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Check Your Physician Contracts

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Contracts and other financial arrangements with physicians and certain other healthcare providers must be structured to comply with the federal Stark,[1] Anti-Kickback,[2] and Civil Monetary Penalties Laws[3] if the physician will refer patients for items or services payable by Medicare, Medicaid or other healthcare programs. Failure to comply may result in overpayments; failure to report and repay such overpayments within 60 days may violate the False Claims Act, subjecting the parties to additional penalties, including treble damages, fines of $5,500 to $11,000 per claim, and exclusion from Medicare and Medicaid.[4] Given the severe penalties for noncompliance, hospitals and other healthcare providers should ensure that their physician contracts comply.

TOP COMPLIANCE CONCERNS FOR PHYSICIAN CONTRACTS. The following are top compliance issues for services contracts with referring physicians or their family members. Many of these same rules apply to contracts with other healthcare providers who may refer patients for services covered by Medicare or Medicaid.[5]

1. Have a current written contract that is signed by both parties. A written contract is not required for physicians who are bona fide employees,[6] but a written contract may help document compliance with other required elements. In contrast, contracts with physicians who are not employed by the other party (i.e., independent contractors) must be in writing and signed by both parties before compensation is paid or services performed.[7] Beware situations in which one or more of the parties failed to execute the contract. Stark contains a limited exception that allows the parties to cure a signature defect by obtaining required signatures within 30 or 90 days, depending on the circumstances;[8] otherwise, the parties' failure to sign an independent contractor agreement will create Stark and Anti-Kickback problems.

2. Ensure the contract has not expired, lapsed or terminated. Sometimes a contract will expire but the parties continue to perform as if the contract were still in force. This will not violate regulations applicable to employment contracts,[9] but it will create compliance problems for independent contractors.[10] Stark contains an exception that allows the parties to an independent contractor agreement to continue performance for up to six months after the contract expired if certain conditions are met;[11] otherwise, the failure to have a current written agreement with referring independent contractors will most likely violate Stark. Parties may minimize the risk by including automatic renewal provisions.

3. Identify the services to be performed. Employment contracts must be for identifiable services.[12] Contracts with independent contractors must specify the services to be performed.[13] If the entity has more than one contract with the independent contractor, the contracts should reference

each other or a master list of all the contracts.[14]

4. Pay fair market value for the services provided. Overpaying or underpaying a referring physician violates Stark and may be viewed as payment for referrals under the Anti-Kickback Statute.[15] Fair market value depends on the particular facts of the situation, including the nature, volume, and value of services performed and the price paid for similar services in the market exclusive of referrals.[16] While MGMA and other published compensation surveys are helpful, the parties must still ensure the compensation reflects the physician's particular circumstances. When evaluating fair market value, be sure to consider all remuneration provided to the physician, including compensation, benefits, insurance, or anything else of significant value.

5. Set the compensation formula in advance. If an employer intends to require employed physicians to refer services to the employer as discussed in item 7, below, the employed physician's compensation formula must be set in advance.[17] For independent contractors, the compensation formula must always be set in advance and be objectively verifiable.[18] Do not adjust an independent contractor's compensation retroactively. To comply with the Anti-Kickback safe harbor for personal services agreements, the aggregate compensation—not just the compensation formula—must be set in advance.[19]

6. Do not pay based on the volume or value of referrals or other business generated by the physician.[20] Paying the physician based on his or her referrals for ancillary services or services performed by others is the quintessential Stark and Anti-Kickback violation. Compensation formulas based on the overall productivity or profitability of a facility, department or practice may violate the regulations because productivity will typically vary with the volume or value of the physician's referrals to others. With that said, an entity may pay physicians for services the physician personally performs, e.g., per work RVUs, professional fee revenue, etc.[21] In addition, qualifying group practices may compensate physicians based on their personal productivity, "incident to" services, and/or a share of the group's overall profits.[22]

7. Do not require referrals unless certain conditions are satisfied. Stark expressly allows entities to require employed or independent contractor physicians to refer patients to the entity if certain conditions are satisfied. Among other things, the requirement to make referrals must be included in a written agreement signed by the parties, and the compensation formula must be set in advance for the term of the agreement and must be consistent with fair market value.[23] The requirement to make referrals does not apply if the patient expresses a preference for a different provider; the patient's insurer determines the provider; or the referral is not in the patient's best medical interests in the physician's judgment.[24] Finally, the required referrals must relate solely to the physician's services covered by the scope of the agreement (i.e., the entity cannot require referrals while the physician is providing services outside the agreement), and the referral requirement must be necessary to effectuate the legitimate business purposes of the contract.[25] The Anti-

Kickback Statute does not contain a similar exception.

8. Do not pay to induce reduction in services. The Civil Monetary Penalties law generally prohibits hospitals from paying physicians to reduce or limit services to Medicare or Medicaid beneficiaries.[26] The law prohibits "gainsharing" arrangements whereby hospitals share cost savings with referring physicians unless the arrangement has been approved by the federal government in an advisory opinion or the arrangement is structured to satisfy new exceptions applicable to accountable care organizations.[27]

9. Do not make additional payments or provide free or discounted items or services outside the contract unless the arrangement fits within a separate regulatory exception. The contract should clearly identify the compensation for the identified services. Providing additional items or services outside the contract (e.g., bonuses; payments "on the side"; free use of space, equipment or personnel; free or discounted services; perks; or any other payments or "freebies" not covered by the contract) may create a separate financial relationship that triggers Stark or the Anti-Kickback Statute unless the additional item or service fits within a separate regulatory exception.[28]

10. Ensure that the arrangement is commercially reasonable.[29] The arrangement must make business sense and further legitimate business purposes even if there were no referrals between the parties. Do not contract for unnecessary services. The aggregate services contracted for may not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.[30]

11. Ensure the parties perform the services as specified in the agreement. Paying a physician for services that were not performed may be viewed as paying for referrals. The parties to a contract may sometimes become lax or their performance may change. Both the contracts and the physician's performance should be reviewed periodically to ensure the physician is rendering the services for which he or she is being paid consistent with contract requirements.

12. Beware contract changes during the initial year. Independent contractor arrangements generally may not be changed within the first year of the agreement.[31] If an independent contractor agreement is terminated during the first year, the parties may not enter a new agreement for substantially similar services on different terms during the initial one-year period.[32] Contracts for less than one-year may be renewed during the one-year period so long as they renew on the same terms so that the terms relevant to compensation do not change during the initial one-year period.[33] The foregoing limits generally do not apply to employment agreements.[34]

13. Remember contracts with physicians' family members. Stark applies to financial relationships with a referring physician's family members as well as the physician, including spouses, parents, children, siblings, grandparents, or grandchildren.[35] If you contract or have a financial arrangement with a physician's family members, ensure that

arrangement also complies with the relevant Stark rules.

14. Include the Medicare Access Clause. If CMS will pay for or reimburse the entity for the physician's services, independent contractor agreements must generally include a clause that requires the physician to maintain records relevant to the physician's services and grant HHS access to such records for a period of four years. Failure to include the required access clause may result in denial of payment or repayment to Medicare.

IF YOU HAVE A VIOLATION. Federal law prohibits entities from submitting Medicare and Medicaid claims for payment if the contract violates Stark or the Anti-Kickback Statute. Furthermore, this period of disallowance continues until any problem with the contract has been resolved and any overpayment has been repaid; simply fixing the problem prospectively does not cure past problems. If claims were improperly submitted, the entities are generally obligated to report and repay the amount improperly received within 60 days.[36] If the violation did not involve intentional misconduct, providers may notify the applicable Medicare contractor and submit the repayment per CMS's interim report and repay rule.[37] For significant Stark violations, providers should use CMS's Self-Referral Disclosure Protocol to self-report the violation.[38] For significant Anti-Kickback or Civil Monetary Penalties Law violations, providers may want to self-report using the OIG's recently revised Self-Disclosure Protocol.[39] Providers facing significant exposure may want to consult with an experienced healthcare attorney.

REMEMBER STATE LAWS. In addition to the federal rules discussed above, healthcare entities should check their own state laws that may apply, including state anti-kickback or self-referral laws; fee-splitting statutes; corporate practice of medicine laws; etc. Individual states may also have their own self-reporting and/or repayment rules.

CONCLUSION. As anything else in medicine, an ounce of prevention is worth a pound of cure. Given the significant penalties for noncompliance, it is better to ensure that contracts are structured properly at the outset, and that ongoing compliance is periodically monitored throughout the contract term. If there is a violation, the parties should take immediate action to address the situation and minimize liability.

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[1]The Ethics in Patient Referrals Act ("Stark") generally prohibits physicians from referring patients to entities with which the physician (or the physician's family member) has a financial relationship for certain designated health services payable by Medicare unless the transaction is structured to fit within a regulatory safe harbor. 42 USC § 1395nn; 42 CFR § 411.353.

[2]The federal Anti-Kickback Statute generally prohibits offering, soliciting, paying or receiving remuneration to induce referrals for items or services payable by federal healthcare programs unless the transaction fits within a regulatory safe harbor. 42 USC § 1320a-7b(b); 42 CFR § 1001.952. Significantly, the Anti-Kickback Statute is violated if "one purpose" of the

proposed transaction is to induce such referrals unless the arrangement fits within one of the regulatory safe harbors. *United States v. Greber*, 760 F.2d 68 (3d Cir. 1986).

[3]Among other things, the Civil Monetary Penalties Law prohibits a hospital from knowingly making a payment to a physician as an inducement to reduce or limit services provided to Medicare beneficiaries. 42 USC § 1320a-7a(b).

[4]42 CFR § 1320a-7k(d); 77 F.R. 9179 (2/16/12).

[5]Although Stark is limited to financial arrangements with physicians or their family members, the Anti-Kickback Statute applies to arrangements with any referral source.

[6]42 CFR § 411.357(c) and § 1001.952(i).

[7]42 CFR § 411.357(d), (l), and § 1001.952(d).

[8]42 CFR § 411.353(g).

[9]See 42 CFR § 411.357(c) and § 1001.952(i).

[10] 42 CFR § 411.357(d) and (l).

[11]42 CFR § 411.357(d)(1)(vii).

[12]42 CFR § 411.357(c).

[13]42 CFR § 411,357(d) and (l).

[14]42 CFR § 411.357(d)(1)(ii).

[15]42 CFR § 411.357(d), (l), and § 1001.952(d). The OIG has also suggested that payments to an employee that do not reflect fair market value may suggest that there is not a bona fide employment relationship under 42 CFR § 1001.952(i).

[16]See 42 CFR § 411.351, definition of "fair market value."

[17]42 CFR § 411.354(d)(4).

[18]42 CFR § 411.357(d). To fit within the Anti-Kickback Statute safe harbor, the aggregate compensation must be set in advance, not just the formula. 42 CFR § 1001.952(d).

[19]42 CFR § 1001.952(d).

[20]42 CFR § 411.357(d), (l), and § 1001.952(d).

[21]42 CFR § 411.357(d), (l), and § 1001.952(d).

[22]See 42 CFR § 411.352 and § 411.355

[23]42 CFR § 411.354(d)(4).

[24]42 CFR § 411.354(d)(4).

[25]42 CFR § 411.354(d)(4).

[26]42 USC § 1320a-7a(b)(1); OIG Special Advisory Bulleting, *Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries* (July 1999).

[27]See 76 FR 67992 (November 2, 2011).

[28]Stark contains additional exceptions for, e.g., medical staff incidental benefits; non-monetary compensation less than $300; professional courtesies; OB malpractice insurance; etc. Each exception must satisfy specific regulatory requirements. See 42 CFR § 411.357 and § 1001.952.

[29]42 CFR § 411.957(l) and § 1001.952(d).

[30]42 CFR § 411.957(d), (l) and § 1001.952(d).

[31]See 42 CFR § 411.357(d), (l) and § 1001.952(d).

[32]42 CFR § 411.357(d); see 42 CFR §1001.952(d).

[33]42 CFR § 411.357(l).

[34]See 42 CFR § 411.357(c) and § 1001.952(i).

[35]42 CFR § 411.353.

[36]42 USC § 1320a-7k(d); 77 FR 9179.

[37]77 FR 9179.
[38]See guidance at http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html.
[39]See guidance at http://oig.hhs.gov/compliance/self-disclosure-info/index.asp.

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