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CMS Adopts Operational Restrictions for Independent Diagnostic Testing Facilities

On November 1, 2007, the Centers for Medicare and Medicaid Services (CMS) issued the display copy of the final CY 2008 Physician Fee Schedule rule with provisions affecting Independent Diagnostic Testing Facilities (IDTFs). Notably, CMS adopted new standards which could have a significant impact on many IDTFs. CMS also revised several existing performance standards.

New IDTF Standards

Restrictions on Sharing and Lease Arrangements. In response to its concern regarding potential fraud and over utilization of Medicare services, CMS proposed a new performance standard for IDTFs which provided that an IDTF could not "share space, equipment, or staff or sublease its operations to another individual or organization." Based on public comments, CMS removed the prohibition on sharing of staff and excluded hospital-based and mobile IDTFs from the new standard.

As finalized, the new standard provides that a fixed-based IDTF **may not**:

1. Share a practice location with another Medicare-enrolled individual or organization;
2. Lease or sublease its operations or its practice location to another Medicare-enrolled individual or organization; or
3. Share diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

With one exception, this standard is effective January 1, 2008. The exception is that CMS provided a one year transition period for currently enrolled IDTFs that are sharing a practice location with another Medicare-enrolled individual or organization. In order to permit such IDTFs time to find new office space or revise its business model, CMS is delaying the effective date of the sharing provision for existing IDTFs (item #1) until *January 1, 2009*. IDTFs that enroll after the effective date or have applications still pending as of January 1, 2008, do not benefit from the one-year transition period.

In response to comments, CMS provided the following additional guidance regarding the sharing of space. The standard does not prohibit an IDTF from sharing common areas such as hallways, parking areas and waiting rooms. However, a multi-specialty clinic cannot occupy or be co-located within the same practice location as an IDTF. For example, a multi-specialty clinic and an IDTF could not enroll or remain enrolled using the same suite number within the same office building.

CMS provided some clarification regarding the prohibition on maintaining or establishing leasing or subleasing agreements and from sharing diagnostic testing equipment used in taking the initial diagnostic test. Specifically, an

IDTF may acquire leased space or equipment if the space or equipment is used solely by the IDTF. However, the IDTF may not lease or sublease its practice location or specified diagnostic equipment to another Medicare-enrolled individual or organization or to a third party. CMS indicates that this restriction is, in part, in response to the emergence of arrangements in which a physician practice leases a block of time from an IDTF or agrees to pay a per services fee to use the IDTF facility.

Mobile IDTFs were excepted out of the standard based on comments that such limitations would limit beneficiaries' access to necessary mobile services and increase the cost of providing necessary diagnostic care.

CMS excepted hospital-based IDTFs out of the standard based on comments asserting that hospital-based IDTFs are inherently located within a larger facility type and, based on the needs of the hospital, may appropriately share space or clinical equipment to gain operating efficiencies with little additional risk to the Medicare program or its beneficiaries.

Preclusion of Hotels and Motels as Testing Sites. CMS revised the standard addressing an "appropriate site" to preclude hotels and motels from being considered an appropriate site for an IDTF setting. This revision impacts IDTFs that conduct sleep studies in hotel and motel settings. The effective date of this provision is January 1, 2008, which does not provide much time for affected IDTFs to make alternative arrangements.

Limitation on Retrospective Billing. Currently, IDTFs have the ability to retrospectively bill Medicare for services provided up to 27 months prior to enrollment in the Medicare program. Effective January 1, 2008, an IDTF may bill retrospectively only to the date of initial enrollment which is the later of (1) the date of filing of a Medicare enrollment application that is subsequently approved by the Medicare carrier; or (2) the date the IDTF first started furnishing services at its new practice location. The "date of filing" is the date that the Medicare carrier receives a signed provider enrollment application that the carrier is able to process for approval. CMS adopted this approach to ensure that Medicare carriers are able to verify that an IDTF meets all program requirements at the time of filing and before payment for services occurs.

Revisions to Existing Standards

Comprehensive Liability Insurance Policy. In response to the comments related to increased administrative burden, CMS is not requiring that the Medicare contractor be included as a Certificate Holder on the comprehensive liability policy as was proposed. Instead, IDTF's must provide the contact information for the issuing insurance agent and underwriter. CMS also now requires that the IDTF maintains the policy in force at all times, provides coverage of at least \$300,000 per incident, and notifies the CMS-designated contractor in writing of any policy changes or cancellations.

Changes in Enrollment Information. Currently, IDTFs are required to report all changes in information within 30 days of the change. Effective January 1, 2008, only changes in ownership, changes of location, changes in general supervision, and adverse legal actions must be reported to Medicare within 30 days of the change. All other changes to the information in the enrollment application must be reported within 90 days. CMS plans to revise the CMS Form 855B to specify what items must be reported within 30 and within 90 days. In addition, CMS is developing the Provider Enrollment, Chain, and

Ownership System (PECOS) Web which will permit enrollment and reporting of changes via the internet. CMS hopes to implement PECOS Web by March 2008.

Beneficiaries' Questions and Complaints. CMS chose to adopt the proposed revisions to the beneficiary complaint process with certain modifications in order to limit the paperwork burden on IDTFs. IDTFs will be required to answer, document, and maintain documentation of written clinical complaints, rather than all questions and complaints as proposed. The documentation, which must be maintained at the physical site of the IDTF (the home office for mobile IDTFs) should include, but not be limited to: 1) the name, address, telephone number and health insurance claim number of the beneficiary; 2) the date the complaint was received, the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint; and 3) if an investigation was not conducted, the name of the person making the decision and the reason for the decision.

Supervising Physician. CMS is removing from the regulation at 42 C.F.R. § 410.33(b)(1) the sentence that provided that the IDTF supervising physician is responsible for the overall operation and administration of the IDTF. This provision was deleted in part because CMS believed that the provision had the unintended consequence of appearing to shift the overall administrative responsibility from owners or administrative staff employed by an IDTF to the supervising physician.

CMS is also revising this regulation to clarify the meaning of what constitutes "three IDTF sites" for purposes of limiting the number of sites for which a physician can provide general supervision. A physician can supervise no more than three IDTF sites, and "three IDTF sites" includes both fixed sites and mobile units where three concurrent operations can be performed.

Physical Facility – Hand Washing and Patient Privacy. CMS clarified in the final rule that IDTF suppliers that provide services remotely and do not see beneficiaries at a practice location are not required to provide hand washing and adequate patient privacy accommodations at that location.

Comments on the final rule are due 60 days from the date of publication in the Federal Register which is expected later this month. If you have questions regarding the IDTF performance standards please contact your regular Hall Render attorney or Regan E. Tankersley at rtankersley@hallrender.com or 317-977-1445, Scott Geboy at sgeboy@hallrender.com or 414-721-0451, or Lori A. Wink at lwink@hallrender.com at 414-721-0456.

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