AMERICAN ACADEMY OF SLEEP MEDICINE

January 19, 2012

Daniel R. Levinson
Inspector General
Office of Inspector General OIG -120-N
Department of Health and Human Services
Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Levinson:

Thank you for providing the American Academy of Sleep Medicine (AASM) with the opportunity to offer comments on the December 29th, 2012, Federal Register regarding the *Solicitation of New Safe Harbors and Special Fraud Alerts (OIG-120-N).* The AASM is recommending the development of a safe harbor for a Board Certified Sleep Medicine Physician (BCSMP) to order and provide DME (e.g., CPAP, APAP equipment) to Medicare patients for use in the treatment of obstructive sleep apnea (OSA).

The current practice model of care for OSA is fragmented in its present state. Oftentimes, physicians untrained in sleep medicine infer a diagnosis of OSA based on a computer-generated, simplistic report provided by a commercial home sleep testing company and subsequently write a prescription for auto-titrating positive airway pressure (APAP). The treatment of the patient is then passed to a DME company without the involvement of a qualified physician. This fragmentation in care occurs because current Medicare policy and Stark law prevent the diagnosing physician from providing both the diagnostic procedure and the treatment.

Another potential scenario under the current model, a BCSMP diagnoses a patient with OSA based on an in-center polysomnography (PSG) and CPAP titration then writes a prescription for a PAP device which includes the appropriate mask based on the titration and fitting conducted at the sleep center. Oftentimes, that prescription is not filled properly by the DME company. It is our contention that DME companies may provide inadequate educational training to patients and conduct minimal patient follow-up, which results in adherence to therapy challenges, redundancy of services and inadequate information flow among health care providers.

Additionally, the subsequent follow-up visit with a physician within a 90 day period is often difficult to coordinate and many times the required information from the DME company is not available or complete. It is our contention this model must change for sleep medicine care to improve for patients and reduce the cost of care to Medicare. If the fragmentation in the current practice model for sleep medicine is to be addressed properly, the BCSMP must have the

ability to not only diagnose the patient but also provide the treatment therapy and monitor the progress of the patient long-term. We believe that such a model for patient care will increase access to high quality, coordinated and cost effective diagnostic and treatment services for OSA, led by the BCSMP.

According to the November, 2009 Improper Medicare FFS Payments Report Executive Summary, there was $5.4 billion paid in improper payments and projected the error rate to be 51.9 percent. While more than CPAP and APAP equipment are included in this DME projected error rate, the report goes on to say, ...Once CMS clarified that clinical review judgment may not override documentation requirements, more errors were found on DME items. The involvement of multiple parties can cause a delay in documentation receipt and incomplete documentation. CMS also recently clarified that documentation produced to the supplier alone is insufficient to warrant payment of the claim... It is our understanding that the overall projected DME error rate for 2010 has risen even higher, over the 70th percentile.

The AASM is respectfully requesting a waiver of the application of the Physician Self-Referral Law, the Federal anti-kickback statute and certain civil monetary penalties (CMP), as is the CMS deemed authority status for DME accreditation. The AASM's request is very circumscribed; we are requesting that BCSMPs be allowed to distribute DME equipment (e.g., CPAP, APAP) and supplies to patients who have been diagnosed OSA. We further believe that only equipment and supplies related to the treatment of OSA should be included in the waiver. If our request is granted for a waiver of the applicable laws, the AASM will identify specifically which CPT codes, ICD-9-CM codes and HCPCS equipment and supply codes will be included in this waiver.

In the 2012 OIG Work Plan, two reviews planned include "Frequency of Replacement of Supplies for Durable Medical Equipment" and "Medicare Payments for Durable Medical Equipment Claims with Modifiers," which echo the concerns expressed by the AASM. We believe that cutting out the middle man (the DME supplier) and requiring each BCSMP dispensing DME CPAP equipment to have an up-to-date compliance program with self-audit as its core appears to be an ideal method of controlling the supply issues.

Expected Outcomes

1. **Access to health care:** The AASM's proposed modification to the Safe Harbor Provisions will increase the opportunity for patients with OSA to receive the coordinated physician services, equipment and supplies that are medically necessary to diagnose and treat OSA from one entity – the BCSMP and his/her staff.
2. **Quality of health care services and improved adherence**: The AASM believes the quality of care provided to the patient will increase dramatically as would the patient's adherence with the PAP treatment as there would be no hand-off to other providers and all care, including testing, treatment and long-term follow-up, would be directed and managed by the BCSMP.
3. **Patient freedom of choice among health care providers:** The patient will retain the freedom of choice to select who delivers the services related to diagnosing and treating his/her sleep disorder. The modification to the Safe Harbors proposed by the AASM will restrict the patient's choice of a DME provider if they chose a sleep center that has an integrated care model, which will require that the BCSMP order and dispense the DME. However, the coordinated care received in a sleep center would be, in the AASM's opinion, a beneficial trade-off for the patient. Further it will substantially reduce the time delay from diagnosis to treatment initiation.
4. **Competition among health care providers:** Each of the centers (with the ability to dispense DME equipment related to OSA) could compete in the same market place. The other providers of sleep services (IDTFs performing sleep testing and independent Out of Center Sleep Testing Companies, sleep centers without the three part accreditation) could be at a disadvantage and unable to compete with the integrated model of care, because they would not be able to offer the complete coordinated care provided by the BCSMP in the integrated sleep program.
5. **Reduced cost to the Federal health care programs:** The cost to the Federal health care program should decrease dramatically because only medically necessary services, supplies and equipment will be

prescribed and delivered to the patient in-person. The mandatory compliance program mentioned above will have as a component a self-audit of each physician's practice which would review codes billed, frequency of visits, and quantity of supplies dispensed to determine if all services and supplies provided were medically necessary. With the restrictions discussed above related to a small number of DME billing codes available to the BCSMP to report as part of the waiver agreement, CMS and the OIG can easily perform data analysis to determine if there are outliers among the BCSMPs and request records for medical review, if necessary.

6. **Provision of services in medically underserved areas or to medically underserved populations:** The concept of the BSCMP managing patient care can be replicated in underserved areas and made available to medically underserved populations.

Steps the AASM Has Taken to Promote Compliance Among Its Members

Listed below are some of the many activities the AASM has conducted to promote compliance with Federal and State laws concerning the practice of sleep medicine:

- Requested a specialty designation from CMS for BCSMP, which was granted but which has yet to be published, to ensure that BCSMPs can be identified in the data reviewed by payers
- Invited Carrier and DME Medicare Medical Directors to give presentations at the AASM's annual "Business of Sleep Medicine" course for the past three years
- Provided recommendations to all insurers who requested review of their sleep related policies, based on evidence contained in AASM published Practice Parameters and Guidelines
- Worked very closely with the staff of One PI, the Medicare contractor who provided the Comparative Billing Reports to all providers who reported sleep medicine codes, to determine the cause of any incorrect billing
- Appointed a Coding and Compliance Committee, which educates member on all issues related to coding, compliance and billing, including working with the American Medical Association's Current Procedural Terminology (CPT) Panel and Relative Value Update Committee (RUC)
- Provided numerous presentations to our members on compliance plan development, documentation requirements, Medicare policies, Evaluation and Management Services Documentation Guidelines, procedure coding
- Developed a specific section on the AASM website entitled "Coding Corner", which provides correct coding information as well as acts as a repository for each weekly update sent to our members by email containing CMS requirements related to the practice of sleep medicine
- Strengthened the Standards for Accreditation for AASM Sleep Center Accreditation, Durable Medical Equipment Accreditation and Out of Center Sleep Testing Accreditation to involve quality care and compliance

Below is a historical account of the AASM's efforts to secure the changes to the current Medicare and Stark Laws:

- Integrated Disease Management Models/Nationally Accredited Disease Management Accreditation
- AASM Non-Medicare DME Accreditation
- May 5, 2011 In-person Meeting in Baltimore with Dr. Louis Jacques To Discuss Nationally Accredited Disease Management Accreditation
- October 27, 2001 Follow-up Letter to CMS - Dr. Jacques, Dr. Gilfillan, Dr. Lee, Dr. Bough, Ms Bastinelli

Integrated Disease Management Models/Nationally Accredited Disease Management Accreditation

In the November 19, 2008, Federal Register (pages 69855-69860), there is a section entitled, "Prohibition Concerning Payment of Continuous Positive Airway Pressure (CPAP) Devices," which discusses the lack of integrated disease management models or nationally accredited disease management programs. Centers for Medicare and Medicaid Services (CMS) indicated in this document that they are ...unaware of any current model

(of a disease management program) that encompasses accreditation for both OAS diagnosis and CPAP under a single accreditation certificate...

In response to these statements, the AASM met in March 2009 with CMS Officials in Baltimore to discuss the concerns raised by CMS related to the lack of a "nationally accredited disease management accreditation." In June 2009, AASM requested that CMS approve the AASM's DME accreditation program to deem entities furnishing DME. CMS representatives indicated that the window of opportunity for entities to become Medicare DME "deemed authorities" had ended and there was no discussion within CMS as to when the next opportunity would be for an entity to become a CMS deemed authority.

AASM Non-Medicare DME Accreditation

The AASM decided to develop a non-Medicare DME accreditation program to offer to private payers, using the published CMS DME accreditation criteria as the basis for the AASM non-Medicare standards. A copy of a document that compares AASM non-Medicare accreditation standards to the CMS DME requirements as well as to the ACHC and The Compliance Team accreditation standards which are Medicare deemed authorities for CMS DME accreditation. As indicated in the attached document, the standards found in the AASM non-Medicare DME accreditation are **more stringent** than the ACHC and The Compliance Team CMS DME standards. (See attachment A.)

Integrated Sleep Management Program

On May 5, 2011, the members of American Academy of Sleep Medicine's leadership and staff met with Drs. Louis Jacques and Ross Brechner. The purpose of the meeting was to request the opportunity for the AASM to partner with CMS on a project designed to test the effectiveness of an integrated sleep management delivery model for the treatment of sleep disorders with the AASM serving as the accrediting body for project test locations.

The AASM received positive feedback related to the concept of this project and Dr. Jacques indicated he and his staff would like to discuss the proposal with the CMS Innovation Center to determine if this Proposal for an Integrated Sleep Management Delivery Model best fit with the Innovation Center or in the Rulemaking Center at CMS. The waiver of the application of the Physician Self-Referral Law, the Federal anti-kickback statute and certain civil monetary penalties (CMP) is needed to test the Integrated Sleep Management Delivery Model, as is the CMS deemed authority status for DME accreditation.

On October 27, 2011, the AASM sent a follow-up letter to CMS. To date, the AASM has not received a response to this letter.

Thank you for providing the AASM with the opportunity to respond to your request for solicitation of new safe harbors. We are available to answer any questions you may have related to our recommendations and welcome the opportunity to discuss this request in person or during a conference call. Executive Director Jerry Barrett is our contact person, and he can be reached at (630) 737-9700. We sincerely appreciate your consideration of our request and look forward to your response.

Sincerely,
Nancy A. Collop, MD
President

cc: Jerome A. Barrett, Executive Director