Self-Referral Of Diagnostic Imaging Services Targeted In 2009 Medicare Physician Fee Schedule Proposed Rules

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On June 30, 2008, the Centers for Medicare and Medicaid Services (CMS) posted on its website the proposed updates to the Medicare Physician Fee Schedule (MPFS) for 2009 which, in addition to a 5.4% decrease in payment, include what will undoubtedly be a controversial proposal to require independent diagnostic testing facility (IDTF) enrollment of physician office based imaging providers and significant revisions to the purchased diagnostic test (anti-markup) rule. This article summarizes the proposed updates and discusses the potential impact of the proposed rules on diagnostic imaging arrangements.

I. IDTF Enrollment Requirements for Physician Offices

Under the current Medicare enrollment requirements physicians and nonphysician practitioners (NPPs) who perform diagnostic testing services for their own patients are not required to enroll with Medicare as an IDTF. As a result, Medicare currently has a dual standard with respect to imaging services provided to its beneficiaries. IDTFs must perform imaging services in accordance with certain recently expanded quality and performance standards set forth at 42 C.F.R. § 410.33 while individual physicians and NPPs and physician and NPP organizations (Physician Entities) are not subject to any such quality standards. CMS expressed concern in the 2009 MPFS Proposed Rule that such Physician Entities may be providing diagnostic testing services without the benefit of qualified nonphysician personnel.

In an attempt to address its concerns regarding the quality of services provided by Physician Entities, CMS is proposing to add a new § 410.33(j) to the IDTF performance standards that would require that any physician or NPP organization furnishing diagnostic testing services (except diagnostic mammography services) enroll as an IDTF and be subject to most of the IDTF performance standards set forth at § 410.33 except for the following:

- § 410.33(g)(6) - A Physician Entity is not required to maintain additional liability insurance for each practice location.
- § 410.33(g)(8) - A Physician Entity is not required to maintain a formal compliant process.
- § 410.33(g)(9) - A Physician Entity is not required to post the IDTF standards.
- § 410.33(g)(14)(ii) - A Physician Entity is not required to post a sign with its business hours.
§ 410.33(g)(15)(i) - A Physician Entity is not required to separately enroll each practice location.

CMS is proposing to define a “physician or nonphysician practitioner organization” as any physician or NPP entity that enrolls in the Medicare program as a sole proprietorship or organizational entity such as a clinic or group practice.

The rule as currently proposed would have the sweeping effect of requiring essentially any physician or NPP office that performs diagnostic imaging services—including radiologist-owned and non-radiologist-owned imaging offices—to enroll in Medicare as an IDTF and be subject to the IDTF performance standards including, most importantly:

- The requirement that nonphysician personnel be properly licensed or certified to perform diagnostic imaging services.
- The requirement that the IDTF designate a supervising physician who must evidence proficiency in the performance and interpretation of each diagnostic test the IDTF performs.
- The requirement that any supervising physician who provides general supervision can do so at no more than three IDTF sites.
- The prohibition on an IDTF: (i) sharing its practice location with another Medicare-enrolled individual or organization; (ii) leasing or subleasing its operation or its practice location to another Medicare-enrolled individual or organization; or (iii) sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

Bluntly, this proposal is a frontal attack on self-referral. If adopted as proposed, this rule could result in a significant decline in the number of Physician Entities that offer diagnostic imaging services to their own patients because it could be difficult for non-radiologist owned offices to secure properly qualified nonphysician personnel. In addition, if Medicare contractors continue to interpret the proficiency requirements to essentially require radiologist supervision of diagnostic imaging services, it could be difficult for other specialty practices to satisfy the proficiency requirements. Finally, the proposed rule could result in a demise of leasing arrangements in which two or more physician groups lease an imaging center on a part-time basis in order to bill third-party payors for imaging services provided to their own patients at the center. This proposed rule will undoubtedly generate controversy as it could significantly limit the ability of non-radiologist specialty groups to bill for imaging services provided to their own patients.

CMS is specifically requesting public comment about whether it should:

- Establish additional exceptions to the IDTF performance standards for Physician Entities.
- Allow Physician Entities to perform certain types of diagnostic tests without using qualified nonphysician personnel.
- Limit the enrollment requirement to diagnostic tests that involve more costly equipment and testing.
• Apply the policy only to imaging services or whether it should include other testing such as electrocardiograms.
• Limit the policy to advanced imaging services such as CT, MRI, and nuclear medicine.

If adopted, the IDTF enrollment rule would become effective September 30, 2009 for Physician Entities that are already enrolled in Medicare. Any newly enrolling entities would be subject to the rule effective January 1, 2009.

II. Anti-Markup Provisions

A. 2008 MPFS Final Rule

Due to concerns that physicians who profit from their own self-referrals may be fueling the significant increase in diagnostic testing utilization, CMS in its 2008 Medicare Physician Fee Schedule final rule (2008 MPFS Final Rule) expanded the scope of both the purchased diagnostic test rule and the Medicare reassignment rules by applying the anti-markup prohibition to both the technical and professional component of diagnostic tests when they are billed by the ordering physician.[3] This anti-markup prohibition would apply to all diagnostic tests (other than tests paid under the Medicare clinical diagnostic laboratory test fee schedule).

Specifically, the anti-markup prohibition would apply if the ordering physician bills for the technical and/or professional component of a diagnostic test and that technical or professional component is:

1. **Performed in a location outside of the office of the billing physician.** If the billing physician is part of a group practice, the “office of the billing physician” is defined as the space in which the physician provides substantially the full range of patient care services that the group practice provides generally, or

2. **Obtained from an “outside supplier.”** An “outside supplier” is any person or entity that is not an employee of the billing physician and who does not reassign his/its right to Medicare payment to the physician practice. Reassignment, or rather lack thereof, is the key to this element being triggered.

These changes to the anti-markup provision were originally scheduled to take effect on January 1, 2008. However, shortly after the 2008 MPFS Final Rule was released, CMS was inundated with requests from the public to further clarify the definition of an “office,” “net charge,” “outside supplier,” and generally provide additional guidance on how, in reality, the rule would apply to a variety of different arrangements that, prior to issuing the rule, were legally permissible and compliant with the Stark Law. In order to respond to these requests (and possible legal action against the agency), CMS issued a final rule delaying until January 1, 2009, the applicability of above changes to the technical and professional components of most diagnostic testing services.

B. Proposed Revisions

Of Managed Health Care Sues Insurer To Stop Balance Billing Practices
U.S. Court In Illinois Questions Breach Of Contract Claim In “Silent PPO” Case
Medicaid
Spending Bill Containing Moratoria On Six Medicaid Rules Signed Into Law
GAO Says CMS Should Require States Receiving Medicaid HCBS Waivers To Report Deaths Of Individuals With Developmental Disabilities
California Appeals Court Denies Accident Victim’s Motion To Strike Medi-Cal Lien Against Settlement Proceeds
GAO Says CMS Should Take Steps To Improve Oversight Of States’ Medicaid Supplemental Payments
Medical Malpractice
Foreign Object Exception To Medical Malpractice Limitations Period Does Not Apply To Organ Left Behind During Surgery, Arkansas High Court Says
Medicare
D.C. Circuit Finds Secretary Not Required Prior To DRA To

http://www.healthlawyers.org/PrinterTemplate.cfm?Section=Health_Lawyers_Weekly1&... 07/14/2008
CMS is seeking public comment on two alternative proposals for revising the anti-markup provisions to clarify the language of the provisions and address public concerns and comments.

*Under the first alternative approach*, the anti-markup provision would apply if the professional component or technical component of a diagnostic test is ordered by a billing physician and is either:

1. Purchased from an outside supplier, or
2. Performed or supervised by a physician who does not share a practice with the billing physician or physician organization.

A performing or supervising physician can be considered to “share” a practice if that physician is employed by or contracts with a single physician or physician organization on either a full-time or part-time basis. However, a performing or supervising physician does not “share a practice” with the billing physician or organization if that physician is an employee of or independent contractor with more than one billing physician or organization. Thus, supervising or interpreting radiologists who provide supervision or interpretation services to more than one physician or physician organization cannot “share” in that practice and their services could trigger the anti-markup restriction.

This first proposal, if adopted, could potentially have the unintended consequence of decreasing the quality of diagnostic imaging services provided to Medicare beneficiaries by precluding non-radiology practices from contracting with radiologists to provide supervision services. Instead, non-radiology practices will utilize one or more of their own physicians to provide such supervision services. Whether the supervising physician will provide quality services will likely depend on whether the proposed IDTF enrollment requirements are adopted and, if so, how CMS determines whether a supervising physician satisfies the proficiency requirements. If CMS contractors continue the general trend of interpreting the proficiency requirements to essentially require supervision by a radiologist, the above proposal could result in a significant decline in in-office imaging services. If, however, CMS contractors expand their interpretation of proficiency to permit non-radiologists to supervise imaging services, the provision of in-office imaging by non-radiologists may continue unabated.

*Under the second alternative approach*, CMS would maintain the current regulatory text that applies the anti-markup provisions to the technical and professional components of diagnostic tests performed outside the “office of the billing physician or other supplier.” CMS is proposing, however, to more broadly define the “office of the billing physician or other supplier” to include space in which diagnostic testing is performed provided that it is located in the same building in which the billing physician or other supplier regularly furnishes patient care. The term “same building” does not include mobile vehicles, vans or trailers or services provided in the parking lot of a medical office building.

The above change in definition would address concerns expressed by
physicians who had previously structured diagnostic testing arrangements in reliance on the “same building” requirements of the in-office ancillary services exception to the Stark Law that those physicians would now be forced to terminate the arrangements because they would no longer be financially feasible. If this change is adopted, it could significantly decrease the expansive scope of the anti-markup provisions and thus have little, if any, impact on the proliferation of imaging services billed by ordering physicians since such physicians tend to structure their imaging arrangements to meet the “same building” requirements of the Stark Law. In fact, CMS gave as an example a scenario in which several physician practices have medical offices located in the same building and the practices share one location in that building where they perform diagnostic testing. CMS stated that the anti-markup provision would not apply to billings submitted by those ordering physicians because the diagnostic tests were performed in a location that satisfies the “same building” requirements.

In addition to expanding the definition of an office, CMS also is proposing to clarify that:

- With respect to physician organizations, the “office of the billing physician” is a medical office space where the ordering physician provides substantially the full range of patient care services that he or she provides generally rather than applying the test to the physician organization as a whole.

- The anti-markup provision would apply: (i) if the technical component is conducted outside the office of the billing physician or other supplier, even if the supervision is performed from within the office and (ii) if the supervision of the technical component takes place outside the office of the billing physician or other supplier, even if the technical component is performed inside of the office. This second clarification is likely to generate public comment as it is unclear how the provision would apply to diagnostic tests that do not otherwise require physician presence onsite during the performance of the test (e.g., plain film x-ray). Would this provision preclude an orthopedic group from contracting with a radiologist to supervise the performance of non-contrast MRIs if the radiologist is not present onsite in the orthopedic group’s office?

- The technical component of a diagnostic test is not purchased from an outside supplier if the technical component is both conducted and supervised within the office of the billing physician or other supplier and the supervising physician is an employee or independent contractor of the billing physician or other supplier.

CMS is also seeking public comment on two alternative proposals to the above clarification regarding outside suppliers. The first alternative is to clarify that the technical component is purchased from an outside supplier if the technical component is conducted by a technician who is not an employee of the billing physician, regardless of whether the services are performed in the office and supervised by an employee or independent contractor physician.

The second alternative is to clarify that the technical component is not purchased from an outside supplier even if it is performed by a non-employee
of the billing physician outside the office of the billing physician if the
supervising physician is an employee or independent contractor of the billing
physician and performs the supervision in the office of the billing physician.
CMS notes, however, that under this second alternative the technical
component would still be subject to the anti-markup provisions if the technical
component is performed or the supervision provided outside the office of the
billing physician.

- For purposes of determining the “performing supplier’s net charge,” the
  “performing supplier” with respect to the technical component is the
  physician who supervised the technical component. The “performing
  supplier” with respect to the professional component is the physician
  who performed the professional services.

Finally, CMS is specifically soliciting public comments on:

- How it should define the term “net charge” and whether it should allow
  some overhead costs to be recovered by billing suppliers.
- Whether it should develop a provision prohibiting reassignment in
  certain situations and require the physician supervising the technical
  component or performing the professional component to bill Medicare
directly.
- Whether it should further delay the effective date of the anti-markup
  provisions beyond January 1, 2009. As proposed, the anti-markup rule
  would be effective January 1, 2009.

III. Comments on Proposed Rulemaking

The deadline for submitting comments on any item in the 2009 MPFS

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[1] The Senate voted by a margin of 69-30 to pass legislation that had
previously passed the House of Representatives to avert the Medicare
payment cut. CMS announced it would hold claims with dates of service the
first 10 business days of July in order to allow time for congressional
intervention to stop the payment reduction.
