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# Medicare

## **Comments and Responses Regarding Draft Local Coverage Determination: Polysomnography and Sleep Studies**

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As an important part of Medicare Local Coverage Determination (LCD) Polysomnography and Sleep Studies development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Polysomnography and Sleep Studies LCD. The official notice period for the final LCD begins on April 15, 2009, and the final determination will become effective on July 1, 2009.

### **Comment:**

One commenter disagreed with the number of sleep naps allowed for the Multiple Sleep Latency Testing (MSLT) in the diagnosis of narcolepsy. He said that according to the American Academy of Sleep Medicine (AASM), the proper number of naps required during a MSLT is four, and if there is only one sleep onset REM period (SOREP) during the four naps, then a fifth nap may be required (reference: Arand D, Bonnet M, Hurwitz T, et.al., *The Clinical Use of the MSLT and MWT. SLEEP*, Vol 28, No. 1, 2005, pp. 123-144). He said this paper is an evidence-based review from the AASM and accurately reflects the current data concerning the procedure for MSLTs in the diagnosis of narcolepsy.

### **Response:**

The section in the policy that refers to the number of sleep naps in MSLT is in italics and is taken directly from the CMS manual (CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 70). This section may be out of date. We suggest the commenter approach the AASM to ask CMS for a revision of the manual and supply the supporting scientific literature for the change.

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### **Comment:**

One commenter stated that the diagnosis of obstructive sleep apnea (OSA) is somewhat contentious with regard to the technology employed. There are those in the sleep community that feel that it can only be appropriately diagnosed with full polysomnography. However, the data and the need clearly

show that well done studies may be done in the home environment in an unattended setting. This is consistent with the national Medicare policy and recent review that occurred last spring. The major caveat is that the performance needs to be done by someone experienced with the technology and the interpretation needs to be done by someone trained in sleep medicine that also has experience with portable modalities.

**Response:**

The credentialing requirements for both sleep laboratory physician directors and polysomnographic technicians is specified in the "Other Comments" section of the LCD.

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**Comment:**

The same commenter stated that the causes for obstructive sleep apnea that are listed are incomplete and at least one is somewhat misleading (i.e., reference to obesity). The wording here could be improved to be more appropriate and accurate.

**Response:**

Additional information regarding additional causes of OSA were requested from this commenter and they will be evaluated for inclusion into the policy when they are received.

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**Comment:**

The same commenter stated that there is no definition of RDI. This needs clarification in order to avoid abuse.

**Response:**

The definition of RDI has been added to the LCD.

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**Comment:**

The same commenter said that under the section referencing "split-night" studies, there is a logical inconsistency. Requiring that CPAP must eliminate or nearly eliminates respiratory events during REM and non-REM sleep cannot be ascertained beforehand. He said there is no guarantee that a full night of titration could perform the same function. Hence this line should be eliminated. He said the caveats associated with this section should be that: 1) CPAP titration may be carried out for more than three hours; and that the diagnostic portion confirms the diagnosis of obstructive sleep apnea.

**Response:**

The language has been clarified.

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**Comment:**

The same commenter stated that there is no definition for what constitutes a “cardiorespiratory sleep study.” This should be clarified.

**Response:**

References to “cardiorespiratory studies” have been removed.

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**Comment:**

The same commenter stated that the statement regarding polysomnography for parasomnias should state a Type I - attended study must include documented technologist observations.

**Response:**

This item is already in the LCD under the required list of measurements.

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**Comment:**

The same commenter stated that due to the technical difficulties associated with portable polysomnography, both attended and unattended, interpretations and oversight for the performance needs to be under the guidance of an experienced sleep physician. He felt the statement “the laboratory physician must review the entire raw data recording for every patient studied” was an insufficient standard. He said the physician needs to have training and be current in the practice of sleep medicine. Failure to adhere to such standards will allow individuals who are not particularly capable of performing such studies to render services. Also, there appears, he continued, to be no clear limitation on the location of the sleep laboratory. As such, a distant facility, perhaps even out-of-state, might perform such studies. He requested some specific limitations on the availability the physician (with some caveats to address limited access areas) might be beneficial.

**Response:**

In the “Other Comments” section of the policy there are requirements listed for physicians who direct the sleep lab and for polysomnogram technologists. Regarding the location of the sleep laboratories, we have followed the standards set forth by the American Academy of Sleep Medicine (AASM) and the requirements of the CMS.

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**Comment:**

One commenter requested that home sleep testing be allowed in places of service 31 and 32 (assisted living facilities).

**Response:**

These places of service will be added to the "Carrier or Part B MAC" billing guidelines in the Supplemental Instructions Article (SIA).