

CMS PROPOSED NEW HOSPITAL OUTPATIENT AND PHYSICIAN FEE SCHEDULE POLICIES AND RATES FOR CY 2007

On August 8, CMS posted on its website proposed CY 2007 Medicare rates and policies for hospital outpatient departments under the Hospital Outpatient Prospective Payment System (HOPPS Proposed Rule) and physicians' services paid under the Physician Fee Schedule (the PFS Proposed Rule). Hospital inpatient services are not addressed by these proposals.

Medicare payment for the overhead, equipment, supplies and non-physician clinical personnel (technical component or TC) of echocardiography and other services provided in hospital outpatient departments is made based on the Ambulatory Payment Classification (APC) of the service involved. Payments to physicians, imaging centers, clinics, and other non-hospital providers are made under the Physician Fee Schedule (PFS), with separate payment amounts designated for TC services and for the physician's interpretation or other professional service ("professional component" or "PC").

The following are the salient features of these Notices that are of interest to ASE members:

- Overall, the rates in the HOPPS Proposed Rule reflect a 3.2% increase in the HOPPS conversion factor. Under this Proposed Rule, Medicare payment to hospitals for echo TC services will increase marginally.
- The proposed PFS includes substantial changes in both the conversion factor and the relative value units that determine Medicare payment for virtually all physicians' services, including echocardiography services.
 - While prior projections indicated that the conversion factor would be reduced by about 4.6% under the existing update formula, more recent projections indicate that the decrease in the conversion factor will be in the range of 5.1%. However, Congress may pass legislation to preclude this across-the-board reduction from going into effect.
 - The rates set forth in the PFS Proposed Rule reflect a significant proposed increase for evaluation and management services. To pay for this increase, Medicare payment for work relative value units (which comprise most of the RVUs for professional component services) will be reduced across the board by 10%.
 - CMS is also proposing changes in the methodology for determining payment for physicians' practices expenses, and these changes will be phased in over the next four years. Altogether, under the Proposed Rule, it is estimated that relative value units for office-based echocardiography services will be reduced by approximately 23% by 2010, when the

methodological changes related to payment for practice expenses are fully phased in.

- Effective January 1, 2007, the Deficit Reduction Act (DRA) will limit the TC for echo services provided in physicians' offices and other non-hospital settings to the APC rates for comparable echo services in hospitals. However, because the proposed CY 2007 TC for echo services in physicians' offices and other non-hospital settings is lower than the proposed APC rates for comparable echo services in hospitals, the DRA will not affect echo services in CY 2007, if the proposed rates are adopted in the final rule (to be issued this Fall).
- The PFS Proposed Rule also includes proposed changes to the reassignment regulations that may affect independent contractor relationships with non-cardiology and other practices that provide echo services. A brief summary is provided.
- The PFS Proposed Rule also includes proposed changes to the Stark Law, which may affect the ability of small cardiology practices to provide echo services and that may alter the types of shared facility arrangements that qualify for a Stark Law exception. A brief summary of the proposed changes is provided. ASE members are advised to request qualified counsel to review the potential impact of these changes on their practices.
- CMS is proposing to significantly modify the standards applicable to Independent Diagnostic Testing Facilities (IDTFs) that seek to participate in the Medicare Program. The new proposed standards for IDTFs accompany this memo, and some on Capitol Hill are considering extending these standards to physicians office facilities.

A chart setting forth current and proposed CY 2007 PFS and OPD rates for the primary echocardiography services, accompanies this memo. Also included for comparison is the same data for a number of general ultrasound and nuclear cardiology services. **This chart does not reflect the projected 5.1% reduction in the conversion factor OR the additional 10% budget neutrality adjustment for W-RVUs (which would reduce Medicare payment for professional component services by an estimated 6-7% below the amounts set forth on the attached chart.) Due to the complexity of the changes made in the PFS this year, it is possible that the final rates will differ substantially from those set forth in the PFS Proposed Rule.**

Proposed Changes to Reassignment Rules

The Medicare law prohibits Medicare payment to anyone other than the Medicare beneficiary or the physician or other person who performed the service for the beneficiary, unless the arrangement qualifies for an exception. One exception the Medicare program to make payment to a billing entity (like a physician group) for services provided by an independent contractor if certain conditions are met. Prior to the Medicare Prescription Drug Improvement and Modernization Act of 2003 (the “MMA”), payment could be made only if the independent contractor’s services were performed on the premises of the billing entity. The MMA enables the services of independent contractors to be regardless of whether the services are performed on the premises of the billing entity.

To prevent abusive arrangements, CMS is proposing to amend the rules to preclude billing entities from marking up TC services provided by an independent contractor and is considering whether it should impose conditions on when a billing entity (like a physician group) can bill for a reassigned professional component of a diagnostic test (e.g. echocardiography professional components). The conditions CMS is considering are: (a) the test must be ordered by a physician who is financially independent of the person or entity performing the test and also of the physician or medical group performing the interpretation; (b) the physician or medical group performing the interpretation does not see the patient; and (c) the physician or medical group billing for the interpretation must have performed the TC of the test. ASE likely will be commenting on this aspect of the Proposed PFS Rule.

Proposed Changes to Physician Self-Referral Rules

In the Proposed Rule, CMS seeks to modify the “physician services” and the “in-office ancillary services” exceptions to the Stark Law prohibition on physician referrals for DHS to an entity with which the physician has a financial relationship. Under the current regulations, an independent contractor physician must furnish echocardiography PC services on the group’s premises in order for the group to be able to bill for those services. Moreover, the group can bill for the technical component of echocardiography services only if certain “location” requirements are met: echocardiography TC services must be furnished in the same building where the group performs a certain amount of physician services or in a “centralized building.”

CMS is proposing to modify the definition of “centralized building” at 42 C.F.R. § 411.351 for purposes of both of these exceptions, to include a minimum square footage requirement of 350 feet (although it would not apply to space owned or rented in a building in which no more than three group practices own or lease space in the same building) and to require that the space contain, on a permanent basis, the necessary equipment to perform substantially all of the echocardiography services performed in the space. According to CMS, the purpose of the proposed change is to prevent abusive arrangements such as pod labs while not disqualifying legitimate, stand-alone physician offices that are unusually small.

CMS is seeking comments on whether there should be a minimum square footage requirement, whether it should be 350 feet and whether there should be any exceptions to the requirement. Further, CMS is soliciting input on other possible changes to the “centralized building” requirement.

Proposed Supplier Standards for Independent Diagnostic Testing Facilities

Independent Diagnostic Testing Facilities (IDTFs) are entities that are not hospitals or physician practices and that provide certain diagnostic services, including echocardiography services.

On June 30, 2006, the HHS OIG issued a report on the results of its review of claims billed by IDTFs for services provided to Medicare beneficiaries in CY 2001 and found a potential \$71 million in improper payments made to IDTFs, resulting from poor or missing documentation or lack of medical necessity. CMS further notes that it has determined that a number of IDTFs in California and other states are perpetrating schemes to defraud the Medicare program.

To address this problem, CMS is proposing to establish new IDTF standards, and IDTFs would have to be in compliance with these standards in order to obtain or retain enrollment in the Medicare program. And, if at any time CMS determines that an enrolled IDTF no longer meets the standards, its billing privileges would be revoked.

The 14 proposed IDTF supplier standards require an IDTF to:

- (1) Operate its business in compliance with all applicable federal, state and local licensure and regulatory requirements with regard to health and safety of patients;
- (2) Provide complete and accurate information on its enrollment application and report any change in enrollment information within 30 calendar days;
- (3) Maintain a physical facility at an appropriate site. For purposes of this standard, a post office box or commercial mailbox would not be considered a physical facility. The physical facility would be required to contain space for equipment appropriate to the services designated on the enrollment application, facilities for hand washing, adequate patient privacy accommodations, and the storage of both business records and current medical records;
- (4) Have all applicable testing equipment available at the physical site, excluding portable equipment. A catalog of portable equipment, including equipment serial numbers, would be maintained at the physical site. In addition, portable equipment would be made available for inspection within two business days of a CMS inspection request. The IDTF would be required to maintain a current inventory of the equipment (including serial/registration numbers), provide this information to the designated fee-for-service contractor and notify the contractor of any changes in equipment;
- (5) Maintain a primary business phone under the name of the business. The business phone would be located at the designated site of the business. The telephone number or toll free numbers would be available in a local directory and through directory assistance;

- (6) Have a comprehensive liability insurance policy of at least \$300,000 or 20 percent of its average annual Medicare billings, whichever is greater, that covers both the place of business and all customers and employees of the IDTF. The insurance policy would be carried by a non-relative owned company. The policy would be required to list the serial numbers of any and all equipment used by the IDTF;
- (7) Agree not to directly solicit patients, which includes, but is not limited to, a prohibition on telephone, computer, or in-person contacts. The IDTF would accept only those patients referred for diagnostic testing by an attending physician, who is furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Nonphysician practitioners may order tests as set forth in § 410.32(a)(3);
- (8) Answer beneficiaries' questions and respond to their complaints. Documentation of those contacts would be maintained at the physical site;
- (9) Openly post these standards for review by patients and the public;
- (10) Disclose to the government, any person having ownership, financial or control interest, or any other legal interest in the supplier at the time of enrollment or within 30 days of a change;
- (11) Have its testing equipment calibrated per equipment instructions and in compliance with national standards;
- (12) Have technical staff on duty with the appropriate credentials to perform tests. The IDTF would be required to produce the applicable federal or state licenses and/or certifications of the individuals performing these services;
- (13) Have proper medical record storage and be able to retrieve medical records upon request from CMS or its designated fee-for-service contractor within 2 business days; and
- (14) Permit CMS, including its agents and its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF's compliance with these proposed standards. The IDTF would be required to provide access, during regular business hours, to CMS and beneficiaries, as well as maintain a visible sign posting the normal business hours of the IDTF.

In addition to the above standards, CMS is proposing to revise 42 C.F.R. § 410.33(b)(1) to provide that physicians will be limited to providing supervision to "no more than three (3) IDTF sites." Further, CMS seeks to define the "point of the actual delivery of services" as the correct "Place of Service" for the claim form in the case of diagnostic testing performed outside the IDTF's physical location.

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