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SURVIVAL STRATEGIES FOR

PHYSICIAN-OWNED ENTITIES

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Below is an overview of laws to consider when assessing an arrangement involving physician investment and/or involvement.

OVERVIEW OF FRAUD AND ABUSE LAWS

Federal fraud and abuse laws (e.g., the Stark Law and the Anti-Kickback Statute) only apply if a healthcare entity is treating beneficiaries of Government Payors.¹ On the other hand, state fraud and abuse laws and commercial bribery laws apply regardless of an entity's involvement with Government Payors. Absent unusual circumstances, an arrangement that complies with the federal laws will comply with the state laws. Accordingly, the state laws will only be discussed in this memo when the federal laws are not applicable.

A. The Stark Law

Under the Stark Law (“*Stark*”), a physician cannot (i) refer patients to an entity (ii) for the furnishing of designated health services (“*DHS*”) (iii) if there is a financial relationship between the referring physician and the entity, (iv) unless an exception applies; and the entity may not bill any individual, third-party payor, or other entity for DHS furnished pursuant to a prohibited referral. Therefore, to determine whether Stark applies to a given scenario, one should ask:

1. Is there a financial relationship?
2. Is it between a *physician* and an entity?
3. Does the entity provide DHS (thus making it a “*DHS Entity*”)?
4. Is the physician in a position to make referrals to the entity?

If the answer is “no” to any of those questions, Stark does not apply. If the answer is “yes” to all of those questions, then one should consider whether an exception applies.

¹ Recent cases have the federal government arguing that violations of state commercial bribery laws are also violations of the U.S. Travel Act, and, therefore, carry with them fines, penalties (including criminal penalties), and sanctions under federal law. While the outcome of these cases are pending, it is important to understand that not taking Government Payors does not make one immune from actions by federal enforcement agencies.

1. Is there a financial relationship? Stark defines a financial relationship as: (1) An ownership or investment interest of a referring physician in the entity furnishing DHS (e.g., stock, membership units),² or (2) a compensation arrangement between the referring physician and the entity furnishing DHS. The reason for the financial relationship is irrelevant (for purposes of determining if a financial relationship exists), but categorizing it as either investment/ownership or compensation is necessary for knowing which exceptions might apply. Additionally, the financial relationship could be direct or indirect, and a financial relationship with a referring physician's immediate family member is imputed to the referring physician.
2. Is the relationship between a physician and an entity? The definition of physician under Stark includes doctors of medicine, osteopathy, podiatry, and optometry.
3. Does the entity provide DHS? The Social Security Act provides the complete list of DHS.³ If the entity did not provide PT services it would not be a DHS Entity, and any financial relationships with physicians would not be subject to Stark and would, accordingly, be permissible as long as they complied with AKS.
4. Is the physician in a position to make referrals to the entity? Stark defines "referral" broadly to include essentially any physician request, order, or establishment of a plan of care that includes the provision of DHS. In most cases, the key factor in determining whether a physician is a referral source for a DHS entity is the potential for overlap in patient populations. For example, a pediatrician is not going to be a referral source for a DHS Entity that focuses exclusively on geriatric medicine.
5. Does an Exception Apply? The exceptions to Stark are strictly construed, meaning one must meet every element of the exception for the arrangement to be compliant. Some exceptions apply to both ownership and compensation arrangements, but most apply specifically and exclusively to one or the other. Therefore, determining which exceptions may apply requires, first, classifying the physician's financial relationship with the DHS Entity as either ownership/investment or compensation.

B. The Anti-Kickback Statute

AKS broadly prohibits any individual or entity from knowingly and willfully offering, paying, soliciting, or receiving remuneration in order to induce or reward the referral of business reimbursable under any Federal health care programs. Remuneration includes the transfer of

² An ownership or investment interest may "be through equity, debt, or other means..." and includes such things as stock, partnership shares, membership units, loans, and bonds. It does not include items such as interest from a retirement plan or stock options, but the stock option is considered a "compensation arrangement" until it is exercised or converted to equity and becomes an "ownership or investment interest." See 42 C.F.R. § 411.354(b).

³ 42 U.S.C. § 1395nn(h)(6).

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