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Stark Requirements for Physician Contracts

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Entities that employ or contract with physicians must ensure their agreements are structured to comply with the federal Ethics in Patient Referrals Act ("Stark")[1] if they intend to bill Medicare for services rendered or referred by the physicians. Under Stark, if a physician (or a member of the physician's family) has a financial relationship with an entity, the physician may not refer patients to the entity for certain designated health services ("DHS")[2] payable by Medicare unless the financial relationship is structured to fit within a regulatory safe harbor.[3] Entities may not bill Medicare for services improperly referred and, if they have done so, the entity must repay amounts improperly received. Failure to report and repay within 60 days may result in additional civil penalties of $15,000 per claim as well as False Claims Act liability.[4] Repayments can easily run into the hundreds of thousands if not millions of dollars. Given the potential liability, it is critical that physician arrangements be structured to fit within the regulatory safe harbors.

Employment Arrangements. To fit within the Stark safe harbor applicable to employment contracts,[5] the employment agreement with the physician (or their family member) must satisfy all of the following:

1. The employment must be for identifiable services.
2. The amount of the remuneration under the employment must be (i) consistent with the fair market value of the services; and (ii) not determined in a manner that takes into account, directly or indirectly, the volume or value of any referrals by the referring physician. This does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician.
3. The agreement must be commercially reasonable even if no referrals were made to the employer.

   Unlike independent contractor arrangements, employment contracts are not required to be written; the compensation need not be set in advance; and the compensation may be amended at any time.

Independent Contractor Arrangements. If the physician (or their family member) is paid as an independent contractor instead of as an employee, then the agreement must satisfy either the Stark "personal services"[6] or "fair market value"[7] safe harbor. Those safe harbors generally require the following:

1. The arrangement must be in writing, signed by the parties, and

cover only identifiable items or services, all of which are specified in the agreement. Unwritten, unsigned or expired contracts do not comply, with very limited exceptions.[8]

2. The agreement may not be modified within its first year. The agreement may be terminated at any time within the first year, but if it is terminated, the parties may not enter a similar agreement for the same services within the original one year period.
3. The writing must specify the compensation that will be provided under the arrangement. The compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician. Like the employment safe harbor, a physician may be paid based on services he or she personally performs.
4. The arrangement must be commercially reasonable, taking into account the nature and scope of the transaction, and further the legitimate business purposes of the parties.[9]

It is extremely important that entities ensure they have current, written agreements whenever they pay outside physicians (or a physician's family members) to provide items or services, including but not limited to payments for professional services, call coverage, medical directorships, or consulting.

Group Practice Compensation. Stark also applies to referrals for DHS within a group. Stark's "physician services"[10] and "in-office ancillary services"[11] exceptions protect most referrals, but only if the group qualifies as a "group practice" as defined by Stark. Among other things, the definition requires that physicians in the group may not receive compensation based on the volume or value of his or her referrals for DHS.[12] Physician group members may be paid productivity bonuses based on services they personally perform or "incident to" services.[13] They may also be paid a share of overall profits subject to certain conditions.[14] Groups should carefully review the "group practice" compensation requirements to ensure that their compensation structures satisfy the conditions if they intend to rely on the "physician services" or "in-office ancillary services" safe harbors.

Other Laws. In addition to Stark, providers and other entities must ensure that their arrangements comply with other relevant laws, including the federal Anti-Kickback Statute and any applicable state laws. The Anti-Kickback Statute generally prohibits offering, paying, soliciting, or receiving remuneration to induce or reward referrals for items or services payable by government health care programs, including Medicare and Medicaid.[15] The federal Anti-Kickback Statute is violated if "one purpose" of the transaction is to induce prohibited referrals unless the arrangement is structured to fit within a regulatory safe harbor.[16] Although the Anti-Kickback safe harbor requirements vary in some details from the Stark safe harbors,[17] entities are likely to comply with the Anti-Kickback Statute if they structure their arrangements to comply with Stark. Regardless, entities must carefully and periodically review their physician contracts to ensure compliance with the

applicable laws.

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[1]42 USC 1395nn and 42 CFR 411.351 *et seq*.
[2]"Designated health services" include (i) clinical laboratory services; (ii) physical and occupational therapy, and outpatient speech-language pathology services; (iii) radiology and certain other imaging services; (iv) radiation therapy services and supplies; (v) durable medical equipment and supplies; (vi) parenteral and enteral nutrients, equipment and supplies; (vii) prosthetics, orthotics, and prosthetic devices and supplies; (viii) home health services; (ix) outpatient prescription drugs; and (x) inpatient and outpatient hospital services. (42 CFR 411.351).
[3]42 CFR 411.353.
[4]42 CFR 411.353(b)-(d); 42 USC 1320a-7k(d).
[5]42 CFR 411.357(c).
[6]42 CFR 411.357(d).
[7]42 CFR 411.357(l).
[8]*See* 42 CFR 411.353(g) and 411.357(d)(vii).
[9]*See* 42 CFR 411.357(d) and (l).
[10]42 CFR 411.355(a).
[11]42 CFR 411.355(b).
[12]42 CFR 411.352(g).
[13]42 CFR 411.352(i)(1) and (3).
[14]42 CFR 411.352(i)(2).
[15]42 USC 1320a-7b(b)).
[16]*U.S. v. Greber*, 760 F.2d 68, 69 (3rd Cir. 1985); 42 CFR 1001.952.
[17]*See*, e.g., 42 USC 1001.952(d) and (i).
