Leasing and Infrastructure Deals

What to Avoid, What May Be OK, Where Is It All Headed?

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Disclosure:
Nothing to Disclose

Introduction

- A different analytical tack.
- Models, and an organizational construct.
- What models no longer work?
- What models still may work?
- Concluding thoughts.

A Different Analytical Tack

Recent Developments

- Opinions from boards of medicine.
- Recommendations by the Medicare Payment Advisory Commission ("MedPAC").
- Scrutiny by state attorneys general.
- Regulatory mindset of the Centers for Medicare & Medicaid Services ("CMS"):
  - Efforts to limit the in-office ancillary services exception under the Stark Law.
  - Particular focus on, and concern over, the dramatic growth in utilization of diagnostic imaging services.

Recent Developments (cont.)

- Performance standards for independent diagnostic testing facilities ("IDTFs"), . . .
- . . . and proposed requirements for every physician group (including every radiology group) that's providing diagnostic tests to enroll as an IDTF.
- Anti-markup rules for diagnostic tests.
- Proposed revised definition under the Stark Law rules of who will be considered to be an "entity" furnishing designated health services ("DHS").
- Proposed changes to Stark Law exceptions to bar payments based on percentage of revenue or per-unit of service.

A Different Analytical Approach

- Usually it's best to know what currently in-force laws allow and don't allow, then figure out what kinds of deals work.
- However, with the volume of recent developments relevant to leasing and infrastructure deals, it seems to make more sense now to first lay out the models that have been used, and then work through a process of elimination.
  - It also seems reasonable to assume that most, if not all, of the proposed regulatory changes will be put into effect in the form as proposed (or at least in a largely similar form).
- The question becomes what models no longer work, and then what models may still work?

Better Title for Presentation?

- Perhaps today's presentation would be more appropriately entitled "Leasing and Infrastructure Deals: Do any Viable Models Still Exist?"

Models for Leasing and Infrastructure Deals

An Organizational Construct

An Organizational Construct

- For purposes of this presentation, leasing and infrastructure deals are collectively referred to as “leases” (except where the context otherwise dictates).

An Organizational Construct (cont.)

- Enrolled entities as lessors.
- Non-enrolled entities as lessors.
- What's leased: "turn-key infrastructure" *v.* asset only.

Enrolled Entities as Lessors

- IDTFs.
- Diagnostic radiology group practice/clinics ("DRGP/Cs").
- Radiology groups.
- Other physician groups.
- Hospitals.

Non-Enrolled Entities as Lessors

- Entities that are not enrolled with Medicare, *a.k.a.*:
  - Asset companies.
  - Equipment companies.
  - Leasing companies.
  - Infrastructure ventures.
- Might be owned by radiologists, other physicians, hospitals, other persons or entities, or any mix thereof.

What's Leased?

- ***Turn-Key Infrastructure***: Some lessors make available "all four legs of the table" needed to provide the technical component ("TC") of diagnostic tests:
  - Space.
  - Equipment.
  - Supplies.
  - Personnel.
- ***Asset Only***: Other lessors only lease certain assets:
  - Space.
  - Equipment.

A Model That No Longer Works:

IDTF As Lessor

New IDTF Performance Stds.

- On January 1, 2007, 14 new Medicare performance standards went into effect for IDTFs.
- When CMS issued the final 2008 Medicare Physician Fee Schedule ("MPFS"), it created a new 15th performance standard and modified some of the other standards.
  - With the exception of one piece of the 15th standard, these all 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.)

- 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.)

- 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 Std.

- 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).

A Model That No Longer Works:

Physician Group As Lessor

(***If*** the group is required to enroll as an IDTF)

Proposed IDTF Enrollment Requirement for Physician Groups

- When CMS issued the proposed 2009 MPFS, it proposed to require each "physician or nonphysician practitioner organization" that furnishes diagnostic testing services **EXCEPT DIAGNOSTIC MAMMOGRAPHY 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 [sic] clinic or group practice." 42 C.F.R. § 424.502 (proposed).

Effect of the IDTF Enrollment Proposal

- Every physician group that furnishes diagnostic testing services would be required to enroll as an IDTF.
  - CMS would no longer distinguish DRGP/Cs.
  - 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.)

- Physician groups 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 groups to share space.

Effect of the IDTF Enrollment Proposal (cont.)

- 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 group (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 group or a hospital).

A Model That No Longer Works:

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 interests in the entity)

"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 final FY 2009 inpatient prospective payment schedule rules ("IPPS"), CMS finalized it's previous proposal to redefine the term "entity" under the Stark Law.

"Entity" Redefinition (cont.)

- 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 which has the right to payment pursuant to a valid reassignment. 42 C.F.R. § 411.351.
- This change will become effective October 1, 2009.

"Entity" Redefinition (cont.)

- The critical issue for a non-enrolled entity lessor will be whether it is "performing" the DHS.
- CMS chose to give little 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 the lessor 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.
- Consequently, any referral for such DHS by a physician who directly or indirectly holds an ownership 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)***.
  - 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.)

- 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 the lessor only makes available space, equipment and supplies, but not the personnel, would the lessor fall outside the new entity definition?

A Model That No Longer Works:

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)

When Might the Lease Need to Fit Within a Stark Law Exception?

- If the lease creates 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."
  - Remember the new "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.
  - The result is to make many indirect compensation arrangements direct.
- If the lease creates an "indirect compensation arrangement" that must fit within the exception for "indirect compensation arrangements."

Percentage of Revenue and Per Unit of Service Leases Prohibited

- In the final FY 2009 IPPS, CMS finalized it's previous proposal 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)-(b).
- 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).
- 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).
- 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."
    - 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 leases."

Time-Based Rental Arrangements (cont.)

- 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 [we] consider them to be covered by our revisions in this final rule."
  - 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).

What Models Should/May Work?

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 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.
  - Be aware of state-specific enforcement actions, such as the whistleblower lawsuits pending in Illinois (which have been joined by the state's Attorney General).
  - ***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. 08-10.**
    - ***NOTE THAT CITATION IN MATERIALS IS INCORRECT!***

Models That Should Work (cont.)

- Leases based on a percentage of revenue or per unit of service.
  - ***But only if*** the lease does not create 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."
  - Be aware of the "stand in the shoes" provision.
  - ***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. 08-10.**

Models That *May* Work

- Traditional block leases, *e.g.*, fixed schedule with fix aggregate rental payment, for space and/or equipment.
  - ***Even if*** physicians who make referrals for DHS which is provided using the infrastructure directly or indirectly hold an ownership interest in the lessor.
    - The issue: how broadly will CMS construe "perform," *i.e.*, will the lessor be deemed to be the DHS entity.

Models That *May* Work (cont.)

- 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. 08-10.**

Concluding Thoughts

Not Many Viable Models Still Exist

- Because of IDTF performance standard no. 15, the parties who have most commonly been the lessors are effectively prohibited from continuing these arrangements.
- Similarly, the redefinition of “entity” under the Stark Law and the prohibition on leases based on a percentage of revenue or per unit of service (when they need to fit within an applicable Stark Law exception) has made some common approaches for structuring rental payments non-viable.

Utility of "Fair Market Value Opinions"

- Remember all of the other requirements applicable to leases, *e.g.*, the payment thereunder must be in the range of fair market value on commercially reasonable terms and conditions and cannot 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.
  - Lawsuits and other regulatory activity by state attorneys general and state legislatures.
- 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.
- **Remember the "contractual joint venture" concerns CMS has stated under the anti-kickback statute, particularly as most recently articulated in OIG Advisory Opinion No. 08-10.**

THANK YOU!

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