

Stark Update

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STARK - Plain Language



If a **Physician** (or immediate family member) has a direct or indirect **Financial Relationship** with an **Entity**, unless an exception applies:

- the **Physician** may not **Refer** any **Designated Health Services ("DHS")** to the **Entity**,
- the **Entity** may not bill for any **DHS** referred by the physician,
- no Medicare payments may be made for **DHS** referred by the physician, and
- the **Entity** must refund all moneys collected for **DHS** referred by the physician (unless no actual knowledge or reckless disregard re: the physician's identity)

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Personal Services Exception


- Remuneration from an entity to a physician if:
 - Set out in writing and specifies services covered,
 - Term of agreement is at least one year,
 - Compensation is (1) set in advance, (2) FMV, and (3) not determined by considering volume or value of referrals or other business between parties,
 - Writing covers all services provided by physician; each agreement cross-references all others; or contract database,
 - Aggregate services don't exceed reasonable and necessary,
 - 6 month holdover**

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Employment Exception

Amounts paid by an entity to a physician who is a bona-fide employee if:

1. Employed to provide identifiable services;
2. Compensation paid:
 - Is consistent with FMV, and
 - Does not take into account the volume or value of referrals.
3. The arrangement would be *commercially reasonable* even if no referrals were made
 - Is consistent with FMV, and
 - Does not take into account the volume or value of referrals.




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Leases – Rental of Office Space/Rental of Equipment Exceptions

Covers payments by lessee to lessor for the use of office space

- Agreement in writing, signed by the parties, specifies the premises
- Term of at least one year
- Amount of space is reasonable and necessary for legitimate business purposes
- Space is used exclusively by lessee (except pro-rata share of common areas)
- Rent is set in advance and consistent with fair market value
- Rent not determined in a manner that considers volume or value of referrals
- Agreement is commercially reasonable even if no referrals
- Six month holdover allowed on same terms after a term of at least one year**



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RAPID CITY REGIONAL MEDICAL CENTER

JUSTICE DEPARTMENT ANNOUNCES SETTLEMENTS With South Dakota Hospital and Doctors for \$6,525,000

WASHINGTON, DC (December 20, 2002) – Rapid City Regional Hospital has agreed to pay the United States \$6 million to resolve allegations that the facility improperly charged Medicare for referrals from doctors with whom it had improper financial relationships, the Justice Department announced today. The doctors have agreed to pay the government an additional \$525,000 to settle claims that they overcharged Medicare for their patients' office visits.



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Regulatory Update

New Exceptions and Clarifications

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New Exception: Payments to a Physician for Recruitment of an NPP

Remuneration by a hospital, Federally Qualified Health Clinic (FQHC) or Rural Health Clinic (RHC) to a physician to assist in recruiting a non-physician practitioner to the geographic area served by the hospital, FQHC or RHC, if:

- i. Set out in writing and signed by (1) the hospital, FQHC or RHC, (2) the physician, and (3) the NPP;
- ii. Not contingent on referrals from the physician or NPP;
- iii. Remuneration
 - A. does not exceed 50% of the actual compensation, signing bonus and benefits paid by the physician to the NPP during a period not to exceed the first two consecutive years, and
 - B. is not determined in a manner that takes into account volume or value of services by the physician or the NPP;
- iv. Total compensation to the NPP does not exceed FMV for the patient care services provided by the NPP to the physician practice's patients;

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New Exception: Payments to a Physician for Recruitment of an NPP

- v. NPP has not, within one year of the commencement of the compensation arrangement
 - A. practiced in the geographic area served by the hospital, FQHC or RHC; or
 - B. been employed or otherwise been employed by a physician or physician organization that has a medical practice site located in the geographic area served by the hospital, FQHC or RHC.
- vi. A. The NPP has a direct (employment or contract compensation – NOT ownership) arrangement with the physician (no agency or physician to physician/group);
B. Substantially all (75%) of the NPP's services are primary care or mental health services;
- vii. Physician does not impose practice restrictions that unreasonably impose NPPs ability to provide patient care services in the geographic area served by the hospital;
- viii. No underlying AKS violation.

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New Exception: Payments to a Physician for Recruitment of an NPP

- Must maintain records of actual amount of remuneration from hospital to physician, and from physician to NPP, for at least 6 years
- NPP means:
 - Physician assistant
 - Nurse practitioner
 - Clinical nurse specialist
 - Nurse mid-wife
 - Clinical social worker
 - Clinical psychologist
- Exception can be used once every three years per referring physician
- Does not cover ownership by NPP

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New Exception: Timeshare Arrangements

Remuneration provided under an arrangement for the use of premises, equipment, personal items, supplies or services (the "Stuff") if:

1. Set out in writing, signed by the parties, specifies the Stuff, covered by the arrangement;
2. Arrangement is between a physician and a hospital or physician organization of which the physician is not an owner, employee or contractor;
3. The Stuff is used (i) predominantly for the provision of E&M services to patients, and (ii) on the same schedule;
4. The equipment covered by the arrangement is (i) in the same building where E&M services are furnished, (ii) not used to furnish DHS other than as incidental to services furnished at the time of the E&M services, and (iii) is not advanced imaging equipment, rad onc equipment or clinical or pathology lab equipment.

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New Exception: Timeshare Arrangements

5. Not conditioned on a referral of patients by the physician to the leasing hospital or physician organization;
6. Comp is set in advance, consistent with FMV, and not determined—
 - in a manner that takes into account volume or value of referrals or other business generated,
 - using a formula based on
 - a percentage of revenue earned, billed, collected or otherwise attributable to the use of the Stuff, or
 - per-unit of service fees that are not time-based but that reflect services provided using the Stuff.
7. Arrangement is commercially reasonable even with no referrals,
8. No violation of AKS
9. No possessory leasehold interest in space

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New Exception: Timeshare Arrangements

- New exception does not undermine the ability to rely on existing exceptions, just one more choice (therefore, won't affect existing, compliant, arrangements)

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Other Changes

- Clarifications regarding physician owned hospital's ownership percentages and marketing requirements
- Establishment of a rule for determining the Geographic Area Served by FQHC's and RHC's for use in physician and NPP recruitment
 - Lowest number of contiguous zip codes from which 90 percent of patients come
- Adjustments to uniformly use "takes into account" the volume or value of referrals
- Retention payments may be based on physicians income over no more than the previous 24 months (had been over previous 24 months)
- Holdover now indefinite: BUT
 - Must continue on same terms, and
 - Must meet all exception requirements (i.e., FMV)

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Other Changes:

- Non-compliance with signature requirement: now have 90 days without regard to the former "knowing" and "inadvertent" standards
 - Arrangement still must comply with all other elements of the exception
 - Exception still may only be used once every three years
 - Electronic signatures might meet the signature requirement

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Clarification: the "writing" and "term" requirements

- Not necessarily a uniform contract
- Providers may rely on a series of writings in combination with a course of conduct
- Similarly the "term of at least one year" requirement may be met if contemporaneous writings establish that the arrangement in fact lasted for at least one year
- Do these clarifications and the changes noted above mean that your compliance strategy should be adjusted?

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Recent Developments, Settlements and Enforcement Initiatives

What They Should be Telling Us

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Halifax Health, Daytona Beach, FL

- Halifax Health Medical Center (582 bed tax-assisted hospital)
- -Allegations – employed physician's bonuses varied with volume or value of referrals to the hospital
- -Possible damages near \$1 Billion
- -Hospital settles for \$85 Million
- -One of the largest settlement to date (may be largest for a single hospital)

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Toumey Healthcare, Sumpter, SC

- Toumey - sole community hospital, 266 beds
- Part-time employment arrangements with 19 physicians
- Allegations that compensation was not FMV and not commercially reasonable
- 3/2010: Judgment for \$45M
- 10/3/13: Judgment for \$237M

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Employment Relationships Matter

- Twomey (Sumter, SC) \$73M – part time salaries in excess of FMV and not commercially reasonable
- Halifax Health (Daytona, FL) \$85M – compensation that considered volume or value of referrals
- Kings Daughter’s Medical Center (Ashland, KY) \$40.9M – cardiologist salaries in excess of FMV
- North Broward Hospital District (9/2015 – Fort Lauderdale, FL) \$69.5M – salaries in excess of FMV and taking into account volume or value of referrals
- Adventist (9/2015 – FL) \$118M – bonuses based on tests and procedures ordered
- Memorial Health (12/2015 – Savannah, GA) \$9.9M – salaries for three internal medicine physicians in excess of FMV

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Its Not Just Hospitals

- Amedisys (4/2015 – GA) \$150M – providing staff services to physicians at below FMV
- Recovery Home Care (3/2015 – FL) \$1.1M – physician payments for patient chart review fees in excess of work performed
- Hebrew Home Health Network (SNFs) (6/2015 – FL) \$17M – “Ghost” medical director arrangements with no actual duties
- 21st Century Oncology (12/2015 – FL) – bonuses based on the number of tests ordered

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Medicaid – and Children’s Hospital – are in!

- All Children’s Hospital (4/2014 – Tampa, FL) \$7M – salaries in excess of FMV

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Individual and Physician Accountability is an Emerging Trend

- Columbus Regional (9/2015 - Columbus, GA) \$35M (Dr. Andrew Pippas \$425,000) – Excess (of FMV) salary and medical director payments
- Hebrew Home Health – CEO and Administrator also required to pay settlements

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Watch linkage with the new Overpayment Regulations & Yates

- New Regulations: 60 day report and return requirements
 - New “reasonable diligence” standard
- Yates Memo – “One of the most effective ways to combat corporate misconduct is by seeking accountability from individuals who perpetrated the wrongdoing.

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Qui Tam Trends: whistleblowers

- Halifax: **compliance department staff**
- Twomey: **physician** who refused to sign an employment agreement
- Westchester: **compliance officer**
- North Broward: **physician** who refused to sign an employment agreement
- Columbus Regional: **former cancer center administrative director**
- Memorial Health: **former CEO**
- All Children's: former **director of operations for the medical group**
- Hebrew Home Health: **CFO**

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Questions?

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