

STARK LAW DECISION TREE

A. Basic Threshold Requirements.

1. Does the arrangement involve a **physician**?¹ (If yes, go to 2; if no, then no Stark issue)
2. Is the physician making a **referral**?² (If yes, go to 3; if no, then no Stark issue)
3. Is the referral for **designated health services (DHS)**³ payable by **Medicare**? (If yes, go to 4; if no, then no Stark issue)
4. Does the physician (or any of his or her **immediate family members**)⁴ have a **financial relationship**⁵ with the **entity**⁶ furnishing (*i.e.*, billing for or performing) the DHS? (If yes, go to 5; if no, then no Stark issue)

B. Financial Relationship — Ownership/Investment Interest.

5. Is the physician's financial relationship a **direct ownership/investment interest in the DHS entity**?⁷ (If yes, go to 9(a); if no, go to 6)
6. Is the physician's financial relationship an **indirect ownership/investment interest**⁸ (*e.g.*, there is an "unbroken chain" of persons or entities with ownership/investment interests). (If yes, go to 9(c); if no go to 8)

C. Financial Relationship – Compensation Arrangements.

7. Is the physician's financial relationship a **direct compensation arrangement**⁹ (*i.e.*, the physician receives remuneration directly from, or gives remuneration directly to, an entity furnishing (*i.e.*, billing for or performing) DHS) (If yes, go to 9(b); if no, go to 8)

¹ See definition of **physician** at 42 C.F.R. § 411.351.

² See definition of **referral** at 42 C.F.R. § 411.351.

³ **Designated health services:** clinical laboratory services; physical therapy, occupational therapy, and outpatient speech language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. See CMS code list of certain DHS (listed by CPT/HCPCS codes - https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html) and see 42 C.F.R. § 411.351 for specific definitions of the DHS categories.

⁴ See definition of **immediate family member** at 42 C.F.R. § 411.351.

⁵ See definition of **financial relationship** at 42 C.F.R. § 411.354(a).

⁶ See definition of **entity** at 42 C.F.R. § 411.351.

⁷ See definition of **ownership/investment interests** at 42 C.F.R. § 411.354(b).

⁸ See definition of **indirect ownership/investment interests** at 42 C.F.R. § 411.354(b)(5).

⁹ See definition of **direct compensation arrangement** at 42 C.F.R. § 411.354(c)(1).

8. Is the physician's financial relationship an **indirect compensation arrangement**¹⁰ (e.g., there is an "unbroken chain" of financial relationships that include at least one compensation arrangement with an entity furnishing (i.e., billing for or performing) DHS) (If yes, go to 9(c); if no, must analyze relationship under 6 and 7 again)

D. Exceptions.

9. Is there an applicable exception?
- a. **Ownership Exceptions.** Does the relationship fit all of the requirements of an all purpose exception¹¹ or an ownership interest exception?¹² (If yes, then no Stark issue; if no, may not enter into arrangement)
- b. **Compensation Arrangement Exceptions.** Does the relationship fit all of the requirements of an all purpose exception⁹ or a direct compensation arrangement exception?¹³ (If yes, then no Stark issue; if no, may not enter into arrangement)
- c. **Indirect Compensation Arrangement Exceptions.** If the indirect financial relationship contains at least one compensation arrangement, then does the relationship fit all of the requirements of the indirect compensation arrangement exception?¹⁴ (If yes, then no Stark issue; if no, may not enter into arrangement)

¹⁰ See definition of **indirect compensation arrangement** at 42 C.F.R. § 411.354(c)(2).

¹¹ **All Purpose Exceptions:** Physician Services (42 C.F.R. § 411.355(a)); In-Office Ancillary Services (42 C.F.R. § 411.355(b)); Prepaid Plans (42 C.F.R. § 411.355(c)); Academic Medical Centers (42 C.F.R. § 411.355(e)); Implants Furnished by ASCs (42 C.F.R. § 411.355(f)); Dialysis-Related Outpatient Prescription Drugs (42 C.F.R. § 411.355(g)); Preventive Screening, Immunizations, and Vaccines (42 C.F.R. § 411.355(h)); Eyeglasses and Contact Lenses following Cataract Surgery (42 C.F.R. § 411.355(i)); and Intra-Family Rural Referrals (42 C.F.R. § 411.355(j)).

¹² **Ownership Interest Exceptions:** Publicly Traded Securities (42 C.F.R. § 411.356(a)); Mutual Funds (42 C.F.R. § 411.356(b)); Rural Providers (42 C.F.R. § 411.356(c)(1)); Hospitals in Puerto Rico (42 C.F.R. § 411.356(c)(2)); and Whole Hospital Ownership/Investment (42 C.F.R. § 411.356(c)(3)(iii)).

¹³ **Direct Compensation Arrangement Exceptions:** Rental of Office Space (42 C.F.R. § 411.357(a)); Rental of Equipment (42 C.F.R. § 411.357(b)); Bona Fide Employment (42 C.F.R. § 411.357(c)); Personal Services Arrangements (42 C.F.R. § 411.357(d)); Physician Recruitment (42 C.F.R. § 411.357(e)); Isolated Transactions (42 C.F.R. § 411.357(f)); Remuneration Unrelated to DHS (42 C.F.R. § 411.357(g)); Group Practice Arrangements with Hospitals (42 C.F.R. § 411.357(h)); Payments by a Physician (42 C.F.R. § 411.357(i)); Charitable Donations by a Physician (42 C.F.R. § 411.357(j)); Non-monetary Compensation (42 C.F.R. § 411.357(k)); Fair Market Value (42 C.F.R. § 411.357(l)); Medical Staff Incidental Benefits (42 C.F.R. § 411.357(m)); Risk-Sharing Arrangements (42 C.F.R. § 411.357(n)); Compliance Training (42 C.F.R. § 411.357(o)); Referral Services (42 C.F.R. § 411.357(q)); Obstetrical Malpractice Insurance Subsidies (42 C.F.R. § 411.357(r)); Professional Courtesy (42 C.F.R. § 411.357(s)); Retention Payments in Underserved Areas (42 C.F.R. § 411.357(t)); Community-Wide Health Information Systems (42 C.F.R. § 411.357(u)); Electronic Prescribing Items and Services (42 C.F.R. § 411.357(v)); Electronic Health Records Items and Services Exception (42 C.F.R. § 411.357(w)); Assistance to Compensate a Non-Physician Practitioner (42 C.F.R. § 411.357(x)) and Timeshare Arrangements (42 C.F.R. § 411.357(y)).

¹⁴ **Indirect Compensation Arrangement Exception:** 42 C.F.R. § 411.357(p).