Provider-Based Status under Siege: Do the Benefits Justify the Costs of Compliance?

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I. WHAT IS PROVIDER-BASED STATUS AND WHEN DO REQUIREMENTS APPLY?

A. For Federal governmental payment purposes, a hospital may treat a subordinate facility either as part of the hospital, referred to as "provider-based," or as freestanding. The implications of provider-based status or freestanding status for Medicare (and in some instances Medicaid) payment, certification, coverage, billing, and practitioner supervision are significant.

B. Provider-based status generally refers to the relationship between a main provider and the three different types of provider-based facilities/organizations (hereinafter "facility"): (i) department of a provider—generally referred to as hospital outpatient departments; (ii) provider-based entity—examples include rural health clinics ("RHCs"), skilled nursing facilities ("SNFs"), and home health agencies ("HHAs"); and (iii) remote location of a hospital that furnishes inpatient services under the hospital's certification and Centers for Medicare & Medicaid Services' ("CMS") Certification Number ("CCN").

C. The Medicare/Medicaid provider-based status regulatory requirements (codified at 42 C.F.R. § 413.65) apply to a facility if the status of the facility as provider-based or freestanding affects: (i) Medicare or Medicaid payment amounts; (ii) the scope of benefits available to a Medicare beneficiary in or at the facility; and (iii) the deductible or coinsurance liability of a Medicare beneficiary in or at the facility.

D. Because of the financial impact of the treatment of a facility as provider-based, there are various efforts underway to control those costs. Additionally, providers are seeing increased regulatory scrutiny, interest and potential compliance concerns arising from certain failures to achieve or maintain provider-based compliance

II. SIGNIFICANCE OF PROVIDER-BASED STATUS.

A. Payment Implications. There are a variety of payment implications and differences between hospital provider-based and freestanding/non-hospital settings under the Medicare (and often Medicaid and commercial payor programs), including:

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1. Medicare generally pays a higher aggregate payment for diagnostic and therapeutic services furnished in the hospital outpatient department setting compared to the same services performed in other provider/supplier settings. This is generally true even though physician fees are reduced for professional services furnished in hospital outpatient departments (lower practice expense relative value units) in what is known as the "site of service differential." Thus, the total payment (facility fee plus reduced physician fee) is generally more for a service furnished in provider-based department of a hospital than for the same service furnished in a freestanding physician clinic.

    a. Hospital facility fees for outpatient department services may include use of the following: (i) hospital facilities, including the use of the emergency room; (ii) services of nurses, nonphysician anesthetists, psychologists, technicians, therapists and other aides; (iii) medical supplies, such as gauze, oxygen, ointments and other supplies used by physicians or hospital personnel in the treatment of outpatients; (iv) surgical dressings; (v) splints, casts, and other devices used for reduction of fractures and dislocations; (vi) prosthetic devices; and (vii) leg, arm, back and neck braces, trusses, and artificial legs, arms and eyes. *See* Medicare Benefit Policy Manual (Pub. 100-02), Chapter 6, Section 40.

2. Following a hospital acquisition, operating the acquired facility as a remote location of a main provider under the main provider's Medicare CCN rather than as a separate hospital may result in greater overall payment, depending on Medicare indirect medical education payment amounts and disproportionate share payment amounts to the acquiring hospital.

3. A hospital may count medical residents who train in hospital outpatient departments for purposes of Medicare direct graduate medical education payments and indirect medical education payments without regard to the requirements for counting residents' training time in non-provider settings.

4. Unless contracts specifically exclude them, all hospital outpatient departments will be included within the scope of a hospital's third-party payer contracts, but hospital-owned physician clinics will require separate contracts.

5. Hospitals may access discounted drug pricing through 340B program. Patients registered as outpatients at provider-based locations of hospitals eligible to participate in 340B may be included in the population that benefits from such discounts.

6. Historically, provider-based RHCs, SNFs, and HHAs received greater Medicare payment amounts than such facilities that were independent and not provider-based. The implementation of PPS methodologies has eliminated this payment advantage in many instances.

B. Coverage – Generally.

1. Medicare. For certain services, Medicare will only cover and pay if the services are performed in a hospital or other Medicare-certified setting, versus a non-certified, freestanding entity.

a. For example, Medicare only covers and pays for partial hospitalization services if provided in a hospital outpatient department or in a community mental health center. 42 U.S.C. § 1395x(s)(2)(B); 42 C.F.R. § 410.110.

2. Commercial. Commercial payers sometimes refuse to cover facility fees related to physician services furnished in hospital outpatient departments.

C. Practitioner Supervision (discussed in Section XI, infra).

D. Medicare Billing. Hospital services performed in outpatient departments are billed to Medicare contractors on form UB-04 (CMS-1450). Physician services performed in outpatient departments are billed to Medicare contractors on CMS-1500s claim forms. This is sometimes referred to as a "split bill." In comparison, services performed in a freestanding clinic only result in one bill. Physician services provided in a freestanding clinic are billed to Medicare contractors on form 1500s; there is no facility fee.

E. Certain Other Payment/Billing Implications of Provider-Based Status.

1. Prohibition on Hospital Outpatient Unbundling. The Medicare outpatient services unbundling rule prohibits Medicare payment for non-physician services to a hospital outpatient during an encounter by a provider or supplier other than the hospital, unless the services are furnished under an arrangement with the hospital. *See* 42 C.F.R. § 410.42.

2. Incident To Services. The Medicare rules expressly prohibit Medicare coverage of the services of physician-employed auxiliary personnel furnished to hospital outpatients as services "incident to" physicians' services. 42 C.F.R. § 410.26(b)(1). There is a related part B concept known as the "shared/split" service under which certain non-physician practitioners can have their services combined with a physician's services in order to generate a single service under the physician's CMS-1500. Shared/split services are permissible in the provider-based hospital outpatient department as well as the inpatient and emergency department settings. Medicare Claims Processing Manual (CMS Pub. 100-04), Ch. 12, Section 30.6.1.B.

F. Medicare Conditions of Participation.

1. The Medicare Conditions of Participation ("CoPs") for Hospitals apply to hospital outpatient departments, which must satisfy the requirements for medical staff, physical environment, and outpatient services. See 42 C.F.R. §§ 482.22, 482.41 and 482.54. These CoPs do not apply to freestanding physician clinics. As a result, hospital outpatient

departments generally are more costly to construct and operate than freestanding physician clinics.

2. In Survey & Certification Memorandum S&C-12-17-Hospitals published on February 17, 2012, by the CMS Office of Clinical Standards and Quality/Survey & Certification Group, CMS promulgated a new policy for practitioners ordering hospital outpatient services. This new policy generally provides that hospital outpatient services may be ordered and patients may be referred for hospital outpatient services by a practitioner who is: (i) responsible for the care of the patient; (ii) licensed in, or holds a license recognized in, the jurisdiction where he/she sees the patient; (iii) acting within the scope of his/her practice under State law; and (iv) authorized by the medical staff to order the applicable outpatient services under a written hospital policy that is approved by the governing body. This includes both practitioners who are on the hospital medical staff and who hold medical staff privileges that include ordering the services, as well as other practitioners who are not on the hospital medical staff but who satisfy the hospital's policies for ordering applicable outpatient services and for referring patients for hospital outpatient services. This policy interprets 42 C.F.R. § 482.54, the CoP governing outpatient services.

III. IMPLICATIONS OF THE BIPARTISAN BUDGET ACT AND IMPLEMENTATION

A. The Bipartisan Budget Act of 2015 was passed on November 2, 2015.

B. The legislation precludes payment under OPPS for any off-campus, provider-based clinics that had not provided any services prior to the date of the statute's enactment.

1. An exception applies for dedicated emergency departments.

C. CMS has implemented via Federal Register preamble certain policy considerations.

1. Other than for extraordinary circumstances, hospitals cannot relocate grandfathered, provider-based relocations.

2. CMS has created a new payment system that allows hospitals to bill for non-grandfathered sites on a CMS 1450, but pays them at a rate that is meant to be equivalent to the physician fee schedule rate.

D. The 21st Century Cures Act, enacted in December, 2016, allows some hospitals that had been in the process of establishing new provider-based clinics as of the date of enactment of the Bipartisan Budget Act to qualify for a "mid-build" exception to the statute's strictures. Applications for such status were due 60 days from the date of the enactment of the 21st Century Cures Act.

IV. PROVIDER-BASED STATUS REQUIREMENTS-GENERALLY.

A. The provider-based status requirements are codified at 42 C.F.R. § 413.65, and are further explained in Program Memorandum (Intermediaries) Transmittal A-03-030 (April 18, 2003), with an accompanying Sample Attestation Form.

B. The provider-based requirements generally apply for purposes of both Medicare and Medicaid program payments. Accordingly, Medicaid program payments for services performed in a facility subject to the provider-based requirements but failing to meet all such applicable requirements will not be made at Medicaid hospital rates unless the State revises its State plan to permit such payments. *See* 65 Fed. Reg. 18434, 18506 (April 7, 2000); 67 Fed. Reg. 49981, 50083 (August 1, 2002).

C. Since October 1, 2002, CMS has not required providers to obtain an affirmative provider-based determination from their CMS Regional Offices before treating a facility as provider-based for Medicare/Medicaid payment purposes. *See* 67 Fed. Reg. 49981, 50084-085 (August 1, 2002); Program Memorandum (Intermediaries) Transmittal A-03-030 (April 18, 2003). There is one possible exception to this general rule. The provider-based regulations include that off-campus departments that "provide physician services of a kind normally provided in a physician's office" are presumed to be freestanding unless determined to be provider-based. 42 C.F.R. § 413.65(b)(4). This provision has not been the subject of any formal interpretation by CMS or decisional law interpreting this "presumption." However, in the 2014 OPPS final rule in the context of a discussion about freestanding physician practices being converted to hospital off-campus outpatient departments, CMS affirmatively stated that it has not required hospitals to seek from CMS a determination of provider-based status since October 1, 2002. *See* 78 Fed. Reg. 74826, 75061 (December 10, 2013). Even for other facilities, however, there is some potential ambiguity as to the possible negative consequences for a hospital that does not obtain a positive provider-based determination for a facility and thereafter CMS determines that the facility does not satisfy the applicable provider-based requirements. *See* Section III.F.2.b. herein.

D. Facilities for which provider-based determinations are made include departments of a provider (outpatient departments), remote locations of a hospital, and satellite facilities.

E. Facilities for which provider-based determinations are not made: ASCs; comprehensive outpatient rehabilitation facilities; HHAs; SNFs (distinct part SNF integration conditions are codified at 42 C.F.R. § 483.5); hospices; inpatient rehabilitation units that are excluded from the inpatient PPS for acute hospital services; independent diagnostic testing facilities ("IDTFs") that furnish only services paid under a fee schedule; end stage renal disease facilities;

departments of providers that perform functions necessary for the successful operation of the provider but do not furnish services of a type for which separate payment could be claimed under Medicare or Medicaid (for example, laundry or medical records departments); ambulances; and RHCs affiliated with hospitals having 50 or more beds (independent RHCs and hospital-based RHCs with more than 50 beds are both paid based on an all-inclusive per-visit rate; an RHC that is provided-based to a hospital with less than 50 beds is eligible to receive an exception to the all-inclusive, per-visit payment limit). Further, CMS is indifferent to provider-based status in any other instance where the status of the facility as provider-based or freestanding will not affect Medicare payments to the facility. 65 Fed. Reg. 18434, 18506 (April 7, 2000) ("[I]t would not be either necessary or appropriate to make provider-based determinations with respect to facilities or organizations if by law their status (that is, provider-based or free-standing) would not affect either Medicare payment levels or beneficiary liability."). In the 2010 IPPS final rule CMS revised its policy with respect to clinical diagnostic laboratories owned by critical access hospitals ("CAHs"), requiring these facilities to meet the provider-based requirements. *See* 74 Fed. Reg. 43754, 43941 (August 27, 2009). In some instances, however, there may be an impact for Medicaid of being provider-based, but not Medicare. Generally, the voluntary attestation process is not available for these cases.

F. There are certain benefits to providers in seeking and receiving affirmative provider-based determinations.

1. Limit overpayments on a go-forward basis.

2. Limit overpayments on a retrospective basis. The applicable regulations contain a confusing discussion of the benefits of attesting in connection with potential incorrect payments. If a hospital does not submit an attestation for a facility and receive an affirmative provider-based determination and CMS determines that the facility does not satisfy all of the applicable provider-based requirements, the agency could attempt to recover the difference between total payments actually made to the hospital and total payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements for services at the facility for all cost reporting periods subject to reopening. 42 C.F.R. § 413.65(j)(1)(ii). If a hospital submits an attestation but CMS subsequently determines that the facility does not, in fact, satisfy the applicable provider-based requirements, Program Memorandum (Intermediaries) Transmittal A-03-030 states that CMS would not recover all past payments for periods subject to reopening. Instead, the agency would recover only the difference between the amount of payment that actually was made since the date the hospital submitted a complete attestation for a provider-based determination to its Medicare administrative contractor and the appropriate CMS Regional Office and the amount of payments that the agency estimates should have been made in the absence of compliance with the requirements during the time period.

   a. Program Memorandum (Intermediaries) Transmittal A-03-030 states in pertinent part: "If CMS subsequently discovers that the

facility for which an attestation has been made and approved in fact does not meet the provider-based rules, then CMS would not recover all past payments for periods subject to reopening, but instead would recover only the difference between the amount of payment that actually was made since the date the complete attestation for a provider-based determination was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements during that time period. For example, if a facility opens and begins billing as provider-based on October 1, 2002, the potential main provider submits an attestation on December 1, 2002, and the attestation is disapproved by CMS on February 1, 2003, then CMS will recover only the overpayments since December 1, 2002. . . . However, if that main provider had not submitted an attestation and CMS determined that the facility is not provider-based, CMS would recover the overpayment for the period beginning October 1, 2002" (Emphasis added). The phrase "approved in fact" is not explained and CMS does not apply the concept in its example.

b. The applicable Medicare regulation adds some more ambiguity to this point, as it provides that a hospital may bill and be paid for services furnished in a prospective provider-based facility from the date the hospital submits an attestation for the facility. The regulation provides: "*Temporary treatment as provider-based*. If a provider submits a complete attestation of compliance with the requirements for provider-based status for a facility or organization that has not previously been found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section, the provider may bill and be paid for services of the facility or organization as provider-based from the date it submits the attestation and any required supporting documentation until the date that CMS determines that the facility or organization does not meet the provider-based rules. If CMS subsequently determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that actually was made since the date the complete attestation of compliance with [the] provider-based requirements was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements. For purposes of this paragraph (k), a complete attestation of compliance with [the] provider-based requirements is one that includes all information needed to permit CMS to make a [provider-based determination]." 42 C.F.R. § 413.65(k) (Emphasis added).

c. Further, when a main provider attests and receives a positive provider-based determination, and subsequently a material change occurs in the relationship between the main provider and the facility, and the main provider properly reports the material change to CMS, then treatment of the facility as provider-based

would cease only with the date that the agency determines that the facility no longer qualifies for provider-based status. By contrast, a provider that does not submit a provider-based attestation, or obtains an affirmative determination but fails to report the subsequent material change, could face a recovery of the difference between provider-based and freestanding payment for all cost reporting periods subject to reopening. For example, if a main provider opens a facility and begins billing as provider-based on January 1, 2014, but does not submit an attestation and the facility does not meet all the applicable provider-based requirements, and CMS discovers on April 1, 2014, that the main provider is billing inappropriately as provider-based, the agency will recover overpayments since January 1, 2014. 42 C.F.R. § 413.65(l).

V. WHAT ARE HOSPITAL SERVICES FURNISHED "UNDER ARRANGEMENTS"?

A. Introduction.

1. In an "under arrangements" relationship, a hospital contracts with another entity to provide services to hospital patients. The service is provided by the contracted entity rather than by the hospital, but it is treated as a hospital service and billed by the hospital.

2. The contracted entity is paid a fee, often on a "per-service" basis, by the hospital. The hospital's agreement with the contracted entity must require the entity to look solely to the hospital for payment.

3. The contracted entity may be owned by physicians or other parties. In some cases, hospitals and physicians form a joint venture to own the contracted entity, but physician ownership is now rare because of the limitations under the Stark Law discussed in Section XI below.

4. Unlike the provider-based requirements, the under arrangements statutory, regulatory and manual requirements do not require that a vendor furnishing services under arrangements to hospital patients be integrated with the hospital.

5. In preamble commentary to the provider-based status regulations, CMS explained that the Medicare statute's under arrangements provision (42 U.S.C. § 1395x(w); Social Security Act 1861(w)) is intended to apply only to arrangements in which a provider obtains "specialized health care services that it does not itself offer, and that are needed to supplement the range of services that the provider does offer its patients." 67 Fed. Reg. 49981, 50091 (August 1, 2002). The Medicare statute (42 U.S.C. § 1395x(w)) and implementing Medicare regulations (42 C.F.R. § 409.3) are silent as to the limitation of under arrangements services to "specialized health care services."

B. Under arrangement services coverage and payment conditions (42 U.S.C. § 1395x(w) (definition of "under arrangements"); 42 U.S.C. § 1395x(b)(3)

(Medicare coverage for services furnished under arrangements); 42 C.F.R. § 409.3; Medicare General Information, Eligibility and Entitlement Manual (Pub. 100-01), Chapter 5, § 10.3).

1. Payment of the hospital must discharge the liability of the beneficiary or any other person to pay for the service.

2. The hospital cannot "merely serve as a billing mechanism" for the performing entity but rather "must exercise professional responsibility over the arranged-for services." (Medicare General Information, Eligibility and Entitlement Manual, CMS. Pub. 100-01, Chapter 5, §10.3).

3. The hospital's professional supervision over arranged-for services requires application of many of the same quality controls as are applied to services furnished by salaried employees.

4. The hospital accepts the patient for treatment in accordance with its admission policies.

5. The hospital maintains a complete and timely clinical record on the patient, including diagnoses, medical history, physician's orders and progress notes relating to all services received.

6. The hospital maintains liaison with the patient's attending physician concerning the patient's progress and the need for any revised orders.

7. The hospital's utilization review and quality assurance programs apply to the service.

8. These conditions do not expressly include Medicare certification of an entity that only furnishes services under arrangements and does not itself bill Medicare. Entities that submit claims directly to Medicare are required to enroll. Mobile IDTFs that furnish diagnostic services are required to enroll in Medicare and with one exception must bill Medicare directly for technical component diagnostic tests they perform; mobile IDTFs that furnish diagnostic services under arrangements with hospitals must enroll but are not required to bill Medicare directly for such services. 42 C.F.R. § 410.33(g)(17).

C. Additional possible indicia of hospital exercising the requisite professional responsibility over arranged-for services (a/k/a Dennis Barry's Top Ten List).[2]

1. An individual is registered as a hospital patient prior to receiving services from the under arrangements entity.

2. The individual receives the same notices and signs the same forms as a patient receiving services directly from the hospital.

[2] List first published in *Dennis Barry's Reimbursement Advisor*, Apr. 2007.

3. The physician ordering services to be furnished by the under arrangements entity is on the hospital's medical staff and the services ordered are within the physician's scope of privileges.

4. The hospital confirms that the under arrangements entity is Medicare-certified and properly licensed.

5. The hospital has a written contract with the under arrangements entity that details the hospital's professional responsibility obligations.

6. The hospital's administrator is responsible for the services furnished by the under arrangements entity, reviews the entity's policies and procedures at the beginning of the relationship and verifies that such policies and procedures conform with the hospital's policies and procedures and The Joint Commission requirements for services provided under contractual arrangements (The Joint Commission requirements are discussed below).

7. If the under arrangements entity furnishes the services outside of the hospital, the hospital's administrator responsible for the services should visit the entity's premises and review with a manager of the entity compliance with appropriate quality standards.

8. The entire medical record of services performed at the entity and furnished to hospital patients under arrangements is created and retained in a manner consistent with hospital policies and procedures and applicable Joint Commission standards, and a legible copy of that record is transmitted to the hospital in the same time frames as services furnished directly by the hospital.

9. The under arrangements entity completes incident reports in a timely fashion whenever such a report would be required if the event occurred in the hospital and transmits such reports to the hospital upon completion.

10. The utilization review, infection control, and any other relevant hospital committees review care furnished to hospital patients by the under arrangements entity on the same basis as they review services furnished directly by the hospital.

D. Medicare definition of "outpatient" (42 C.F.R. § 410.2).

1. "Outpatient means a person who has not been admitted as an inpatient but who is registered on the hospital . . . records as an outpatient and receives services (rather than supplies alone) directly from the hospital."

2. A hospital that bills for outpatient services furnished under arrangements must ensure that the patient is properly registered as a hospital outpatient.

3. If a hospital registers an individual as an outpatient, does not furnish any services directly to the person but renders the proper professional

supervision over services furnished under arrangements, the individual should be considered an outpatient under present Medicare requirements, although CMS has not directly addressed this issue.

E. Conditions of Participation for Hospitals.

1. A hospital furnishing services under arrangements to its patients must ensure that the services are furnished in compliance with applicable Medicare requirements, including the Conditions of Participation for Hospitals, and the condition specific to the particular service, for example, outpatient services (42 C.F.R. § 482.54), radiologic services (42 C.F.R. § 482.26), and surgical services (42 C.F.R. § 482.51).

2. A hospital's governing body is responsible for hospital services furnished directly or under contracts. The governing body must ensure that an under arrangements entity furnishes services that permits the hospital to comply with all applicable conditions of participation and standards for the contracted services. The governing body must ensure that the services performed under a contract are provided in a safe and effective manner. The hospital must maintain a list of all contracted services, including the scope and nature of the services provided. 42 C.F.R. § 482.12(e).

F. The Joint Commission standards for under arrangements services, Comprehensive Accreditation Manual for Hospitals: The Official Handbook (2013), Leadership Standard (LD) 04.03.09.

1. Standard LD.04.03.09–"Care, treatment, and services provided through contractual agreement are provided safely and effectively."

2. Rationale–"The same level of care should be delivered to patients regardless of whether services are provided directly by the hospital or through contractual agreement. Leaders provide oversight to make sure that care, treatment, and services provided directly are safe and effective. Likewise, leaders must also oversee contracted services to make sure that they are provided safely and effectively."

3. Application–"The only contractual agreements subject to the requirements in Standard LD.04.03.09 are those for the provision of care, treatment and services provided to the hospital's patients. This standard does not apply to contracted services that are not directly related to patient care. In addition, contracts for consultation or referrals are not subject to the requirements in Standard LD.04.03.09. However, regardless of whether or not a contract is subject to this standard, the actual performance of any contracted service is evaluated at the other standards in this manual appropriate to the nature of the contracted service."

4. Certain elements of performance.

a. Clinical leaders and medical staff have an opportunity to provide advice about the sources of clinical services that are to be provided through contractual agreement.

b. The hospital describes, in writing, the nature and scope of services provided through contractual agreements. (note: documentation required)

c. Designated leaders approve contractual agreements. (note: documentation required)

d. Leaders monitor contracted services by establishing expectations for the performance of the contracted services. (note: In most cases, each licensed independent practitioner providing services through a contractual agreement must be credentialed and privileged by the hospital using their services.)

e. Leaders monitor contracted services by communicating the expectations in writing to the provider of the contracted services.

f. Leaders monitor contracted services by evaluating these services in relation to the hospital's expectations.

g. Leaders take steps to improve contracted services that do not meet expectations.

h. When contractual agreements are renegotiated or terminated, the hospital maintains the continuity of patient care.

G. The Joint Commission standards for under arrangements services, Comprehensive Accreditation Manual for Hospitals: The Official Handbook (2013), The Accreditation Process (ACC), Contracted Services. "The Joint Commission evaluates an organization's management and oversight of the quality of care, treatment, and services (for which there are Joint Commission standards) provided under contractual arrangements. The Joint Commission reserves the right to evaluate, as part of its survey, the care, treatment, and services provided by another organization or provider on behalf of the applicant organization. It may survey performance issues between the contracted organization and the applicant organization, regardless of the accreditation decision of the contracted organization. The Joint Commission also surveys care, treatment, and services provided on site under contract."

H. Hospital coverage requirements and under arrangements services.

1. Hospital inpatient services (42 U.S.C. § 1395x(b)(3)). The Medicare statute's definition of "inpatient hospital services" provides, in part, that these services include "diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements." A 1979 Blue Cross Association administrative bulletin prohibited coverage for certain services furnished under arrangements to hospital inpatients: coronary intensive care, pharmacy drugs, central supply items, IV solutions, and operating rooms.

2. Hospital outpatient diagnostic services (42 C.F.R. § 410.28; Medicare Benefit Policy Manual (Pub. 100-02), Chapter 6, Section 20.4). The Medicare regulation states that hospital outpatient diagnostic services may be furnished by a hospital or under arrangements and either in the hospital, in a provider-based department, or in a nonhospital location under arrangements.

3. Hospital outpatient therapeutic services incident to a practitioner's service (42 C.F.R. § 410.27; Medicare Benefit Policy Manual (Pub. 100-02), Chapter 6, Section 20.5). The Medicare regulation describes that hospital outpatient therapeutic services incident to a practitioner's services may be furnished by a hospital either directly or under arrangements but that all such services must be furnished in the hospital or in a department of the hospital. The Medicare manual includes similar language.

4. Routine under arrangements services. The FY 2012 IPPS final rule provided that therapeutic and diagnostic services are the only services that can be furnished under arrangements outside of the hospital to Medicare beneficiaries and be recognized for Medicare payment purposes. Routine services (bed, board, nursing, and other related services) must be furnished in the hospital. Preamble language indicates that routine services furnished under arrangement outside the hospital are not recognized for Medicare payment purposes. 76 Fed. Reg. 51476, 51711-714 (August 18, 2011). CMS expressed concern that IPPS-excluded hospitals were obtaining routine services, including ICU services, under arrangements from IPPS hospitals. In the FY 2013 IPPS final rule, CMS extended the compliance date for this requirement to cost reporting periods beginning on or after October 2013. 77 Fed. Reg. 53258, 53453-53455 (August 31, 2012). CMS further delayed application of this new policy until services furnished on or after January 1, 2015. *See* FY 2014 IPPS final rule, 78 Fed. Reg. 50496, 50744 (August 19, 2013).

5. Other hospital outpatient therapeutic services.

    a. X-ray therapy and other radiation therapy services (42 C.F.R. § 410.35).

        i. Regulation does not expressly cover x-ray therapy and other radiation therapy services furnished under arrangements.

        ii. No express location requirement. These services are subject to the location requirements of 42 C.F.R. § 410.27, however, as further discussed in Section X below.

b. Outpatient physical therapy services (42 C.F.R. § 410.60).

i. Regulation expressly provides that outpatient physical therapy services may be provided directly or under arrangements.

ii. No express location requirement.

VI. PROVIDER-BASED STATUS REQUIREMENTS (42 C.F.R. § 413.65(d) AND (e)).

A. Requirements applicable to both on-campus and off-campus (located more than 250 yards from the main provider's main buildings) facilities (42 C.F.R. § 413.65(d)).

1. Licensure. The department of the provider, remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except in areas where the State requires a separate license, or in States where State law does not permit licensure of the provider and the prospective provider-based facility under a single license. Note that State licensure requirements often include physical plant conditions.

a. In a 2012 decision, the Department of Health and Human Services' Departmental Appeals Board sustained an administrative law judge's determination that the denial by CMS of provider-based status for three off-campus facilities affiliated with a hospital was consistent with the provider-based status requirements. CMS had denied provider-based status to the three facilities as they were not included on the hospital's license. *Union Hospital, Inc.*, DAB Dec. No. 2463 (June 11, 2012).

2. Clinical services. The clinical services of the facility seeking provider-based status and the main provider are integrated as evidenced by the following:

a. Professional staff of the facility have clinical privileges at the main provider.

b. The main provider maintains the same monitoring and oversight of the facility as it does for any other department of the provider.

c. The medical director of the facility maintains a reporting relationship with the chief medical officer or other similar official of the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the main provider and the chief medical officer or other similar official of the main provider, and is under the same type of supervision and accountability as any other director, medical or otherwise, of the main provider.

d. Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility,

including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility and the main provider.

e. Medical records for patients treated in the facility are integrated into a unified retrieval system (or cross reference) of the main provider.

f. Inpatient and outpatient services of the facility and the main provider are integrated, and patients treated at the facility who require further care have full access to all services of the main provider and are referred when appropriate to the corresponding inpatient or outpatient department or service of the main provider.

3. Financial integration. The financial operations of the facility are fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility. The costs of a facility that is a hospital department are reported in a cost center of the provider. Costs of a provider-based facility other than a hospital department are reported in the appropriate cost center(s) of the main provider. The financial status of any provider-based facility is incorporated and readily identified in the main provider's trial balance.

4. Public awareness. The facility seeking status as a department of a provider, a remote location of a hospital, or a satellite facility is held out to the public and other payers as part of the main provider. When patients enter the provider-based facility, they are aware that they are entering the main provider and are billed accordingly. This has been an area of considerable Fiscal Intermediary/MAC and Regional Office attention. There is a considerable body of informal experience and practice, on a Region-by-Region basis, about how hospitals much satisfy this requirement.

5. Obligations of hospital outpatient departments and hospital-based entities. Hospital outpatient departments and hospital-based entities are required to satisfy certain provider-based obligations included in Section 413.65(g) (discussed further below).

B. Additional provider-based requirements applicable to off-campus facilities (42 C.F.R. § 413.65(e)).

1. Operation under the ownership and control of the main provider. The facility seeking provider-based status is operated under the ownership and control of the main provider, as evidenced by the following:

a. The business enterprise that constitutes the facility is 100 percent owned by the provider.

b. The main provider and the facility seeking status as a department of the provider, a remote location of a hospital, or a satellite facility have the same governing body.

c. The facility is operated under the same organizational documents as the main provider. For example, the facility must be subject to common bylaws and operating decisions of the governing body of the provider where it is based.

d. The main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies (such as fringe benefits or code of conduct), and final approval for medical staff appointments in the facility.

2. Administration and supervision. The reporting relationship between the facility seeking provider-based status and the main provider must have the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its existing departments, as evidenced by compliance with all of the following requirements:

a. The facility is under the direct supervision of the main provider.

b. The facility is operated under the same monitoring and oversight by the provider as any other department of the provider, and is operated just as any other department of the provider with regard to supervision and accountability. The facility director or individual responsible for daily operations at the entity–

i. Maintains a reporting relationship with a manager at the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and its existing departments; and

ii. Is accountable to the governing body of the main provider in the same manner as any department head of the provider.

c. The following administrative functions of the facility are integrated with those of the provider where the facility is based: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services. Either the same employees or group of employees handle these administrative functions for the facility and the main provider, or the administrative functions for both the facility and the entity are either: contracted out under the same contract agreement; or handled under different contract agreements, with the contract of the facility being managed by the main provider.

3. Location. There are different methods of proving that the off-campus facility is located in close enough proximity to the main provider to be provider-based.

a. 35 mile rule. The facility is located within a 35-mile radius of the campus of the hospital that is the potential main provider. The 35 mile rule is a straight-line test, not a road-driven test.

b. 75/75 alternative. The facility demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria and demonstrates that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12-month period–

i. At least 75 percent of the patients served by the facility reside in the same zip code areas as at least 75 percent of the patients served by the main provider; and

ii. At least 75 percent of the patients served by the facility who required the type of care furnished by the main provider received that care from that provider.

c. Disproportionate share alternative.

d. Children's hospital neonatal intensive care unit exception.

e. A facility may satisfy the location condition only if it is located in the same State as the main provider or, when consistent with the laws of both States, in adjacent States.

VII. PROVIDER-BASED STATUS OBLIGATIONS (42 C.F.R. § 413.65(g)).

A. EMTALA.

1. On-campus outpatient departments. The EMTALA screening and stabilization or transfer obligations apply to a hospital on-campus facility treated as an outpatient department. These obligations include the general EMTALA requirements, signage/posting requirements, maintaining a list of on-call physicians, maintaining a central log and records of transfers to and from the facility, and reporting improper transfers.

2. Off-campus outpatient departments.

a. The EMTALA screening and stabilization or transfer obligations apply to a hospital off-campus facility treated as an outpatient department only if it is considered a "dedicated emergency department" as defined at 42 C.F.R. § 489.24. A "dedicated emergency department" is defined as a hospital facility that meets at least one of three conditions: (i) the facility is licensed by the State in which it is located under applicable State law as an emergency room or emergency department; (ii) the facility is held

out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or (iii) during the calendar year immediately preceding the calendar year in which a determination is made, based on a representative sample of patient visits that occurred during that calendar year, the facility provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment. An off-campus dedicated emergency department is required to comply with the same EMTALA requirements as on-campus outpatient departments.

b. An outpatient department that is not a "dedicated emergency department" is not subject to EMTALA. For a hospital outpatient department that is not a "dedicated emergency department," if an individual would present for emergency care, it would be appropriate for the department to call an emergency medical service if it is incapable of treating the patient, and to furnish whatever assistance it can to the individual while awaiting the arrival of emergency medical service personnel. Hospitals are required to have appropriate protocols in place for dealing with individuals who come to off-campus facilities seeking emergency care. 68 Fed. Reg. 53221, 53248-49 (Sept. 9, 2003).

3. Provider-based entities. The EMTALA obligations do not apply to provider-based entities (*e.g.,* RHCs) that are located on or off a hospital's campus. Provider-based entities are not part of the hospital; they are not included under the certification and provider number of the main provider hospital. If an individual presents for emergency care to an on-campus provider-based entity, may be appropriate for the entity to call the emergency medical service if it is incapable of treating the patient, and to furnish whatever assistance it can to the individual while awaiting the arrival of emergency medical service personnel. The hospital on whose campus the provider-based entity is located should not incur an EMTALA obligation with respect to the individual. 68 Fed. Reg. 53222, 53249-250 (September 9, 2003).

B. Physician billing. Physician services performed for patients in hospital outpatient departments or hospital-based entities (other than rural health clinics) must be billed with the correct Medicare site-of-service indicator (POS 22, outpatient department, and not POS 11, physician clinic). CMS Transmittal 2613, issued on December 14, 2012, includes guidance on POS codes, partly in response to the request by the Office of Inspector General ("OIG") that CMS strengthen its education process. If physicians incorrectly include POS 11 on their claims for payment for services furnished in a hospital outpatient department, this error could jeopardize the hospital outpatient department's provider-based status.

C. Provider agreement. Hospital outpatient departments must comply with all the terms of the hospital's provider agreement.

D. Non-discrimination. Physicians working in hospital outpatient departments or hospital-based entities are obligated to comply with the non-discrimination provisions codified at 42 C.F.R. § 489.10(b).

E. Treat all Medicare beneficiaries as hospital outpatients. Hospital outpatient departments must treat all Medicare beneficiaries, for billing purposes, as hospital outpatients. The department cannot treat some Medicare beneficiaries as hospital outpatients and others as physician office patients. Note that this rule does allow commercial beneficiaries to be treated as physician office patients.

F. Three-day payment window rule. Nondiagnostic services and diagnostic tests furnished in a hospital outpatient department or hospital-based entity may be subject to the Medicare three-day payment window rule if the patient is subsequently admitted to the hospital as an inpatient within the requisite time period. The three-day payment window rule also applies to hospital wholly owned or wholly operated nonprovider-based entities.

G. Written notice to beneficiary of liability. For Medicare beneficiaries who receive treatment in an off-campus hospital outpatient department or hospital-based entity (and the treatment is not subject to the EMTALA requirements), the hospital is required to provide written notice to each beneficiary, before the delivery of services, of the amount of the beneficiary's potential liability (coinsurance liability for the outpatient visit and for the physician service). If the hospital cannot determine the exact type and extent of care needed, the hospital may furnish a written notice to the patient explaining that the beneficiary will incur a coinsurance liability to the hospital that he/she would not incur if the facility was not provider-based. The hospital may furnish an estimate based on typical or average charges for visits to the facility, while stating that the patient's actual liability will depend upon the actual services furnished by the hospital.

H. Health and safety rules. Hospital outpatient departments must meet applicable hospital health and safety rules. Specifically, "[t]he hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association" (42 C.F.R. § 482.41(b)(1)(i)). In Survey and Certification Memorandum S&C-11-05-LSC to State Survey Agency Directors from the Director, CMS Survey and Certification Group (December 17, 2010, revised February 18, 2011), CMS revised the Medicare State Operations Manual, Appendices A, I and W, to expressly describe the specific Life Safety Code requirements that apply to various types of provider-based facilities.

VIII. PROVIDER-BASED MANAGEMENT CONTRACTS PRINCIPLE, "UNDER ARRANGEMENTS" PRINCIPLE, AND JOINT VENTURES PRINCIPLE.

A. Management contracts principle (42 C.F.R. § 413.65(h)).

1. This principle applies only to off-campus facilities subject to the provider-based requirements that are operated under management contracts. The special requirements do not apply for management contracts relating to operation of on-campus facilities. The regulations do not define a "management contract." A turn-key arrangement where many operational responsibilities are contracted to a third party may be

considered a management contract regardless of how it is characterized by the parties.

2. The facility must satisfy the applicable provider-based requirements and obligations.

3. In addition, the main provider (or an organization that also employs the main provider's staff and that is not the management company) employs the staff of the facility who are directly involved in the delivery of patient care, except for management staff and staff who furnish patient care services of a type that would be paid for by Medicare under a fee schedule established by regulations under 42 C.F.R. Part 414. Other than staff that may be paid under such a Medicare fee schedule (*e.g.*, physicians, physician assistants, CRNAs), the main provider may not obtain staff who deliver patient care from the management company as "leased employees" (personnel who are actually employed by the management company but provide services under a staff leasing arrangement). A main provider may obtain staff from a third party (other than the management company) for the off-campus facility only if it also obtains staff for its main location from the same third party.

4. The administrative functions of the facility are integrated with those of the main provider.

5. The main provider has significant control over the operations of the facility.

6. The main provider itself is party to the management contract, rather than the contract being held by a parent organization that has control over both the main provider and the facility.

B. "Under arrangements" principle (42 C.F.R. § 413.65(i)). Provider-based status is not permitted for any facility or organization that provides all of its patient care services under arrangements. Hospitals may not contract out entire departments and claim them as provider-based. (*See* 65 Fed. Reg. 18434, 18518-519 (April 7, 2000)). Note that, unlike the management contracts and joint venture principles, no distinction is made concerning whether the facility or organization is on-campus or off-campus.

C. Joint ventures principle (42 C.F.R. § 413.65(f)).

1. In order for a facility operated as a joint venture to be considered provider-based, the facility must –

   a. Be partially owned by at least one provider;

   b. Be located on the main campus of a provider who is a partial owner (regardless of whether or not it is a majority owner);

   c. Be provider-based to that one provider on whose campus the facility is located; and

d. Meet all the applicable provider-based requirements.

2. CMS has not expressly defined what it means to be "operated as a joint venture" for purposes of implicating the joint ventures principle.

IX. MEDICARE ENROLLMENT/CERTIFICATION.

A. A hospital that desires to add a department must submit to its Medicare administrative contractor a Medicare Enrollment Application Form CMS-855A adding the facility as a new practice location. A Medicare administrative contractor's acceptance of the 855A does not signify that the contractor has determined that the facility satisfies the applicable provider-based status requirements.

B. The CMS Regional Office Division of Financial Management makes determinations regarding provider-based and freestanding designation. *See* Medicare State Operations Manual, Chapter 2, § 2004. The State survey agency will determine whether a hospital's prospective remote location of a hospital will be considered part of the hospital or must be certified as a separate hospital. "A hospital may establish an additional hospital facility so organizationally or geographically separate as to make it impossible to operate as a multi-campus hospital. Each location of a single hospital must meet the applicable CoPs. A certification of noncompliance at the CoP level at any of the hospital locations affects the certification of the hospital as a whole. Consequently, when noncompliance at the CoP level is found, the hospital will either be denied participation or terminated from participation in the Medicare/Medicaid program. . . . [A]ll locations of a single hospital must comply with applicable State licensure laws. When it is determined that any of the hospital locations does not comply with State licensure laws, the hospital as a whole will either be denied participation or terminated from participation in the Medicare/Medicaid program." Medicare State Operations Manual, Chapter 2, § 2024.

C. State Survey and Certification Memorandum S&C-09-08, Center for Medicaid and State Operations/Survey and Certification Group (October 17, 2008).

1. In this memorandum CMS explains that when a hospital adds a new remote location, "[w]hether or when a survey of the new location is conducted *generally* will not affect the timing of when Medicare payments for services at the new site begin, since creation/acquisition of the off-site location is under the hospital's or CAH's [Critical Access Hospital] existing provider agreement. Although CMS has the authority to conduct a survey of the expanded portion of the hospital/CAH, a survey may not be necessary if the provider furnishes the RO [Regional Office] with sufficient information to make a determination about its proposed expansion, either at the time of its initial request or subsequently. . . . Generally, CMS will require a survey where new locations provide inpatient or surgical services, or, in the case of an acquisition of an existing participating provider, where the RO has concerns about that provider's compliance with Medicare's health and safety standards. . . . In the case of an accredited, deemed hospital or CAH that creates or acquires an off-site facility for which it seeks provider-based or satellite status, the AO

[Accrediting Organization] may enter into an agreement with the provider/supplier to "extend" the hospital's or CAH's accreditation to the expanded facility(ies). In such cases, CMS expects the AO to conduct a survey of the facilities covered by the extension agreement within six months of the date of the agreement. . . . If the RO has specific concerns about the expanded facility's compliance with health and standards, however, it may request an earlier survey date by the AO and/or authorize a SA [State Agency] validation survey" (Emphasis in original).

2. In this memorandum CMS also describes the implications of an accredited hospital acquiring another accredited hospital and operating the acquired hospital facility at the same location as a remote location of the acquiring hospital. CMS considers that the acquiring hospital has assumed/incorporated the acquired hospital's provider agreement (with the potential successor liability) but that the acquired hospital's CCN is retired and only the acquiring hospital's CCN is used for services furnished in the remote location. The memorandum goes on to provide that "[t]here is no requirement for a new survey post-CHOW [Change of Ownership] by the AO, although the RO has the discretion to authorize an SA validation survey if the RO has concerns about the acquired provider's compliance with Medicare's health and safety standards."

3. CMS also indicates in this memorandum that if the acquiring provider does not assume the provider agreement of the acquired hospital, "The AO of the new owner may not extend accreditation to the newly acquired facility under this circumstance. The RO informs the provider that a survey of the acquired facility(ies) will be necessary and that it may not bill Medicare for services provided at the proposed expansion location until a survey is conducted and a compliance determination is made that all pertinent Federal requirements have been met. The AO may conduct a new accreditation survey of the acquired entity only after the CHOW has occurred."

D. State Survey and Certification Memorandum S&C-13-60-ALL, Center for Medicaid and State Operations/Survey and Certification Group (September 6, 2013).

1. CMS reiterates in this memorandum that a remote location or satellite facility "must be of the same type of hospital as the main campus."

2. CMS also explains that if an acquiring hospital rejects assignment of an acquired hospital's Medicare provider agreement and the acquiring hospital intends to operate the acquired facility as a remote location, the acquiring hospital is not eligible for Medicare payment for services at the prospective remote location until the remote location has completed a process analogous to that applied to an initial application for Medicare enrollment. The acquiring hospital must notify CMS that it is rejecting assignment of the acquired hospital's provider agreement and that it is creating a provider-based remote location. The acquiring hospital cannot treat this transaction merely as a change of information and provide notice to CMS through submission of an 855A of its addition of a new

practice location. The remote location must undergo a full certification survey of all applicable Medicare CoPs in the same way as would a prospective hospital applying for initial enrollment in Medicare. If the acquiring hospital is deemed to meet the CoPs through accreditation, the accreditation organization cannot extend the accreditation of the acquiring hospital to the prospective remote location; instead, the accreditation agency must conduct a full accreditation survey of the facility. The survey by the accreditation agency may not be scheduled and conducted until the acquisition is complete, the Medicare administrative contractor has completed its review of the Form 855A and made a recommendation for approval to the CMS Regional Office, and the remote location is fully operational and providing services to patients. The effective date for participation of the remote location and payment for any Medicare services furnished therein is determined under the same procedure that would have been used if the acquiring hospital had not included the acquired facility as a remote location.

E. *Mission Regional Hospital Medical Center v. Centers for Medicare and Medicaid Services*, Dec. No. CR2458 (November 2, 2011).

1. This case is relevant to hospitals that acquire other hospitals and seek to operate the acquired hospitals as provider-based inpatient remote locations.

2. Mission Regional Hospital Medical Center acquired the assets of another Medicare-participating hospital, South Coast Medical Center. The acquiring hospital declined to accept the acquired hospital's provider agreement (with its potential successor liability). Effective the same date the acquiring hospital sought to add to its CCN the acquired hospital as an inpatient remote location under the provider-based status requirements. CMS refused to recognize the addition of the acquired hospital as an inpatient remote location of the acquiring hospital until the remote location was successfully surveyed for Medicare certification purposes. CMS considered the acquiring hospital's refusal to accept the acquired hospital's provider agreement as a voluntary termination of the acquired hospital, thus necessitating a full Medicare survey of the previously-certified acquired hospital as a prerequisite to billing Medicare for services furnished in the facility. CMS notified the acquiring hospital that it could not properly bill Medicare for services furnished in the former acquired hospital until the State survey agency or a Medicare deemed accrediting organization completed a Medicare certification survey and CMS determined that all applicable Medicare requirements have been met. The Departmental Appeals Board granted CMS's motion for summary judgment, holding that the former acquired hospital facility did not meet all Medicare requirements until it was successfully surveyed for Medicare certification purposes, and thus, the acquiring hospital could not properly bill Medicare for services performed in its inpatient remote location until following a successful survey.

F. Effective July 15, 2010, The Joint Commission began accrediting hospitals in accordance with their CCNs. This means that there must be a one-to-one match

between a Joint Commission accreditation award and a hospital CCN. Accordingly, when a hospital participates in Medicare as a multi-campus hospital with multiple inpatient locations, the hospital must have one governing body, one unified medical staff and one nursing staff for all locations.

X. 340B DRUG DISCOUNT PROGRAM AND PROVIDER-BASED REQUIREMENTS.

A. The Veterans Health Care Act of 1992, § 602, enacted section 340B of the Public Health Service Act. Section 340B implements a drug pricing program under which manufacturers sell covered outpatient drugs to "Covered Entities." Participation in the 340B Drug Discount Program results in significant savings of between 20 and 50 percent on the cost of pharmaceuticals for safety net providers. "Covered Entities" historically included federally qualified health centers and disproportionate share hospitals ("DSH"), to name a few.

B. In the Patient Protection and Affordable Care Act of 2010 ("PPACA"), § 7101, Congress amended the 340B Drug Discount Program to increase the types of hospitals that are eligible to participate in the program and receive discount drugs. Children's hospitals, critical access hospitals ("CAHs"), rural referral centers ("RRCs") and sole community hospitals ("SCHs") now may qualify as "Covered Entities" and participate.

C. Provider-based departments of these Covered Entities may also participate in the 340B Drug Discount Program if they satisfy certain conditions. In a September 19, 1994 notice (59 Fed. Reg. 47884), the Health Resources and Services Administration ("HRSA") described that in order for a DSH outpatient department to participate in the 340B Drug Discount Program, an appropriate hospital official must attest to the following: (i) the 340B eligible outpatient clinic is an integral part of the hospital; and (ii) the outpatient facility is reimbursable on the hospital's most recently-filed cost report.

D. Notwithstanding some proposed guidance to the contrary, HRSA has indicated that an outpatient department must have been included on a hospital's most recently-filed Medicare cost report before it can be considered for participation in the 340B Drug Discount Program.

XI. MEDICARE SUPERVISION REQUIREMENTS FOR HOSPITAL OUTPATIENT THERAPEUTIC SERVICES AND SUPPLIES INCIDENT TO A PHYSICIAN'S OR CERTAIN NONPHYSICIAN PRACTITIONER'S SERVICE AND DIAGNOSTIC SERVICES FURNISHED TO OUTPATIENTS.

A. Outpatient services and supervision requirement – generally.

1. Supervision requirements apply only to hospital outpatient services and not inpatient services, at least for now.

2. Services excluded from hospital outpatient services coverage requirements otherwise applicable to hospital therapeutic services include the following. Medicare Benefit Policy Manual, Chapter 6, § 20.

   a. Physical therapy, speech-language pathology or occupational therapy services when they are furnished "as therapy" meaning under a therapy plan of care. *See* Medicare Benefit Policy Manual, Chapter 15, §§ 220 and 230.

   b. Services that are covered and paid under the End Stage Renal Disease Prospective Payment System. *See* Medicare Benefit Policy Manual, Chapter 11.

3. Outpatient therapeutic services – generally.

   a. Therapeutic services are all nondiagnostic services, including but not limited to the services listed in the Medicare statute at Section 1861(s)(2)(B) [42 U.S.C. § 1395x(s)(2)(B)] as incident to the services of physicians.

   b. Therapeutic services aid the physician in the treatment of a patient.

   c. Therapeutic services and supplies that hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) that are incident to the services of physicians and, effective January 1, 2010, to certain nonphysician practitioners ("NPPs") in the treatment of patients. 42 U.S.C. § 1395x(s)(2)(B); 42 C.F.R. § 410.27; Medicare Benefit Policy Manual, Chapter 6, § 20.5.

   d. Hospital outpatient therapeutic services must be performed in the hospital or in hospital provider-based departments to be covered for Medicare payment purposes. 42 C.F.R. § 410.27(a)(1)(iii).

   e. Hospital outpatient therapeutic services must be performed under the direct supervision (or other level of supervision as directed by CMS for the particular service) of a physician or appropriate NPP, subject to certain conditions.

   f. Hospital outpatient services must be performed in accordance with applicable State law. 42 C.F.R. § 410.27(a)(1)(v), as added in the 2014 OPPS final rule (78 Fed. Reg. 74826 (December 10, 2013)).

4. Outpatient diagnostic services – generally.

   a. A hospital outpatient diagnostic service is an examination or procedure to which a patient is subjected, or that is performed on materials derived from a hospital outpatient, in order to obtain information to aid in the assessment of a medical condition or the

identification of a disease. 42 U.S.C. § 1395x(s)(2)(C); 42 C.F.R. § 410.28; Medicare Benefit Policy Manual, Chapter 6, § 20.4.

b. Hospital outpatient diagnostic services must be furnished within the hospital or in a provider-based department, or provided by another entity in a non-hospital facility and billed by the hospital under arrangements.

5. Hospital outpatient therapeutic services incident to a physician's/NPP's service and diagnostic services supervision requirements.

a. The supervision requirements for outpatient therapeutic services furnished incident to a physician's/NPP's service and diagnostic services requirements are not included in the Medicare statute. *See* 42 U.S.C. § 1395x(s)(2)(B) (therapeutic) and 42 U.S.C. § 1395x(s)(2)(C) (diagnostic).

b. These supervision requirements were originally included in the Medicare manuals (Medicare Intermediary Manual § 3112.4 – therapeutic; Medicare Carriers Manual § 2050 – diagnostic).

c. In the 2000 OPPS final rule, the Health Care Financing Administration ("HCFA", the predecessor to CMS) codified these supervision requirements in the federal regulations (42 C.F.R. § 410.27 – therapeutic; and 42 C.F.R. § 410.28 – diagnostic).

B. Supervision requirements for hospital outpatient therapeutic services incident to a physician's/NPP's service (42 C.F.R. § 410.27). Medicare Part B pays for hospital therapeutic services and supplies furnished incident to a physician or certain NPP's (clinical psychologist, licensed clinical social worker, physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse-midwife) service, which are defined as all services and supplies furnished to hospital outpatients that are not diagnostic tests and that aid the practitioner in the treatment of the patient, including drugs and biologicals that cannot be self-administered, provided the following conditions are met:

1. The services are furnished by or "under arrangements" by the hospital.

2. The services are an integral although incidental part of a practitioner's services.

3. The services are performed in the hospital or in a department of the hospital.

4. The services are provided under the direct supervision (or other level of supervision as specified by CMS for the particular service) of a practitioner, subject to the following requirements:

    a. For services furnished in the hospital or in an outpatient department of the hospital (both on-campus and off-campus), "direct supervision" means that the practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the practitioner must be present in the room when the procedure is performed. Direct supervision no longer requires that the supervisory practitioner remain present within a particular physical boundary.

    b. For therapeutic services that require practitioner direct supervision, the supervisory practitioner may be present in locations such as physician offices that are close to the hospital or hospital provider-based department where the services are being furnished but are not located in actual hospital space, provided the supervisory practitioner is immediately available. Similarly, for an off-campus provider-based department, the supervisory practitioner may be present in a location in or near the off-campus provider-based department, provided that during the duration of the therapeutic service requiring direct supervision the practitioner is immediately available. "Immediate availability requires the immediate physical presence of the supervisory physician or . . . [NPP]. CMS has not specifically defined the word "immediate" in terms of time or distance; however, an example of a lack of immediate availability would be situations where the supervisory physician or . . . [NPP] is performing another procedure or service that he or she could not interrupt. Also, for services furnished on-campus, the supervisory physician or . . . [NPP] may not be so physically distant on-campus from the location where hospital/CAH outpatient services are being furnished that he or should could not intervene right away. The hospital or supervisory practitioner must judge the supervisory practitioner's relative location to ensure that he or she is immediately available." Medicare Benefit Policy Manual, Chapter 6, § 20.5.2.

    c. "The supervisory physician or . . . [NPP] must have, within his/her State scope of practice and hospital-granted privileges, the knowledge, skills, ability, and privileges to perform the service or procedure. Specially trained ancillary staff and technicians are the

primary operators of some specialized therapeutic equipment, and while in such cases CMS does not expect the supervisory physician or . . . [NPP] to operate this equipment instead of a technician, CMS does expect the physician or . . . [NPP] to be knowledgeable about the therapeutic service and clinically able to furnish the service." Medicare Benefit Policy Manual, Chapter 6, § 20.5.2.

d. "The supervisory responsibility is more than the capacity to respond to an emergency, and includes the ability to take over the performance of a procedure or provide additional orders. CMS would not expect that the supervisory physician or . . . [NPP] would make all decisions unilaterally without informing or consulting the patient's treating physician or . . . [NPP]. In summary, the supervisory physician or . . . [NPP] must be clinically able to supervise the service or procedure." Medicare Benefit Policy Manual, Chapter 6, § 20.5.2.

e. "Considering that hospitals furnish a wide array of very complex outpatient services and procedures, including surgical procedures, CMS would expect that hospitals already have the credentialing procedures, bylaws, and other policies in place to ensure that hospital outpatient services furnished to Medicare beneficiaries are being provided only by qualified practitioners in accordance with all applicable laws and regulations. For services not furnished directly by a physician or . . . [NPP], CMS would expect that these hospital bylaws and policies would ensure that the therapeutic services are being supervised in a manner commensurate with their complexity, including personal supervision where appropriate." Medicare Benefit Policy Manual, Chapter 6, § 20.5.2.

f. Certain therapeutic services and supplies may be assigned either general supervision or personal supervision. "'General supervision' means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician." 42 C.F.R. § 410.32(b)(3)(i). "'Personal supervision' means a physician must be in attendance in the room during the performance of the procedure." 42 C.F.R. § 410.32(b)(3)(iii).

g. NPPs may provide the required supervision of services that they may personally perform in accordance with State law and all additional applicable requirements including requirements for the particular type of NPP.

h. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy.

i. Nonsurgical extended duration therapeutic services ("NSEDTS") are hospital outpatient therapeutic services that can last a significant period of time, have a substantial monitoring component that is typically performed by auxiliary personnel, have a low risk of requiring the physician's or appropriate NPP's immediate availability after the initiation of the service, and are not primarily surgical in nature. For NSEDTS Medicare requires a minimum of direct supervision during the initiation of the service, which may be followed by general supervision at the discretion of the supervising physician or appropriate NPP. "Initiation" means the beginning portion of the nonsurgical extended duration therapeutic service which ends when the patient is stable and the supervising physician or appropriate NPP determines that the remainder of the service can be delivered safely under general supervision.

5. In the FY 2012 OPPS Final Rule (76 Fed. Reg. 74122, 74360-371, 74580-581 (Nov. 30, 2011)), CMS clarified that therapeutic services and supplies described by benefit categories other than the hospital outpatient incident to services under Section 1861(s)(2)(B) of the Medicare Act (for example, radiation therapy services) are subject to the conditions of payment in 42 C.F.R. § 410.27 when they are furnished to hospital outpatients and paid under the Medicare OPPS. CMS revised the regulatory provisions and Medicare Benefit Policy Manual, Chapter 6, § 20.5, accordingly.

6. Independent Review Process. CMS has designated the Federal Advisory Panel on Ambulatory Payment Classification Groups ("APC Panel") as the body that will review and advise the agency regarding the appropriate level of supervision for individual hospital outpatient therapeutic services. The scope of the APC Panel's authority is limited to recommending to CMS the appropriate level of supervision for individual hospital outpatient therapeutic services. CMS posts its preliminary decisions on the OPPS web site for a 30-day period of public review and comment. After consideration of any public comments, CMS issues its final decisions that are effective either in July or January following the most recent APC Panel meeting.

7. Hospital outpatient therapeutic services that are considered NSEDTS or only subject to general supervision are included in a document "Supervision File – Hospital Outpatient Therapeutic Services (November 27, 2012) available on the CMS web site.

C. Outpatient diagnostic tests (42 C.F.R. § 410.28). Medicare Part B pays for hospital diagnostic services furnished to outpatients, including drugs and biologicals required in the performance of the services (even if those drugs or biologicals are self-administered), provided the following conditions are met:

1. The outpatient diagnostic tests are furnished by, or "under arrangements" made by, a participating hospital.

2. The tests are ordinarily furnished by, or "under arrangements" made by, the participating hospital for its outpatients for the purpose of diagnostic study.

3. The tests would be covered as inpatient hospital services if furnished to an inpatient.

4. Diagnostic tests furnished to hospital outpatients by an entity other than the hospital are subject to the outpatient unbundling rules and thus, generally must be billed by the hospital.

5. The particular diagnostic test must be performed under the appropriate level of supervision by a physician, general, direct, or personal, as included in the Medicare Physician Fee Schedule Relative Value File. NPPs cannot supervise diagnostic tests. The definition of direct supervision/immediately available that applies for outpatient diagnostic tests is generally the same as for outpatient therapeutic services. 42 C.F.R. § 410.28(e)(1). For diagnostic tests that require direct supervision, the supervisory physician may be present in locations such as physician offices that are close to the hospital or hospital provider-based department where the services are being furnished but are not located in actual hospital space, provided the supervisory physician is immediately available. Similarly, for an off-campus provider-based department, the supervisory physician may be present in a location in or near the off-campus provider-based department, provided that during the duration of the diagnostic test requiring direct supervision the physician is immediately available. Medicare Benefit Policy Manual, Chapter 6, § 20.4.4. For diagnostic services furnished "under arrangement" in non-hospital facilities, direct supervision continues to require physician presence in the office suite ("in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure"). 42 C.F.R. § 410.28(e)(2); Medicare Benefit Policy Manual, Chapter 6, § 20.4.5.

D. Compliance Issues.

1. "Immediate availability" is the sole temporal/proximity criterion for direct supervision of on-campus and off-campus therapeutic and diagnostic outpatient services.

    a. Supervisory physician/NPP must be physically present, interruptible, and able to furnish assistance and direction throughout the performance of the procedure.

    b. The key is documenting the supervisory physician's/NPP's immediate availability.

2. Supervisory physician/NPP.

    a. Knowledge.

    b. Ability.

    c. Acting within scope of hospital privileges.

    d. Clinically appropriate to supervise the service/test and clinically able to furnish the service/test if necessary (not necessarily required to be the same specialty as the service/test he/she supervises).

    e. Prepared to step in and perform the service, even if not expert in the equipment used, not just respond to an emergency.

3. Nonsurgical extended duration therapeutic services.

    a. Personnel understand what are NEDTS.

    b. Properly document direct supervision/general supervision.

E. Compliance tips.

1. Review provider-based departments by location (on-campus, off-campus) and by type of service (therapeutic, diagnostic).

2. Review operations.

    a. Appropriate designated supervisory physicians/NPPs (designation, privileges, clinically appropriate)?

        i. Hospital bylaws?

        ii. Supervision agreements?

    b. Immediate availability?

    c. How contact?

    d. Verify compliance with supervision requirements for diagnostic tests (general, direct, personal).

F. Potential consequences for non-compliance with the direct supervision requirements.

1. Recoupment of overpayments. A Medicare contractor could determine that a hospital's outpatient services are non-covered services and seek recoupment of overpayments for services for which the proper supervision was not rendered.

2. Violation of Medicare Conditions of Participation for Hospitals. CMS or Medicare surveyors possibly could allege that a hospital's failure to comply with the outpatient therapeutic incident to supervision requirements is a violation of the Governing Body Condition of Participation for Hospitals, specifically the condition that a hospital's governing body must ensure that every Medicare patient is under the care of a physician. 42 C.F.R. § 482.12(c)(1).

3. Implication of federal False Claims Act (codified at 31 U.S.C. § 3729). It is conceivable that a hospital's failure to comply with the outpatient physician supervision requirements could also result in implication of the federal False Claims Act ("FCA") (whether the action is initiated by a whistleblower or the federal government).

XII. STARK LAW.

A. Introduction.

1. The Federal physician self-referral law (the "Stark Law") (42 U.S.C. § 1395nn) prohibits a physician from referring Medicare patients to entities with which the physician has a "financial relationship" for the provision of "designated health services" ("DHS") and prohibits entities from billing for DHS furnished pursuant to a prohibited referral. Under the Stark Law, a "financial relationship" can consist of a compensation arrangement, an ownership interest, or an investment interest. A "compensation arrangement" is defined as any arrangement involving any remuneration (directly or indirectly, overtly or covertly, in cash or in kind) between a physician (or an immediate family member of a physician) and an entity. 42 U.S.C. § 1395nn(h)(1). "Designated health services" is defined as: clinical laboratory services; physical and occupational therapy services; radiology services, including magnetic resonance imaging, computerized axial topography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; outpatient speech-language pathology services; and inpatient and outpatient hospital services. 42 U.S.C. § 1395nn(h)(6). Unlike the Anti-Kickback Statute, the Stark Law does not contain an intent requirement. Therefore, if an arrangement implicates the Stark Law, physician referrals are prohibited unless the arrangement complies with the requirements of an exception.

2. The Stark Law will be implicated whenever there is a direct or indirect financial relationship between a hospital and a physician. Thus, it will be implicated in any under arrangements relationship of a hospital if the provider of the under arrangements services is a physician (or immediate family member) or physician group, or if a physician (or immediate family member) has an ownership or investment interest in, or compensation relationship with, the service provider.

B. Application to Under Arrangements Relationships - Definition of "Entity."

1. In 72 Fed. Reg. 38122 (July 12, 2007) (the "2008 MPFS Proposed Rule"), CMS proposed revising the definition of "entity" to include both the party that performs the designated health service and the hospital that submits claims to Medicare for designated health services furnished under arrangements. In the preamble discussion in the 2008 MPFS Proposed Rule, CMS expressed a number of concerns regarding services furnished by hospitals under arrangements with physician-owned entities. It indicated it was particularly concerned about hospital outpatient services reimbursed on a per-service basis, such as imaging services, and understood there are hospital-physician ventures providing imaging services under arrangements that were previously provided directly by the hospital. CMS stated that there often appears to be no legitimate reason for such arranged services, other than to allow the referring physicians "to make money on referrals." 72 Fed. Reg. at 38186.

2. In 73 Fed. Reg. 48343 (August 19, 2008) (the "2009 IPPS Final Rule"), CMS adopted the change to the definition of "entity" substantially as proposed in the 2008 MPFS Proposed Rule. Specifically, 42 C.F.R. § 411.351 was amended to include "the person or entity that has performed services that are billed as DHS" and "the person or entity that has presented a claim to Medicare for the DHS." Recognizing that the changes would require many arrangements to be restructured, a delayed effective date of October 1, 2009 was set for this change.

3. Services that are not DHS when billed by a physician group or by a facility such as an ASC or IDTF are considered DHS for application of this principle when billed by a hospital because hospital inpatient and outpatient services are DHS. 73 Fed. Reg. at 48730. The one exception CMS makes in this regard is lithotripsy, which is not considered DHS because of the decision in *American Lithotripsy Society v. Thompson*, 215 F. Supp. 2d 23 (D.D.C. 2002).

4. As a result of the change in the definition of "entity", where a physician-owned entity performs services that are billed by the hospital "under arrangements," both the hospital and the physician-owned entity are treated as DHS entities with respect to those services. The physician's ownership interest in the physician-owned entity must therefore meet an ownership exception if that physician makes referrals for the relevant services. Under arrangements relationships between hospitals and physician-owned entities thus generally continue to be a viable option only under the following circumstances:

   a. The services are provided in a rural area by a "rural provider" as defined in 42 C.F.R. § 411.356(c)(1). The rules implementing PPACA place restrictions on physician ownership of a rural hospital (see 42 C.F.R. §411.356(c)(1) and 411.362), but the definition of hospital in 42 C.F.R. §411.351 expressly excludes entities that perform services for hospital patients under arrangements.

b. The owning physicians do not make a "referral" for the services within the meaning of the Stark Law. Personally performed services are excluded from the definition of referral under 42 C.F.R. § 411.351, but CMS warns in the preamble that "the fact that a referring physician performs the professional component, and thus there is no 'referral' for the professional component, does not alter the fact that there is a 'referral' for the TC or the facility fee." 73 Fed. Reg. at 48730. Certain requests for services by pathologists, radiologists and radiation oncologists are also excluded from the definition of referral under 42 C.F.R. § 411.351, leaving the possibility for under arrangements ventures for clinical diagnostic laboratory services, diagnostic radiology services or radiation therapy services if ownership is limited to the appropriate specialty and the venture is otherwise appropriately structured.

c. A venture to provide lithotripsy services under arrangements is permitted, because as noted above these services are not considered DHS even when billed by the hospital.

5. CMS declined to specifically define what it means to perform a service. By way of example, however, it indicated that a service is performed by a physician organization if the organization does the medical work and could bill for the service. Conversely, an entity that leases or sells space or equipment, furnishes supplies that are not separately billable, *or* provides management, billing services or personnel is not performing the service. 73 Fed. Reg. at 48726. (Also see the reiteration of this discussion in the 74 Fed. Reg. 61738 (November 25, 2009) (the "2010 MPFS Final Rule"), at 61933, in which emphasis is added to the word "or".) It is unclear when by providing a package of space, equipment, supplies and/or support services an entity will cross the line into performing the DHS service.

In the 2010 MPFS Final Rule, CMS acknowledged it had received numerous inquiries concerning the revised definition of entity and what it means to perform a service. While declining to issue a specific proposal, CMS solicited comments to determine if further guidance is necessary and what clarifications may be beneficial. 74 Fed. Reg. at 61933.

6. Litigation by the Council for Urological Interests challenged the changes in the Stark law affecting under arrangements relationships, but summary judgment was granted to the government by the District Court of the District of Columbia in May 2013. *Council for Urological Interests v. Sebelius*, D.D.C., No. 1:09-cv-0546, (May 24, 2013). .

XIII. FEDERAL ANTI-KICKBACK STATUTE.

A. Introduction.

1. The Anti-Kickback Statute imposes criminal and civil money penalties on any entity that knowingly or willfully pays or offers to pay, or solicits or receives any remuneration directly or indirectly, overtly or covertly, in

cash or in kind, in exchange for the referral of patients for any item or service which is covered in whole or in part by a federal health care program. 42 U.S.C. § 1320a-7b. The Anti-Kickback Statute also prohibits arranging for or recommending the purchase of goods or services for which payment may be made in whole or in part under a federal health care program in exchange for remuneration. The Anti-Kickback Statute is an intent-driven statute (*e.g,.* a violation requires proof of illegal intent to induce referrals). Thus, analysis of a proposed venture often necessitates a review of all of the facts and circumstances, and design of safeguards to reduce the risk of a violation. Concerns and potential safeguards applicable to under arrangements ventures are discussed below.

B. Safe Harbors.

1. The relationship between a hospital and an entity providing under arrangements or other services could be structured to meet the "safe harbor" for personal services and management contracts. 42 C.F.R. § 1001.952(d).

2. The protection of a safe harbor is available only if all of its elements are met, but arrangements outside a safe harbor are not per se illegal, and will be reviewed on a case-by-case basis, in light of all the relevant facts and circumstances. The personal services safe harbor and equipment rental safe harbor each require the aggregate compensation to be set in advance and thus do not permit payment that fluctuates based on the extent of services or equipment usage that is required. Moreover, if the services and equipment are provided on less than a full-time basis, the exact schedule for the intervals is required. It would be very difficult, therefore, to structure an under arrangements relationship, in which the parties are unlikely to be able to predict in advance the amount and timing for services that will be needed over the course of a year, to meet these safe harbors. However, an approach to mitigate risk under the Anti-Kickback Statute is to structure the relationship to comply as closely as possible to the safe harbor.

3. The OIG has consistently declined to provide safe harbor protection to per-use fee arrangements. See, for example, 56 Fed. Reg. 35952 (July 29, 1991), 64 Fed. Reg. 63504, 63526 (November 19, 1999), and Appendix G to the OIG Semiannual Report to Congress for April-September 2002. The OIG has also made clear in advisory opinions that such arrangements are "disfavored," because of concerns that they promote overutilization. See, for example, OIG Advisory Opinion 03-8 (April 3, 2003); OIG Advisory Opinion 99-12, fn 4 (November 23, 1999). Also see OIG Advisory Opinion 09-17 (October 7. 2009), OIG Advisory Opinion 10-14 (August 30, 2010), OIG Advisory Opinion 10-23 (October 28, 2010) and OIG Advisory Opinion 10-24 (October 28, 2010) (further discussed below). A key issue is whether the total amount paid under the per-use fee arrangement will vary based on referrals generated by the recipient of the fee. If so, the fee may provide an inappropriate incentive for referrals.

C. Contractual Joint Venture Analysis.

1. The OIG issued a Special Advisory Bulletin on Contractual Joint Ventures on April 23, 2003 (the "Advisory Bulletin"), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf. In the Advisory Bulletin, the OIG focused on arrangements where a health care provider in one line of business (the "Owner") expands into a related health care business by contracting with an existing provider of a related item or service (the "Supplier") to provide the related item or service to the Owner's existing patient population, including Medicare and Medicaid patients. The Supplier not only manages the line of business for the Owner, but may also supply it with inventory, employees, space, billing, and other services. In other words, the Owner contracts out substantially the entire operation of the related line of business to the Supplier—otherwise a potential competitor—receiving in return the profits of the business as remuneration for its federal program referrals.

2. The Supplemental Guidance mentions under arrangements relationships in its discussion of contractual joint ventures, stating that, standing alone, they "do not fall within the scope of problematic contractual joint ventures described in the Special Fraud Alert; however, these relationships will violate the anti-kickback statute if remuneration is purposefully offered or paid to induce referrals (*e.g.,* paying above-market rates for the services to influence referrals or otherwise tying the arrangements to referrals in any manner). These 'under arrangements' relationships should be structured, when possible, to fit within an anti-kickback safe harbor." 70 Fed. Reg. 4858, 4866 fn. 49 (January 31, 2005). As noted above, the inability to predict the extent of services required makes satisfaction of a safe harbor unlikely.

3. The risk factors for contractual joint ventures are worth consideration in analyzing an under arrangements venture. To the greater extent the hospital provides infrastructure for the venture – i.e., the hospital plays the role of Supplier and the under arrangements service provider/physician owners have the role of Owner as described in the Advisory Bulletin – the more suspect the relationship will be.

D. OIG Advisory Opinions Addressing Under Arrangements Transactions.

1. The OIG released three advisory opinions in 2010 addressing under arrangements relationships entered into by hospitals to obtain sleep lab services, Advisory Opinions 10-14 (August 30, 2010), 10-23 (October 28, 2010 and 10-24 (October 28, 2010). In all three opinions, the services provider was a company (the "Company") that had no physician or hospital ownership, provided the equipment, supplies and technical staff needed for the sleep services, and was entitled to payment from the hospital regardless of whether the hospital received reimbursement for the services. Both Advisory Opinion 10-14, which addressed an arrangement with a per-unit fee and no marketing services, and Advisory Opinion 10-24, which addressed an arrangement with a fixed fee that included marketing services, were favorable. Advisory Opinion 10-23,

which addressed an arrangement with a per-unit fee that included marketing services, was unfavorable, with the OIG stating, "we cannot conclude that the Arrangement poses a sufficiently low risk that we should protect it."

2. The key factor affecting the variation in outcome among these three opinions was the inclusion of marketing services. Specifically, in Advisory Opinion 10-23, the per-unit fee included compensation for services of a part-time marketing manager who visited offices of physician referral sources and marketed the sleep services at health fairs, as well as assisting the hospital's marketing department in issues relating to sleep services. In Advisory Opinion 10-24, similar marketing services were provided, but on a full-time basis and for payment of a fixed annual fee. The OIG concluded that the marketing aspect of the arrangement resulted in the Company being in a position to generate referrals, and in Advisory Opinion 10-23 found that the per-unit fee design was suspect because the Company would receive greater fees the more successful its marketing efforts were, and because incorporation of the compensation for marketing into the per-unit fee for the sleep services did not allow for transparent assessment of the marketing services and related compensation. In Advisory Opinion 10-24, in contrast, the fixed fee design and full-time nature of the services mitigated "against any undue or additional incentive to generate unnecessary or an increased volume of sleep tests."

3. A similar analytic framework was applied in all three opinions. First, the relevant safe harbors were reviewed – and in Advisory Opinion 10-24, the compliance with all components of the safe harbor other than specification of precise intervals of services was a favorable factor. Second, characteristics of a suspect under arrangements transaction were reviewed. The suspect characteristics identified in all three opinions were as follows:

    a. The hospital pays above-market rates for the services to influence referrals. An under arrangements entity could be in a position to influence referrals if it provides marketing services, has an independent patient base, or is owned directly or indirectly by referral sources for the hospital, such as physicians.

    b. The under arrangements entity accepts below-market rates to secure referrals from the hospital to the entity, its owners or affiliates.

    c. The hospital owns an interest in the under arrangements entity and thus receives remuneration in the form of investment returns in exchange for referrals to the entity or an affiliate. Hospital ownership also raises the specter of undue influence in awarding the contract for services, with the attendant risk that the contract would be awarded based on actual or anticipated referrals.

d. A referral source for the hospital owns an interest in the under arrangements entity. The OIG notes that even if the services are provided at fair market value, the referral source could have an incentive to condition other referrals to the hospital on the hospital's award of a contract to the under arrangements entity.

e. The transaction includes the furnishing of items and services in addition to those within the scope of the under arrangements services, or includes the furnishing or items or services to patients who are not hospital patients.

4. In each of the favorable opinions, the OIG also discussed safeguards that it viewed as reducing risk, including the following:

a. The ordering and interpreting physicians had no financial interest in the under arrangements entity.

b. The hospital payment for the services was not conditioned on its ability to receive reimbursement for the sleep tests, and the arrangement thus did not provide an additional benefit to the hospital by protecting it from collection risk.

c. The hospital assumed business risk and contributed substantially to the services, including provision of necessary space, furnishings, a medical director and administrative services, thus making the arrangement distinguishable from a turnkey contractual joint venture.

5. In each of the sleep lab opinions, the requestor certified that the arrangement fully complied with all Medicare coverage and payment requirements for under arrangements services. In the two favorable opinions, the OIG indicated that its opinion would have no force and effect in the event that the arrangement did not comply with these requirements.