Effective July 1, 2013

- **THE PATIENT'S MEDICAL RECORD MUST CONTAIN** sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered.
- A Physician, Physician Assistant (PA), Nurse Practitioner (NP), or Clinical Nurse Specialist (CNS) must have a Face-to-Face evaluation with the beneficiary prior to the written DME order and document the Face-to-Face evaluation in the patient’s medical records.
- **THE FACE-TO-FACE EVALUATION MUST BE SIGNED OR CO-SIGNED BY A PHYSICIAN.**
- The Face-to-Face evaluation must occur during the six months prior to the written order for each item.
- For CPAP, the evaluation must occur prior to the sleep study.

A detailed written order for the item must be received before the delivery of the item can take place and must include minimally the following information:
(See Face-to-Face quick reference guide)

1. Prescriber’s NPI
2. Beneficiary name
3. Date of order
4. DME item ordered
5. Signature of prescriber
6. Date of prescriber’s Signature

A detailed written order for the item must be received before the delivery of the item can take place and must include minimally the following information:

1. NPI# 1234767890
2. Name: William Smith
3. Date: 07/01/2013
4. Address: 555 My Street, Any Town
5. Signature of Prescriber: John Doe, M.D.
6. Date of Order: 07/15/1960

**Rx** Provide CPAP at 12 cm/h2O, fit patient for appliance/mask, provide heated humidification

**Documentation in Medical Records Required by CMS**

- **Documentation Requirements**
  - Duration of patient’s condition
  - Clinical course
  - Prognosis
  - Nature and extent of functional limitations
  - Other therapeutic interventions and results

- **Key Items to Address**
  - Why does the patient require the item?
  - Do the physical examination findings support the need for the item?
  - Signs and symptoms that indicate the need for the item
  - Diagnoses that are responsible for these signs and symptoms
  - Other diagnoses that may relate to the need for the item
HCPCS code(s) affected include the following:

E0601

Coverage Criteria

The physician must document the Face-to-Face clinical evaluations and re-evaluations in a detailed narrative note in their charts in the format that is used for other entries. For the initial evaluation, the report would commonly document pertinent information about the following elements, but may include other details:

- History
  - Signs and symptoms of sleep disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches
  - Duration of symptoms
  - Validated sleep hygiene inventory such as the Epworth Sleepiness Scale

- Physical Exam
  - Focused cardiopulmonary and upper airway system evaluation
  - Neck circumference
  - Body mass index

Specific Coverage Criteria

An E0601 device is covered for the treatment of obstructive sleep apnea (OSA) if the below criteria are met:

- The beneficiary has a Face-to-Face clinical evaluation by the treating physician prior to the sleep test to assess the beneficiary for obstructive sleep apnea.
- The beneficiary has a sleep test that meets either of the following criteria (1 or 2):
  - The Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or
  - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or
  - Hypertension, ischemic heart disease, or history of stroke.
- Patients who fail CPAP may be moved to a bi-level device (E0470) if an E0601 has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or a home setting.

Ineffective is defined as documented failure to meet therapeutic goals using an E0601 during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings).

If an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an E0470 does not require a new initial Face-to-Face clinical evaluation or a new sleep test.

If an E0601 device has been used for more than 3 months and the beneficiary is switched to an E0470, a new initial Face-to-Face clinical evaluation is required, but a new sleep test is not required. A new 3 month trial would begin for use of the E0470.