face-to-face evaluation of the patient is missing from IIS' records; however, IIS maintains that the documentation of the evaluation in IIS' records is not necessary in order for the sleep disorder center to receive reimbursement. The OIG misinterpreted the requirements of the LCD by requiring IIS' claim records to include the physicians' face-to-face evaluations. The LCD requires that prior to any sleep testing, the patient must have a face-to-face evaluation that includes the factors noted above in Section II(A)(1). While the LCD requires the sleep disorder clinic to maintain a record of the attending physician's order for the sleep test, there is no requirement that the sleep disorder clinic maintain a record of the physician's evaluation.

Additionally, the absence of a face-to-face evaluation from the claim's record is not determinative of whether the physician performed the evaluation. The face-to-face evaluation was likely performed and would be present in the physician's file for the patient. However, the OIG did not request this documentation from the physicians and their conclusion may have changed if they considered this documentation in their review of the claims. Furthermore, 35 of the deficiencies noted by the OIG were for continuous positive airway pressure ("CPAP") follow-up tests, which (as discussed below) do not require a separate face-to-face evaluation.

**2. Documentation outside of physicians' notes should be considered.**

The OIG's chart specified that all of the physicians' face-to-face evaluations for the patients were missing the documentation requirements listed in #2 and/or #3 of the LCD. Even if a strict interpretation of the LCD is taken, the OIG misinterpreted the requirements of the LCD by disregarding important documentation in the claims' records because the OIG auditors required

the specified element to appear in the referring physicians' notes, a requirement that is not reflected in the language of the LCD.<sup>12</sup>

The LCD requires that prior to any sleep testing, the patient must have a face-to-face evaluation that includes the factors noted above in Section II(A)(1). As we discussed above in Section II(B)(1), the LCD requires the sleep disorder clinic to maintain a record of the attending physician's order for the sleep test, but the LCD does not require the sleep disorder clinic to maintain a record of the physician's evaluation. Even though IIS maintained a record of the physician's evaluation for 112 patients records, it is certainly not a requirement of the LCD.<sup>13</sup> Furthermore, the LCD does not require that the elements be recorded in the physician's examination notes, merely that the evaluation be performed. Thus, in cases where there is some indication that the physician did the requisite evaluation that would satisfy the documentation requirements in LCD L29949, even if the LCD's documentation requirements were not all documented in the physician's evaluation notes, the OIG should recognize the performance of the evaluation and not consider the patient's record to be missing those specific LCD requirements. For example, for 22 claims, the OIG noted that the claim's record was missing documentation of the Epworth sleepiness scale results for the beneficiary since that information was not included in the physician's examination notes, even though results were included on the referral form the physician used to order the sleep study for the beneficiary.<sup>14</sup>

Additionally, in those cases where a specific element is missing from any documentation of the patient's record that was completed by the physician, the OIG should consider whether the evaluation was performed but not appropriately documented by the physician<sup>15</sup> or if the element itself is of an arbitrary nature described above. For example, almost all of the documentation completed by the physicians were missing the patient's neck circumference. However, as explained above, merely documenting a patient's neck circumference in the patient's record provides little clinical significance as to whether a sleep study is reasonable and necessary for the patient. In fact, although the neck circumference measurement was missing from almost all of the physician examination notes, the patients' records had other risk factor(s) noted by the

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<sup>12</sup>For nine claims, the OIG's chart noted that the physician's identifiers were missing from the face-to-face evaluation and/or the physician's order. The OIG disregarded the CMS-1500 claim submission forms that indicate the physician's identifying information. Thus, for these nine claims, the physician's identifiers were present but the OIG disregarded the CMS-1500 forms in its review.

<sup>13</sup> For those patient records where the face-to-face evaluation was missing, the physician's evaluation of the patient was evidenced by the copy of the physician's order for sleep testing in the record, which is an explicit requirement of the LCD.

<sup>14</sup> Also, for 7 claims, the OIG noted that the claim's record was missing the face-to-face evaluation, which would include documentation of the Epworth sleepiness scale results, even though the results were included on the referral form.

<sup>15</sup> As mentioned above, IIS has had significant difficulty over the years with requesting treating physicians to document the elements of the LCD. As further discussed below, IIS has attempted to educate providers on including each element in their patient examination notes. However, since this is not a requirement for the physician visit, there is a disconnect in the requirements and an apparent reluctance on behalf of the physician's to comply with IIS' requests.

treating physician, supporting that the patients had clinical signs and symptoms indicative of OSA to support the performance of a sleep study.<sup>16</sup>

### **3. 35 CPAP titration studies (HCPCS 95811) were properly billed.**

Another aspect of the OIG's misinterpretation of the LCD concerns follow-up CPAP testing, represented by HCPCS 95811, after the performance of an underlying polysomnography test or home sleep test. In the Draft Report, the OIG noted missing face-to-face evaluations for 10 claims. However, the LCD does not require any separation between the performance of a polysomnography test and a CPAP. For example, a polysomnography could be performed and if clinically indicated, a CPAP could be performed during the same sleep test (referred to as a split night CPAP). In this scenario, there would not be a separate face-to-face evaluation prior to the performance of the CPAP. The OIG's requirement of a face-to-face evaluation when a CPAP is performed on a different date is a misinterpretation of the LCD. In those instances, IIS faxes an order to the treating physician attaching the results of the underlying test. If the treating physician agrees that the CPAP is clinically indicated, the physician returns a signed order to IIS. Since the report for the underlying test is attached (which in many instances, includes the patient's Epworth Sleepiness Scale score, neck circumference, and body mass index), the physician is able to review any required elements that have been noted by IIS and/or the patient, which the physician may not have noted in the examination notes. When considered as a whole, the records for 35 patients who received this type of sleep study include all of the documentation required by the LCD and were properly billed.

### **III. IIS has strengthened controls to comply with Medicare requirements.**

The OIG's third recommendation is that the IIS "strengthen controls to ensure full compliance with Medicare requirements." Notwithstanding IIS' contentions set forth above, IIS agrees with this recommendation. IIS continuously tries to improve its procedures in order to comply with Medicare requirements. Since the enactment of the LCD, IIS has tried different procedures to comply with the LCD. After the OIG's audit, IIS has taken the following, additional steps to improve its controls in an attempt to comply with the OIG's interpretation of the LCD requirements:

- IIS has contacted approximately 1,100 physicians and notified them of the specific elements to be included in their examination notes for patients being referred to IIS for sleep studies.
- During in-office physician visits, IIS representatives educate the physicians on the specific elements of the LCD.

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<sup>16</sup> The OIG's chart specified that the record for claim 82 (study performed on July 22, 2011) was missing documentation supporting the actual test was performed (missing technician report, interpretation report, and raw data). Mr. Becker located this documentation for claim 82, supporting the sleep study was performed. This documentation is available for the OIG's review upon request.

- When IIS receives an order from a physician for a sleep study, IIS' staff use an intake form to determine whether the documentation sent by the physician contains the elements. The intake form has a checklist for the IIS staff to utilize in determining what specific element is missing from the physician's documentation. If an element is missing, IIS contacts the physician's office by faxing the office a form specifying the missing element. IIS does not schedule a patient for a sleep study until the physician has updated the documentation.

And while IIS concurs with the third recommendation, strengthening controls has come at a cost to IIS and the Medicare beneficiaries it serves. As of September 24, 2015, Mr. Becker reports that 29 patients were waiting for physician-ordered sleep studies because the physician's evaluation was missing some of the arbitrary documentation required by the LCD. Therefore, while IIS continues to encourage and strive for compliance, the result is that patients are delayed in accessing the critical care they need.

#### **IV. Conclusion**

IIS contends that First Coast's LCD L29949 should be disregarded because it is inconsistent with the NCD and it imposes arbitrary documentation requirements on physicians who refer patients to IIS for sleep studies. The sleep studies provided to the patients were medically necessary based on the NCD's guidelines. For the patients whose records were reviewed by the OIG, IIS' records contain the requisite signs and symptoms indicative of OSA to support the performance of the sleep studies at issue. Therefore, IIS does not concur with the first two recommendations of the OIG in the Draft Report.

Sincerely,

HOLLAND & KNIGHT LLP

/Lynne M. Halbrooks/  
Counsel for International Institute of Sleep

LMH:hjg