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The "Stark" Truth: The Impact of Recent and Proposed Changes on Physician Practices

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Today's Presentation

- Quick history of the last 18 months of physician self-referral jurisprudence
  - What was proposed, what comments were sought, and what are the final rules?
- Structuring (and potentially unwinding) deals
  - The impact of the final "stand in the shoes" rules
  - New Stark rules:
    - "Entity" redefinition
    - Unit of service (per-click) lease arrangements and percentage-based compensation formulae
  - Independent diagnostic testing facility ("IDTF") performance standard no. 15, and proposed IDTF enrollment requirements for "physician and nonphysician practitioner organizations"
- Under arrangement and other leasing models
  - What w*on't* work, what s*hould* work, and what m*ay* work

Today’s Presentation (cont'd)

- Anti-markup rules
  - Where they stand
  - Interaction with the Stark Law in-office ancillary services exception
  - Interaction with the IDTF enrollment requirements
- Compliance
  - Alternative method for compliance with signature requirements
  - Period of disallowance following noncompliance
  - Burden of proof
- Recruitment after Phase III

Today's Presentation (cont'd)

- Update on issues still on the CMS table and what we can expect through 2008 and beyond
  - Further revisions to anti-markup provisions
  - New exception for incentive payment and shared savings programs
  - Disclosure of financial relationships report
  - Possible changes to the in-office ancillary services exception

A Quick History

What Was Proposed, What Comments Were Sought, and What Are the Final Rules?

All these Rules that We've Seen

- Phase III
  - Final rule
  - Delay rule
  - Correction notice
- CY 2008 PFS
  - Proposed rule
  - Final rule
  - January 3, 2008 final rule
- FY 2009 IPPS
  - Proposed rule
  - Final rule
  - Correction notice
- CY 2009 PFS
  - Proposed rule
  - Final rule (expected November 1, 2008)

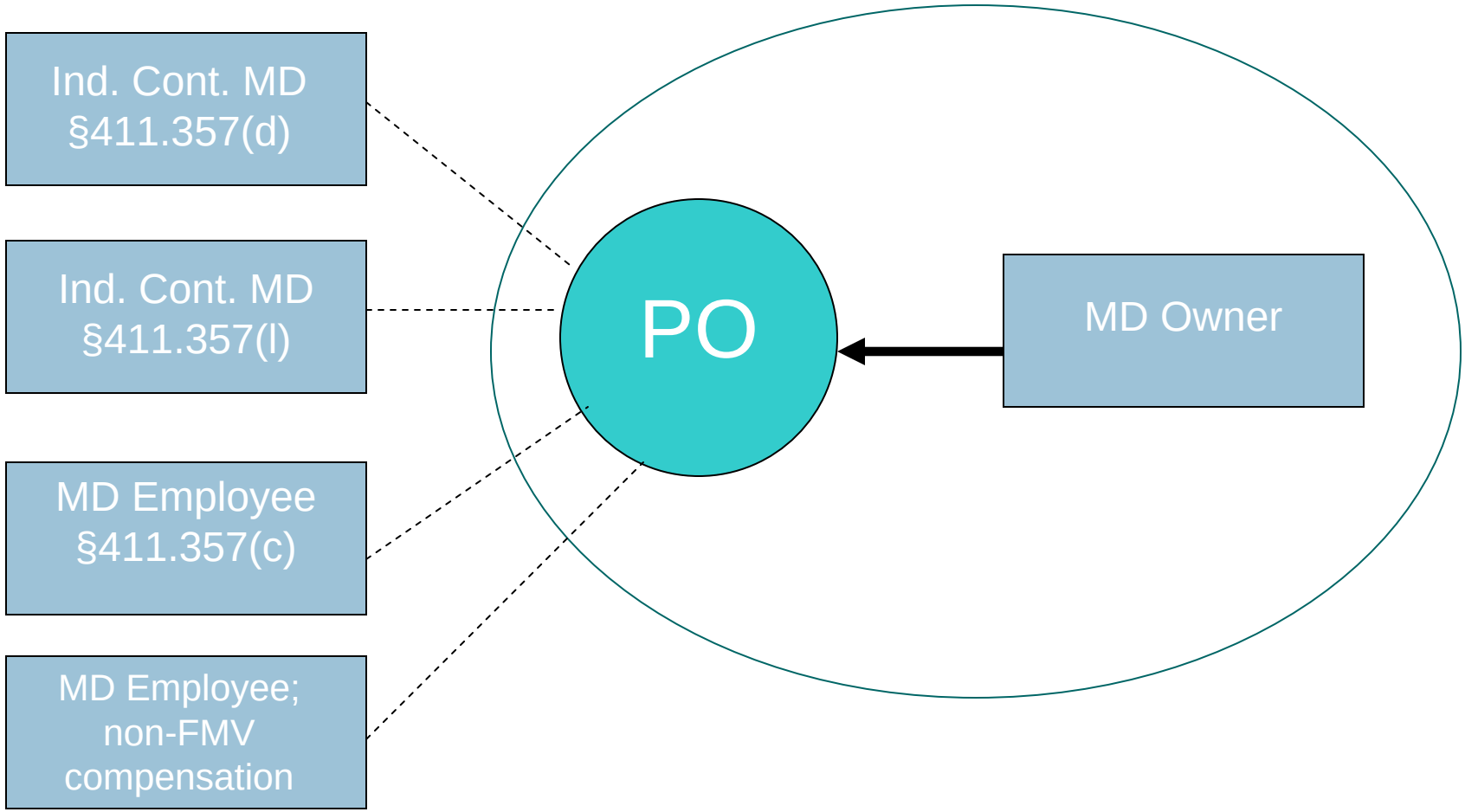
FY 2009 IPPS Final Rule

- Physician “stand in the shoes” provisions
- Period of Disallowance
- Alternative Method for Compliance with Signature Requirements
- Percentage-based Compensation Formulae
- Unit of Service (“Per-click”) Payments in Lease Arrangements
- Services Provided “Under Arrangements” (Services Performed by an Entity Other Than the Entity That Submits the Claim)
- Exception for Obstetrical Malpractice Insurance Subsidies
- Ownership or Investment Interest in Retirement Plans
- Burden of Proof

FY 2009 IPPS Final Rule

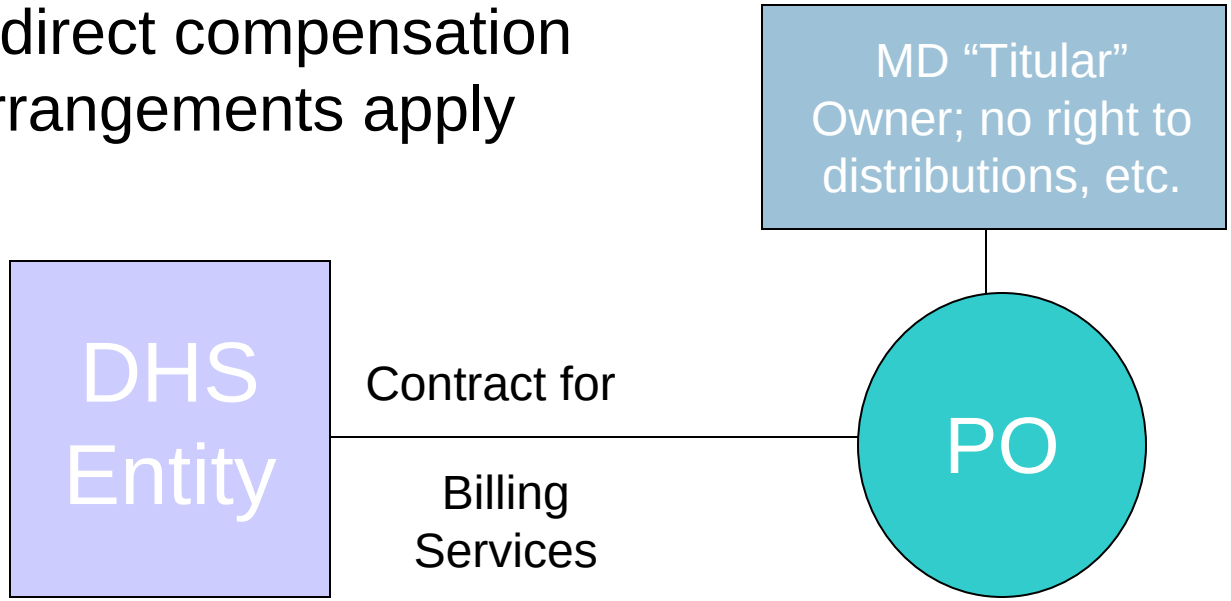
- Physician “stand in the shoes” (SITS) provisions
  - Effective date: October 1, 2008
  - Policy: A physician is deemed to stand in the shoes of his or her physician organization if the physician has an ownership or investment interest in the physician organization.
  - Exception: A physician whose ownership or investment interest is titular only does not stand in the shoes of the physician organization.
  - Rationale: Simplicity

Final Rule: Physician SITS Only Owners SITS



Final Rule: Physician SITS Exception for Titular Owners

** Titular owner does not SITS; rules regarding indirect compensation arrangements apply



FY 2009 IPPS Final Rule

- Physician “stand in the shoes” provisions
  - “Opt in” SITS: A non-owner or titular owner physician is permitted to stand in the shoes of his or her physician organization
    - Addresses concerns of DHS entities that may not be aware or cannot ascertain the status of all physicians in a physician organization with which the DHS has a compensation arrangement
  - SITS provisions do not apply to an arrangement that satisfies the requirements of the exception in §411.355 for academic medical centers.
  - New rule does not require restructuring of agreements structured to comply with the Phase III SITS rules.

FY 2009 IPPS Final Rule

- Revised Definitions
  - *Physician* means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Act. A physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.
  - *Physician organization* means a physician, a physician practice, or a group practice that complies with the requirements of §411.352.
    - Removed the following language describing a “physician”: “(including a professional corporation of which the physician is the sole owner)”

FY 2009 IPPS Final Rule

- Entity “stand in the shoes” provisions
  - Not finalized
  - No conventions for applying physician and entity “stand in the shoes” provisions necessary (and, therefore, none finalized)
  - Warning: interposing entities in a chain of financial relationships between a DHS entity and a referring physician may run afoul of fraud and abuse laws

FY 2009 IPPS Final Rule

- Period of disallowance
- Alternative method for compliance with signature requirements
- Burden of proof
  - More on each of these subjects later in "Compliance" discussion

FY 2009 IPPS Final Rule

- Percentage-based Compensation Formulae
  - Effective Date: October 1, 2009
  - Amends 4 compensation exceptions
    - Office space lease arrangements
    - Equipment lease arrangements
    - Fair market value compensation arrangements
    - Indirect compensation arrangements
  - Targeted approach; addresses primary CMS concerns
  - Proposal in CY 2008 PFS proposed rule would have limited percentage-based compensation formulae to personally performed physician services ONLY

FY 2009 IPPS Final Rule

- Percentage-based compensation formulae (cont'd)
  - Rental charges for the rental of office space or equipment may not be determined using a formula based on—
    - A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space; or
    - A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed on or business generated through the use of the equipment.

FY 2009 IPPS Final Rule

- Unit of Service ("Per-click") Payments in Lease Arrangements
  - Effective Date: October 1, 2009
  - Amends 4 compensation exceptions
    - Office space lease arrangements
    - Equipment lease arrangements
    - Fair market value compensation arrangements
    - Indirect compensation arrangements
  - Includes both physician as lessor and DHS entity as lessor
    - Proposal in CY 2008 PFS proposed rule included only physician as lessor, but sought comments regarding the inclusion of DHS entity as lessor

FY 2009 IPPS Final Rule

- Unit of Service ("Per-click") Payments in Lease Arrangements (cont'd)
  - Rental charges for the rental of office space or equipment may not be determined using a formula based on—
    - Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties.

FY 2009 IPPS Final Rule

- Services Provided "Under Arrangements" (Services Performed by an Entity Other Than the Entity That Submits the Claim)
  - Effective Date: October 1, 2009
  - Revised the definition of "entity" at §411.351
    - Modified from proposal in CY 2008 PFS proposed rule
    - Prior to October 1, 2009, a person or entity is considered to be furnishing DHS if it is the person/entity to which CMS makes payment for the DHS
    - Both parties to an arrangement may be considered an "entity" if one party performs the DHS and the other party bills for the DHS

FY 2009 IPPS Final Rule

- Services Provided "Under Arrangements" (Services Performed by an Entity Other Than the Entity That Submits the Claim) (cont'd)
  - *Entity* means—
    - A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it—
      - Is the person or entity that has *performed* services that are billed as DHS to which CMS makes payment for the DHS, directly or upon assignment on the patient's behalf; or
      - Is the person or entity that has *presented a claim* to Medicare for the DHS . . .

FY 2009 IPPS Final Rule

- Exception for Obstetrical Malpractice Insurance Subsidies
  - Effective Date: October 1, 2008
  - Retains existing exception that incorporates the safe harbor to the federal anti-kickback statute (at §1001.952(o))
    - Applies to subsidies provided by any entity
  - Parties may choose, instead, to satisfy the prescribed criteria of §411.357(r)(2)
    - All commenters agreed with CMS concerns regarding narrow scope of previous exception
    - Applies to subsidies provided by hospitals, FQHCs, and rural health clinics
  - Elements set forth in handout

FY 2009 IPPS Final Rule

- Ownership or Investment Interest in Retirement Plans
  - Effective Date: October 1, 2008
  - Clarifies that the exception from the definition of “ownership” includes only an interest in an entity that arises from a retirement plan offered by that entity to the physician (or a member of his or her immediate family) through the physician’s (or family member’s) employment with that entity

Quick History Lesson

- CY 2009 PFS Rule
  - Proposed rule, 73 FR 38502 (July 7, 2008)
  - Final rule, expected November 1, 2008

CY 2009 PFS Proposed Rule

- One Stark proposal and one anti-markup proposal
  - Proposed new exception for “incentive payment and shared savings programs”
  - Proposed revisions to the anti-markup rules
- Discussed in detail below

Other Sources for Guidance

- Advisory Opinions
  - Two opinions issued so far in 2008
    - CMS-AO-2008-01 (regarding whether an arrangement under which a hospital licenses a custom software interface for use by medical staff physicians in their private offices to order or communicate the results of tests and procedures furnished by the hospital would constitute a compensation arrangement under section 1877 of the Act)
    - CMS-AO-2008-02 (regarding whether a physician's investment in a diagnostic center meets the requirements of the rural provider exception)
- FAQs
  - Issued following Phase III
  - More to come with respect to FY 2009 IPPS final rule and CY 2009 PFS final rule?

Structuring Deals (and Potentially Unwinding Them)

Final "Stand in the Shoes" Rule: More Compensation Arrangements Are Now Direct

- Under the final "stand in the shoes" provision, a physician is now generally treated as "standing in the shoes" of his or her group practice (and any other "physician organization"), for purposes of applying the rules that describe direct and indirect compensation arrangements, if the physician has an ownership or investment interest in the group practice or other physician organization. 42 C.F.R. 411.354(c)
  - A "physician organization" is defined to mean "a physician, a physician practice, or a group practice that complies with the requirements of [42 C.F.R.] § 411.352." 42 C.F.R. § 411.351
  - A physician is allowed to opt into standing in the shoes of his or her physician organization
  - The rule does not apply to a physician whose ownership or investment is titular only, *i.e.*, it excludes the ability or right to receive the financial benefits of ownership or investment
- The result is to make many indirect compensation arrangements direct, which then requires them to fit within different exceptions
  - For example, a lease that would be a "direct compensation arrangement" between the lessor and the lessee (after application of the stand in the shoes rule) would need to fit within the exceptions for "rental of office space," "rental of equipment" or "fair market value compensation"
    - Note: this exception may not be used for the lease of office space
- If there is still an "indirect compensation arrangement" then it must fit within the exception for "indirect compensation arrangements"
- Note that for now CMS has declined to finalize a DHS entity "stand in the shoes" rule

“Entity” Redefinition

- Remember what the core Stark Law prohibition says, *i.e.*, a physician shall not make a referral to an “entity” for the furnishing of DHS, *etc.*
- In the FY 2009 IPPS final rule, CMS finalized it’s previous proposal to redefine the term “entity” under the Stark Law

“Entity” Redefinition (cont’d)

- CMS has changed the definition of a DHS “entity,” which currently is limited to the person or entity to which Medicare makes payment or which has the right to payment, to instead be the person or entity that has ***“performed services that are billed as DHS”*** as well as the person or entity that has presented a claim to Medicare for the DHS or to which the right to payment has been reassigned in accordance with §424.80(b)(1) (employer) or (b)(2) (payment under a contractual arrangement) of this chapter (other than a health care delivery system that is a health plan (as defined at 42 C.F.R. §1001.952(l)), and other than any managed care organization, provider-sponsored organization, or independent practice association with which a health plan contracts for services provided to plan enrollees)
- This change will become effective October 1, 2009

“Entity” Redefinition (cont'd)

- The critical issue will be whether the person or entity is “performing” the DHS
- CMS provided minimal guidance on the issue
  - “We decline to provide a specific definition of ‘perform,’ but rather [we] intend that it should have its common meaning”
  - “Physicians and other suppliers and providers generally know when they have performed a service and when they are entitled to bill for it”
- At the same time, however, CMS did state
  - “We do not consider an entity that leases or sells space or equipment used for the performance of the service, or furnishes supplies that are not separately billable but used in the performance of the medical service, or that provides management, billing services, or personnel to the entity performing the service, to perform DHS”

Effect of the "Entity" Redefinition

- If a lessor (such as an under arrangement venture) leases turn-key infrastructure that is used by another entity to provide DHS, then CMS would likely deem the lessor to be a DHS entity
  - Look for "all four legs of the table" needed to provide the DHS
    - Space
    - Equipment
    - Supplies
    - Personnel
- Consequently, any referral for such DHS by a physician who directly or indirectly holds an ownership or investment interest in the lessor would be a violation of the Stark Law
  - There likely would be no exception available for the referring physician's ownership interest in the lessor (although don't forget to check the availability of the "rural provider" exception, 42 C.F.R. § 411.356(c)(1))
  - Even if the lessee is a group practice that's in compliance with the in-office ancillary services exception, such exception only applies to the referring physician's ownership interest in the group practice, ***not*** his or her ownership interest in the lessor
  - And yes, CMS has acknowledged that there may be more than one "entity" involved in the furnishing of a DHS, so make sure to identify and analyze all of them

Effect of the “Entity” Redefinition (cont'd)

- A major, unanswered question is to what extent a lessor can “pull the legs off the table” so that the lessor is no longer at risk for being deemed to have performed the DHS.
  - For example, if an under arrangement venture only makes available space, equipment and supplies, but not the personnel, would the venture fall outside the new entity definition?

Percentage of Revenue and Per Unit of Service Leases Prohibited

- In the FY 2009 IPPS final rule, CMS finalized, with modifications, it's previous proposals to prohibit percentage of revenue and per unit of service payments under certain compensation arrangements
- The exceptions for "rental of office space" and "rental of equipment" now include prohibitions on payments using a formula based on
  - "A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated" in the office space or through the use of the equipment or
  - "Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties" 42 C.F.R. § 411.357(a)(5) and (b)(4)
  - Note: it does not matter whether the referring physician is a lessor or a lessee
- The exception for "fair market value compensation" contains the same limitation for any compensation under the arrangement which is for the rental of equipment. 42 C.F.R. § 411.357(l)
  - Note: this exception may not be used for the lease of office space
- The exception for "indirect compensation arrangements" contains the same limitation for any compensation under the arrangement which is for the rental of office space or equipment. 42 C.F.R. § 411.357(p)(1)
- This change will become effective October 1, 2009.

Time-Based Rental Arrangements

- CMS stated
  - On the one hand, “[w]e agree that ‘on demand’ [time-based] rental agreements are problematic” (73 FR 48719)
    - CMS seems to be referring to time-based arrangements under which payment for the leased space or equipment is “on demand” and the aggregate amount of time for which space or equipment is available is ***not*** set in advance.
  - On the other hand, “[w]e decline to accept, at this time, the commenter’s suggestion that we prohibit all time-based leasing arrangements.. . . We believe that time-based rental payments, such a block-time leases, depending on how they are structured, may meet the requirements of the space and equipment lease exceptions” (73 FR 48719-48720)

Time-Based Rental Arrangements (cont'd)

- A major, unanswered question is what type of time-based arrangements will pass muster with CMS
- Some points of guidance
  - CMS views “on demand” leases as “essentially a per-use or per-click type of arrangement, and considers them to be covered by our revisions in this final rule” (72 FR 48719)
  - Furthermore, CMS believes that “the same concerns we identified above with respect to certain per-click lease arrangements can exist with certain time-based leasing arrangements, particularly those in which the lessee is leasing the space or equipment ***in small blocks of time*** (for example, once a week for 4 hours), or ***for a very extended time*** (which may indicate the lessee is leasing space or equipment that it does not need or cannot use in order to compensate the lessor for referrals)” (emphasis added) (73 FR 48720)

New IDTF Performance Stds.

- On January 1, 2007, 14 new Medicare performance standards went into effect for IDTFs
- When CMS issued the CY 2008 PFS final rule, it created a new 15th performance standard and modified some of the other standards
  - With the exception of one piece of the 15th standard, the 15th standard and the modifications to the other standards went into effect on January 1, 2008

Performance Std. No. 15

- With the exception of hospital-based and mobile IDTFs, a fixed-base IDTF does not include the following
  - Sharing a practice location with another Medicare-enrolled individual or organization;
  - Leasing or subleasing its operation or its practice location to another Medicare-enrolled individual or organization; or
  - Sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization. 42 C.F.R. § 410.33(g)(15)
- With respect to the new prohibition on the sharing of space, CMS adopted a 1-year transition period (until January 1, 2009) for IDTFs that are currently enrolled and are sharing a practice location with another Medicare individual or organization

Performance Std. No. 15 (cont'd)

- In the preamble to the new rule, CMS provided virtually no guidance regarding what qualifies as a hospital-based IDTF
- Informally CMS has said it means an IDTF that operates within the four walls of a hospital

Performance Std. No. 15 (cont'd)

- Sharing of staff is not prohibited
- Sharing of “common areas” is also not prohibited as long as it is “non-clinical” space
  - Specific examples: hallways, parking and waiting rooms.
  - Unclear because not mentioned: registration desk/area, file rooms, back office areas, *etc.*
  - But no one can “co-locate” in the same practice location as the IDTF
- CMS has informally indicated that the prohibition on sharing equipment was intended to prevent IDTFs from leasing their equipment (as the lessor) TO other persons, but was not intended to prevent IDTFs from leasing equipment (as the lessee) FROM other persons

Effect of the Performance Stds.

- Read broadly, this performance standard would seem to prohibit any entity enrolled as an IDTF (other than a hospital-based or mobile IDTF) from leasing turn-key infrastructure or from leasing its space or equipment to another Medicare-enrolled individual or organization (such as a physician group or a hospital)

Proposed IDTF Enrollment Requirement for Physician Practices

- When CMS issued the CY 2009 PFS proposed rule, it proposed to require each “physician or nonphysician practitioner organization” that furnishes diagnostic testing services to enroll as an IDTF. 42 C.F.R. § 410.33(j) (proposed)
- For newly enrolling entities, the effective date would be January 1, 2009, otherwise, it would be September 30, 2009

“Physician or NPP Organization”

- CMS proposed to define a “physician or nonphysician practitioner organization” as “any physician or nonphysician practitioner entity that enrolls in the Medicare program as a sole proprietorship or organizational entity such as clinic or group practice.” 42 C.F.R. § 424.502 (proposed)

Effect of the IDTF Enrollment Proposal

- Every physician practice that furnishes diagnostic testing services would be required to enroll as an IDTF
  - CMS would no longer distinguish “diagnostic radiology group practices/clinics” (owned by hospitals and radiologists)
  - Radiology groups would be treated no differently than any other types of physician groups
- The net effect: under Medicare there would only be two types of enrollment categories for entities furnishing the TC of diagnostic imaging
  - IDTF
  - Provider-based, *i.e.*, hospital-based

Effect of the IDTF Enrollment Proposal (cont'd)

- Physician practices would be subject to the most significant of the IDTF performance standards. 42 C.F.R. § 410.33(j) (proposed)
- In particular, they would be subject to performance standard no. 15, except for that part of the standard that prohibits the sharing of a practice location with another Medicare-enrolled individual or organization
  - CMS recognized that it is common for physician practices to share space

Effect of the IDTF Enrollment Proposal (cont'd)

- Just like the effect that performance standard no. 15 already has had on IDTFs, if it's read broadly, then it would seem to prohibit a physician practice (that would be required under the proposal to be enrolled as an IDTF) from leasing turn-key infrastructure or from leasing its equipment to another Medicare-enrolled individual or organization (such as another physician practice or a hospital)

Under Arrangement and Other Leasing Models

What *Won't* Work,

What *Should* Work, and

What *May* Work

Under Arrangement and Other Leasing Models That *Won't* Work

- IDTF as lessor
- Physician group as lessor (***If*** the group is required to enroll as an IDTF)
- Non-enrolled entity lessors leasing turn-key infrastructure (***If*** physicians who make referrals for DHS which is provided using the infrastructure directly or indirectly hold ownership or investment interests in the entity)
- Leases based on a percentage of revenue or per unit of service (***If*** the lease needs to fit within one of the applicable Stark Law exceptions)

Under Arrangement and Other Leasing Models That *Should* Work

- Traditional block leases, *e.g.*, fixed schedule with fix aggregate payment, for turn-key infrastructure where the lessor is a non-enrolled entity or is a hospital
  - ***But only if*** no physician who makes referrals for DHS which is provided using the infrastructure directly or indirectly holds an ownership or investment interest in the lessor
    - The issue: the lessor will likely be deemed to be the DHS entity, and there's probably no exception available under the Stark Law for the referring physicians' ownership or investment interests
  - ***Also*****,** be aware of the "contractual joint venture" concerns CMS has stated under the anti-kickback statute, particularly as most recently articulated in OIG Advisory Opinion No. 01-10

Under Arrangement and Other Leasing Models That *Should* Work (cont'd)

- Leases based on a percentage of revenue or per unit of service
  - ***But only if*** the lease does not constitute either a “direct compensation arrangement” between the lessor and the lessee, that must fit within the exceptions for “rental of office space,” “rental of equipment” or “fair market value compensation,” or an “indirect compensation arrangement,” that must fit within the exception for “indirect compensation arrangements”
  - ***And be aware*** of the “stand in the shoes” provision
  - ***And also be aware*** of the “contractual joint venture” concerns CMS has stated under the anti-kickback statute, particularly as most recently articulated in OIG Advisory Opinion No. 01-10

Under Arrangement and Other Leasing Models That *May* Work

- Traditional block leases, *e.g.*, fixed schedule with fix aggregate rental payment, for space and/or equipment (but not personnel)
  - ***Even if*** physicians who make referrals for DHS which is provided using the infrastructure directly or indirectly hold an ownership or investment interest in the lessor
    - The issue: how broadly will CMS construe "perform," *i.e.*, will the lessor be deemed to be the DHS entity

Under Arrangement and Other Leasing Models That *May* Work (cont'd)

- Leases with time-based rental payments, such a block-time leases, depending on how they are structured.
  - "On demand" leases, under which the aggregate amount of time for which space or equipment is available is not set in advance, probably will not work
  - It's not clear what other time-based approaches will work
  - ***Also be aware*** of the "contractual joint venture" concerns CMS has stated under the anti-kickback statute, particularly as most recently articulated in OIG Advisory Opinion No. 01-10

Utility of “Fair Market Value Opinions”

- Remember that many of the compensation arrangement exceptions require that the payment thereunder be in the range fair market value on commercially reasonable terms and conditions and not be determined in a manner that takes into account the volume or value of referrals or other business generated by or among the parties
- Although fair market value is not by itself a defense, it’s almost always better to have some backup in the file showing that a disinterested third party expert analyzed and opined as to what was fair market value

Miscellaneous Considerations

- Even if a lease can be structured to comply with Federal law, don't forget to consider the implications under:
  - Opinions issued by state boards of medicine.
  - Legislative developments
  - Regulatory activity by state attorneys general, such as the whistleblower lawsuits which have been joined by the state's Attorney General
- Also, the anti-markup rule for diagnostic tests is a work in progress, and may make it more desirable to structure leases one way rather than another way

Anti-markup Rules

Anti-markup First Alternative Proposal CY 2009 PFS Proposed Rule

- Proposed to apply anti-markup provision in all cases where the PC or TC of a diagnostic testing service is either:

  (i) purchased from an outside supplier or

  (ii) performed or supervised by a physician who does not share a practice with the billing physician or physician organization (as defined at §411.351)

- Would specify that a physician who is employed by or contracts with a single physician or physician organization shares a practice with that physician or physician organization
  - When a physician provides his or her efforts for a single physician organization (whether those efforts are full-time or part-time), he or she has a sufficient nexus with that practice to justify not applying the anti-markup provision
  - A physician who is an employee of, or independent contractor with, more than one billing physician or physician organization would not "share a practice" for purposes of §414.50 with any of the physicians or physician organizations with which he or she is affiliated

Anti-markup Second Alternative Proposal CY 2009 PFS Proposed Rule

- Provides clarification regarding anti-markup requirements finalized in the CY 2008 PFS final rule
  - Specifically, clarifying guidance pertaining to what would constitute the “office of the billing physician or other supplier”

- Also proposes an exception to the application of the anti-markup provision for diagnostic tests ordered by a physician in a physician organization that does not have any owners who have the right to receive profit distributions

- Soliciting comments on:
  - Defining “net charge”
  - Whether, in addition to or in lieu of the anti-markup provision, we should prohibit reassignment in certain situations and require the physician supervising the technical component or performing the professional component to bill Medicare directly; and
  - Whether we should delay the application of the provisions finalized in the November 27, 2007 final rule with comment period or the proposed revisions in this proposed rule (to the extent that they are finalized), or both, beyond January 1, 2009

Interaction between the Anti-markup Rules and the Stark Law In-office Ancillary Services Exception

Application of Anti-markup Rules to Stark Compliant Arrangements

- Even if an arrangement involving diagnostic testing services is in compliance with the Stark Law, it must still be analyzed for applicability of and compliance with the Anti-markup Rules

- For example, current compliance with the “in-office ancillary services” exception does NOT (by itself) obviate the need to comply with the Anti-markup Rules

Application of Anti-markup Rules to non-DHS

- The Anti-markup Rules generally apply "[for] services covered under section 1861(s)(3) of the Act and paid for under part 414 of this chapter [42 CFR] (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special billing rules set forth in section 1833(h)(5)(A) of the Act)"

- Certain types of diagnostic tests that are subject to the Anti-markup Rules fall outside the Stark Law definition of "*designated health services*" and, therefore, are not subject to the Stark Law

Compliance with the Anti-markup Rules and the Impact on Stark Law Compliance

- The Stark Law definition of "*entity*" has been changed
- It now reads that "[f]or purposes of this subpart [the Stark Law regulations], 'entity' does not include a physician's practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup provision is applicable in accordance with § 414.50 of this chapter [42 CFR] and section 30.2.9 of the CMS Internet-only Manual, publication 100-04, Claims Processing Manual, Chapter 1 (general billing requirements)"
- In other words, the core Stark Law prohibition, *i.e.*, a physician shall not make a referral to an "entity" for the furnishing of designated health services, etc., does not apply to a physician practice when the practice bills for the TC or PC of a diagnostic test in accordance with the Anti-markup Rules

Compliance with the Anti-markup Rules and the Impact on Stark Law Compliance (cont'd)

- One consequence is that when the TC and the PC of a diagnostic imaging test is billed globally by a group practice in compliance with the Anti-markup Rules, the radiologist does not need (for Stark Law compliance purposes) to be physically present on the premises of the group practice when she or he renders the professional interpretation

Do the Anti-markup Rules, In Effect, Modify the In-Office Ancillary Services Exception?

- Consider the “centralized building” method of satisfying the location element under the “in-office ancillary services” exception for locations providing diagnostic tests (which are subject to the Anti-markup Rules)
  - In the prototypical centralized building arrangement, the ordering physician in the group practice usually provides no patient care services at the location
  - Under such circumstances, the Anti-markup Rules would apply
- The group practice must comply with the Anti-markup Rules or else face the consequences of failure to comply, so it will comply

Do the Anti-markup Rules, In Effect, Modify the In-Office Ancillary Services Exception? (cont'd)

- If it complies, the group practice would not constitute an "entity" under the Stark Law
- Consequently, the core Stark Law prohibition would not apply
- And the in-office ancillary services exception is never even reached
- Result: The centralized building method of satisfying the location element has become moot for many common arrangements

Interaction Between the Anti-markup Rule and the Proposed IDTF Enrollment Requirements

What Does Being an IDTF Mean for Physician Practices?

- Once it is enrolled as an IDTF, a physician practice would be subject to virtually all of the major quality-related and other compliance obligations and reimbursement requirements that IDTFs are currently subject to for their Medicare patients 42 C.F.R. § 410.33
- For example, “[each] supervising physician [for an IDTF] must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed in the IDTF” 42 C.F.R. § 410.33(b)(2)
- Wisconsin Physician Services (“WPS”), and some other local Medicare carriers throughout the U.S. that collectively have jurisdiction over a large number of states, have issued local carrier decisions (so-called “LCDs”) in which they have determined that in order to satisfy the proficiency requirement, IDTFs must use board certified (or some carriers have also allowed board-eligible) radiologists for all supervision, including general, direct and personal

What Does Being an IDTF Mean for Physician Practices? (cont'd)

- Given CMS' desire to achieve consistency and uniformity for all diagnostic procedures, carriers that have issued these LCDs will presumably impose the same requirement for physician practices who enroll as IDTFs as a result of the new enrollment rules
- In other words, physician practices subject to the jurisdiction of the carriers that have issued these LCDs (such as WPS) would have to use radiologists for supervision
- A radiologist would have to be physically present for direct and personal supervision procedures (not for general supervision procedures)
  - But remember that each radiologist cannot be a generally supervising physician for more than three IDTF sites (42 C.F.R. § 410.33(b)(1))
- This is a big enough issue as it is, but there potentially may be an even bigger supervision issue

How Does the Anti-markup Rule Affect Physician Practice IDTFs?

- First, remember that the anti-markup rule generally would never apply to an IDTF or other imaging facility owned by persons, such as diagnostic radiologists, who do not order diagnostic tests from the facility
  - The issue largely, if not exclusively, pertains only to so-called “self-referring physician groups”
- In its discussion of the second alternative approach for revising the anti-markup rule, which is captioned as a “site-of-service” approach, CMS states that “if either the conducting of the TC [the technical component] *or the supervising of the TC* takes place outside the office of the billing physician or other supplier, the anti-markup provision would apply [to the TC]”
  - The context seem seems to strongly suggest that this is a bright-line in the eyes of CMS
- In order to avoid having the rule apply, billing physicians will make sure that they have a supervising physician in their “office” when they perform a diagnostic procedure
- Moreover, in its discussion CMS simply refers to “supervision,” with no distinction between general, direct or personal
  - A common sense reading would be that CMS meant ALL supervision
- Now put the new IDTF requirements together with the anti-markup proposals, and it gets real interesting

How Does the Anti-markup Rule Affect Physician Practice IDTFs? (cont'd)

- If a billing physician group is in a state (such as Illinois) for which the Medicare carrier (WPS) has issued a LCD requiring radiologists to provide all supervision for IDTFS, the group will have to use radiologists
- And if the group wants to avoid being subject to the anti-markup rule for the TC, then it will have to assure that "the supervising of the TC takes place" inside the group's office
- ***RESULT***: Taken together, in many states (*e.g.*, Illinois) the new IDTF requirements and the site-of-service approach to the anti-markup rule would require radiologists to be physically present in the office of the billing physician group at ALL times during which diagnostic procedures are being performed, including those which only require general supervision

Compliance

Alternative Method for Compliance with Signature Requirement

- Creates a “grace period” for both inadvertent and knowing noncompliance
  - 90 consecutive calendar days for inadvertent failure to comply with signature requirements
  - 30 consecutive calendar days for knowing failure to comply with signature requirements
  - Clock begins at commencement of compensation arrangement
- All other elements of applicable exception must have been satisfied
- Does not matter whether referrals have been made or compensation has actually been paid

Alternative Method for Compliance with Signature Requirement (cont'd)

- Key considerations:
  - Is effective on October 1, 2008
  - Only applies to failure to obtain a signature
  - Can only be used once every three years with respect to each referring physician
  - Could be very useful in light of the strict position that CMS has taken on "relating back" agreement
    - It does not seem to matter to CMS whether state law would hold an agreement to be in full force and effect, as of the stated effective date, even if the agreement was executed at some date thereafter

Period of Disallowance

- Begins (in all cases) at the time the financial relationship fails to satisfy the requirements of an applicable exception
- Ends no later than
  - Where the noncompliance is unrelated to compensation, the date that the financial relationship satisfies all of the requirements of an applicable exception
  - Where the noncompliance is due to the payment of excess compensation, the date on which all excess compensation is returned by the party that received it to the party that paid it and the financial relationship satisfies all of the requirements of an applicable exception
  - Where the noncompliance is due to the payment of compensation that is of an amount insufficient to satisfy the requirements of an applicable exception, the date on which all additional required compensation is paid by the party that owes it to the party to which it is owed and the financial relationship satisfies all of the requirements of an applicable exception

Period of Disallowance (cont'd)

- Key considerations
  - Effective Date: October 1, 2008
  - The rule creates something similar to a "safe harbor"
  - But it only places an outside limit on the period of disallowance in the three specified circumstances
  - And other than what was set forth above, CMS provided no clear guidelines for determining when the end of the period of disallowance has occurred
    - Parties will have to continue to make the determination on a case-by-case basis
    - It's a facts and circumstances analysis
  - Likewise, the beginning and end of a financial relationship will not coincide necessarily with the beginning and end of a written agreement
  - Finally, be aware that CMS provided no guidance on when noncompliance is never corrected or excess or required compensation is not repaid/paid

Burden of Proof

- Effective Date of Rule: October 1, 2008 (but existing policy)
- Burden of proof (burden of persuasion) at each level of appeal is on the entity submitting the claim for payment
  - Must establish that the service was not furnished pursuant to a prohibited referral
- Burden of production on each issue at each level of appeal is initially on the claimant, but may shift to CMS or its contractors (and may shift back)
- Codification of existing policy

Recruitment After Phase III

Recruitment after Phase III

- Recruitment Basics (refer to materials)
- Recent AOs
- FAQs
- Informal questions asked of CMS
- More detailed information available in handout

What's Next?

Update on issues still on the table at CMS and what we can expect through 2008 and beyond

What's Next?

- CY 2009 PFS proposed rule
  - Comment period ended August 29, 2008
  - Display date for final rule scheduled November 1, 2008
  - Included proposals on:
    - Revisions to anti-markup provisions
    - New exception for incentive payment and shared savings programs
    - New requirements for physician and nonphysician practitioner entities to enroll as IDTFS to provide diagnostic tests

What’s Next?

- Disclosure of Financial Relationships Report
- Revisions to the in-office ancillary services exception?

Further Revisions to Anti-markup Rules

- Two alternative approaches proposed in CY 2009 PFS proposed rule
- Final rule expected November 1, 2008

Proposed New Exception for Incentive Payment and Shared Savings Programs

- In CY 2009 PFS proposed rule, CMS proposed an exception that would permit remuneration provided by a hospital to physicians on its medical staff under incentive payment and shared savings programs
- Published July 7, 2008 in the Federal Register (73 FR 38502)
- Comment period closed August 29, 2008

Proposed New Exception for Incentive Payment and Shared Savings Programs (cont'd)

- Specifies conditions that must be satisfied
  - Many conditions mirror those found important by the Office of the Inspector General in the 10 favorable advisory opinions it has issued to date for gainsharing programs
  - Addresses more than traditional gainsharing programs
  - Covers only programs in hospitals
  - Consistent with, but goes beyond OIG opinions to date
  - Extremely narrow application, but indicates willingness to consider expansion
- More detailed information available in handout

Scope of the Proposed Exception

- Incentive Payment Programs
  - P4P
  - Quality improvement payments
  - Do not involve cost sharing
- Shared Savings Programs
  - Includes traditional gainsharing
  - “Hybrid models” combining cost sharing measures and quality improvement

Solicitation of Comments on the Proposed Exception

- Expansion of proposed exception
  - Beyond hospitals
  - Pass-through payments (similar to recruitment payments)
- Separate exceptions for incentive payments and shared savings programs
- Location of exception in § 411.355
  - Arguably, the “stand in the shoes” provision would not apply

Other Available Exceptions

- Even if finalized as proposed, it is not the only available exception for these types of incentive payment and shared savings arrangements
- Potentially available exceptions
  - Personal service arrangements
  - Employment
  - Fair market value compensation arrangements
  - Indirect compensation arrangements
- Potentially, no exception is necessary

Disclosure of Financial Relationships Report

- Under 42 C.F.R. §411.361, CMS may require an entity to provide information concerning its financial relationship(s) with a physician, including the extent and/or value of the physician's ownership or investment interest in the entity or compensation arrangement with the entity.
- In May 2007, CMS published a notice of its proposed information collection, including the disclosure instrument (the DFRR)
- After considering public comments, CMS published a revised version of the DFRR on September 14, 2007

Disclosure of Financial Relationships Report

- CMS withdrew its PRA package from OMB review and instead included a revised PRA package for the DFRR in the FY 2009 IPPS Proposed Rule in order to
  - Promote transparency
  - Seek meaningful comments
  - Revised burden estimates
- The proposed DFRR information collection instrument and instructions can be found in Appendix C to the FY 2009 IPPS proposed rule

DFRR – FY 2009 IPPS Proposed Rule

- Announced and sought public comment on the information collection request in the FY 2009 IPPS proposed rule (60-day notice) (73 FR 23700)
  - to identify arrangements that potentially may not be in compliance with the physician self-referral statute and implementing regulations; and
  - to identify practices that may assist CMS in any future rulemaking concerning the reporting requirements and other physician self-referral provisions (73 FR 23697)

DFRR – FY 2009 IPPS Proposed Rule

- CMS indicated that it will send the DFRR to 500 hospitals (of the more than 6000 that participate in the Medicare program)
- Hospitals that receive the DFRR will have 60 days to complete it and return it to CMS
- Failure to disclose information in a timely manner may result in civil monetary penalties of up to $10,000 per day

DFRR – FY 2009 IPPS Proposed Rule

- Specific comments solicited with respect to –
  - General comments on the information collection instrument (the DFRR)
  - Whether the collection effort should be recurring and, if so, whether it should be implemented on an annual or other periodic basis
  - Whether CMS is collecting too much or not enough information
  - Whether CMS is collecting the correct or incorrect type of information

DFRR – FY 2009 IPPS Proposed Rule

- Specific comments solicited with respect to (cont'd) –
  - The amount of time it will take hospitals to complete the DFRR
  - The costs associated with completing the DFRR
  - The amount of time hospitals should be given to complete the DFRR and return their responses to CMS
  - Whether CMS should direct the collection instrument to all hospitals and, if so, whether CMS should stagger the collection so that only a certain number of hospitals are subject to the DFRR in any given year

DFRR – FY 2009 IPPS Proposed Rule

- Specific comments solicited with respect to –
  - How CMS should select the hospitals that will receive the DFRR
  - Whether hospitals, once having completed the DFRR, should have to send in yearly updates and report only changed information

DFRR – FY 2009 IPPS Final Rule

- In FY 2009 IPPS final rule, CMS discussed comments received in response to proposed rule's solicitation of comments
- Stated that it was proceeding with the collection
- Revised burden estimate to 100 hours
- Signaled that it may send the DFRR to less than 500 hospitals

DFRR – What's Next?

- Current status
  - Upcoming publication of the 30-day notice in the Federal Register
  - Comments sent directly to OMB
  - CMS responds to comments received and revises DFRR as necessary
  - Collection of information process complete when approval received from OMB

Revisions to the In-office Ancillary Services Exception?

- In the CY 2008 PFS proposed Rule, CMS expressed concern that services furnished under this exception are not sufficiently connected to the physician practice and that proliferation of in-office laboratories and the migration of sophisticated and expensive imaging or other equipment in physician offices may not be appropriate (72 FR 38181-38182)
- CMS specifically solicited comments on:
  - Whether certain services should not qualify for the exception
  - If and how changes should be made to “same building” and “centralized building” definitions
  - Whether non-specialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned by the non-specialists
  - Any other restrictions on ownership or investment in services that would curtail abuse

Revisions to the In-office Ancillary Services Exception?

- CMS received hundreds of comments in response to its solicitation
- Any changes to the in-office ancillary services exception would be made through a proposal subject to public comment in a future rulemaking

Questions and Answers