THE PURCHASED DIAGNOSTICS RULE AS A SELF-REFERRAL GAP FILLER

Thomas E. Bartrum

Medicare's purchased diagnostics rule (PDR), which was adopted as part of the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987), originally provided a means by which Medicare could pay a physician for a diagnostic test neither performed nor supervised by the billing physician (or another physician in the billing physician's practice) on the condition that the billing physician would be prohibited from marking up the diagnostic test supplier's charges for the diagnostic test.[39]

Existing Medicare law at the time of OBRA 1987 allowed diagnostic x-ray and other diagnostic tests to be billed by either the physician ordering the diagnostic test or the entity performing the test, but not both.[40] The House version of OBRA 1987 would have restricted the right to bill for diagnostic tests solely to the entity performing or supervising the test.[41] The conference agreement, however, continued the existing practice of paying the ordering physician for purchased diagnostic tests provided that: (a) the billing physician identifies the supplier of the diagnostic test and (b) Medicare reimbursement for the purchased diagnostic test is capped at the supplier's charges to the billing physician net any discounts.[42]

Final regulations implementing the PDR were issued in 1991 and, with minor technical changes over the years, have remained as originally enacted. However, after considering the issue over the past two MPFS update periods, CMS has issued a final rule that significantly expands the scope of the PDR. The final rule expands the PDR so that it applies to:

- the TC of a diagnostic test whenever a "billing physician or other supplier"[43] (or another related to the "billing physician or other supplier" via common ownership or control (Related Entity)) either:
  - purchases the TC from an "outside supplier"[44] or
  - the TC is performed at a site other than the "office of the billing physician or other supplier"; and
- the professional component (PC) whenever a "billing physician or other supplier" (or a Related Entity) either:
  - purchases the PC from an "outside supplier" or
  - the PC is performed at a site other than the "office of the billing physician or other supplier."

CMS is defining the "office of the billing physician or other supplier" as the space where the physician or other supplier regularly furnishes patient care. If the "billing physician or other supplier" is a "physician organization" (as defined in Phase III of the Stark II final regulations) the "office of the billing physician or other supplier" is the space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally.[45] Hence, the revised PDR standards are much more restrictive than the standards that CMS currently uses in the Stark law's "same building" definition in the in-office ancillary services exception.

As expanded, the anti-markup provision of the PDR means that Medicare payment (including applicable coinsurance and deductibles) for the component of the diagnostic test subject to the PDR will be the lesser of:

- the performing supplier's net charge to the billing physician or other supplier;
- the billing physician or other supplier's actual charge; or
- the fee schedule amount if the performing supplier had billed the component directly.

In the final rule, CMS requires that net charges be determined without regard to any charge that is intended to reflect the cost of equipment or space obtained by the performing supplier from the billing physician or other supplier.

The PDR changes set forth in the final rule were originally to go in effect on January 1, 2008. However, in response to considerable confusion regarding the application, mechanics, and scope of the revised PDR rule, CMS announced on December 28, 2007 that it was delaying the effective date of certain parts of the revised PDR final rule until January 1, 2009.[46] Specifically, as of January 1, 2008, the PDR final rule, as summarized above, only applies to: (1) the TC when purchased from an "outside supplier" and (2) certain anatomic pathology diagnostic tests (apparently both the TC and PC of such tests). This delay, however, should not be seen as a retreat because it remains fairly certain that CMS plans to expand the reach of the PDR to address its concerns regarding inappropriate utilization.

The cry to expand the PDR to address inappropriate utilization is not new and derives largely from the dual purposes that CMS has acknowledged the PRD serves: "sav[ing] program costs by eliminating the profit when a physician buys a diagnostic service from an outside supplier" and "reduc[ing] provision of unnecessary services by taking away the markup."[47] Nonetheless, when CMS (then the Health Care Financing Administration) first proposed the PDR regulations, it declined to expand the scope of the PDR to address medically unnecessary services and inappropriate referrals.

> *Comment:* Several commenters suggested that as a means of reducing waste and overuse of radiology services, the Medicare program should prohibit physicians from referring patients to imaging centers in which they have investments as well as prohibit payment for x-rays performed in the physician's office on the physician's referral. One commenter suggested that legislation should be enacted to

prevent an individual physician from being paid for imaging procedures he or she prescribes.

Response: These matters are beyond the scope of this rule, although carriers should deny payments for diagnostic services they determine are not medically necessary. Referral issues are appropriately addressed through regulations promulgated by the OIG.[48]

Such regulatory restraint was clearly abandoned by CMS in the final rule expanding the PDR. Not only does CMS revise the PDR to eliminate much of the flexibility that currently exists under the Stark law's in-office ancillary services exception, but it declares that the expanded PDR "will be an effective deterrent to the ordering of medically unnecessary tests" intended to "minimize program and patient abuse."[49] Further, CMS indicates its intent to "monitor the effectiveness of our site-of-service approach in addressing our concerns regarding potential overutilization" and amend the PDR as necessary in the future to further address such concerns.[50]

CMS justifies this approach on the basis that the easing of the reassignment prohibition enacted as part of the Medicare Prescription Drug Benefit, Improvement and Modernization Act of 2003 (MMA) has "created incentives for conduct that we believe increases the risk of overutilization and abuse of the Medicare program."[51] Such a justification is telling because, in effect, CMS has simply imposed onto the PDR the pre-MMA reassignment exception for certain healthcare delivery systems, which required that the reassigned service be performed in space that the billing healthcare delivery system either owns or leases.[52]

In the final rule, CMS misconstrues certain aspects of the legislative history of the PDR. For instance, in expanding the PDR to cover the PC, CMS asserts that Congress' omission of the PC of diagnostic tests in OBRA 1987 "may have been inadvertent."[53] However, the conference report clearly provides that:

> [t]he mark-up is eliminated as follows: If a physician bills a global fee for a service . . . , then the carrier limits the global fee to the sum of (i) the reasonable charge for associate professional service plus (ii) the lower of the reasonable charge for the technical component of the test or the actual acquisition cost (net of any discount). If a physician bills separately for a technical and professional component, then separate limits apply.[54]

CMS justifies the expansion of the PDR from physicians to suppliers on the basis of fairness and consistency. Specifically, CMS declared that "making the rule applicable to all suppliers ensures fair and equitable treatment among types of suppliers and also ensures that the potential for overutilization is addressed regardless of the particular type of supplier involved."[55] It is unclear, however, why CMS' concerns regarding fairness and overutilization do not extend beyond suppliers.[56] For example, do the same concerns not arise when a physician-owned hospital bills for diagnostic tests ordered by its physician owners but purchased from another supplier? If CMS truly desires to even the playing field (and payment) regardless of the site of service for a particular service, then one would think that they would be pushing to expand the PDR from suppliers to both suppliers and providers. Otherwise, one may suspect that the revised PDR final rule has more to do with controlling costs associated with diagnostic imaging than any other policy objective. In any event, given the trend towards payment on the basis of quality data, it would seem more appropriate to use medical necessity criteria than the blunt instrument of payment restrictions as the way in which to avoid inappropriate utilization.

CONCLUSION

This article has identified and discussed apparent contradictions, and the resulting tension, between Medicare programmatic policy objectives and the reality of running a multi-billion dollar program in an increasingly constrained fiscal environment. While on the one hand CMS articulates policies relating to quality of care, most of its administrative action, as reflected by its rulemaking, is focused on cost containment initiatives.

Moreover, even when viewed through the cost containment lens, the actions of Congress and CMS have created a system that, while seemingly applicable universally, creates disparities among sites of services, sometimes resulting paradoxically in an incentive to furnish services in a more costly setting. As a result, healthcare professionals and entities, and their legal counsel, are all the more challenged to carefully identify and to comply with applicable rules.

Thomas E. Bartrum is a partner in the Health Practice Group of the Washington, DC office of Drinker Biddle Gardner & Carton where he counsels clients on fraud and abuse issues, Stark law compliance, Medicare reimbursement, healthcare operations and hospital-physician joint ventures.

[39] Omnibus Budget Reconciliation Act of 1987, 100 Pub. L. No. 203, 101 Stat. 1330, § 4051 (Dec. 22, 1987) (codified at 42 U. S.C. §1395u(n)). At times, the PDR is also referred to as Medicare's Anti-Mark Up Provision.
[40] 42 U.S.C. § 1395u(n) (1987).
[41] Conference Report on H.R. 3545, "Omnibus Budget Reconciliation Act of 1987," Dec. 21,1987, H. Rpt. 100-495, 133 Cong. Rec. H.12103.
[42] Id.
[43] It should be noted that the PDR has been expanded so that it now applies to Medicare suppliers as well as physicians.
[44] CMS does not define "purchase" for purposes of the application of the PDR. However, in its commentary to the final rule, CMS makes the assertion that "reassigned tests are function-ally the equivalent of purchased tests." 72 Fed. Reg. 66225, 66314 (Nov. 27, 2007). An "outside supplier" is defined as someone who is not an employee of the billing physician or other supplier and who does not furnish the test or interpretation under a reassignment that meets the requirements of 42 C.F.R. §424.80 (the exceptions to the reassignment rules).
[45] A "physician organization" is defined as a physician, a physician's professional corporation, a physician practice or a "group practice" as defined by the Stark Law. 42 C.F.R. §411.351.
[46] 73 Fed. Reg. 404 (Jan. 3, 2008).
[47] 65 Fed. Reg. 25792 (June 5, 1991) (proposed Medicare Physician Payment Update for FY1992).
[48] Id.
[49] 72 Fed. Reg. at 66310, 66319.
[50] .Id. at 66317.
[51] Id. at 66308. Section 962 of the MMA, Pub. L.No. 108-17, created a statutory exception to Medicare's reassignment prohibition for certain contractual arrangements.
[52] See Medicare Carriers Manual, Part 3, §3060.3 (Pub. 14-3) (1996).
[53] 72 Fed. Reg. at 66315.
[54] See supra note 41. Note that, at the time of the conference report, Medicare still reimbursed physicians under its reasonable charges system.
[55] 72 Fed. Reg. at 66309.
[56] As used herein, the terms "suppliers" and "providers" are used in their technical sense. A "supplier" is a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services. 42U.S.C. §1395x(d). A "provider of services"means a hospital, critical access hospital,skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, in certain situations, a fund. 42 U.S.C. § 1395x(u). This definition is expanded somewhat by 42 U.S.C. §1395n(a) (2), which includes a clinic, rehabilitation agency, or public health agency to the extent that such is furnishing outpatient physical therapy or speech pathology services.