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The Basics of Self-Referral of Ancillary Services

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Stark

After observing the strong correlation between physician self-referrals, and an increase in certain services ancillary to direct patient care, Congress began enacting the Stark regulations in 1992. The regulations make it illegal for a physician or a direct family member to profit from the referral by the physician of a designated health service (DHS). There are currently twelve items and services that are classified as DHS[1]. Because they are frequently used by physicians in their daily practices as well as being quite profitable if properly run, two of those services, clinical labs and imaging services, are desirable businesses for physicians. While both are prohibited referrals for physicians who own them, certain exceptions exist. Chief among those is the in-office ancillary services exception. A host of criteria must be met to qualify. In general, the requirements are:

1. The service must be owned by a physician group that is truly a group, not a loose conglomeration of practices arranged to look like a group simply to benefit from the self-referral exception. The group must be a single legal entity, have two or more physician owners or employees who perform most of their services for the group, have a centralized decision-making system and bill under the same number;
2. The physician group must abide by strict supervision requirements; the service must be supervised by the referring physician or another physician in the practice group;
3. The DHS services must meet a location requirement: It must be rendered in the same building as a member of the group, or in a centralized site used exclusively by the physician group for providing the ancillary services;
4. The DHS must be billed by the group.

Each of these general requirements has several layers of sub-criteria and limitations that should be closely examined by a group contemplating utilizing the exception. Skirting these requirements can lead to significant liability, including criminal, licensing and financial penalties.

If a group is properly formed and if its ancillary service is set up correctly, physician groups can profit from their self-referrals. That profit, however, cannot be directly related to the volume or value of referrals made by any particular physician. Profits can be distributed per capita, based on distribution of the group's non-DHS revenues or pursuant to a productivity bonus based on factors such as RVUs or other profit source calculations. Whatever the calculation of profit

distribution, it is important to apply the calculation prospectively, and never retroactively.

While Stark applies to federal healthcare programs, some states, have parallel statutes that extend the Stark principles to all health care services.

Anti-Kickback and Safe Harbors

The federal Anti-Kickback Statute, 42 U.S.C. 1320a-7b (b) (AKS) is broader than the Stark regulations and must be considered in conjunction with a Stark analysis of a proposed ancillary service. The AKS prohibits remuneration for referrals for services payable by Medicare or Medicaid. Several safe harbors are available to protect certain arrangements from being prosecuted as violations of the AKS including provisions regarding employment, independent contractors and group practices. While similar, they are not identical to the Stark exceptions. For instance, the anti-kickback safe harbor for independent contractor physicians would only protect contracted services for which the aggregate annual remuneration is set in advance; for example, $4,000 per month. Comparatively, the Stark exception counterpart (the personal services arrangement exception) requires that there be an objectively verifiable compensation formula set in advance, but not the aggregate compensation; for example, 30% of collections from services personally performed by the physician.

While compliance with Stark does not automatically result in a physician's compliance with the AKS, it is likely to bring the relationship closer to being within a safe zone under the anti-kickback statute if it does not fall within any of the anti-kickback safe harbors. The Safe Harbor Regulations can be found at 42 CFR 1001.952 (a)-(u), and include specific rules regarding investments in other practices, rental of space and equipment, contracts, business sales, referral services, remuneration of employees, waivers, reduced cost-sharing, recruitment and price reductions, among others.

While some of the rules and regulations in these areas appear straightforward, when taken together, they can be complex and challenging to interpret. The AKS is even more difficult to navigate than Stark because it offers fewer "bright line" rules. Even if a provider does not fall into one of the AKS safe harbors, it may still not be violating the law.

The Office of the Inspector General (OIG) is particularly concerned with laboratories, imaging and surgery centers. This area of the law is still relatively new, and always evolving. Paying close attention to applicable regulations is imperative when looking at establishing one of these services.

When considering setting up an ancillary service, always seek the advice of counsel. The applicable regulations and associated opinions of the Office of the Inspector General of CMS are frequently updated and modified.

[1]CMS provides a list of the CPT codes of the items and services that are categorized as DHS at http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html

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