August 29, 2008

Acting Administrator Kerry N. Weems
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1403-P
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Subject: *CMS-1403-P; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule*; 73 *Fed. Reg.* 38,502 (July 7, 2008).

Dear Acting Administrator Weems:

The undersigned organizations are writing to you with respect to the proposed extension of the anti-markup prohibition to a broad range of diagnostic services provided by physician practices, including not only diagnostic imaging services but also a broad range of other diagnostic tests, such as audiology, allergy testing, gastrointestinal and neurological testing. We very much appreciate the Centers for Medicare and Medicaid Services (CMS) decision to delay the extension of the anti-markup rule pending further consideration of the concerns raised by the undersigned organizations and other members of the public; however, we are deeply disappointed by the agency's current proposal, as set forth in the CY 2009 Physician Fee Schedule Proposed Notice. As discussed in more detail below, we believe CMS should withdraw both the delayed provisions in the CY 2008 Physician Fee Schedule and the current proposal. The anti-markup rule should not be applied to any diagnostic test that is provided directly by a physician group practice to Medicare patients in compliance with the restrictions imposed by the federal physician self-referral law (Social Security Act, §1877) (the "Stark Law") or to diagnostic tests that are exempt from the Stark Law.

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 from the anti-markup prohibition 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." Last year, CMS expanded the anti-markup rule to apply to some services provided within a group practice based on new site-of-service distinctions more restrictive than those permitted for Stark law purposes. Application of the expanded anti-markup prohibition was subsequently delayed (except with respect to certain pathology services), as the result of strenuous objections raised by the physician community.

The Proposed Notice sets forth two principal "options" (with various "sub-options") for extension of the anti-markup rule, both of which would affect diagnostic services provided directly by physician practices and not through outside suppliers. We note that proposed

regulatory language is only provided with respect to one of these options (and not all of its "sub-options").

Under the first option, the anti-markup rule would not apply if a service is provided or supervised by a physician who "shares a practice" with the billing practice. This option mirrors the statutory language, but the preamble suggests a definition of "shares a practice" that is inconsistent with a common sense interpretation (i.e., if a physician contracts with more than one group, s/he does not "share a practice" with any group). Under the second option, the applicability of the anti-markup provisions would depend upon site-of-service distinctions, and in this respect is fundamentally similar to, although technically different from, last year's rule, the application of which was deferred. Inexplicably, this option as proposed is more restrictive for group practices than it is for solo practitioners.

Neither of these options addresses the primary concerns raised by the physician community last year. We continue to believe that the application of the anti-markup rule to services provided within a bona fide group practice based on site-of-service exceeds CMS' statutory authority. Section 1842 (n) specifically precludes application of the rule to services provided by physicians who "share a practice," and it is difficult for us to understand how CMS can reasonably conclude that a physician who is, for example, a full time employee of a group practice does not "share a practice" with the group simply because s/he provides or supervises a diagnostic service at the hospital or at another location. (In fact, since the statute specifically exempts services provided "by a physician" from the scope of the anti-markup prohibition, it is difficult for us to understand the legal rationale for applying the prohibition to professional component services at all.)

Moreover, we have serious concerns about the other option set forth only in the preamble. While the Proposed Rule provides no regulatory language defining what it means for physicians to "share a practice" for the purposes of the anti-markup rule, the preamble states that a physician who provides or supervises diagnostic services for more than one physician practice will not be considered to be "sharing a practice" with any of them. No such requirement applies under the Stark Law or implementing regulations, and in fact this new approach would be directly inconsistent with carefully crafted Stark law requirements that must be met in order for physicians who practice together to (1) be considered a *bona fide* group for Stark purposes and (2) provide and bill Medicare for diagnostic imaging and other "designated health services" under the "in office ancillary services" exception.

Since the anti-markup prohibition and the Stark Law were both enacted to determine whether, and under what circumstances, physician groups may provide and charge for ancillary services, including diagnostic tests, there appears to be no justification for interpreting the scope of these provisions differently. Furthermore, given that the anti-markup provision in Section 1842(n) with its relatively general language came first, and the much more specific requirements of the Stark Law in Section 1877 came later, it appears to us that Congress has now defined specifically what it means for physicians to "share a practice" for Medicare purposes. Yet, the Proposed Rule suggests that CMS has interpreted the scope of these provisions differently, and has done so without providing any rationale.

In short, under both options, CMS would impose significant additional, and potentially conflicting, site-of-service or practice requirements on the provision of diagnostic services by physician practices that are already subject to the Stark Law's complex and burdensome requirements. In addition, under both options, practices that provide diagnostic services that Congress deliberately exempted from the Stark Law requirements would find themselves subject to new and potentially burdensome restrictions on their provision of diagnostic tests. The Stark Law initially included all radiology and "other diagnostic" services, but was subsequently amended to apply only to radiology services, which indicates that Congress determined that the provision of non-radiological diagnostic tests did not pose a substantial risk of program abuse.[1] CMS' proposals would expand the anti-markup restrictions to diagnostic services that Congress specifically acted to exclude from the Stark Law restrictions.

To demonstrate the serious problem CMS would create for physician practices under the regulatory language currently proposed, services that are provided within a physician office but not meeting the "shares a practice" or site-of-service tests would be subjected to the same payment limitation placed on services purchased from outside suppliers. While an outside supplier is able to set a charge to include that supplier's direct costs and overhead, under the current regulatory text found at 42 C.F.R. § 414.50(a)(2)(i), physician organizations would not even be allowed to recoup the costs of equipment, space and medical records management for services performed within their practices.

In sum, we believe CMS should abandon its proposal to address its concerns about utilization by further expanding the anti-markup rule, especially in light of Congress' inclusion of new accreditation standards and an appropriateness demonstration for advanced imaging in the Medicare Improvements for Patients and Providers Act (MIPPA). The undersigned request that CMS withdraw the delayed portions of the 2008 PFS and any further proposed revisions.

Sincerely,

American Academy of Dermatology Association
American Academy of Family Physicians
American Academy of Home Care Physicians
American Academy of Neurology Professional Association
American Academy of Otolaryngology-Head and Neck Surgery
American Academy of Physical Medicine and Rehabilitation
American Association of Clinical Endocrinologists
American Association of Clinical Urologists
American College of Cardiology
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 Rheumatology

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[1] See Section (b)(6) of Pub. L. 103-432 §152(b)(1), (2), substituting "services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services" for "or other diagnostic services."

American College of Surgeons
American Gastroenterological Association
American Medical Association
American Osteopathic Academy of Orthopedics
American Osteopathic Association
American Society for Gastrointestinal Endoscopy
American Society of Addiction Medicine
American Society of Echocardiography
American Society of Clinical Oncology
American Society of Nuclear Cardiology
American Society of Plastic Surgeons
Association of American Medical Colleges
Heart Rhythm Society
Joint Council of Allergy, Asthma and Immunology
Medical Group Management Association
Society for Cardiovascular Angiography and Interventions
Renal Physicians Association
Society of Cardiovascular Computed Tomography
Society of Cardiovascular Magnetic Resonance
The Endocrine Society