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Mobile Leasing Diagnostic Testing Arrangements

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There have been a number of healthcare legislative initiatives in recent years designed to restrict or substantially limit diagnostic testing arrangements and regulatory enactments have necessitated the restructuring of certain imaging transactions. However, a physician's ability to furnish and bill for diagnostic testing services under a properly constructed mobile leasing model remains a legally supportable framework to enhance physician practice revenue. This article provides a brief overview of the elements that comprise a typical leasing model structure and examines some of the healthcare regulations that must be considered in connection with these arrangements. It also discusses the current legal status of the leasing model, which permits (and, we expect, will continue to permit) appropriately structured diagnostic testing arrangements in the physician office setting.

The Leasing Model

Although there may be minor structural variations, the leasing model typically comprises the following elements. A mobile leasing entity (the "mobile company") enters into a written contractual agreement with a physician group under which it leases certain portable diagnostic testing equipment, a qualified technologist, and often the associated imaging supplies to enable the physician group to furnish certain diagnostic testing services to patients of the practice in the group's office. Although the mobile company will supply the leasing services,

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the physicians (as the lessees) will exercise the required degree of supervision of the diagnostic testing services and, thus, the physicians will be the entity that is considered to be the provider of (and entitled to bill for) the diagnostic services.

In practice, the leasing services model provides physician groups with in-office access to the equipment, personnel, and supplies with which they are then able to furnish the technical component (TC) of the diagnostic testing services to their patients. The physicians will bill Medicare and other third party payors for the diagnostic tests. The leasing services must be structured as a block lease arrangement, subject to certain minimum hourly requirements (which subject the physicians to genuine financial risk and, as a result, enable the physicians to rebut the characterization of the arrangement as an "on demand" lease). The physicians must pay the mobile company a fixed fee for the contractually leased block of time (ie, without reference to the number of studies performed), in which the fee must be (i) supportable as fair market value and (ii) established in advance of the arrangement. Note that, in addition to being the provider of the TC (through the leasing services arrangement), provided that certain

standards are met, the physician group also can furnish (and bill for) the professional component (PC) of the diagnostic tests.

Healthcare Regulatory Considerations

Because diagnostic testing arrangements (including the leasing model) potentially implicate a number of different healthcare regulations, physicians employing a leasing model in connection with furnishing imaging services through their practices must ensure their particular contractual arrangements are constructed in a manner that complies with all applicable legal requirements. While any meaningful legal analysis is dependent upon the facts and circumstances of the particular transaction, it has been our experience that, so long as certain structural safeguards are integrated into the arrangement (ie, in particular, factors that [i] demonstrate the nexus between the physician group's core services and the diagnostic imaging services, and [ii] permit the group to show that the group is at sufficient financial risk under the leasing services arrangement), the leasing model can be structured in a manner that complies with the Federal Stark Law, Medicare's

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Anti-Markup Rule (AMR), Medicare's independent diagnostic testing facility (IDTF) regulations, and the Medicare and Medicaid Anti-kickback Statute (AKS). As a result, physicians can lawfully bill for the diagnostic testing services provided pursuant to the leasing model.

The Federal Stark Law

Physicians that furnish diagnostic imaging services under the leasing model must determine whether, under the group's particular structure (including the location in which the tests will be furnished), they will be able to provide the services in a manner that meets Stark's in-office ancillary services exception (IOASE). Notably, a physician practice will be able to furnish (and lawfully bill for) diagnostic testing services under the leasing model, provided that the practice (i) qualifies as a "group practice" under Stark, (ii) bills for the testing services under the group's provider number, (iii) supervises the tests in accordance with applicable Medicare rules, and (iv) furnishes the diagnostic testing services in the same building in which the group's physicians furnish professional medical services unrelated to the tests (eg, physicians' services). If these elements are met, which, in the majority of physician practices should be reasonably achievable, the testing services will comply with the IOASE.

Further, with respect to those physician groups that will bill for the PC of the services, if an employed physician provides the interpretation, for purposes of compliance with the Stark physician services exception (PSE), there is no on-site requirement. However, the Medicare AMR will apply to the services which means that if the physician provides the PC of the services off-site, he/she must "share a practice" with the physician by providing at least 75% of his/her professional services for such physician group.

The Medicare Anti-Markup Rule

Physicians that operate under a leasing model must also ensure that their diagnostic testing arrangements are structured in a manner that does not cause the services to fall within the purview of the AMR's payment limitations. The Centers for Medicare and Medicaid Services (CMS)

adopted 2 alternative tests for determining the applicability of the AMR:

1. Alternative 1. If the performing physician (ie, the physician who supervises the TC, performs the PC, or both) performs substantially all (ie, at least 75%) of his or her professional services for the billing physician or other supplier, the services will not be subject to the AMR payment limitations.
2. Alternative 2. TCs conducted and supervised in, and PCs performed in, the "office of the billing physician," which includes the "same building," by an employee or independent contractor physician avoid the AMR payment limitation.

Notably, physicians should readily be able to satisfy Alternative 1 if they provide at least 75% of their professional services through the billing practice. It is also possible for the physicians to satisfy Alternative 2, provided that the physicians furnish and supervise the services in-office.

Medicare IDTF Regulations

Pursuant to guidance issued by CMS, the leasing model does not fall within the purview of the IDTF regulations. Thus, physicians that employ leasing services can bill Medicare directly for the diagnostic imaging services furnished in conjunction with the leasing model (ie, without the need for the group to enroll as an IDTF).

The Medicare and Medicaid Anti-kickback Statute

Although the leasing model does implicate certain legal risks that the Office of Inspector General typically reviews in its AKS joint venture guidance, a carefully structured leasing model will incorporate compelling mitigating factors which reduce risk. For example, the leasing model contemplates a block leasing schedule, which requires the physicians to utilize the leasing services for a minimum amount of time per week (or month, depending upon the nature of the test). The physicians must pay a fair market value fee for the blocks of time to which they subscribe, irrespective of the volume of services that they provide (and thus the revenue derived from the services). In this way, a group cannot subscribe for the leasing

services solely when the group is assured of earning a profit (ie, on an "on-demand" basis). As a result, the group is required to bear the financial risk that the contractual payments to the mobile company potentially might exceed the revenue from the diagnostic imaging services furnished in connection with the leasing services.

Finally, an appropriately structured leasing model should also permit the group to show a reasonable nexus between the diagnostic testing services provided in the physician's office and the physician's core medical practice. If these elements are in place, the physician group should be in reasonable position to defend the arrangement as being compliant with the AKS.

The Current State of Mobile Leasing Arrangements

Despite healthcare regulatory changes that have been enacted in recent years, the law currently permits appropriately structured diagnostic testing arrangements in the physician office setting utilizing the leasing model. Accordingly, incorporating diagnostic imaging into a practice can permit physician groups to expand the continuum of care provided to patients, while, at the same time, enhancing practice group revenue. Although a leasing model will need to integrate certain elements (ie, safeguards of the type discussed above) to mitigate potential legal risks, if these are included, in the substantial number of cases, a leasing model can be structured in a manner that achieves a physician group's business objectives, while at the same time complying with applicable healthcare regulatory constraints. 🌱

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