

Gainsharing: Potentially Powerful, But Problems Persist

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“Gainsharing”

- Incentivizing physicians to reduce hospital costs
- Legal barriers:
 - Civil monetary penalty re: incentivizing physicians to “reduce or limit” medical services (OIG)
 - Anti-Kickback Law (OIG)
 - Stark Law (CMS)
- **OIG Special Advisory Bulletin – July 1999**
 - Sharing overall (non-specific) savings with physicians: NO
- **OIG Advisory Opinion 01-01**
 - Specific, transparent cost savings
 - No effect on quality of care
 - Docs get 50% of savings for Year 1 only (compared to Base Year)

What's New: "Product Standardization" of Devices

- Medical devices:
 - \$20+ billion market; huge hospital cost center
 - Manufacturers greatly affect physician referrals by direct relationships: consultancies, grants, gratuities, etc.
- Six OIG Advisory Opinions: 05-01 through 05-06
 - OIG: OK for hospitals to pay physicians to change referral patterns of medical devices (!)
 - OIG: OK to require participating physicians to use "standardized" product, except where medically inappropriate
 - OIG: theory applicable to full range of cardiac devices
- Gives hospitals new and potentially powerful strategy in pricing battles with device manufacturers.

Significant Limitations

- Primary payout in Year One only
 - OK to share 50% of savings over Base Year
- Rigorous clinical equivalence analyses to name “standardized” device(s)
 - A black box at present
 - OIG approves some analyses, but not others
- Complete transparency of process, even to patients
- Payout shared equally by participating physicians
- Full selection of devices maintained by hospital
- No rewards for increased volume of procedures
- Severity case mix analysis – no cherry picking

Major Open Issues

- Question: *How will physicians behave in future years?*
 - Multi year primary payouts possible?
 - May be OK to share 50% of marginal savings in years 2, 3, etc.
 - Reduce physician primary payout to, say 16%, but add Years 2 and 3?
- Question: *How perform clinical equivalence analyses?*
 - More OIG guidance needed
- Question: *Stark Law compliance?*
 - No clear answer, absent further CMS guidance

Other Considerations

- GPOs and consultants will market gainsharing
- Proposed legislation
(S.1002 – Grassley/Baucus)
- Increasing enforcement pressure on device manufacturer marketing
 - Five ortho companies received major investigatory subpoenas on 3/30/05
 - Erosion of power to influence physician preference

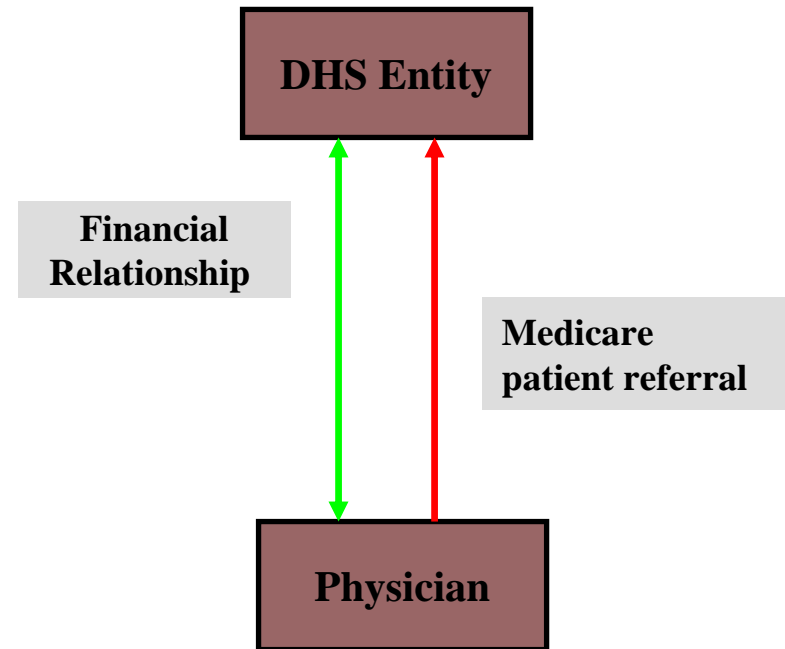
Gainsharing & The Stark Law

Principal Sources

- Statute: 42 U.S.C. § 1395nn
- Statute: 42 U.S.C. § 1396b(s)
- Phase I: 42 C.F.R. § 411 *et. seq.*
- Phase II: 69 Fed. Reg. 16053 (Interim Final Rule)
- Phase II: Final Rule (?)
- Phase III: (?)

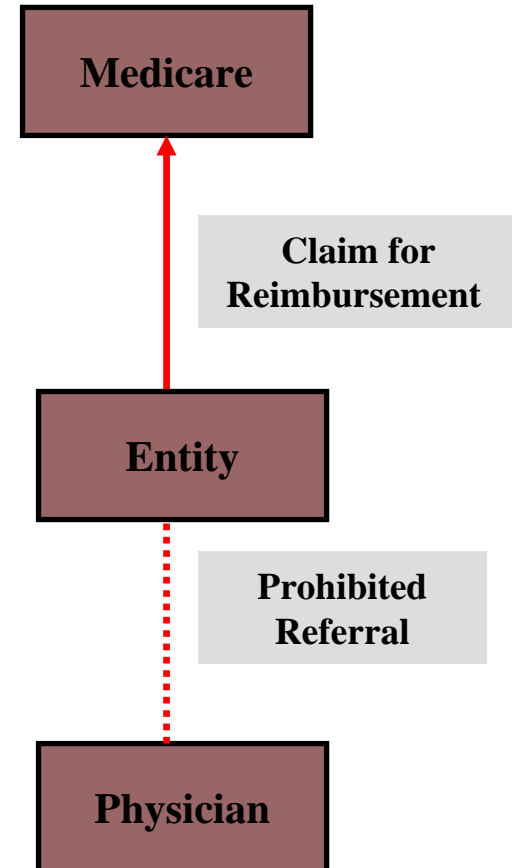
Prohibitions

- Two Basic Prohibitions
 - First, if a “physician” (or “immediate family member”) has a “financial relationship” with an “entity,” then the physician may not “refer” Medicare patients “to” the entity for the furnishing of “designated health services,” unless an exception applies



Prohibitions

- Two Basic Prohibitions
 - Second, an entity may not bill Medicare (or any other individual or entity) for services furnished pursuant to a prohibited referral



Sanctions

- Denial. CMS will not pay claims for improperly referred DHS
- Refund. Entity has duty to refund
- Civil Monetary Penalties.
 - \$15,000 for knowingly presenting or causing another to present improper claim
 - \$100,000 for “scheme” to circumvent
- Exclusion

Elements of a Stark Violation

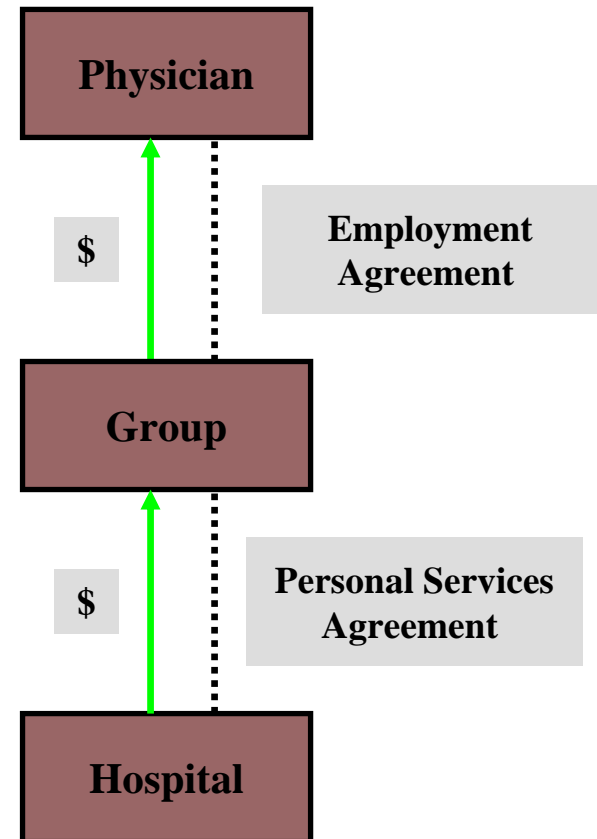
- Physician
- Referral
- To
- Entity
- For furnishing of DHS
- Reimbursable by Medicare
- Physician (immediate family member) has “financial relationship” with entity

Financial Relationship

- Indirect Compensation Arrangement
 - Complicated
 - In order for a physician to have an “indirect compensation arrangement” with an entity, three conditions must be satisfied

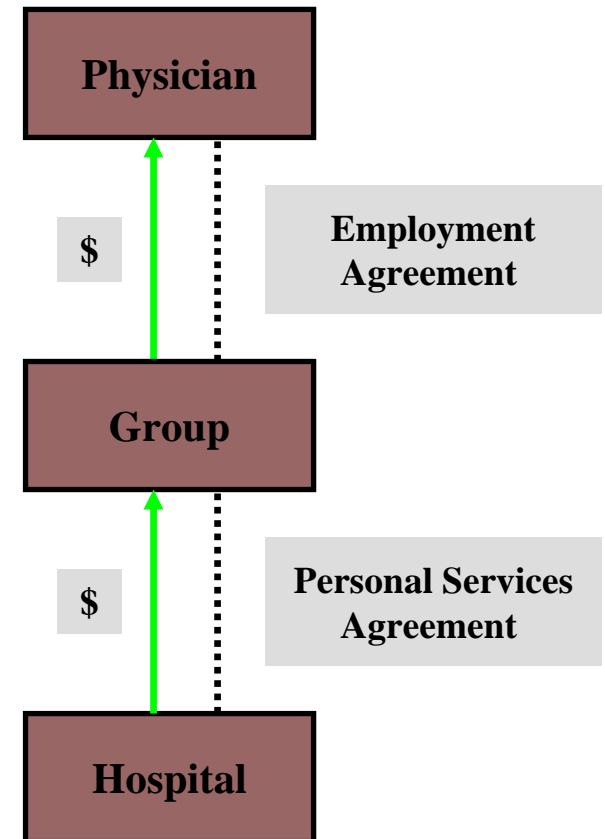
Financial Relationship

- First, there must be an unbroken chain of financial relationships between physician and DHS entity
 - Example: Hospital hires Group to furnish part-time medical directorship services; Group assigns duties to an employed, salaried Physician



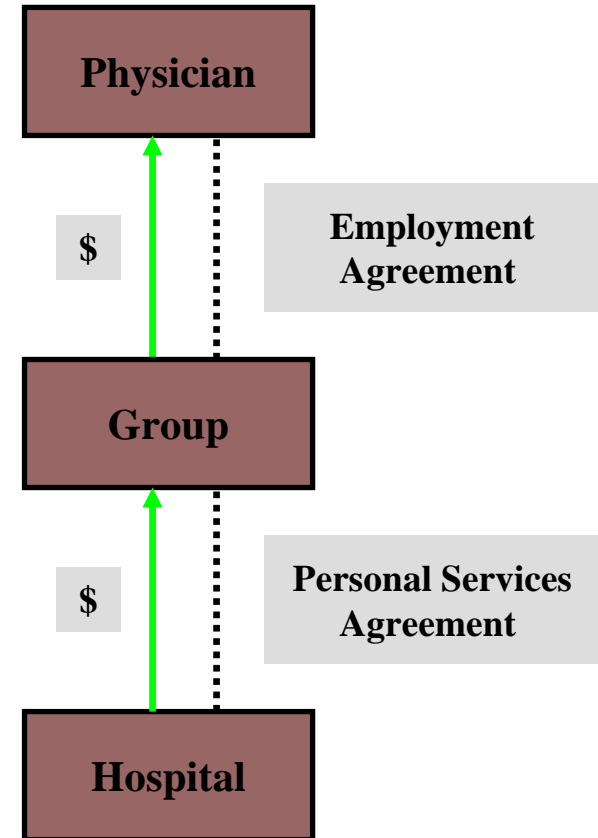
Financial Relationship

- Second, physician receives aggregate compensation from entity in chain with which he has a direct financial relationship that varies with volume or value of referrals by physician for DHS entity
 - Example: Apply test to Group-Physician compensation arrangement



Financial Relationship

- Third, DHS entity knows/should know that physician compensation varies with volume or value of referrals to DHS entity
 - CMS: DHS entity has no duty to inquire unless circumstances “exist such that a failure to follow-up with an inquiry would constitute deliberate ignorance or reckless disregard”

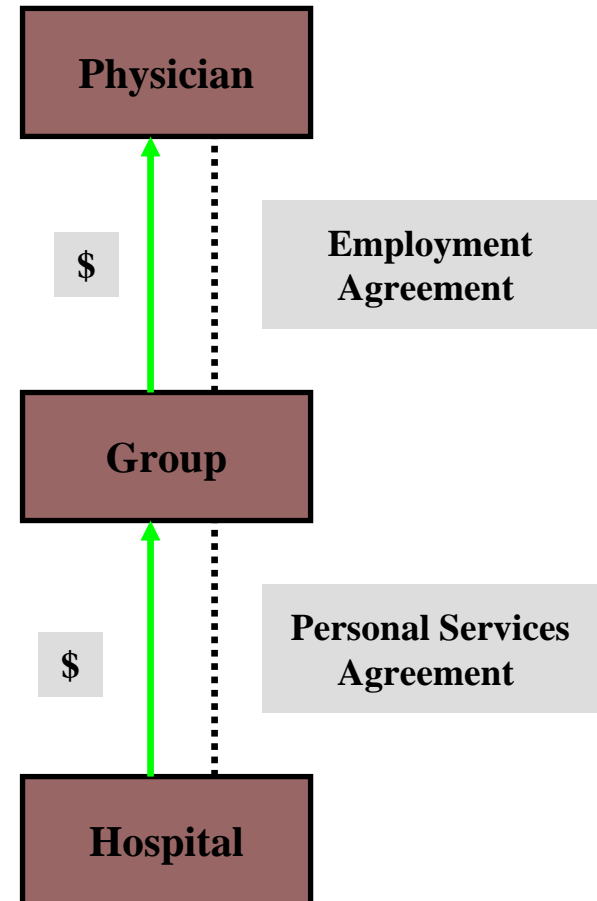


Exceptions

- Indirect Compensation Arrangement Exception
 - Complicated
 - Three conditions

Exceptions

- First, physician compensation is FMV and does not vary with volume or value of referrals by physician to DHS entity
- Second, physician agreement in writing, signed, and specifies services covered by arrangement
- Third, the arrangement does not violate the AKL



Gainsharing Analyzed

Gainsharing Analyzed

