

What You Need to Know About Ancillaries

Health Law Webinar

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Fredrikson

Where Law and Business Meet[®]

Who is Ann Sillary?

- Diagnostic tests:
 - *Imaging.*
 - *Lab.*
- Therapeutics:
 - *PT/OT/SLP.*
 - *Pharmacy.*
 - *DMEPOS.*
- ASCs.

The Four Questions:

- Can we do it?
 - *Licensure/Scope of practice.*
 - *CON.*
- Where can we do it/Who must supervise?
 - *State law.*
 - *Payer rules.*

The Four Questions:

- Who do we need to tell about it?
 - *Conflict of interest issues.*
 - *Registration/certification.*
- Can we bill for it?
 - *Stark.*
 - *Payer rules.*

Things to Keep in Mind

- It is very easy for lawyers to say “no” (with some notable exceptions!).
- Be a skeptic.
- State law is really important.
- Our job is to tell you what you can do.
- “Can” and “should” may be different.



Laws Governing Ancillaries

- Medicare Antikickback statute.
- Stark.
- State Antikickback, Stark, Fee Splitting Provisions, Supervision (and maybe CON).
- Medicare billing and supervision rules.

Know the Lingo: Stark

- Civil, not criminal. Intent doesn't matter. Applies when physician refers to an entity that provides Designated Health Services ("DHS.") Applies only to referrals for DHS, **but** it applies to **all** compensation. If there is compensation, must meet an exception.
- Applies even if the compensation isn't related to the DHS. If a physician is paid to be a consultant, and they order DHS you provide, it applies.
- It's the plan of care, not the referral.
- Be wary of relationships with grandparents, grandchildren, spouses and more.

“Designated Health Services”

- Clinical laboratory.
- Physical therapy.
- Occupational therapy.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrition.
- Prosthetics and orthotics.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

Know the Lingo: Antikickback

- Felony. Intent controls. When “one purpose” of payment is to influence referrals for a federal health care program. Safe harbors, but they are narrow and you don’t have to meet one.
- Doesn’t apply to payments within an entity.

56 F.R. 35952 (July 29, 1991)

“Comment: Many commenters requested the OIG to clarify that payments between corporations which have common ownership are not subject to the statute. Commenters cited as examples intracorporate discounts and payments between two wholly-owned subsidiaries. Some commenters argued that referral arrangements between two related corporations do not constitute "referrals" within the meaning of the statute, and suggested that the OIG define the word "referral" to exclude such activity.

Response: We agree that much of the activity described in these comments is either not covered by the statute or deserves safe harbor protection. We believe that the statute is not implicated when payments are transferred within a single entity, for example, from one division to another. Thus, no explicit safe harbor protection is needed for such payments.

Know the Lingo: Tax Exempt Edition

- “Private inurement” occurs when a person gets an undeserved benefit from a tax exempt organization.
- “Intermediate sanctions” allow the IRS to recoup the money, plus penalties, from the recipient.

CON

- State law controls.
- Created at a time of cost-based reimbursement.
- Seems to encourage monopolies.
- Do CON provisions make sense as a matter of policy or law?

CON

- Be prepared to challenge the idea of the statute. Free market fans should hate CON.
- Many state statutes have exceptions. Determine whether you can do things in a physician office, with a hospital, or in some other way avoid a hearing.
- Note capital expenditure reporting requirements.

CON

- Most laws apply to equipment. Ventures for service lines may not require approval.
- Ventures that use existing equipment may not require approval.
- CON is more political than most health care regulation.

State Laws

- State antikickback laws -- may be broader than the federal law.
- Fee splitting -- may prohibit a physician from sharing revenues with nonphysicians, and/or physicians outside of the group except on the basis of work performed, but may not apply.
- Many states require disclosure. Some specify how.

Medicare Framework

- Most ancillaries are either diagnostic or therapeutic. The difference matters.
- For Medicare, many therapeutic services must be “incident to” a physician.
- Diagnostic tests are not “incident to.” SSA1861(s).
- Implications for supervision, credit in the comp. formula.

It's Different In (Or Out Of!!!) the Hospital

- Under 42 C.F.R. § 410.27(a)(1)(iii) hospital outpatient therapeutic service must be:
 - *“In the hospital or CAH or in a department of the hospital or CAH, as defined in [§ 413.65 of this subchapter](#), except for mental health services furnished to beneficiaries in their homes through the use of communication technology;”*
- While services can be “under arrangements,” the location restriction appears as an “and.”
- Contrast this with 42 C.F.R. § 410.27 which had no geographic language for DIAGNOSTIC services.
- One could think that means therapeutic services must be in the hospital. Hold that thought...

Hospital Supervision Under Medicare Part B:

Therapeutic:

- *Under the general supervision (or other level of supervision as specified by CMS for the particular service) of a physician or a nonphysician practitioner as specified in paragraph (g) of this section, subject to the following requirements: and*
- *In accordance with applicable State law.*

42 CFR § 410.27(a)(1)(iv,v)

Diagnostic:

- *Furnished by or under arrangements made by the participating hospital only when the diagnostic services are furnished under one of the three levels of supervision (as defined in [paragraphs \(e\)\(1\)](#) through [\(3\)](#) of this section) specified by CMS for the particular service by a physician or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nonphysician practitioner (physician assistant, nurse practitioner, clinical nurse specialist, certified nurse-midwife or certified registered nurse anesthetist).*

42 CFR § 410.28(e)

Can Hospitals Do Offsite Therapy? CMS Sure Thinks So!

- See Medicare Benefit Policy Manual Chapter 15 Section 220:

When therapy services may be furnished appropriately in a community pool by a clinician in a physical therapist or occupational therapist private practice, physician office, outpatient hospital, or outpatient SNF, the practice/office or provider shall rent or lease the pool, or a specific portion of the pool. The use of that part of the pool during specified times shall be restricted to the patients of that practice or provider. The written agreement to rent or lease the pool shall be available for review on request. When part of the pool is rented or leased, the agreement shall describe the part of the pool that is used exclusively by the patients of that practice/office or provider and the times that exclusive use applies. Other providers, including rehabilitation agencies (previously referred to as OPTs and ORFs) and CORFs, are subject to the requirements outlined in the respective State Operations Manual regarding rented or leased community pools.

Quirks Ordering/Supervising Tests

- Medicare: Only a professional who is treating the patient may order. “Professional” includes CNS, clinical psychologists, clinical social workers, nurse-midwives, NP and PAs if in scope of license
- Medicare now permits NPPs to supervise tests. Must bill under the SUPERVISING, not ordering, professional.

Medicare Supervision

- All diagnostic tests require some level of supervision. The fee schedule lists which test require general, direct and personal supervision.
- Many therapeutic services must be “incident to”, but NOT ALL! Incident to requires “direct supervision.”

What Does it Mean to Provide “General” Supervision?

- “General supervision” means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and **the maintenance of the necessary equipment and supplies** are the continuing responsibility of the physician.

42 CFR 410.32

What Does it Mean to Provide “General” Supervision?

- This language doesn't comport with reality.
- Practically, who would the tech would ask if the tech had questions about a particular scan?
- It is essential that the supervision arrangements be clear.

Direct Supervision

- Some tests, particularly imaging involving contrast media, requires direct supervision.
- Direct supervision requires being “present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure.”

42 CFR 410.32

What Does in the “Office Suite” Mean?

- It isn't clearly defined. The physician does NOT need to be in the same room. Being in the same suite number is helpful, but being on a different floor in the same building is arguably fine. If the physician could reach the patient in 30 seconds or less, you have a strong argument. MACs have discretion on the policy, however.

Proposed Rule 63 FR 1659

Jan. 9, 1998

- We are not proposing that there must be any particular configuration of rooms for an office to qualify as one office “suite.” However, direct supervision means that a physician must be in the office suite and immediately available to provide assistance and direction. **Thus, a group of contiguous rooms should in most cases satisfy this requirement.** We have been asked whether it would be possible for a physician to directly supervise a service furnished on a different floor.

Proposed Rule 63 FR 1659

Jan. 9, 1998

- We think the answer would depend upon individual circumstances that demonstrate that the physician is close at hand. The question of physician proximity for physician referral purposes, as well as for incident to purposes, **is a decision that only the local carrier could make based on the layout of each group of offices.** For example, a carrier might decide that in certain circumstances it is appropriate for one room of an office suite to be located on a different floor, such as when a physician practices on two floors of a townhouse.

Personal Supervision

- *Personal supervision* means a physician must be in attendance in the room during the performance of the procedure.

IDTF Supervision

- Tests in an IDTF require an additional level of supervision.
- Physician can only supervise 3 or fewer sites.
- Supervisor must “evidence proficiency” in the performance and interpretation of tests.
- Only the supervisor of record can do the supervision.

Crud, we don't have a written order. Are we toast?

Program Integrity Manual, CMS Pub 100-08 §3.3.2.4, Signature Requirements

- *If the signature is missing from an order, MACs and CERT shall disregard the order during the review of the claim (e.g., the reviewer will proceed as if the order was not received).*
- *If the signature is missing from any other medical documentation (other than an order), MACs and CERT shall accept a signature attestation from the author of the medical record entry.*

Crud, we don't have a written order. Are we toast?

- Not so fast!!
- Depends on several things, including the type of entity, the service in question etc.
- Whoever wrote that failed to read the Halloween 1997 Federal Register issue.

IDTFs Are Different

- “Some commenters have requested the **rationale for requiring specific written orders for tests performed by IDTFs while not imposing the same requirement on testing in physician offices.** The rationale for requiring testing by IDTFs to be ordered in writing by the treating physician is based in our (and, more specifically, HCFA’s contractors’) experience with IPLs. There have been instances in which IPLs have offered ‘free’ screening to Medicare beneficiaries in shopping malls and senior citizen centers.

62 Fed. Reg. 59048, 59072

The Fun Of Going Through Manuals

220.1.1 - Care of a Physician/Nonphysician Practitioner (NPP) (Rev. 179, Issued: 01-14-14, Effective: 01-07-14, Implementation: 01-07-14)

Although there is no Medicare requirement for an order, when documented in the medical record, an order provides evidence that the patient both needs therapy services and is under the care of a physician. The certification requirements are met when the physician certifies the plan of care. If the signed order includes a plan of care (see essential requirements of plan in §220.1.2), no further certification of the plan is required. Payment is dependent on the certification of the plan of care rather than the order, but the use of an order is prudent to determine that a physician is involved in care and available to certify the plan.

(The CORF services benefit does not recognize an NPP for orders and certification.)

Medicare Benefit Policy Manual Chapter
15 – C section 220

How Can Physicians Divide Ancillary \$?

- Physicians often like credit for “their referrals.”
- Potential issues:
 - *Stark (different for hospital and clinic. Hospitals may be more limited in ability to compensate physicians for ancillaries, depending on their structure.)*
 - *State law*
 - *Collegiality*
 - *Tax exemption if applicable.*

Stark

- The “group practice” exception has many factors, including prohibition of compensation based on volume/value of referrals for Designated Health Services (“DHS”).
- Personally performed services are not “referrals.”
- Now applies to all DHS, not just Medicare

“Designated Health Services”

- Clinical laboratory.
- Physical therapy.
- Occupational therapy.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrition.
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- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

Stark

- Under Stark if less than 5% of all revenue of a physician group, and 5% of each physician's comp is from DHS, you get a “pass.”
- Stark does NOT require equal division of compensation.

Stark Got Tougher 1/1/22

- Under the changes:
 - *All DHS revenue for the group/subgroup must be aggregated.*
 - *Handles “profit shares” and “productivity bonuses” differently.*
 - *Subgroups for profit shares must have at least five physicians, with the same allocation methodology for ALL DHS within the group.*
 - *This now applies to non-Medicare DHS revenue.*
- Stark really does NOT require equal division of DHS.

Productivity Bonuses In Group Practice*

- Can credit for services personally performed or incident to if not directly related to volume on the value of referrals (may directly relate to referrals for incident to).
- Deemed not to relate to the volume or value if:
 - *Personally performed by the physician,*
 - *Not DHS and not considered DHS if payable by Medicare, or*
 - *Revenues from DHS are less than 5% of total revenue and each physician's compensation.*

*You need to be sure you are a group practice!!!!

Options for DHS Under the Compensation Formula

- Productivity (RVUs, visits etc.).
- “Profit share.”
- Choose an allocation and stick with it.
- Equal division.
- Seniority.
- Any combo of above, provided it is used consistently for all DHS within the group/subgroup of 5.
- Anything else unrelated to creating the plan of care.
- Don’t forget state law!

Hospital Comp. Formula Options

- Fair market value for work done.
- Credit for non-DHS “incident to” ok. DHS “incident to” can be credited only if a group practice.
- If the physician performs an ancillary, compensation for that is permitted.

In-Office Ancillary Services

- Designed to cover services furnished in the clinic.
- Service must be delivered by Dr. or group member or under the supervision of a group practice physician.
- The exception will NOT protect:
 - *DME (other than crutches, walkers, manual wheelchairs, etc.). Note prosthetics and orthotics are NOT DME!!!!*
 - *some infusion pumps (external ambulatory pumps are ok, PEN pumps are not).*

Advanced Imaging Notice

- Give written notice to all MR/CT/PET pts. (E-mail is ok.)
- At time of referral (i.e. NOT registration).
- Must indicate patient can go elsewhere.
- Address/phone for at least 5 “suppliers” within 25 miles. (If fewer than five, list them. If none, no notice necessary.)
- Can say more; may wish to warn about insurance coverage.

DME

- Physicians can't own DME provided to Medicare or Medicaid patients in an urban area (MSA).
- Things commonly called “DME” are really orthotics and prosthetics. Physicians can own orthotics/prosthetics if they meet the in-office ancillary exception.
- Beware of “supply closet” ventures.
- Beware of revalidation surveys!!!

Can We Share Ancillaries?

- Often yes, but the rules are truly bizarre.
 - *If you have an ASC, the ASC space must be used exclusively by the ASC, during the ASC’s hours of operation. You can’t share its scanner.*
 - *A clinic can’t share space with an IDTF. (A hospital can. Go figure.)*
 - *The Medicare “anti-markup” rule applies to diagnostic tests (primarily imaging) unless you “supervise” the test, or meet a same building test.*
- If you can do it, it’s profitable.

Alone Or With Others?

- Generally, anything you do alone is less risky than a joint venture. (Of course, “less risky” does not necessarily mean it is safe.)
- Generally, in a JV, the more participants the higher the risk.

Urban vs. Rural

- In a rural area (which means outside of a MSA), if 75% of the patients live in a rural area, joint ownership is possible. This makes joint ventures much easier in rural areas.
- In urban areas, ventures in the same building are the best bet.
- JV means different things to different people. Joint ownership doesn't always work, but there are other options.

Outsourcing Peril?

- April 2003 OIG bulletin warns of scrutiny of joint ventures.
 - *Focus is on situations where one organization leases turnkey type services from another organization with an intent to bill for them.*
 - *The government argues that any profit is improper.*
 - *We don't buy it, but you need to know it's there.*

Outsourcing Peril?

- Is it too good to be true?
- Consider two factors:
 - *Would parties without a referral relationship enter the deal?*
 - *Is the total return to you commensurate with your risk?*

Sharing Therapeutic Services

- Unique to rural: Create an entity to provide therapy or other treatment.
 - *Multiple physicians/clinics/hospitals own the entity. Entity bills, revenue split based on ownership.*
 - *Pro: Easy. Very low risk.*
 - *Con: Almost none. Revenue can only be divided on ownership. Need to obtain new provider contracts.*

Sharing Diagnostic or Therapeutic Services

- Not unique to rural areas: Physicians can share with hospital if equip placed in clinic building (at least for diagnostic. Therapeutic is fuzzier), or if no Medicare/caid is billed.
- In urban areas, LLC can't be "providing" the service.
- Costs allocated among the participants, though not "per click" for equipment or space. (Per click is OK for staff.)
- Each entity bills.
- Pros: use existing contracts, relatively low risk, profit linked to use.
- Cons: Administrative challenges? Physicians can't get hospital reimbursement.

Two Clinics Sharing

- If not a DHS, primarily a state law issue.
- If DHS, likely need to be in the same building, and meet additional tests.

Sharing Space and Equipment: What Is “Exclusive Use?”

- Stark’s lease exception requires that the tenant/person leasing equipment have exclusive use of the space/equipment.
- CMS says that “**in effect**, [the rules] require that space and equipment leases be for established blocks of time.”

Sharing Space and Equipment

- CMS says “a physician sharing a DHS facility in the same building must control the facility and the staffing (for example, the supervision of the services) at the time the designated health service is furnished to the patient. To satisfy the in-office ancillary services exception, an arrangement must meet all of the requirements of [the rule] not merely on paper, but in operation. As a practical matter, this likely necessitates a block lease arrangement for the space and equipment used to provide the designated health services....We note that common per-use arrangements are unlikely to satisfy the supervision requirements of the in-office ancillary exception and may implicate the anti-kickback statute.”

Sharing Space and Equipment: What Is Supervision?

- The diagnostic test rules (and therefore Stark) require that a physician “supervise” a diagnostic test to bill for it.
- The question: Can two consecutive tests be supervised by different entities??

Sharing Diagnostic Services (Imaging)

- Unique to Rural: Establish an Independent Diagnostic Testing Facility.
 - *Multiple physicians/clinics/hospitals own the IDTF. IDTF bills, revenue split based on ownership.*
 - *Pro: Easy. Very low risk. If hospital reimbursement is higher, can use “under arrangements.” (Note: ONLY BECAUSE ITS RURAL!)*
 - *Con: IDTF rules are difficult. Revenue can only be divided on ownership. Need to obtain new provider contracts.*

IDTF's May Not Share Space/Equipment

- A fixed IDTF may not:
 - *Share a practice location.*
 - *Lease or sublease its operations.*
 - *Share diagnostic testing equipment “used in the initial diagnostic test”.*

with another Medicare-enrolled individual or organization
EXCEPT a hospital.

Well, Maybe...

- 72 FR 66222, 66291 says “This does not preclude an IDTF from leasing any part of its practice location or equipment used in conducting the initial diagnostic procedure to another Medicare-enrolled individual or group to conduct diagnostic testing activities.”

Stark Trap: Who Is Your Entity?

- Definition of “entity:”

- The entity billing for the service AND
 - The entity providing the service.
- *The entity definition makes it difficult to provide “Under arrangements” services if the physician who orders the service is providing it “under arrangements.”*
- *If a physician is leasing equipment to a hospital, and sending patients to the equipment, beware.*

Can We Do a Per Click Lease?

- Stark's limitation on "per use" leases has changed over time.
- If a physician is referring patients to a service, the physician may not be compensated on a "per click/per use" or percentage basis.
 - *Example: Physician owns scanner, leases it to hospital for \$500/scan. That is impermissible.*

Can We Do a Per Click Lease?

- The same lease is permissible if the payment is a flat fee per month.
- Per click/per use leases are still permissible if the owner does not refer to the lessee.
 - *Example: Clinic or hospital leases scanner from a mobile imaging company where the mobile imaging company is not owned by local physicians.*

Can Two Clinics in One Building Share a Scanner?

- If you don't do Medicare, yes. (Keep an eye on state law.)

Can Two Clinics in One Building Share a Scanner for Medicare?

- Probably. If both clinics operate 35 hours a week, then yes if:
 - *The techs are properly supervised.*
 - *Each group employs the tech (either separate techs or a shared employee.) Other models might also work, but this is the safest.*
- CMS believes block leases are necessary. I would argue a per-click lease may work if the parties don't send DHS back and forth.
- You must supervise the tests!

Can Two Clinics in One Building Share a Scanner for Medicare?

- If either clinic operates less than 35 hours a week, then things are much more complicated.
- It may work if the only Medicare patients scanned by the part-time clinic are patients who see a physician at that office.

Can Two Clinics Share a Scanner in a Building Across the Street?

- Not if they want to be able to bill Medicare for the scans.

Can a Group Lease Time on Another Group's Scanner?

- Yes. However, to bill Medicare, the conditions for two clinics in one building sharing a scanner must be met.

Can You Accept Outside Referrals?

- YES. A few states have limits, but we're not aware of any that prohibit it.
- The “no” was based on language in Medicare Manuals saying that if a substantial portion of an entities revenue was from outside referrals, it must be an IDTF.
- That language has been deleted.
- Any comp. must meet a Stark exception.



Anti-markup of Diagnostic Test

- Regulation at 42 CFR 414.50 limit the mark-up of diagnostic tests.
- Applies unless the performing supplier “shares a practice” with an ordering supplier or the test is in the office of billing physician.
- “Sharing a practice” means 75% of their services are billed by the supplier. supplier.

Has CMS Overstepped its Authority?

CMS Claims Authority

- “Further, we see no reason to distinguish between the TC and the PC of the diagnostic tests for purposes of the anti-markup provisions. Although the Congress did not establish an anti-markup provision in Section 1842(n)(1) of the Act or elsewhere for the PC of diagnostic tests, the omission may have been inadvertent. That is, it is not immediately clear why the Congress, if it wished to prevent overutilization of diagnostic testing, would not have desired an anti-markup on the PC, because without such provision, the incentive to order unnecessary tests (in profit on the PC) remains. We believe that, in order to fully effectuate Congress’ intent to prevent or limit the ordering of unnecessary diagnostic tests, it is necessary to impose an anti-markup provision on the PC of diagnostic tests.”

The Anti-markup Statute 1842(n)

- If a physician's bill or a request for payment for services billed by a physician includes a charge for a **diagnostic test described in section 1861(s)(3)** (other than a clinical diagnostic laboratory test) for which the bill or request for payment does not indicate that the **billing physician** personally **performed** or **supervised** the performance of the test **or that another physician with whom the physician who shares a practice** personally **performed** or **supervised** the performance of the test, the amount payable with respect to the test shall be determined as follows:

Interpretations Are NOT Diagnostic Tests under 1861(s)(3)

Medical and Other Health Services

- (s) The term “medical and other health services” means any of the following items or services:
 - (1) *physicians' services;*
 - (2)(A) *services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service...;*

Interpretations Are NOT Diagnostic Tests under 1861(s)(3)

- (3) **diagnostic X-ray tests** (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary and including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act[407]), diagnostic laboratory tests, and other diagnostic tests;

The Anti-markup Statute 1842(n)

- If a physician's bill or a request for payment for services billed by a physician includes a charge for a **diagnostic test described in section 1861(s)(3)** (other than a clinical diagnostic laboratory test) for which the bill or request for payment does not indicate that the **billing physician** personally **performed** or **supervised** the performance of the test **or** that **another physician with whom the physician who shares a practice** personally **performed** or **supervised** the performance of the test, the amount payable with respect to the test shall be determined as follows:

Billing for Reads

- Medicare policy permits you to bill for reads done offsite if:
 - *Contract permits Medicare to collect overpayment from either party.*
 - *The person doing the service has unrestricted access to claims you submit.*
- Medicaid still varies by state.
- Note Medicare assets anti-markup applies to offsite reads unless reader “shares a practice.”

The Stark Trap

- Many assert Stark prohibits off-site reads.
- The theory is based on the definition of a “physician in the group practice.”
- Question: can an IK offsite be considered “a physician in the group practice?”

The Stark Trap

- “An independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) for the group practice under a contractual arrangement with the group practice to **provide services to the group practice’s patients in the group practice’s facilities.**”

The “72 Hour Rule”

- Actually a “3 Calendar day rule.”
- When a diagnostic test is performed by an entity “wholly owned or operated” by a hospital 3 days before an admission, it bundles with DRG.
- A logistical headache.

Surgery/ASC JV

- Reimbursement better as hospital based or ASC?
- To get hospital reimbursement, must be on campus.
 - *Can create a “department of the hospital.”*
- ASC can be placed anywhere.
 - *ASC safe harbor is narrow, but risk is low.*

ASC Joint Ventures

- Stark does not apply, but the antikickback law does. The safe harbors are very narrow, and almost never help.
- The safe harbor has weird contradictions: investment can't be based on referrals, yet investors must perform services at the facility.
- Avoid “cherry picking” investors; be wary of how the venture is marketed.

ASC Joint Ventures

- Stark:

- *ASCs are not a Designated Health Service.*
- *Therefore, if no comp flows between the hospital and the clinic, no Stark issue created.*
- *If the hospital is subsidizing the ASC, then you could still have potential Stark issues because any compensation between the hospital and the clinic triggers Stark.*

ASC JV Analysis

- The Medicare Antikickback Statute is the biggest risk for most ASCs.
- The question: Is anyone paying for referrals:
 - *Is the hospital paying physicians to send inpatients their way?*
 - *Beware of paying internists/FPs to get the surgical referrals?*

ASC Safe Harbor

- There is a hospital/physician safe harbor:
 - *Investment terms can't be related to referrals.*
 - *Can't borrow/get guarantee from hospital to finance the venture.*
 - *Payout proportional to investment.*
 - *No discrimination against federal beneficiaries.*
 - *No use of hospital space/equipment w/o safe harbor-compliant lease.*

ASC Safe Harbor

- Safe harbor con't:
 - *All ancillaries to gov. pts. must be related to ASC services and services must be billed by ASC.*
 - *Hospital can't include costs on cost report.*
 - *Hospital may not be in a position to make or influence referrals directly or indirectly to any investor.*

Multispecialty ASCs: 1/3 Test

- 1/3 of each Dr. investor's medical practice income from all sources from the physician's performance of procedures
- 1/3 of each Dr. investor's procedures performed at the investment entity.

Getting Practical

- It can be done.
- You won't meet a safe harbor.
- In rural areas, you may be able to try a different approach, joint venturing the outpatient hospital services. This may result in better reimbursement.

Getting Practical

- If a tax exempt is involved, you must worry about tax exemption in addition to other rules.
- The law as leverage:
 - *The Redlands case.*
 - *CON often creates most leverage.*

Getting Practical

- Don't let individual non-surgeon physicians invest (except anesthesia). An entire clinic investing is less troubling.
- Don't pay a subsidy to physicians.
- Antikickback issues are very fact specific.
 - *The poorly worded memo/e-mail can bite.*
 - *Geography/participants can drive the analysis.*
- Good antikickback analysis is seldom expensive.

Getting Practical

- Never forget about state laws.
 - *Fee splitting.*
 - *CON.*
 - *Antikickback laws.*
 - *Disclosure.*

Can I Have Multiple ASCs?

- Yes, but...
- Creates havoc with the 1/3 test.
- If they have different ownership, consider price fixing issues.

Interesting Option for Physicians

- Divisional merger allows sharing of ancillaries (and some other benefits.)
- How: You become one corporation.
 - *(Depending on payor contracts, may use an existing entity or a new one).*
 - *Divisions can be of any size.*
 - *Parent Board approves divisional decisions.*
 - *Divisions typically set comp, hire, etc. for the division. In short, operationally, little changes, though you must combine retirement plans.*

Whose Name Goes on Laboratory Bills?

- Labs are diagnostic tests.
- Diagnostic tests must be billed under the supervising physician.
- Choose an appropriate physician and recognize the consequences.

Who Can Bill Lab Services?

- Generally the performing lab, but...
- §1833 (h)(5) allows a referring lab to bill if:
 - *Referring lab is in/part of a rural hospital,*
 - *Referring lab is wholly owned by, wholly owned or is owned by someone who also owns the performing lab, or*
 - *No more than 30% of its lab tests are sent out.*

Can I Have Different Fee Schedules for Lab Services?

- Medicare U&C issues.
- Compare advisory opinion 99-13 and 98-8.
- 99-13 involves pathology concluding that discounts may implicate the antikickback statute.
- 98-8 involves DME and permits discounts to reflect lower costs.
- Is profit margin the proper analysis?

Therapy

- PT and OT are DHSs; compensation can't take into account the volume or value of referrals. SLP is not.
- Understand how you bill the services. Services can be billed “incident to” a physician, which requires a physician in the office and involved in the care, or can be billed under the therapist's number. No reimbursement impact.

Therapy

- You have 2 physical therapy locations, one in your main clinic, one free-standing across town.
 - *Can you see Medicare patients at each clinic?*
 - *Can you see NEW Medicare patients?*
 - *Can you credit the physicians for ordering the PT?*

Answers

- PTs can get an independent billing number, so you can provide services at either location.
- Can only see new Medicare if therapists bill independently.
- Stark permits DHS either in the “same building” as a clinic (with some complicated catches) or in an offsite location that you control 24/7.

Answers

- If state law permits, physicians can receive credit for ordering PT/OT for non-Medicare/caid.
- Physicians can get credit for ordering PT/OT for Medicare/caid if the services are “incident to” that physician’s work.

Where Can We Do This?

- Factors to consider:
 - *Supervision*
 - *Is it hospital based?*
 - On campus (250 yards)
 - Provider based (35 miles)
 - *Stark*
 - Contiguous states
 - Centralized location OR same building test.

“Same Building”

- The equipment is located in the physician’s principal place of practice.

This test is satisfied when the services are provided in a building in which the referring physician or group practice:

- A) has an office open at least 35 hours a week; AND
- B) sees patients at least 30 hours a week.

“Same Building”

- The referring physician practices in the building where the services are provided is located at least 1 day a week and the building is the principal place where patients referred see the referring physician.

“Same Building”

- The three elements to this test are:
 - *The physician or group practice has an office in the building that is normally open at least 8 hours a week.*
 - *The referring physician furnishes physician services in that office at least 6 hours a week. Services provided by other group members are not included in this 6 hours calculation.*
 - *The building is the principal place where the referred patient sees the physician.*

“Same Building”

- The services are provided in a building in which the physician or group sees patients at least one day a week and the service is ordered during a patient visit or a physician is present during the service.

“Same Building”

- The physician or group practice has an office in the building that is open at least 8 hours a week.
- The physician or group members regularly practice in that office at least 6 hours a week.
- Either
 - *the physician orders the service during a patient visit; or*
 - *the referring physician or a group practice member is present when the service is furnished.*

Pharmacy

- Remember it is a DHS.
- If you include controlled substances, be very aware of the DEA rules, including diversion reporting.
- There are a bunch of potential regulations/state law. Compounding pharmacies are highly regulated.



Presenter



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Thank you!

Fredrikson

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