Diagnostic Testing Equipment Leasing Companies Appear To Escape IDTF Enrollment Requirements

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Much to the surprise—and consternation—of companies that lease mobile or portable diagnostic testing equipment and those physician practices, hospitals, and other providers that utilize their services, the Medicare Physician Fee Schedule final rule for 2009 (2009 MPFS Rule)\(^1\) included two new provisions that would dramatically modify their traditional leasing company business model. Based on the preamble discussion, the new rules appear to require that each such company enroll with Medicare as an independent diagnostic testing facility (IDTF) and directly bill Medicare for the technical component of diagnostic testing performed on the leased equipment.

Specifically, the 2009 MPFS Rule expands the existing Medicare performance standards for IDTFs to provide that an IDTF must certify in its enrollment application that it:

1. Enrolls for any diagnostic imaging services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed base location.

2. Bills for all mobile diagnostic testing services that are furnished to a Medicare beneficiary, unless the mobile diagnostic service is part of a hospital service provided under arrangement with that hospital.\(^2\)
At first read, it would appear that the new provisions may not apply to a company that merely leases mobile or portable diagnostic testing equipment and/or non-physician personnel (Mobile Company) to a physician practice, hospital, or other Medicare-enrolled supplier or provider since the Mobile Company is not fully “furnishing” the entirety of the diagnostic test. The 2009 MPFS Rule itself provides support for that understanding. For example, according to the newly revised Medicare anti-markup rule, “performing” the technical component (TC) of a diagnostic test includes “both the conducting of the TC as well as the supervision of the TC.” By analogy, if a Mobile Company does not perform or provide the physician supervision of the TC, it is arguably not “performing” or “furnishing” the diagnostic test and, thus, should not be required to enroll with Medicare as an IDTF. Instead, the TC of the diagnostic test is being performed by the physician that provides the supervision that, in the case of a lease arrangement with a Mobile Company, is typically a physician member of the medical group lessee of the equipment. Thus, under that model, the Medicare-enrolled physician group or other provider/supplier that leases the diagnostic testing equipment and/or non-physician personnel from the Mobile Company and also performs the physician supervision of the test should be the entity billing Medicare for the TC services (in accordance, of course, with the revised anti-markup rule).

Unfortunately for Mobile Companies, it appeared that CMS did not—at least initially—interpret the application of the new IDTF standards in the same logical manner described above. In the preamble discussion to the IDTF rules, CMS reported that one commenter urged CMS to exclude from the definition of a “mobile diagnostic testing service” those situations where a company leases diagnostic testing equipment and technicians to a physician practice if the diagnostic testing is: (a) performed in the office of the physician practice; (b) supervised by a physician who shares an office with the physician practice; and (c) billed by the physician practice. Contrary to the approach taken in the new anti-markup rule and its definition of what it means to “perform” the TC, CMS responded that any mobile entity providing diagnostic testing services must enroll for any diagnostic imaging services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed based location.

Many in the industry that previously viewed themselves as merely equipment leasing entities and, thus, had not separately enrolled in Medicare now faced the imminent
prospect of having to enroll in Medicare as an IDTF and obtain a Medicare supplier number—within a seemingly impossible period of less than two months before the January 1, 2009, effective date. CMS was inundated with comments and concerns by representatives of assorted Mobile Companies potentially impacted by this new rule.

In response to public questions and comments on the new IDTF standards and, in particular, the preamble discussion regarding Mobile Company leasing arrangements, CMS on November 16, 2008, issued the following Question and Answer (FAQ) on its website:

**Question:**

My company leases/contracts diagnostic testing equipment and/or non-physician personnel described in 42 C.F.R. 410.33 to an enrolled Medicare provider/supplier (e.g., medical group practice). Do I need to enroll as an Independent Diagnostic Testing Facility (IDTF)?

**Answer:**

Companies that lease or contract with a Medicare enrolled provider or supplier to provide: a) diagnostic testing equipment; b) non-physician personnel described in 42 C.F.R. 410.33(c); or c) diagnostic testing equipment and non-physician personnel described in 42 C.F.R. 410.33(c) are not required to enroll as an IDTF. Medicare continues to evaluate arrangements where both diagnostic testing equipment and non-physician personnel are contracted to a Medicare enrolled provider or supplier and where the Medicare enrolled provider or supplier is billing for diagnostic services.

This was a welcomed clarification much to the relief of Mobile Companies facing the prospect of being without a Medicare supplier number on January 1. This new guidance clearly indicates that Mobile Companies that lease only diagnostic testing equipment and/or non-physician personnel to other Medicare-enrolled entities (but *do not supervise* the tests) will not be required to enroll as IDTFs and directly bill for their testing services.

In fact, this new guidance provides a reprieve from IDTF enrollment not only to Mobile Companies but also to fixed site locations that lease diagnostic testing equipment and/or
non-physician personnel to Medicare-enrolled entities. For example, an MRI imaging suite jointly owned by several physician practices located in the same medical building and leased to those practices would not be required to enroll as an IDTF.

Although CMS had the option of delaying its rule, the agency instead acted to clarify their preamble comments that had created the significant confusion over the scope of new rule. The regulation is set to become effective on January 1, 2009. To date, however, CMS has not written and distributed a transmittal with guidelines for Medicare administrative contractor enrollment staffs on how to implement the new rule. Thus, some confusion and delay may still occur as the rule becomes applicable to those mobile entities that provide the complete technical component service (equipment, staff, and supervision) who must enroll and bill for services as IDTFs.

The reprieve from the Medicare IDTF enrollment requirement may only be temporary given that CMS ominously noted in the FAQ that it is continuing to evaluate leasing arrangements involving diagnostic testing. Thus, Mobile Companies and their legal counsel should pay particularly close attention next year to the 2010 MPFS proposed rule and be prepared to submit comments accordingly.

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[2] Id. at 69933.

[3] Id. at 69935.

[4] Id. at 69764.

[5] Id.