

HEALTH LAW

Update

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Still on the Radar Screen: CMS Proposes Further Restrictions for Physician Groups Providing Diagnostic Imaging

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The Centers for Medicare & Medicaid Services ("CMS") recently proposed regulatory changes that, if implemented, could have a significant impact on physician groups and others who provide and bill for diagnostic tests. These changes would affect the so-called "anti-markup rule" and would also expand to physician groups the Medicare standards for Independent Diagnostic Testing Facilities ("IDTFs"). The proposals appear in the Proposed Calendar Year 2009 Medicare Physician Fee Schedule, issued on June 30, 2008 ("2009 Proposed MPFS"). This Health Law Update provides a general overview of the IDTF and anti-markup proposed changes and discusses some practical implications.

Physician Groups Would Have To Enroll as IDTFs

Under current Medicare regulations, diagnostic imaging services are subject to different standards depending on whether they are performed in an IDTF or in a physician's office. IDTFs must comply with a long list of quality and performance standards, which CMS has repeatedly expanded and refined in recent years.¹ In contrast, physicians and non-physician practitioners who perform diagnostic testing services for their own patients are currently not required to enroll with Medicare as IDTFs and therefore are currently not subject to the same quality and performance standards.

In the 2009 Proposed MPFS, CMS has proposed to expand the standards applicable to IDTFs to apply to "physicians and non-physician practitioner organizations" performing diagnostic testing. Under the proposal, a "physician or non-physician practitioner organization" would be defined as "any physician or non-physician practitioner entity that enrolls in the Medicare program as a sole proprietorship or organizational entity such as a clinic or group practice." If such persons and entities perform diagnostic testing services (other than diagnostic mammography services), they would be required to enroll as an IDTF with Medicare for each practice location furnishing diagnostic testing

¹ See 72 Fed. Reg. 66285 and 71 Fed. Reg. 69695.

services. They would therefore have to comply with many (but not all) IDTF standards found in 42 C.F.R. § 410.33.²

Some of the IDTF standards that *would* apply under the proposed rule include (among others):

- 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 leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization; or
- The prohibition on an IDTF sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

The proposed effective date for this new IDTF enrollment requirement is September 30, 2009 for entities that are already enrolled in Medicare, or January 1, 2009 for entities newly enrolling in Medicare.

Accreditation Requirements

In addition, regardless of whether the IDTF enrollment rule is adopted, physician groups that provide imaging will have to obtain accreditation due to a new requirement enacted by the Medicare Improvements for Patients and Providers Act (MIPPA). Beginning January 1, 2012, the technical component of "advanced diagnostic imaging services" that are billed by physician groups are payable only if the group is accredited by an organization designated by CMS. "Advanced diagnostic imaging services" include magnetic resonance imaging, computerized tomography, and nuclear medicine diagnostic imaging services.

The Anti-Markup Rule

The so-called "anti-markup rule" is a longstanding prohibition on physician practices purchasing the technical component (TC) of diagnostic tests for their patients and then

² Physicians would not have to comply with the following IDTF standards:

- comprehensive liability insurance minimum § 410.33(g)(6)
- documenting beneficiary complaints (§ 410.33(g)(8))
- openly posting IDTF standards (§ 410.33(g)(9))
- openly posting normal business hours (§ 410.33(g)(14)(ii))
- prohibition on sharing space with another Medicare enrolled individual or organization (§ 410.33(g)(15)(i))

billing the Medicare program for those tests at a higher rate. The rule was intended to address potential concerns about over-utilization of diagnostic tests by physicians.

Previous Changes in the 2008 MPFS – Generally Placed on Hold Until January 1, 2009

As discussed in a previous Health Law Update³ CMS expanded the rule last year as part of the 2008 final Medicare Physician Fee Schedule ("2008 MPFS"). First, the 2008 MPFS applied the anti-markup rule to the *professional* component (PC) (i.e. the interpretation) of diagnostic tests as well as the technical component. Second, the 2008 MPFS explicitly applied the rule to all "suppliers" and not just "physicians" and "physician groups." Third, the 2008 MPFS prohibited a mark-up not just when diagnostic tests are purchased from an outside supplier but also when they are performed outside the physician's office (even if not "purchased").⁴ This last standard caused confusion in the industry because the physician's office standard seemed to be different than the "same building" standard under the Stark Law, with which many physician diagnostic imaging arrangements had been structured to comply.⁵

Finally, the anti-markup provision limited the billing physician or other supplier to the lowest of: (a) the performing supplier's "net charge" to the billing physician or supplier (without regard to any charge to the performing supplier by or through the billing physician or other supplier for the cost of equipment or leased space), (b) the billing physician's or other supplier's actual charge, or (c) the fee schedule amount for the test that would be allowed if the performing supplier billed Medicare directly. Again, this change caused controversy and confusion because it appeared to prohibit physicians from taking any overhead charges into account in determining "net charge" and therefore from making any profit at all on diagnostic tests provided to their patients. In fact, physicians could be providing these diagnostic tests at a loss.

All of the changes listed above were to have taken effect as of January 1, 2008. However, due to the heavy volume of questions and concerns that that CMS received,

³ See Health Law Update entitled "The Surprising Anti-Markup Rule: CMS Ends a Busy Year With a Bang," dated December 20, 2007, available at www.bassberry.com.

⁴ Specifically the revised rule applied when either the PC or the TC: (a) was ordered by the physician or other supplier, or by a party related to such physician or other supplier by common ownership or control, and (b) was either purchased from an "outside supplier" or performed at a site other than the "office of the billing physician or other supplier."

⁵ Many physician groups provide designated health services ("DHS") in reliance upon the "in-office ancillary services" exception to the Stark law. This exception generally permits group practices to order and provide DHS in the office of the group practice if the services are truly ancillary to the medical services furnished by the group practice, and certain explicit requirements are met. One of these requirements is that the services be furnished in the "same building" as the group practice, or in a "centralized building" that is used by the group practice for the provision of some or all of the group practice's DHS. 42 C.F.R. § 411.355(b). The terms "same building" and "centralized building" are explicitly defined in the regulation. 42 C.F.R. § 411.351. It is clear under the 2008 MPFS version of the anti-markup rule that a "centralized" building would not qualify as the "office" of the ordering physician, but it is not clear whether the "same building" would qualify as the ordering physician's "office."

just before the end of 2008 the agency delayed the effective date of most of the changes until January 1, 2009 so that it could address these concerns.⁶

Further Changes in the Proposed 2009 MPFS

In the proposed 2009 MPFS, CMS states its intent to address and clarify some of the concerns that were raised about the 2008 rule. Specifically, CMS seeks public comment on two alternate approaches to the anti-markup rule. Each of these approaches would modify the current version of the rule that is slated to take into effect on January 1, 2009.

(1) Approach #1: Dropping the Location Standard. Under the first proposed approach, the anti-markup provision would apply in all cases where the professional or technical component of a diagnostic testing service is either (a) purchased from an outside supplier, *or* (b) performed or supervised by a physician who does not *share a practice* with the billing physician or physician organization. (emphasis added). A physician who is employed by or contracts with a *single* physician or physician organization would be deemed to "share a practice" with that physician or physician organization. However, a physician who is an employee of, or independent contractor with, *more than one* billing physician or physician organization would not "share a practice" with any of them for purposes of the rule. This approach completely abandons the location standard and therefore avoids the confusion about whether the "same office" and the "same building" are different standards.

(2) Approach #2: Refining the Location Standard. Under the second proposed approach, CMS would continue (as in the 2008 MPFS version of the rule) to apply the anti-markup provisions to the technical and professional component of non-purchased tests that are performed outside the "office of the billing physician or other supplier." However, the key difference to the 2008 MPFS version of the rule is that CMS is also proposing to amend the definition of "office of the billing physician or other supplier" to include space in which diagnostic testing is performed that is located in the *same building* in which the billing physician or other supplier regularly furnishes patient care.⁷ This definitional change would address concerns by physicians who had previously structured diagnostic testing arrangements to comply with the "same building" requirements of the in-office ancillary services exception to the Stark law. CMS provided a specific example of one or more physician groups that practice in the same building, and the groups share space in that building that is used for diagnostic testing.

⁶ See Health Law Update entitled "Too Many Surprises in the New Anti-Markup Rule? CMS Has Now Delayed Implementation," dated December 31, 2007, available at www.bassberry.com. The only change that was not delayed was with respect to anatomic pathology diagnostic testing services furnished in space that (1) is utilized by a physician group practice as a "centralized building" for purposes of complying with the physician self-referral rules, and (2) does not qualify as a "same building" under § 411.355(b)(2)(i).

⁷ CMS noted specifically that the definition of "same building" excludes a "mobile vehicle, van, or trailer" (that might provide services in the parking lot of a medical facility).

CMS stated that in such a situation (if other requirements are met) the anti-markup provision would not apply.⁸

The "Net Charge" Dilemma

CMS noted in the 2009 MPFS that some commenters objected to its earlier decision to exclude the overhead costs of the billing supplier when determining "net charge" (see discussion above). Therefore CMS requested additional comments on whether it should allow some overhead costs to be recovered by billing suppliers for services to which the anti-markup provision applies. However, CMS has still not proposed any actual regulatory text to change this definition.

Conclusion

Regardless of the extent to which CMS will modify these proposed rules based on the comments, physicians and physician groups face certain disruption in their practices and the diagnostic testing services they perform. If you have any questions about this *Health Law Update*, please contact any of the attorneys in our Healthcare Industry Practice Area, listed on the following page.

⁸ It seems clear that a "centralized building" will still not qualify as the "office" of the billing physician in any event.

Bass, Berry & Sims Healthcare Attorneys

H. Stanford Adams, Jr.
(615) 742-7775
sadams@bassberry.com

Mary Beth Fortugno
(615) 742-7739
mfortugno@bassberry.com

Anna Grizzle
(615) 742-7732
agrizzle@bassberry.com

Clevonne M. Jacobs
(615) 742-7769
vjacobs@bassberry.com

David King
(615) 742-7890
dking@bassberry.com

T. Scott Noonan, Co-Chair
(615) 742-6273
stnoonan@bassberry.com

Cynthia Y. Reisz
(615) 742-6283
creisz@bassberry.com

Catherine J.B. Sloan
(615) 742-7789
csloan@bassberry.com

Leigh Walton, Co-Chair
(615) 742-6201
lwalton@bassberry.com

H. Lee Barfield, II
(615) 742-6202
lbarfield@bassberry.com

Valere B. Fulwider
(615) 742-7742
vfulwider@bassberry.com

Elisa E. Harris
(615) 742-6553
eharris@bassberry.com

J. James Jenkins, Jr.
(615) 742-6236
jjenkins@bassberry.com

Leslie Maclellan
(615) 742-7818
lmaclellan@bassberry.com

Brenda N. Phillips
(615) 742-6237
bnphillips@bassberry.com

Brian D. Roark
(615) 742-7753
broark@bassberry.com

Danielle M. Sloane
(615) 742-7763
dsloane@bassberry.com

Elizabeth S. Warren
(615) 742-7719
ewarren@bassberry.com

Philip F. Berg
(615) 742-7908
pberg@bassberry.com

Pooneh Ghiassi
(615) 742-7782
pghiassi@bassberry.com

Angela Humphreys
(615) 742-7852
ahumphreys@bassberry.com

Seth A. Killingbeck
(615) 742-7707
skillingbeck@bassberry.com

Claire F. Miley
(615) 742-7847
cmiley@bassberry.com

Shannon Pinkston
(615) 742-7727
spinkston@bassberry.com

Scott B. Shanker
(901) 543-5932
sshanker@bassberry.com

Krista L. Thornton
(615) 742-7734
kthornton@bassberry.com

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