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December 10, 2007

Health Law Client Action Alert

New Medicare Restrictions on Diagnostic Tests Require Restructuring of Many Arrangements by End of 2007

New Medicare rules require the immediate restructuring of any arrangements under which physicians, group practices and certain other parties bill for diagnostic tests (or test interpretations) that are provided outside the office space in which the ordering physicians conduct their practice—even when the services are provided in the same building. Arrangements subject to this new rule include block leasing arrangements. A separate rule will affect many independent diagnostic testing facilities ("IDTF"s).

Effective January 1, 2008, regulations under Medicare Part B will prohibit any physician or other "supplier" from billing for the technical component (TC) or the professional component (PC) of a diagnostic test that was ordered by the physician or supplier (or a related entity) unless:

> (1) that component was performed **both** in the offices of the physician or supplier, **and** by an employee of the physician or supplier or an independent contractor who has assigned his right to bill to the physician or supplier; **or**
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> (2) the amount billed does not exceed the lower of the "net charge" to the billing party by the outside supplier or the Medicare fee schedule amount for the service in question if the outside supplier billed for the service directly. In this case, the bill must identify the party performing the services and the amount of the "net charge" to the billing party.

The second exception prevents the billing party from marking up the cost of the services. Therefore, unless the first exception applies, the ordering physician or group cannot derive any economic benefit from billing for the services.

For this reason, all physicians and other suppliers that order and bill for TCs and/or PCs of diagnostic tests should determine whether those services are performed in the office of the billing physician or supplier (as defined below) by an employee or independent contractor who would be entitled to bill Medicare for the services and who has assigned his or her billing rights to the billing party. If not, the party performing the services must bill directly for Medicare-covered services rendered on or after January 1, 2008, or the second exception must be met.

The new rules apply to any "services covered under Section 1861(s)(3)" of the Social Security Act and paid for under 42 C.F.R. chapter 414 (other than clinical laboratory tests, which are subject to separate rules). Included in this definition are diagnostic X-ray tests, diagnostic

laboratory tests (other than the clinical laboratory tests noted above), and other diagnostic tests, including but not limited to diagnostic radiology, nuclear medicine, ultrasound, transcatheter procedures, transluminal atherectomy, cardiography, echocardiography, diagnostic cardiac catheterization, vascular studies, pulmonary tests, allergy tests, sleep lab tests, and audiologic function tests. (For a complete list, see CMS Memorandum B-01-28.) The rules do not apply to hospital outpatient services covered under Section 1861(s)(2)(C) of the Social Security Act.

The "office of the billing physician or other supplier" is defined as "**medical office space where the physician or other supplier regularly furnishes patient care.**" If the supplier is a "physician organization" (a group or practice entity through which a physician practice is conducted), the "office" is further limited **to space in which the group provides "substantially the full range of patient care services that the physician organization provides generally.**" Block lease arrangements will have difficulty meeting these requirements.

"Net charge" is defined as the amount paid by the billing party to the party that performed the TC or PC, reduced by any amount "that is intended to reflect the cost of equipment or space leased" to the party performing the services "by or through" the party billing for the services.

Most notably, a physician or supplier will be deemed to have ordered the test if the test is "ordered by a party related to the physician or other supplier through common ownership or control" as defined in Medicare regulations. For example, if a diagnostic test is ordered by a radiologist or cardiologist who is employed by a group whose owners also own an IDTF, the IDTF cannot bill for the test unless one of the exceptions is met.

Note that these rules are separate from the Medicare self-referral law (the so-called "Stark Law"). Many arrangements structured to comply with the Stark Law will not meet the requirements of this new anti-mark-up rule.

A separate Medicare rule -- which also becomes effective January 1, 2008 -- applies only to Medicare-certified IDTFs. The rule will, among other things, prohibit IDTFs (other than hospital-based and mobile IDTFs) from (1) "sharing a practice location with another Medicare-enrolled individual or organization" such as a physician group, (2) "leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization," or (3) "sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization." As to prohibition (1) only, this will be deferred to January 1, 2009 for arrangements currently in effect. However, prohibitions (2) and (3) are effective for all IDTFs as of January 1, 2008.

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If you have questions concerning this newsletter, please call Dennis Witherell or Jenifer Belt at 800-444-6659, or Ron Christaldi, Barbara Pankau or Erin Aebel at 800-677-7661.

This newsletter is designed to provide general information on matters of interest to health care providers and practitioners and is not intended to constitute legal advice.