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Part II: Exploration of Common Exceptions to the Stark Law

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Stark Exceptions: Bright line rules?

Upon introducing the bill, Congressman Stark explained:



“[W]hat is needed is what lawyers call a bright line rule to give providers and physicians unequivocal guidance as to the types of arrangements that are permissible and the types that are prohibited. If the law is clear and the penalties are severe, we can rely on self-enforcement in the great majority of cases.”

Stark Exceptions: We have a financial relationship, now what?

- Stark exceptions v. Anti-Kickback “safe harbors”
- Three major categories of Stark exceptions
 - General Exceptions – BOTH Ownership/Compensation
 - Ownership Exceptions
 - Compensation Exceptions

General Exceptions (42 C.F.R. § 411.355)

- Physician Services
- In-office ancillaries
- Prepaid health plans
- Academic Medical Centers
- Implants in ASCs
- EPO and other dialysis drugs in ESRD
- Preventive screening services, immunizations, vaccines
- Eyeglasses and lens following cataract surgery
- Intra-family rural referrals

Group Practice Definition (42 C.F.R. § 411.352)

- Not an exception, but key to Physician Services and In-Office Ancillary Services Exceptions
- Allows for Productivity Bonuses & Profit Sharing
- Highly Detailed Definition

Group Practice Definition (cont'd)

- Single legal entity
- At least two “members” providing full range of services
- “Substantially all” services of members furnished through group
- Members provide at least 75% of physician-patient encounters
- Overhead expenses/income distributed in accordance with previously determined methods
- Unified business

In-Office Ancillary Services Exception (42 C.F.R. § 411.355(b))

- Applies to DHS that are “ancillary” to a physician’s professional services provided by the physician’s practice (excludes most DME and parenteral and enteral nutrients)
- To apply, the DHS must:
 - Be furnished by physician, another physician in “group practice,” or directly supervised by them
 - Be provided in: (1) same building in which physician provides some services unrelated to DHS; or (2) if group practice, can be a “centralized building”
 - Billed by physician, group practice, an entity wholly-owned by the group practice, or by a third-party billing agent

In-Office Ancillary Services Exception (cont'd)

- CMS recognized as “one of the most important exceptions” to Stark law (70 Fed. Reg. 38,181 (July 12, 2007))
- BUT Recent scrutiny due to proliferation of in-office diagnostic testing.
 - MedPac Report (June 2010)
 - H.R. 2914 (2013-2014 Sess.) – Proposes to make IOAS not applicable to certain diagnostic tests, anatomic pathology, radiation therapy services and supplies, and physical therapy services

In-Office Ancillary Services Exception (cont'd)

- ACA Disclosure Requirement
 - For CT, MRI, and PET, referring physician needs to provide written disclosure of ownership of imaging equipment and list of alternative suppliers.
 - Regulation effective January 1, 2011
 - CMS has the authority to add other services to list of disclosure services.

Ownership Exceptions (42 C.F.R. § 411.356)

- Ownership in publicly-traded securities and mutual funds
- Hospitals in Puerto Rico
- Rural provider
- Ownership in “whole” hospital

“Whole” Hospital & Rural Provider Exceptions

- ACA effectively bars physician investment in new hospitals and expansion of existing facilities.
- To qualify for exception:
 - Must have physician ownership/investment as of March 23, 2010; and provider agreement as of Dec. 31, 2010
 - Subject to limited exception process, hospital cannot expand number of operating rooms, procedures rooms, or licensed beds as of March 23, 2010
 - Percentage of total value of physician ownership in hospital, or an entity whose assets include the hospital, must not exceed aggregate percentage as of March 23, 2010
 - Subject to additional conflict of interest, bona fide investment, and patient safety requirements

Compensation Exceptions (42 C.F.R. § 411.357)

- Rental of office space and equipment
- *Bona fide* employment relationships
- Personal services arrangements
- Physician recruitment
- Isolated transactions
- Remuneration unrelated to DHS
- Certain group practice arrangements with hospitals
- Payments by physicians for items and services
- Charitable donations
- Nonmonetary compensation
- Fair market value compensation

Compensation Exceptions (42 C.F.R. § 411.357)

- Medical staff incidental benefits
- Risk-sharing arrangements
- Compliance training
- Indirect compensation arrangements
- Referral services
- Obstetrical malpractice insurance subsidies
- Professional courtesy
- Retention payments in underserved areas
- Community-wide health information systems
- Electronic prescribing items and services
- Electronic health records items and services

Compensation Exceptions: Common Requirements

- In writing, signed by the parties and specifies services or property covered
- Compensation is:
 - Set in advance
 - Fair market value
 - Does not take into account the volume or value of referrals, or other business generated
- Agreement would be commercially reasonable even if no referrals
- Must not violate Anti-Kickback Statute

	Personal Services 42 CFR 411.357(d)	Rental of Office Space/ Equipment 42 C.F.R. 411.357(a)-(b)	Bona Fide Employment 42 C.F.R. 411.357(c)	Fair Market Value 42 C.F.R. 411.357(l)
Do you need a signed writing?	Y	Y	N	Y
Term of at least 1 year?	Y	Y	N	N
Must compensation be FMV?	Y	Y	Y	Y
Set in advance?	Y	Y	N	Y
Not take into account V/V of referrals?	Y	Y	Y (except prod. bonuses)	Y
Percentage-based/per-click comp permitted?	Y	N	Y	Y
6 month holdover provision?	Y	Y	N/A	N

Indirect Compensation Exception (42 C.F.R. § 411.357(p))

- Applies only if there is an "indirect compensation" arrangement (42 C.F.R. § 411.354(c)(2))
 - If no indirect compensation arrangement, no need to apply exception
- If "Stand in the Shoes" applies to create a *direct* financial arrangement must use a direct compensation exception (i.e., personal services arrangement)

Indirect Compensation Exception (42 C.F.R. § 411.357(p))

- Physician compensation is fair market value and does not take into volume or value of referrals, or other business generated
 - Unlike "indirect compensation" definition, exception does not look at *aggregate* compensation
 - Per unit-of-service and percentage based payments permitted (except for leases)
 - Apply special rules on compensation, 42 CFR §411.354(d)(2),(3)
- Compensation is set out in writing, signed by parties, and specifies services (except employment)
- Does not violate Anti-Kickback Statute or other federal/state billing or claims submission

Temporary Noncompliance with Signature Requirements (42 C.F.R. § 411.353(g))

- Agreement otherwise fully complies with applicable exception
- Signatures within 90 consecutive days where failure was inadvertent
- Signatures within 30 days where failure was not inadvertent
- Exception may only be used once every 3 years for same physician

Do you have a Stark Problem?

- Hospital has an employment arrangement with Dr. A, an anesthesiologist, who lacks a written agreement?
 - Any referrals for DHS?
 - *Bona Fide* employment exception does not require agreement
- Hospital leases space to Dr. B, a top orthopedic surgeon, on an as needed basis. The lease expired more than 4 months ago.
 - 6 month holdover provision under rental of office space exception
 - BUT per-click lease arrangement

Common Stark Issues

- No signed agreement
 - Confirm agreement necessary
 - No direct/indirect compensation arrangement?
 - Employment agreement?
 - Other documentation/signatures under State Law?
 - Temporary non-compliance with signature requirement
- Expired Contract
 - Confirm agreement is necessary
 - Would 6-month holdover provision apply?

Common Stark Issues

- New or changed duties
 - Is there any documentation of change? Emails, etc.
- No fair market value assessment
 - Any indication of fair market value at *inception* of arrangement?
 - Internal evaluation of compensation
 - Use outside consultant to determine FMV