DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 409, 410, 411, 414, 415, 424, 485, and 486

[CMS-1403-P]

RIN 0938-AP18

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule.

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would address proposed changes to Medicare Part B payment policy. We are proposing these changes to ensure that our payment systems are updated to reflect changes in medical practice and the relative value

home health patient's POC, for example, a requirement for "direct" patient contact with the physician. We are specifically soliciting comments on these policy options in an effort to gather more information on this issue, and any other possible underlying issues that may exist.

2. Prohibition Concerning Providers of Sleep Tests

[If you choose to comment on issues in this section, please include the caption "OTHER ISSUES—SLEEP TESTS" at the beginning of your comments.]

a. Background

Obstructive Sleep Apnea Hypopnea Syndrome, also known as Obstructive Sleep Apnea (OSA), is the most common of the three different forms of sleep apnea (obstructive, central, or mixed). OSA is associated with significant morbidity and mortality, including excessive daytime sleepiness, concentration difficulty, cardiovascular disease, and stroke. Untreated OSA is associated with a ten-fold increase in the risk of motor vehicle accidents.

Diagnostic tests for OSA are based on detection of abnormal sleep patterns using sleep test devices that record a variety of cardiorespiratory and neurophysiologic signals during sleep time called polysomnography (PSG). Historically, such sleep tests have been furnished in a sleep laboratory attended by a sleep technologist. More

recently, portable sleep test devices have been developed for the diagnosis of OSA in the home (either attended or unattended). Sleep test devices are classified into four types based primarily on the extent of sleep pattern data recorded. The most comprehensive is designated Type I: attended in-facility PSG. The remaining three types concern portable sleep test devices developed for the diagnosis of OSA and used both in attended and unattended settings, often in the home. Type II devices have a minimum of 7 monitored channels; for example, electroencephalogram (EEG), electro-oculogram (EOG), electromyogram (EMG), electrocardiogram (EKG)-heart rate, airflow, respiratory effort, and oxygen saturation. Type III devices have a minimum of 4 monitored channels including ventilation or airflow, at least two channels of respiratory movement or respiratory movement and airflow, heart rate or EKG, and oxygen saturation. Type IV devices do not meet the technical criteria defining the other types, and many measure only one or two parameters, for example, oxygen saturation or airflow, but some Type IV devices measure three or more parameters. There are other technologies that do not readily fall into the classification above.

Sleep testing, like other diagnostic tests, is subject to the provisions in §410.32. Thus, it must be ordered by the physician who is treating the beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Sleep testing must be furnished under the required level of supervision by a physician. If the sleep testing is furnished by an independent diagnostic testing facility (IDTF) the provisions of §410.33 also apply.

A number of treatment approaches have been recommended for persons diagnosed with OSA, depending on severity of the disorder and other clinical factors. Patients with moderate to severe OSA are usually treated at first with continuous positive air pressure (CPAP) devices. The regular use of a CPAP device in these cases has been shown to improve excessive sleepiness, cognitive performance, and quality of life.

A CPAP device is an item of durable medical equipment (DME) used in the home that typically uses air pressure to maintain an open airway and improve airflow to the lungs.

Medicare currently provides national coverage of CPAP only for beneficiaries whose diagnosis of OSA meets the criteria described in the national coverage determination at 240.4 of the National Coverage Determinations (NCD)

Manual. We recently published a revised NCD that expands coverage of CPAP devices to beneficiaries when OSA has been diagnosed by specified home sleep testing. Prior Medicare policy had covered CPAP devices only for beneficiaries whose OSA had been diagnosed by facility-based attended PSG. During the process leading to the revised policy, we received many public comments expressing concern that financial incentives would lead to abusive practices that would harm Medicare beneficiaries and threaten the integrity of the Medicare program. These concerns were expressed not only with respect to home sleep tests, but also those performed in sleep laboratories and other facilities. Therefore, we are proposing to implement a provision that would limit potential abusive practices by removing a significant financial incentive for those practices.

b. Regulatory proposal

Based on public comment and prior agency experience, we believe that the interests of beneficiaries and the Medicare program can be harmed if the provider of a diagnostic test has a vested interest in the outcome of the test itself. In the specific context of this proposed rule, we believe that the individual or entity that directly or indirectly administers the sleep test and/or

provides the sleep test device used to administer the sleep test (referred to hereinafter as the 'provider of the sleep test') has a self-interest in the result of that test if that provider, or its affiliate, is also the supplier of the CPAP device."

This provides incentive to test more frequently or less frequently than is medically necessary and to interpret a test result with a bias that favors self-interest.

Current medical evidence persuasively demonstrates that treatment with a CPAP device is safe for patients who have OSA. Similar evidence is lacking for treatment with a CPAP device of persons who do not in fact have obstructive sleep apnea. A test interpreted with bias or reported falsely may mislead the beneficiary's treating physician and divert the beneficiary from medically appropriate treatment. Moreover, supplying a medically unnecessary CPAP device is a waste of Medicare trust funds.

Based on section 1871(a)(1) of the Act, which provides the Secretary with the authority to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title," and due to our concerns with respect to the potential for unnecessary utilization of sleep tests, we are proposing to

prohibit payment to the supplier of the CPAP device when such supplier, or its affiliate, is directly or indirectly the provider of the sleep test that is used to diagnose a Medicare beneficiary with OSA.

As alternatives we had considered requiring pre-authorization for sleep tests or modifying payments for the services when they are furnished by the same entity but believe these options would either generate undue burden on both the Medicare beneficiary and the claims processing systems or be administratively burdensome.

Therefore, we are proposing to revise the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier enrollment safeguards set forth at §424.57 to protect the Medicare program and its beneficiaries from fraudulent or abusive practices that may be related to CPAP devices. We are proposing to add new definitions to paragraph (a) to define "sleep test" and "CPAP device" and to add a new paragraph (f), which would establish a specific payment prohibition that would not allow the supplier to receive Medicare payment for a CPAP device if that supplier, or its affiliate, is directly or indirectly the provider of the sleep test used to diagnose a beneficiary with OSA.

3. Beneficiary Signature for Nonemergency Ambulance Transport Services

[If you choose to comment on issues in this section, please include the caption "OTHER ISSUES—BENEFICIARY SIGNATURE" at the beginning of your comments.]

In the CY 2008 PFS final rule with comment period, we created an additional exception to the beneficiary signature requirements, in §424.36(b)(6), for emergency ambulance transports (72 FR 66406). The exception allows ambulance providers and suppliers to sign on behalf of the beneficiary, at the time of transport, provided that certain documentation requirements are met. To take advantage of the new exception, an ambulance provider or supplier must maintain in its files: (1) a contemporaneous statement, signed by an ambulance employee who is present during the trip, that the beneficiary was mentally or physically incapable of signing (and that no other authorized person was available or willing to sign); (2) documentation as to the date, time and place of transport; and (3) either a signed contemporaneous statement from the receiving facility that documents the name of the beneficiary and the date and time the beneficiary was received by that facility, or a secondary form of

we expect that the technical correction to the NP qualifications will make the regulations comport with the agency's intent to require a master's degree in nursing as the minimum educational level for new practitioners independently treating beneficiaries and directly billing the Medicare program. Also, the proposed changes to the NP and CNS educational requirement to include the DNP doctoral degree will help to eliminate any concern or confusion for contractors and the nursing industry about whether APNs with doctoral degrees in nursing (but without a master's degree in nursing) meet our program qualifications.

O. Portable x-ray personnel qualifications

We anticipate that there are no program cost savings or increased expenditures associated with the proposed changes discussed in section II.R. of this proposed rule; however, we expect that the revisions to the regulations will have a positive impact on patient care.

P. Prohibition Concerning Providers of Sleep Tests

The proposal contained in section II.T.2 of this proposed rule will reduce Medicare Trust Fund vulnerability to fraud and abuse and protect Medicare Beneficiaries from the burden of unnecessary sleep testing and unnecessary exposure to a medical device. This prohibition will have no effect on most providers as most providers are not

DMEPOS suppliers who would be supplying CPAP devices. Only providers or other entities that perform both sleep testing and supply CPAP machines to beneficiaries they have tested will be impacted.

Q. Beneficiary Signature Requirements for Nonemergency Ambulance Services

We believe that our proposal in section II.T.3. of this proposed rule for allowing the ambulance provider or supplier to sign the claim on behalf of the beneficiary with respect to nonemergency transport services, provided that certain conditions are satisfied, would have no budgetary impact.

R. Revision to the "Appeals of CMS or CMS contractor Determinations When a Provider or Supplier Fails to Meet the Requirements for Medicare Billing Privileges" Final Rule

We expect that the proposal in section II.T.5. of this proposed rule will have an impact on an unknown number of persons and entities; however, we believe that this provision will impact only a small number of providers and suppliers whose billing privileges are revoked due to felony convictions, license suspensions or revocation, or because the provider or supplier is no longer operating at a practice location provided to Medicare. We also believe that while this provision changes the effective date of

submit a claim to Medicare for specified services furnished to the beneficiary.

(b) * * *

(6) An ambulance provider or supplier with respect to emergency or non-emergency ambulance transport services, if the following conditions and documentation requirements are met.

* * * * *

30. Section 424.44 is amended by adding paragraph (a)(3) to read as follows:

§424.44 Time limits for filing claims.

(a) * * *

(3) Within 30 calendar days of the effective date of a revocation of Medicare billing privileges as defined in §424.535 for physician or nonphysician practitioner organizations, physicians, nonphysician practitioners or independent diagnostic testing facilities.

* * * * *

Subpart D--To Whom Payment is Ordinarily Made

31. Section 424.57 is amended by--

A. Amending paragraph (a) by adding the definitions of “Continuous positive airway pressure (CPAP)” and “Sleep test” in alphabetical order.

B. Adding new paragraph (f).

The revisions and additions read as follows:

§424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

(a) * * * * *

Continuous positive airway pressure (CPAP) device means a machine that introduces air into the breathing passages at pressures high enough to overcome obstructions in the airway in order to improve airflow. The airway pressure delivered into the upper airway is continuous during both inspiration and expiration.

* * * * *

Sleep test means an attended or unattended diagnostic clinical test whether performed in or out of a sleep laboratory. The 'provider of the sleep test' is the individual or entity that directly or indirectly administers the sleep test and/or provides the sleep test device used to administer the sleep test.

* * * * *

(f) Payment prohibition. A supplier cannot receive Medicare payment for a CPAP device if that supplier, or its affiliate, is directly or indirectly the provider of the sleep test used to diagnose a beneficiary with obstructive sleep apnea.