



Outpatient Ancillary Services: Creative Structures for Competing Into the Future

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Introduction

- Why ancillary services transactions are being done.
- The “Creative Structures”:
 - Conversion to provider-based or under arrangement.
 - Broader market-wide roll-up joint ventures for ancillary services.
 - Outright acquisitions of ancillary services centers or of joint venture ownership.
 - Co-management and other relationships between hospitals and physicians involving ancillary services.
- Approach that will not be discussed: hospitals doing ancillary services on their own, through *de novo* expansion/development.
- “Think like an investment banker.”

Why Ancillary Services Transactions Are Being Done

- Perhaps at no other time in history has health care, particularly ancillary services, experienced the recent volume and velocity of change.
- The drivers:
 - Health care "reform."
 - Federal scrutiny of various areas of ancillary services.
 - Reimbursement pressure from all governmental and non-governmental payors.
 - More and more (expensive) technology.
 - Heightened tension as hospitals acquire physician practices.
 - Accountable care organizations, as well as other integrative efforts.



Conversion to Provider-Based or Under Arrangement

An Illustration

- The following is just one example of how hospitals and physicians are changing how they provide and bill for ancillary services.
 - HOWEVER: it's one of the most common examples of how conversion to provider-based or under arrangement is utilized.
 - It works well with non-referring physicians (like diagnostic radiologists).
 - AND, diagnostic imaging is an area in which everyone is looking for ways to compete more effectively and survive downward reimbursement pressures.

An Illustration (cont'd)

- On the other hand, when these transactions involve referring physicians, they usually are more limited in what they can accomplish because of Stark Law considerations.
 - In particular, direct or indirect ownership by referring physicians in a venture often limits what that venture can do and how it can be paid.
 - The venture might be limited to acting as an “asset company.”
 - And payments may need to be structured as fixed *versus* per service.

Some Medicare Vernacular

- Physician groups and independent diagnostic testing facilities (“IDTFs”) are considered to be “suppliers” by Medicare.
- Hospitals are considered to be “providers” by Medicare.

Why Convert?

- DRA 2005 reduced technical component (“TC”) reimbursement for suppliers.
- Multiple procedure discounts under Medicare has also reduced reimbursement for suppliers.
- Non-governmental payor reimbursement to suppliers has followed Medicare down, either automatically (through fee provisions) or by negotiation.

Why Convert? (cont'd)

- By contrast, providers very often receive reimbursement from non-governmental payors that is significantly higher than what suppliers receive.
 - Note that conversions generally are not being driven by Medicare: DRA 2005 moved to somewhat equalize outpatient reimbursement for suppliers and providers (although providers sometimes still see higher reimbursement).
 - Rather, it's the advantages for providers on the nongovernmental side that's the big driving force.
- **QUERY**: how long lived is the arbitrage opportunity?

Why Convert? (cont'd)

- Everyone is looking for ways to squeeze out additional revenue and profit/margin.
- A conversion to provider-based or under arrangement can make this happen.

Factual Scenario

- Existing hospital/radiology group joint venture, enrolled with Medicare as either an IDTF or a diagnostic radiology group practice clinic (“DRGPC”), is converted to provider-based or under arrangement.
- Variation: a hospital could buy partially into a center owned/operated by a radiology group (or other entities/persons), and then the resulting joint venture is converted.
- Variation: a hospital and a radiology group could *de novo* form a joint venture to own/operate a center as provider-based or under arrangement.

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History and Purpose of Provider-Based Rules

- The rules: 42 C.F.R. § 413.65.
- Why they were promulgated.
- They are rules of exclusion, not rules of inclusion.
- They specify the requirements that must be satisfied in order for a facility or organization to be treated as part of a main provider.

History and Purpose of Provider-Based Rules (cont'd)

- “Provider-based” is a Medicare enrollment concept, so why even worry about it if conversions are being largely driven by non-governmental reimbursement?
- The answer: because it’s very difficult, if not impossible in most instances, to have a facility operate as a provider for purposes of non-governmental payors while being operated as a supplier for purposes of Medicare.
 - State licensure and certificate of need (“CON”) limitations.
 - Payor contract requirements.
 - Operational burdens.
 - IDTF performance standards limitations on “sharing” or “leasing or subleasing.” 42 C.F.R. § 410.33(g)(15).
- So if you want to be reimbursed like a provider by non-governmental payors, you’re probably going to need to find a way to be reimbursed as a provider by Medicare.

On-Campus v. Off-Campus

- There are fewer requirements to qualify as provider-based if the facility or organization is located on the campus of the potential main provider.
- “**Campus** means the physical area immediately adjacent to the provider’s main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual basis, by the CMS regional office, to be part of the provider’s campus.”

Provider-Based Requirements Applicable to On-Campus AND Off-Campus Facilities or Organizations

- Licensure.
- Clinical integration.
- Financial integration.
- Public awareness.
- Fulfill specified obligations of hospital outpatient departments.

Additional Provider-Based Requirements Applicable ONLY to Off-Campus Facilities or Organizations

- Operation under the ownership and control of the main provider.
- Administration and supervision.
- Location
 - Generally no more than 35 miles from the main provider and in same state or adjacent state when consistent with the laws of both states.
 - Other, narrow ways to satisfy location requirement.

Provider-Based Status for Joint Ventures

- The facility or organization must:
 - Be partially owned by at least one provider,
 - Be located on the main campus of a provider who is a partial owner,
 - Be provider-based to that one provider whose campus on which the facility or organization is located, and
 - Meet all requirements that are applicable to BOTH on-campus and off-campus facilities and organizations.

- As a result, off-campus joint ventured facilities or organizations *per se* cannot qualify under the provider-based rules.

What If a Joint Venture Will Be Involved?

- If on-campus, then may be able to qualify under the provider-based rules.
- If off-campus, cannot qualify under the provider-based rules
- An alternative for off-campus, joint-ventured facilities or organizations may be the under arrangement rule.

Under Arrangement

- The statutes: 42 U.S.C. §§ 1395x(s)(2)(C) and (w)(1).
- The rules: 42 C.F.R. §§ 409.3, 410.27(a), 410.28 and 482.12(e).

Under Arrangement (cont'd)

- Receipt of payment by the billing provider (whether in its own right or as agent), with respect to services for which an individual is entitled to have payment made by Medicare must discharge the liability of such individual or any other person to pay for the services.

Under Arrangement (cont'd)

- The billing provider must exercise professional responsibility for the services obtained under arrangements:
 - Apply same quality controls over under arrangements personnel.
 - Apply its standard admission policies.
 - Maintain a complete and timely clinical patient record.
 - Maintain liaison with under arrangement entity's attending physician.
 - Ensure that medical necessity is reviewed on a sample basis.

Provider-Based v. Under Arrangement

- Be aware that:
 - Any facility or organization that furnishes ALL services under arrangements cannot qualify as provider-based.
 - Providers cannot contract out entire departments under arrangements while claiming them as provider-based.

Provider-Based v. Under Arrangement (cont'd)

- But the big distinction is . . .
 - Provider-based facilities or organizations are not required to satisfy the under arrangement requirements, on the other hand . . .
 - CMS has given mixed signals on whether facilities from which services are obtained under arrangements must satisfy the provider-based requirements.
 - At a minimum, CMS likely will look at the nexus between the joint venture and the hospital.

Provider-Based v. Under Arrangement: The Choice

- If on-campus, convert to provider-based.
 - Parties will need to understand fully and make sure that they are comfortable with the provider-based requirements.
- If off-campus, convert to under arrangements.
 - Again, parties should fully understand and be comfortable with the (less burdensome) under arrangement requirements.

Supervision of Hospital (Provider) Outpatient Diagnostic Services

- The rules: 42 C.F.R. §§ 410.28(a) and (e), 410.32(b) and 413.65.
- See also CMS Manual System, Pub. 100-02 Medicare Benefit Policy, Transmittal 137, Dec. 30, 2010 (Benefit Policy Manual, Ch. 6, §§ 20.4.4, 20.4.5, 20.4.6, 20.5.2, 20.5.3 and 20.7).

Supervision of Hospital (Provider) Outpatient Diagnostic Services (cont'd)

- What the “old” rule was perceived to be.
- The objective of the new rule: to conform the supervision requirements for hospital outpatient diagnostic services as much as feasible with the requirements for such services when reimbursed under the Medicare Physician Fee Schedule (e.g., services provided by physician groups and IDTFs).

Supervision of Hospital (Provider) Outpatient Diagnostic Services (cont'd)

- All services subject to general, direct or personal supervision.
- Be aware of the immediate availability, physical presence and physician qualification requirements.
- In any event, a hospital needs to make sure it is satisfying the supervision requirements.

Process for Conversion to Provider-Based or Under Arrangement

- Check state hospital licensing requirements to ascertain whether provider-based or under arrangements will work and what compliance steps, if any, will need to be taken (either before or after closing).
- In states with a CON or similar regime, analyze the CON implications.
 - If the joint venture already has a CON, can it be “transferred” or will the hospital only need to obtain a certificate of exemption of similar non-substantive review?
 - Can the center be added to the hospital’s existing CON?
 - Will the hospital be required to obtain a completely new CON and go through a full substantive review?

Process for Conversion to Provider-Based or Under Arrangement (cont'd)

- Do market and related research to ascertain:
 - Reimbursement differentials.
 - Non-governmental payor contracting biases and trends.
 - Can existing hospital payor agreements be accessed? Will they require amendment?
- Analyze a sample billing and collection data set.

Process for Conversion to Provider-Based or Under Arrangement (cont'd)

- Decide whether the conversion makes financial sense and whether the financial justification appears to be sustainable for the mid- to long-term.
 - Remember the transactional costs of getting the conversion done.
 - Also remember the potential reduction in equity value of any joint venture if it becomes an under arrangements contractor, dis-enrolls from Medicare, no longer has its own payor contracts, and changes from having multiple customers to having a single customer (*i.e.*, the hospital).

Process for Conversion to Provider-Based or Under Arrangement (cont'd)

- If seeking provider-based status, fully understand the provider-based requirements and resolve among the participants how they will be satisfied.
- In other words, who will be responsible for what, and where will decision-making discretion sit on issues that are key to provider-based qualification?
- Memorialize the resolution in writing somewhere and have parties sign.

Process for Conversion to Provider-Based or Under Arrangement (cont'd)

- If necessary, modify the joint venture's organic documents, *e.g.*, operating agreement and articles of organization (for a limited liability company).
 - Pay particular attention to buy-out rights and obligations, and related valuation methodologies: do they still make sense?
- Enter into or amend existing service agreements for subcontracted items and services.
- Enter into or amend management and medical director agreements.
 - Remember that for off-campus provider-based status, there will be significant limitations on the types and levels of administrative and management services that the hospital can contract out for, *e.g.*, to a physician group.

Process for Conversion to Provider-Based or Under Arrangement (cont'd)

- Enter into an agreement between the hospital and the joint venture that describes:
 - What will the joint venture do?
 - What responsibilities will stay with the hospital?
 - Where will decision-making discretion sit?
 - How will the joint venture be paid by the hospital?
 - “Top Down Approach”: Flow all TC reimbursement to the joint venture, less a reasonable billing and collection fee for hospital and less any expenses attributable to responsibilities retained by hospital.
 - “Bottom Up Approach”: Determine cost of items and services that will be provided by the joint venture to the hospital, and add in a profit margin based on a risk-adjusted rate of return for the joint venture.
 - Remember that hospitals are not always paid in a way that is conducive to segregating the TC reimbursement, so a mechanism may be required to determine formulaically the TC reimbursement in such circumstances, ideally subject to some type of annual or semi-annual reconciliation.

Process for Conversion to Provider-Based or Under Arrangement (cont'd)

- Modify any existing exclusive provider agreement?
- Terminate (or modify) any professional services agreement between the joint venture and the radiology group?
- Be sure to address the supervision requirements for hospital outpatient diagnostic services: who is going to be responsible?

Roll-Up

Factual Scenario

- Existing provider-based outpatient imaging centers, owned by one or more hospitals, and existing IDTFs, DRGPCs and/or other supplier-based imaging centers (owned by one or more physician groups or other entities/persons) are contributed into a new joint venture.
- In return, the previous owners become new owners of the joint venture *pro rata* to value of centers (and any other assets/cash) contributed.
- Joint venture then operates the centers post-closing as provider-based or under arrangement.
 - AND/OR, the joint venture might operate one or more of the centers as IDTFs or DRGPCs.

Roll-Up Considerations

- Generally the same provider-based v. under arrangement analysis.
- However, a roll-up will inherently involve multiple centers thereby making it much more likely that some centers may be on the campus of the main provider while others will be off-campus.
- As a result, the joint venture may be able to qualify certain centers as provider-based and operate the other centers under arrangements with the main provider (or possibly even as IDTFs or DRGPCs).

Process for Roll-Up

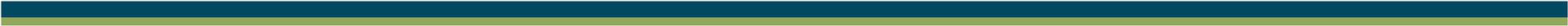
- Do market and related research.
- Analyze a sample billing and collection data set.
- Expect that the provider-based and/or under arrangement analysis will be even more complex (because inherently there are more centers involved).
- The overall transactional process will also be more complicated if multiple hospitals and multiple radiology groups are involved.

Process for Roll-Up (cont'd)

- The transaction will require documents for the formation of the joint venture:
 - Articles of organization and operating agreement (for a limited liability company, if that's the entity of choice).
 - Asset contribution agreement.
 - Loan and/or other financing-related documents
 - Management agreement(s).
 - Professional services agreement(s) (or modifications to any existing exclusive provider agreement).

Process for Roll-Up (cont'd)

- Valuation will be perhaps the biggest economic issue to be negotiated.



Outright Acquisition of Ancillary Services Centers or of Joint Venture Ownership

Factual Scenario

- Hospital acquires existing IDTF, DRGPC or other supplier-based imaging center (e.g., from a radiology group or a self-referring physician group).
- OR, hospital acquires an existing oncology center or urgent care center (again, perhaps from a self-referring physician group).
- Hospital then operates the center post-closing as provider-based.

Acquisition Considerations

- Assuming the center is located with 35 miles of the hospital's campus, the hospital should be able to qualify the center as provider-based.
- If off-campus, there will be significant limitations on the types and levels of administrative and management services that the hospital can contract out for, e.g., to a physician group.

Process for Acquisition

- Hospital should analyze the provider-based requirements and assure itself that it will be able to qualify post-closing.
- At the outset, make sure to analyze the potential tax treatment for the seller and its owners, and structure the deal for tax-efficiency.
 - This applies regardless of who the purchaser is.
- Will likely be transacted as an asset purchase, so prepare an asset purchase agreement.
- Analyze and address any CON and hospital (or other) licensure implications.

Process for Acquisition (cont'd)

- The acquiror (particularly if it's a hospital) will likely obtain a valuation.
- The seller may choose to:
 - Obtain its own valuation, or . . .
 - At a minimum, retain a valuation expert, familiar with the specific ancillary service, to “scrub” the acquiror’s valuation as well as to give the seller a good sense for what is “market” for the ancillary services being sold.



**Co-Management and
Other Relationships
Between Hospitals and Physicians
Involving Ancillary Services**

Why Consider Other Relationships Involving Ancillary Services?

- Physician groups may be well-suited, if not uniquely qualified, to manage and/or provide other functionalities within an ancillary services center.
- Allowing physician involvement may make sense under a hospital's physician practice acquisition/integration strategy.
 - For example, a short term management relationship could smooth the transition from independent practice to hospital-owned practice.
- Certain relationships with hospitals could allow the ancillary services center to grow and thereby expand access within the community to the types of services provided at the center.

Examples of Relationships

- Co-management agreements.
- Medical director agreements.
- Coverage agreements.
- Recruitment support.

Think Like an Investment Banker

- Figure out how the patient care (and the resulting reimbursement) is going to flow, what the various costs and benefits are, and where the real value propositions will be found (clinically and economically).

Quality and Risk Implications

Overview

- Health care reform developments have shifted provider reimbursement for services rendered from payment based on the volume of services provided to payment based on value and compliance with quality metrics and outcomes.
- As hospitals and health systems establish ACOs, CINs and creative arrangements with physicians, they must keep in mind that the business plan must be designed in a way to improve quality, reduce utilization, limit reimbursement loss and reduce legal risks.

Quality and Risk Implications (cont'd)

Overview

- Quality measures and standards include:
 - ACO quality metrics
 - Medicare Value Purchasing Standards
 - P4P standards
 - Readmissions with 30 days of discharge
 - HACs

Quality and Risk Implications (cont'd)

Overview

- Never events
- Physician Quality Reporting System
- ACE State Medicaid programs
- Joint Commission accreditation standards
- NCQA
- Medicare recently announced that by 2018 it wants 50% of all Medicare payments to physicians based on outcomes and 90% of all payments based on outcomes.

Quality and Risk Implications (cont'd)

Risks

- False Claims Act litigation tied to the provision of “worthless” or substandard care.
- Reduced or lost reimbursement.
- Removal from ACO and managed care plans.
- Placement on accreditation watch or worse.
- Enhanced liability exposure under respondeat superior, apparent agency and corporate negligence theories – did you incorporate metrics into your appointment/reappointment/peer review/employment/compensation standards?

Quality and Risk Implications (cont'd)

Risks

- Removal from Medicare/Medicaid program.
- Adverse impact on licensure.
- Antitrust and discrimination risks when deciding to exclude physicians from medical staff, ACO, or managed care membership and participation.

Quality and Risk Implications (cont'd)

Creation of Sensitive and Unprotected Quality Information

- The requirement to integrate quality and performance standards into credentialing, employment, venture, peer review and other operations so as to monitor and enforce performance will result in the creation of a significant amount of adverse incident and patient care issues.
- Most state statutes have limited confidentiality and privilege protections relating to:
 - Scope of patient safety/peer review activities that are protected
 - Types of entities covered, i.e., hospitals, physicians

Quality and Risk Implications (cont'd)

Creation of Sensitive and Unprotected Quality Information

- Can protected information be shared across system without waiving the protections?
- Will the state protections apply in federal antitrust, discrimination and other proceedings and government investigations?

Quality and Risk Implications (cont'd)

Patient Safety and Quality Improvement Act of 2005

- Federal law which allows for the establishment of patient safety organizations (“PSO”).
- Documents, reports, RCAs, data, etc. relating to identified patient safety activities which are collected within a provider’s patients safety evaluation system (“PSES”) and reported to a PSO become patient safety work product (“PSWP”). PSWP can be used for internal operations but:
 - Are not discoverable in state or federal proceedings and cannot be introduced into evidence
 - Protections can never be waived

Quality and Risk Implications (cont'd)

Patient Safety and Quality Improvement Act of 2005

- Information can be freely shared within a system and facilities which are owned, controlled or managed by corporate parent
- Parent can be included even if not a provider
- Joint venture parties can be included via contract and other measures
- PSOs can prepare protected benchmarking quality analyses and similar reports.

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