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MEMBER BRIEFING for The American Academy of Sleep Medicine

Date: August 8, 2007 **Subject:** 2008 Proposed Rule - Physician Fee Schedule

From: Neal A. Cooper **To:** AASM Board of Directors

The Centers for Medicare & Medicaid Services (CMS) issued its proposed rule, suggesting revisions to the physician fee schedule for 2008 in the July 12, 2007, Federal Register.[1] The most noteworthy proposed change may be that payment under the PFS is projected to be "updated" by a reduction of 9.9%.[2] The content of this "PFS proposed rule" goes well beyond ordinary revisions to the physician fee schedule, however, and suggests certain changes to the Stark law[3] that industry analysts did not anticipate for many weeks or months.

In addition to these proposed changes to the Stark law regulations, CMS has also proposed noteworthy changes to the assignment of locality codes and performance standards for independent diagnostic testing facilities (IDTFs), and the expiration of the physician scarcity area add-on. Comments on the PFS proposed rule must be submitted no later than August 31, 2007. It is important to note that these provisions are not the law, but may become the law to the extent that the PFS final rule retains the proposals. This Member Briefing will discuss key provisions of the PFS proposed rule applicable to members of the AASM and its affiliates, and will provide a concise summary of the process for submitting comments on the PFS proposed rule.

I. Proposed Stark Law Changes

CMS surprised the industry somewhat by proposing certain significant proposed changes to the Stark law. CMS has already submitted the "Phase III" final rule of the Stark law regulations to the Office of Management and Budget (the last stop before publication in the Federal Register), and it was not widely anticipated that the PFS would be a vehicle for Stark law changes. Many of the proposals in the PFS proposed rule, however, have not previously been subject to the "notice and comment" period required under the Administrative Procedures Act (APA), so it appears that CMS is using the PFS as an opportunity to satisfy its requirements under the APA. Whatever the motivation, the key changes to the Stark law in the PFS proposed rule are set forth in the following comparative table:

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[1] Accessible on the Internet at: http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/pdf/07-3274.pdf

[2] This reduction is the product of the so-called "sustainable growth rate" formula, which for the past 5 years Congress has legislatively disregarded to prevent payment reductions to the PFS. As of the date this Briefing is issued, H.B. 3162, § 301(c), would eliminate the 9.9% reduction and establish a 0.5% floor for updates to the PFS for 2008 and 2009.

[3] The "Stark law" prohibits physicians from making referrals of designated health services (DHS) to an entity with which the physician, or a member of the physician's family, has a financial relationship, unless an exception applies.

	Current Regulation:	Proposed Regulation:
Services Furnished "Under Arrangements"	CMS believes that current regulation results in a high risk of overutilization and increased program costs associated with services provided under arrangements by hospitals through certain hospital/physician joint ventures	Revises the definition of "entity" in the Stark law regulations to include both the entity that submits the claim to Medicare for the DHS and the entity that "performs the DHS"
		The term "performs the DHS" is not defined
		If finalized, will require restructuring or unwinding of hospital joint ventures in which an entity wholly or partially owned by physicians who refer to the hospital will "perform the DHS"
		CMS seeks comment on MedPAC's recommendation, which would expand the definition of physician ownership to include ownership interests in an entity that derives a substantial proportion of its revenue from a DHS entity
Restrictions on Per-Click Payments in Space and Equipment Leases	Permits time-based or unit-of-service based payments in space and equipment leases	Space and equipment leases may not provide per-click payments to a physician lessor for services that utilize the leased space or equipment rendered by the DHS entity lessee to patients referred by a physician lessor
Percentage-Based Compensation Arrangements	Percentage based compensation is permitted only to compensate a physician for personally performed services, however ambiguities in the rule have resulted in use of percentage compensation in other settings	Clarifies that percentage arrangements may only compensate physician's personally-performed services and must be based solely on revenues directly resulting from those services (perhaps excluding "incident to" services?)
Reassignment and Anti-Markup Provision	Current rules prohibit marking up the technical component of certain diagnostic tests purchased (*i.e.*, to be billed) by a provider other than the provider performing the test	The billing entity would be permitted to bill Medicare no more than its "net charge," which would exclude any amount paid to the performing supplier for leased equipment and space
		If technical component of diagnostic test is not performed by a full-time employee of the billing entity, then the entity may bill no more than its net charge (excluding the cost of such individual performing the test)

Burden of Proof Where a Claim is Denied Based on Prohibited Referral	N/A	In an appeal from a denial of payment for DHS on the basis that the DHS was furnished pursuant to a prohibited referral, the burden falls on the entity submitting the claim to establish that the DHS was not furnished pursuant to a prohibited referral
"Standing in Another Entity's Shoes"	N/A	If a DHS entity owns or controls an entity to which a physician refers patients for DHS, the DHS entity would "stand in the shoes" of the entity that it owns or controls and would be deemed to have the same compensation arrangements as the entity under its ownership or control, collapsing certain indirect compensation arrangements and destroying the applicable exception for affected transactions
Alternative Criteria for Satisfying Certain Exceptions	N/A	Provides an alternative method for a DHS entity and physician to satisfy requirements of an exception where there has been an inadvertent violation of procedural or "form" requirements of an exception (*e.g.*, missing a signature on a lease)
		Requires DHS entity and physician to demonstrate specified criteria, which are then reviewed by CMS
		Does not permit appeal or review of CMS' decision whether to allow alternative method of compliance
Ownership or Investment Interest in Retirement Plans	N/A	Revises definition of ownership and investment interests to exclude interest in retirement plan offered by the entity to the physician or as a result of the physician's employment with the entity to close a perceived loophole
Solicitation of Comments		CMS seeks comments about the above proposed changes, as well as: • potential changes to the in-office ancillary services exception • OB malpractice insurance subsidies • period of disallowance for noncompliant financial relationships

II. Payment Localities

CMS is proposing a "demonstration project" to reconfigure the localities used to adjust a portion of PFS payments to reflect the relative cost differences among areas. The demonstration project will focus on California, in which five relatively high-cost-of-living counties have sued CMS over the inadequacies of the locality scheme. Locality designations drive geographic adjustment factors (GAFs). CMS has the authority to adjust the GAFs, but only to the extent that the adjustments are "budget neutral" as between states. That is, if the GAF is to increase for one locality in California, that increase must be "paid for" by a proportional decrease in one or more other areas within California. CMS has proposed three different methods by which it might implement new locality designations for California. In the most volatile method, one locality will see a 7.6% increase in its GAF, to be offset by several localities experiencing a 7.3% decrease in their GAFs.

Practitioners in California should be aware of the extent to which this demonstration project might affect their payments. Even outside of California, however, providers should be attentive to this development. In June of 2007, the U.S. Government Accountability Office issued a report to the Subcommittee on Health of the House Ways and Means Committee proposing that CMS undertake fundamental changes in the payment locality designations. The GAO report was not specific on the issue of budget neutrality, but it could certainly be read to mean that CMS should consider locality designations that do not achieve budget neutrality (*i.e.*, changes that would redistribute Medicare payments between states). Disregarding budget neutrality as to the payment localities, however, could require legislative intervention. The demonstration project in California may be an important indicator of more global payment locality changes CMS is considering for future years.

III. Proposed Changes to IDTF Performance Standards

CMS has proposed significant revisions to several existing IDTF performance standards, and the addition of two new performance standards. These changes are discussed below, with the changes to the existing standards represented in redline format.[4]

A. Proposed Revisions to Existing IDTF Performance Standards

1. Liability Insurance

CMS proposes to revise the standard at 42 C.F.R. § 410.33(g)(6) to create additional requirements relating to an IDTF's comprehensive liability insurance policy. The IDTF must list the Medicare contractor as a Certificate Holder on the policy, must ensure the policy remains in force at all times, and must promptly notify Medicare in writing of any policy changes or cancellations. IDTFs are responsible for providing the contact information for the issuing insurance agent and the underwriter in order to give Medicare the ability to verify coverage. The proposed revision does not preclude the use of self-insurance to meet the liability insurance standard. Medicare encourages IDTFs to obtain comprehensive liability insurance at least 90 days prior to filing an enrollment application.

> Have a comprehensive liability insurance policy of at least $300,000 ~~or 20 percent of its average annual Medicare billings, whichever amount is greater,~~*per location* that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a non-relative owned company~~ and list the serial numbers of any and all equipment used by the IDTF~~. *Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact*

[4] Deleted text is in ~~strikethrough font~~, and new text is in *underlined italics*.

information for the issuing insurance agent and the underwriter. In addition, the IDTF must—

(i) Ensure that the insurance policy must remain in force at all times and provide coverage of at least $300,000 per incident;

(ii) Notify the CMS designated contractor in writing of any policy changes or cancellations; and

(iii) List the CMS designated contractor as a Certificate Holder on the policy.

Analysis: The substantive nature of this standard is not changing, just the information that Medicare is now requiring to be included with the policy in order for the contractors to easily verify coverage. Adding the carrier as a Certificate Holder may pose some significant practical hurdles, as insurers may balk at the possibility that the Carrier would obtain certain rights under the policy as a result.

2. Enrollment Changes

CMS proposes to revise the standard at 42 C.F.R. § 410.33(g)(2) to include a list of changes that must be reported in 30 days, which include changes in ownership, changes of location, changes in general supervision, and adverse legal actions. All other reportable changes must be reported within 90 days.

Provide complete and accurate information on ~~their~~ *its* enrollment application. ~~Any c~~*C*hange*s* in ~~enrollment information~~ *ownership, changes of location, changes in general supervision, and adverse legal actions* must be reported to the designated fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change. *All other changes to the enrollment application must be reported within 90 days.*

Analysis: The substantive nature of this standard is not changing; Medicare is only clarifying those events that it deems significant enough to be reported within 30 days.

3. Complaint Documentation

CMS proposes to revise the standard at 42 C.F.R. § 410.33(g)(8) to require documentation of the IDTF's complaint process. IDTFs will be responsible for maintaining certain documentation on all written and oral beneficiary complaints, including telephone complaints. The documentation must include the beneficiary's name, address, telephone number, and HIC number; a summary of the complaint, the date it was received, the name of the person receiving the complaint, and a summary of the actions taken to resolve the complaint; and if an investigation was not conducted, the name of the person making the decision and the reason for the decision. For mobile IDTFs this documentation must be stored at their home offices.

Answer*, document, and maintain documentation of all* beneficiaries' questions and respond*ses* to their complaints~~. Documentation of those contacts must be maintained~~ at the physical site~~.~~ *of the IDTF. This includes, but is not limited to, the following:*

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) A summary of the complaint; the date it was received; the name of the person receiving the complaint; and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision. For mobile IDTFs, this documentation would be stored at their home office.

Analysis: The revision imposes specific documentation standards to an existing performance standard, but this additional administrative burden does not substantively affect the operation of the IDTF.

4. Supervising Physician Responsibilities

CMS proposes to revise the standard at 42 C.F.R. § 410.33(b)(1) to delete the language relating to supervising physician responsibilities because it is too restrictive and had the unintended effect of appearing to shift the overall administrative responsibilities of the IDTF to the supervising physician. CMS is also proposing to clarify and expand on the meaning of "three (3) IDTF sites" so that a physician providing general supervision can only oversee a maximum of three separate sites (either fixed or mobile) where concurrent operations are being performed.

> Each supervising physician must be limited to providing supervision to no more than three ~~(3)~~ IDTF sites. ~~The IDTF supervising physician is responsible for the overall operation and administration of the IDTFs, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.~~ *This applies to both fixed sites and mobile units where three concurrent operations are capable of performing tests.*

Analysis: Medicare is proposing to remove the administrative restrictions that it initially placed on supervising physicians while also clarifying that a supervising physician is limited in the number of separate IDTF locations he or she may concurrently supervise. That number is still three, but it includes both mobile and fixed location sites.

B. Proposed New IDTF Standards

1. Initial Enrollment Date

CMS proposes a new standard at 42 C.F.R. § 410.33(i)[5] to establish an initial enrollment date for IDTFs to be the later of: 1) the date of filing of a Medicare enrollment application that is subsequently approved, or 2) the date an IDTF first started rendering services at its new practice location. "Date of filing" is defined as the date the Medicare contractor receives a signed provider enrollment application that the contractor is able to process and approve. CMS expects to implement a web-based enrollment process in most states during CY 2007, which will permit IDTFs to complete and submit enrollment applications online.

> ~~Definition. For purposes of this section, the following definition applies: Point of actual delivery of service. The point of the actual delivery of service means the Place of Service on the claim form. When an IDTF performs a diagnostic test at the beneficiary's residence, the beneficiary's residence is the Place of Service.~~
> Effective date of billing privileges. The effective date of billing privileges for a newly enrolled IDTF is the later of the following:
>
> (1) The filing date of the Medicare enrollment application that was subsequently approved by a fee-for-service contractor;
> (2) The date the IDTF first furnished services at its new practice location; or
> (3) The filing date of the Medicare enrollment application or the date that the Medicare fee-for-service contractor receives a signed provider enrollment application that it is able to process for approval.

[5] There is already a provision at § 410.33(i) that would apparently be replaced by this new standard, as reflected in the redline comparison. It does not appear, however, that CMS intended to delete the existing subsection (i).

Analysis: This change will limit the ability of IDTFs to retroactively bill for services prior to Medicare enrollment. Currently, IDTFs may bill for services rendered up to 27 months prior to their enrollment date. This change will mean that an IDTF can only back-bill to the later of the date it filed its enrollment application or the date it first started rendering services. It is not clear how this standard would apply in the event that CMS retroactively determines that an entity that did not enroll as an IDTF should have enrolled as an IDTF.

2. Certification of No Shared Space/Equipment/Staff

CMS proposes a new performance standard at 42 C.F.R. § 410.33(g)(15) to require each IDTF to certify that it "Does not share space, equipment, or staff or sublease its operations to another individual or organization." CMS believes it is inappropriate for a fixed-base (physical site) IDTF to commingle office space, staff, and equipment, and that commingling office space, staff and equipment, or subleases to another individual or organization, constitutes a significant risk to the Medicare program because it prohibits Medicare contractors from ensuring that each physical site establishes and maintains billing privileges and meets all performance standards. This proposed standard, in conjunction with the current appropriate site standard, expands the interpretation of these standards to state that a motel or hotel is not an appropriate site for an IDTF. In addition, subleasing agreements may also raise concerns because they may implicate the physician self-referral prohibition and the anti-kickback prohibition.

> *Does not share space, equipment, or staff or sublease its operations to another individual or organization.*

Analysis: This proposed standard poses a substantial operational risk to any IDTF currently sharing space with another entity (not just a health care entity) and to those sleep center IDTFs that perform sleep studies in hotel or motel rooms. The fact that it prohibits sharing space with "another" individual or organization could mean that physician group practices that also operate an IDTF (which Medicare can require depending on testing volume) may be able to continue this practice because the group practice and IDTF are essentially the same entity, but that clarification has not been made by CMS. The new standard specifically uses the term "sublease", so it would not appear to prohibit a simple lease by an IDTF that owns (rather than leases) its facility.

IV. Expiration of the Physician Scarcity Area Add-On

Physicians' services furnished in physician scarcity areas were subject to a 5% incentive payment beginning January 1, 2005. This add-on was established by the Medicare Modernization Act, and had a "sunset" of December 31, 2007. In the PFS proposed rule, CMS gives notice of the termination of the incentive add-on, but it is not within CMS' authority to disregard the statutory termination of the incentive payment. It is not clear whether any legislators are contemplating renewing the incentive add-on, but physicians in physician scarcity areas should anticipate losing the 5% add on for services furnished on or after January 1, 2008.

V. Process for Submitting Comments on the Proposed Rule

The easiest method for submitting comments on the PFS proposed rule may be electronically on the CMS website, at http://www.cms.hhs.gov/eRulemaking/. Comments can also be submitted by mail or courier, and page 2 of the PFS proposed rule describes these modes in greater detail (see fn. 1). No matter what the mode of submission, however, comments must be received no later than 5p.m. (EDT) Friday, August 31, 2007.

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VI. Conclusion

The PFS proposed rule suggests that CMS is considering sweeping changes to many regulations directly affecting sleep medicine practitioners. These proposals are not currently the law, but there is a strong likelihood that they may become the law upon issuance of the PFS final rule later this year. Members of AASM and its affiliates are advised to discuss these proposed changes with their business advisors to assess the extent to which the PFS proposed rule would alter their operations, and to consider whether it would be useful or appropriate to comment on the PFS proposed rule.

Prepared by:

Neal A. Cooper
Hall, Render, Killian, Heath & Lyman
ncooper@hallrender.com
317-977-1455 (v)
317-633-4878 (f)
One American Square
Suite 2000 – Box 82064
Indianapolis, IN 46282