

November 30, 2007

Dear Acting Administrator Weems:

The undersigned organizations are writing to urge CMS to delay application of the major revisions to the rule prohibiting the mark-up of diagnostic tests. Substantial modifications of this rule were published for the first time in the final 2008 Physician Fee Schedule (PFS).

The anti-markup rule, which is based on Section 1842(n) of the Social Security Act, precludes physician practices from “marking up” certain diagnostic tests. The statute specifically excludes diagnostic tests that are performed personally by, or supervised by, the billing physician or another physician “with whom [the billing physician or entity] shares a practice.” Accordingly, the implementing regulation, 42 C.F.R. § 414.50, currently limits application of the anti-markup rule to the technical component of diagnostic tests purchased from an outside supplier.

The Notice of Proposed Rulemaking for the CY 2008 PFS proposed tightening and clarifying the anti-markup rule as it applies to technical component services and extending it to the professional component of diagnostic tests. It did not propose extending it to diagnostic services provided within a physician group.

Under the final rule, however, CMS expanded the anti-markup rule to apply to services provided within a group practice. Specifically, CMS expanded the anti-markup rule to apply to both the professional component and the technical component of a diagnostic test provided “outside of the office” of the billing entity. Notably, when the billing entity is a “physician organization” [i.e., a “group practice” for the purposes of the federal restriction on physician self-referral], the “office of the billing physician or other supplier” is defined narrowly as “space in which the physician organization provides *substantially the full range of patient care services* that the physician organization provides generally.” [Emphasis added.]

Where a diagnostic test is provided in a place other than the location (if any) where a physician group provides substantially the “full range” of its patient care services, the group will be required to include a “per procedure” charge on the Medicare claim for the test, as if the group were purchasing the test from an outside supplier rather than providing it directly. The practice will then be paid the lesser of the PFS amount or the internally generated “charge.” If no “charge” is reported on the claim, the practice will not be paid, and the group may be subject to significant sanctions.

Significantly, while there is no definite guidance on how to calculate a “per procedure” charge for services performed by an employee technician or physician, the preamble of the rule suggests that the employee’s salary should be the sole factor used in determining the charge. In other words, physicians and medical groups may not be reimbursed for equipment, facility, overhead or any other expenses for providing diagnostic procedures

that they are legally entitled to provide under the federal physician self-referral regulations.

Informal discussions with CMS personnel suggest that the expanded anti-markup rule will be applied strictly, leading to nonsensical results. For example, under the rule, a sole practitioner who reads an x-ray in a rehabilitation facility would be required to generate a charge to himself. A cardiologist who performs a nuclear study in his practice's office across the street due to physical facility requirements would have to generate a charge to her practice. An orthopedic practice that operates an x-ray facility in an outlying office in a medically underserved area would be subject to the anti-markup rule.

In some situations, it is unclear whether there will be any location where the group provides the "full range" of its patient care services. For example, consider a surgical practice that provides substantial services to hospital inpatients. Does any non-hospital location provide the "full range" of the practice's patient care services? Ironically, the larger a group practice is, the less likely that it will have any space where it provides the "full range" of its services. For example, consider a large multi-specialty clinic whose services are located throughout a medical complex. There may be no office where the "full range" of services is provided: hence the anti-markup prohibition may apply regardless of where the diagnostic test is provided.

We believe that the application of the anti-markup rule to services provided within a bona fide group practice exceeds CMS's statutory authority; the statute specifically precludes application of the rule to services provided by physicians who "share a practice." Moreover, the expansion of the rule to services provided within group practices was never subject to notice and comment rulemaking, and is implicitly inconsistent with the federal self-referral regulations, which explicitly authorize group practices to provide these services.

In addition, the rule is ambiguous on its face; clearly, providers will struggle to understand the impact of this rule and to comply by the January 1, 2008 effective date. Some will incur needless expense to move equipment and modify facilities. Many others will be unable to comply with the new site of service test, and will either have to develop a new system for charging themselves for diagnostic services provided in an off-site location, or cease providing diagnostic tests to Medicare patients, forcing them to travel elsewhere to get the tests they need.

We urge CMS to delay implementation of this provision in order to evaluate the substantial impact these changes will have on health care providers.

Sincerely,

American Academy of Allergy, Asthma and Immunology
American Academy of Dermatology Association
American Academy of Facial Plastic & Reconstructive Surgery

American Academy of Family Physicians
American Academy of Neurology
American Academy of Otolaryngology – Head & Neck Surgery
American Academy of Physical Medicine & Rehabilitation
American Association of Clinical Urologists
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Allergy, Asthma and Immunology
American College of Cardiology
American College of Emergency Physicians
American College of Gastroenterology
American College of Obstetricians and Gynecologists
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American College of Physicians
American College of Radiation Oncology
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Medical Association
American Medical Group Association
American Osteopathic Academy of Orthopedics
American Osteopathic Association
American Society for Gastrointestinal Endoscopy
American Society of Addiction Medicine
American Society of Cataract & Refractive Surgery
American Society of Clinical Oncology
American Society of Echocardiography
American Society of Nuclear Cardiology
American Thoracic Society
American Urological Association
Association of American Medical Colleges
Cardiology Advocacy Alliance
Congress of Neurological Surgeons
Heart Rhythm Society
Infectious Diseases Society of America
Joint Council of Allergy, Asthma and Immunology
Marshfield Clinic
Mayo Clinic
Medical Group Management Association
Park Nicollet Health Services
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery