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Common Stark Concerns for Hospitals

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Unless structured properly, a hospital's financial relationship with referring physicians or other providers may violate the federal Ethics in Patient Referrals Act ("Stark") and Anti-Kickback Statute ("AKS"), resulting in civil and criminal fines, penalties, and repayments. Under Stark, if a hospital has a financial relationship with a physician, the physician may not refer patients to the hospital for certain designated health services[1] payable by Medicare or Medicaid unless the arrangement fits within a regulatory safe harbor. (42 USC § 1395dd; 42 CFR § 411.353). The AKS generally prohibits knowingly offering, paying, soliciting or receiving remuneration to induce referrals for items or services payable by federal healthcare programs unless the arrangement fits within a regulatory safe harbor. (42 USC § 1320a-7b(b); 42 CFR § 1001.952). Below are some of the top compliance concerns arising from relationships with referring providers:

1. No Written Agreement. Except for employment arrangements, Stark and the AKS generally require that financial arrangements are documented in writing and signed by the parties, including arrangements involving the payment for services, sale or lease of space or equipment, recruitment subsidies, etc. (*See, e.g.*, 42 CFR §§ 411.357(a), (b), (d), (e), (l), (p), (y), and 1001.952(b)-(d)). CMS has confirmed that a single formal contract is not necessarily required; instead, "a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement…" (80 FR 71315).

2. Compensation Based on the Volume or Value of Referrals. Stark generally prohibits paying physicians based on the volume or value of their referrals or services ordered by the physician. (42 CFR § 411.357(c), (d), and (l)). Problematic arrangements may include paying physicians a share of profits from a department or service line; giving physicians credit for services performed by advanced practice professionals; crediting physicians for ancillary services ordered by the physician; etc. The AKS generally does not apply to referral-based compensation structures for employees, but does apply to referral-based compensation structures for independent contractors. (42 CFR § 1001.952(d), (i)).

3. Above/Below Fair Market Value. Stark and the AKS generally require that referring practitioners pay or are paid fair market value for items or services provided, including payments pursuant to employment contracts; professional services agreements; use of space, equipment, or personnel; sale of items; etc. (42 CFR §§ 411.357(a)-(d), (f), (i), (l), (p), and 1001.952(b)-(d)). Unless a specific exception applies, overpayments and underpayments presumably induce referrals and trigger Stark and AKS

concerns.

4. Commercially Unreasonable Arrangements. To fit within applicable safe harbors, services agreements and leases must generally be commercially reasonable and serve legitimate business purposes unrelated to referrals. (42 CFR §§ 411.357(a)-(d), (f), (l), (p), and (y), and 1001.952(b)-(d)). Agreements to provide unnecessary items or services are suspect; they may simply be a subterfuge to funnel money to referral sources.

5. Changed Performance. Over time, the parties to an agreement may grow lax and fail to comply with contract terms, including failing to perform contract requirements, or providing services or items that vary from the contract terms. Doing so may cause compliance concerns because there is now no written agreement for the items or services actually provided, or compensation may no longer reflects fair market value for what is really exchanged. Parties need to ensure ongoing compliance and modify the contract as appropriate.

6. Retroactive Payments or Adjustments. For independent contractor arrangements and leases, Stark and the AKS regulations generally require that the compensation or lease rate be set in advance. (42 CFR §§ 411.357(a)-(b), (d), and (l), and 1001.952(b)-(d)). Retroactive adjustments or payments that were not contemplated in the original agreement fall outside the safe harbor. In contrast, compensation in employment agreements need not be set in advance.

7. Amendments within One Year. For independent contractor arrangements and leases, Stark and the AKS generally require that the term of the agreement be for at least one (1) year. Parties may terminate the agreement earlier but, if they do, they may not enter a new agreement within the initial one-year period. (42 CFR §§ 411.357(a)-(b), (d), and (l), and 1001.952(b)-(d)). Amendments or other changes to the agreement during the initial one-year period will likely cause the agreement to fall outside the safe harbor.

8. Use of Hospital Space or Equipment without a Lease. Hospitals sometimes allow visiting specialists or other providers to use hospital space, equipment or personnel without a formal lease or timeshare arrangement. There is generally no problem if the hospital is able to charge a facility or technical fee associated with the physician's use of the space or equipment. (*See*, *e.g.*, 80 FR 71321). However, problems occur if the physician or other provider is permitted to use the space, equipment, or personnel to see their own patients as if they were in their own practice, and/or bills globally for the services. (*See id.*). In such situations, the parties generally need a written lease or timeshare arrangement.

9. Non-Exclusive Leases. The Stark safe harbor for space or equipment leases requires that the physician have exclusive use of the leased space or equipment during the lease term. (42 CFR § 411.357(a)-(b)). If the parties want to share space or equipment, they should enter a timeshare arrangement pursuant to 42 CFR § 411.357(y).

10. "Per-Click", "On Demand", or Percentage-Based Leases. The Stark safe harbor for space or equipment leases generally prevents lease formula's based on a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed in the office space, or per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. (42 CFR § 411.357(a)-(b)).

11. Practice Subsidies, Perks, and other Free or Discounted Items or Services. Stark and the AKS are quite broad: they generally apply to anything of value given by the hospital to referring providers. Problematic arrangements may include "thank you" gifts; free or discounted use of hospital space, equipment or personnel; free or discounted hospital services; free continuing medical education ("CME") programs; practice subsidies; insurance subsidies; etc. Hospitals need to ensure that any subsidies, perks, or other items offered to referring providers fit squarely within an appropriate safe harbor. There are several safe harbors that might apply depending on the circumstances, including:

1. Subsidies to recruit needed providers to the area. (42 CFR § 411.357(e)).
2. Nonmonetary items or services totaling less than $400[2] per year. (42 CFR § 411.357(k)).
3. Incidental benefits of less than $25 offered to medical staff members on the hospital campus. (42 CFR § 411.357(m)).
4. Compliance training. (42 CFR § 411.357(o)).
5. Obstetrical malpractice insurance subsidies. (42 CFR § 411.357(r)).
6. Professional courtesies offered pursuant to an established policy without regard to referrals. (42 CFR § 411.357(s)).
7. Electronic health record subsidies. (42 CFR § 411.357(u)-(w)).

Each of these exceptions have specific requirements that must be fully satisfied to fit within the safe harbor and avoid violations.

13. Joint Marketing Programs. Hospitals and physicians often engage in joint marketing campaigns or efforts. In such cases, hospitals must beware subsidizing the physicians' or providers' fair share. In general, each party should pay fair market value for their share of the marketing expenses.

14. Joint Ventures. Hospitals and referring providers may engage in joint ventures, e.g., joint ownership in an ambulatory surgery center; service line; management services organization; holding company; etc. Such arrangements must be structured carefully to ensure compliance with Stark and AKS regulations. In general, referring providers should pay fair market value for their ownership interest, and the return on the investment should reflect their investment, not based on the volume or value of referrals. Other safe harbor conditions will apply.

Conclusion. If there has been a Stark or AKS violation, prospective compliance is not enough. Stark and AKS violations generally require the parties to report and make appropriate repayments to federal programs pursuant to the HHS repayment rule. (*See* 42 USC § 1320a-7k(d); 42 CFR

§ 401.305). For Stark violations, the hospital will likely want to participate in the Stark Self-Referral Disclosure Protocol ("SRDP"). (*See* https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/self_referral_disclosure_protocol.html). For serious AKS violations, the parties may consider a voluntary self-disclosure under the OIG Self Disclosure Protocol. (*See* https://oig.hhs.gov/compliance/self-disclosure-info/protocol.asp). Hospitals should consult with competent compliance professionals or attorneys to ensure that potential violations are properly analyzed and addressed.

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[1]"Designated health services" include (i) clinical laboratory services, (ii) physical therapy, 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).
[2]The annual limit is subject to annual adjustment depending on the consumer price index.

For questions regarding this update, please contact:
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