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

A. A health care delivery system or hospital theoretically may treat a subordinate facility for Medicare payment purposes either as part of the hospital, referred to as “provider-based,” or as freestanding. The Medicare (and in some instances Medicaid) certification, payment, coverage, billing, and practitioner supervision implications of provider-based or freestanding status are significant.

B. Provider-based status generally means the relationship between a main provider and a department of a provider, provider-based entity, remote location of a hospital, or satellite facility.

C. There are 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 of entities that can be provider-based 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 a hospital’s certification and CMS Certification Number.

D. The current Medicare/Medicaid provider-based status 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; or (iii) the deductible or coinsurance liability of a Medicare beneficiary in or at the facility.

II. SIGNIFICANCE OF PROVIDER-BASED STATUS.

A. 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.

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1 This paper is for informational purposes only and does not constitute legal advice.
2. In Survey & Certification Memorandum S&C-12-17-Hospitals published on February 17, 2012, by the Centers for Medicare & Medicaid Services' (“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 see 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 new policy is effective immediately and interprets 42 C.F.R. § 482.54, the CoP governing outpatient services.

B. Payment Amounts.

1. Medicare generally pays more for diagnostic and therapeutic services furnished in the hospital outpatient department setting compared to the same services performed in other provider/supplier settings. 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. 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.

3. Historically, annual beneficiary-specific physical therapy/speech-language pathology services and occupational therapy services payment limits applied to therapy services furnished in nonprovider-based facilities but not to therapy services furnished in hospital outpatient departments. However, in the Middle Class Tax Relief and Job Creation Act of 2012, signed into law by President Obama on February 22, 2012, Congress has extended application of the therapy caps to therapy services furnished in hospital outpatient departments. Section 3005 of the new law limits the amount that Medicare will pay each year per beneficiary for outpatient speech, occupational and physical therapy furnished in hospital outpatient
departments unless the hospital pursues an exceptions process with its Medicare administrative contractor. It appears that the therapy caps will be based on claims for services provided on or after January 1, 2012.

C. 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. 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. Partial hospitalization services are not covered if the services are performed in a physician’s clinic not certified as a community mental health center, even if hospital-owned or affiliated. CMS has identified procedures that are typically provided only in an inpatient setting and, therefore, are not paid under the Medicare outpatient prospective payment system (“OPPS”). These procedures comprise what is generally referred to as the “inpatient list.” The inpatient list specifies those services that are only paid when provided in an inpatient setting because of the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. CMS applies certain criteria for determining whether or not a procedure should be removed from the inpatient list and covered and paid under the OPPS: (i) most outpatient departments are equipped to provide the services to the Medicare population; (ii) the simplest procedure described by the code may be performed in most outpatient departments; (iii) the procedure is related to codes that have already been removed from the inpatient list; and (iv) CMS has determined that the procedure is being performed in numerous hospitals on an outpatient basis or the agency has determined that the procedure can be safely performed in an ASC and is on the list of approved ASC procedures or has been proposed for addition to the ASC list.

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

D. Coverage – Physician Supervision (discussed in Section X herein).

E. Medicare Billing. Hospital services performed in outpatient departments are billed to Medicare contractors on form CMS-1450 (UB-04). Physician services performed in outpatient departments are billed to Medicare contractors on claim form 1500s. 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.

F. Certain Other 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).

III. PROVIDER-BASED STATUS REQUIREMENTS-GENERALLY.

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

B. The provider-based requirements 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 (Apr. 7, 2000); 67 Fed. Reg. 49981, 50083 (Aug. 1, 2002).

C. Since October 1, 2002, CMS has not expressly 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 (Aug. 1, 2002); Program Memorandum (Intermediaries) Transmittal A-03-030 (Apr. 18, 2003). There is some ambiguity, however, 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: ambulatory surgery centers (“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. Further, CMS is indifferent to provider-based status if the status of the facility as provider-based or freestanding will not affect Medicare or Medicaid payments to the facility. 65
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.
   a. 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 generally will 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).

   b. 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.
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.

The applicable Medicare regulation sheds some ambiguity on 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).

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 October 1, 2011, but does not submit an
attestation and the facility does not meet all the applicable
provider-based requirements, and CMS discovers on February 1,
2012, that the main provider is billing inappropriately as provider-
based, the agency will recover overpayments since October 1,
2011. 42 C.F.R. § 413.65(l).

IV. 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.

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 (Aug. 1, 2002). Neither the Medicare statute (42 U.S.C. § 1395x(w)) nor the implementing Medicare regulations (42 C.F.R. § 409.3) expressly limit *bona fide* under arrangements relationships 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.

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 (Joint Commission requirements 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.

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2 List first published in Dennis Barry’s Reimbursement Advisor, Apr. 2007.
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).


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.”


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, 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. Outpatient under arrangements services. Routine services furnished under arrangement outside the hospital are not recognized for Medicare payment purposes. 76 Fed. Reg. 51476, 51711-714 (Aug. 18, 2011). CMS expressed concern that IPPS-excluded hospitals were obtaining routine services, including ICU services, under arrangements from IPPS hospitals.

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.
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.

V. 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.

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.

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.

a. General rule. The facility is located within a 35-mile radius of the campus of the hospital that is the potential main provider.

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.

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.

VI. 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.

2. Off-campus outpatient departments. 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 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, it is 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 would not incur an EMTALA obligation with respect to the individual. 68 Fed. Reg. 53222, 53249-250 (Sept. 9, 2003).

B. Physician billing. Physician services performed 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). In the HHS OIG Work Plan for FY 2012, the OIG describes that it is reviewing physician coding for professional services furnished in hospital outpatient departments in order to determine whether POS 22 is properly being used rather than POS 11. 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.

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. Prior to enactment of the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010, effective June 25, 2010, the three-day payment window rule for preadmission nondiagnostic services was rarely applicable because the rule required an exact match between the principal ICD-9 CM diagnosis codes for the outpatient services and the inpatient admission. Because of this exact match requirement, very few services furnished in a hospital wholly owned or wholly operated physician’s office or clinic were subject to the rule. However, in the 2010 legislation Congress amended the three-day payment window rule statutory provisions to significantly broaden the nondiagnostic services that are subject to
the rule to include any nondiagnostic service that is clinically related to the reason for a patient’s inpatient admission, regardless of whether the patient’s inpatient and outpatient diagnoses are the same. Now, outpatient nondiagnostic services (other than ambulance and maintenance renal dialysis services) provided to a beneficiary by a hospital, or by an entity wholly owned or wholly operated by the hospital, or by another entity under arrangements with the hospital, on the first, second, or third calendar days (first calendar day for IPPS-excluded hospitals) preceding the date of the patient’s admission are deemed related to the admission and, therefore, must be billed with the inpatient stay, unless the hospital or the hospital wholly owned or wholly operated entity attests that the preadmission nondiagnostic services are clinically distinct or independent from the reason for the beneficiary’s admission. If a hospital or hospital wholly owned or wholly operated entity so attests, the unrelated outpatient hospital nondiagnostic services are covered by Medicare Part B, and the hospital wholly owned or wholly operated entity should include the technical portion of the services in its billing. Effective April 1, 2011, a hospital or hospital wholly owned or wholly operated entity must add Condition Code 51 (Attestation of unrelated outpatient nondiagnostic services) on claims for separately billed outpatient nondiagnostic services for purposes of attesting that the nondiagnostic services are unrelated to the inpatient hospital claim. In addition, beginning July 1, 2012, hospital wholly owned and/or wholly operated entities must append on claims the modifier PD (Diagnostic or related nondiagnostic item or service provided in a wholly owned or wholly operated entity to a patient who is admitted as an inpatient within three days to an IPPS hospital (one day to an IPPS-excluded hospital)) in order to identify preadmission services that are subject to the three-day payment window rule. When the modifier PD is included on claims for services, payment to hospital wholly owned or wholly operated entities will only be for the professional component services for CPT/HCPCS codes with a professional component/technical component split; services without a professional component/technical component split will be paid at the facility rate when they are subject to the rule. The facility rate will be paid to hospital wholly owned or wholly operated entities for codes without a professional component/technical component split in order to avoid duplicate payment for the technical resources required to provide the services.

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.


VII. 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 contact out entire departments and claim them as provider-based. (See 65 Fed. Reg. 18434, 18518-519 (Apr. 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.

VIII. 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.


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 same location as a remote location of the hospital and not as a separate hospital. CMS considers that the acquiring hospital has assumed the acquired hospital's provider agreement (with the potential successor liability) but that the acquired hospital's CMS Certification Number (“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."C


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.

E. The Joint Commission accreditation of hospitals in accordance with their CMS certification numbers and CMS proposal to revise governing body Condition of Participation.

1. 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.
2. CMS has proposed to revise the hospital governing body CoP to enable a multi-hospital system (those having more than one CCN) to be effectively governed by a single governing body. See 76 Fed. Reg. 65891 (October 24, 2011).

IX. 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. In 2000 CMS implemented the provider-based status regulatory requirements. In a January 12, 2007 Federal Register notice (72 Fed. Reg. 1540), HRSA described: “In order for an outpatient facility of a DSH to be eligible for the 340B Program, it must be demonstrated that the outpatient facility is an integral part of the DSH. HRSA has chosen to rely on the category of provider-based facilities as set forth by [CMS] under [Medicare]. This decision has been made because HRSA believes that the requisite integration of facilities necessary to demonstrate that the secondary facility is functioning as part of the DSH under 42 C.F.R 413.65 is appropriate for facilities eligible under the 340B Program. Compliance with the rule for provider-based facilities would provide clear guidance to DSHs that wish to prescribe 340B drugs to patients at these outpatient facilities and ensure that the individuals are truly patients of the DSH. Ultimately the facility's provider-based status must be reflected in the covered entity’s Medicare Cost Report. The covered entity may provide a copy of the attestation provided to its fiscal intermediary pursuant to 42 C.F.R 413.65 to demonstrate compliance with this guideline until such time as the facility is listed on the DSH’s Medicare Cost Report. The DSH shall retain the responsibility to promptly notify the OPA [Office of Pharmacy Affairs] in the event that the
outpatient facility's provider-based status is rejected or otherwise called into question.” 72 Fed. Reg. at 1545.

E. 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.

X. 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. 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 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).

3. 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.

4. 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 effective calendar year 2012 (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.

c. “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.

d. “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.

e. “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.
f. “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.

g. 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).

h. 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.

i. 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.

j. Nonsurgical extended duration therapeutic services 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 nonsurgical extended duration therapeutic services 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. The following services are
considered to be nonsurgical extended duration therapeutic services: C8957 (intravenous infusion for therapy/diagnosis); G0378 (hospital observation service, per hour); G0379 (direct admission of patient for hospital observation care); 96360 (intravenous infusion, hydration, initial); 96361 (intravenous infusion, hydration, each additional hour); 96365 (intravenous infusion, for therapy, prophylaxis, up to 1 hour); 96366 (intravenous infusion, for therapy, prophylaxis, or diagnosis, each additional hour); 96367 (intravenous infusion, for therapy, prophylaxis, or diagnosis, additional sequential infusion); 96368 (intravenous infusion, for therapy, prophylaxis, or diagnosis, concurrent infusion; 96369 (subcutaneous infusion for therapy or prophylaxis, initial, up to 1 hour); 96370 (subcutaneous infusion for therapy or prophylaxis, each additional hour); 96371 (subcutaneous infusion for therapy or prophylaxis, additional pump set-up with establishment of new subcutaneous infusion site(s)); 96372 (therapeutic, prophylactic or diagnostic injection, subcutaneous or intramuscular); 96374 (therapeutic, prophylactic, or diagnostic injection, intravenous push, single or initial substance/drug); 96375 (therapeutic, prophylactic, or diagnostic injection, each additional sequential intravenous push of a new substance); and 96376 (therapeutic, prophylactic, or diagnostic injection, each additional sequential intravenous push or the same substance/drug provided in facility). CY 2011 OPPS Final Rule, 75 Fed. Reg. 71800, 72012-13 (Table 48A) (Nov. 24, 2010).

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 will post 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 will issue its final decisions that will be effective either in July or January following the most recent APC Panel meeting.

C. Outpatient diagnostic tests (42 C.F.R. § 410.28). Medicare Part B pays for hospital diagnostic services furnished to outpatients, including drugs and
biological required in the performance of the services (even if those drugs or biological 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 physician supervision, general, direct, or personal, as included in the Medicare Physician Fee Schedule Relative Value File. The same definition of direct supervision/immediately available applies for outpatient diagnostic tests as for outpatient therapeutic services, with one exception, as described herein. 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.

6. “Immediate availability requires the immediate physical presence of the supervisory physician. CMS has not specifically defined the word “immediate” in terms of time and distance; however, an example of a lack of immediate availability would be situations where the supervisory physician is performing another procedure or service that he or she could not interrupt. Also, for services furnished on-campus, the supervisory physician may not be so physically distant on-campus from the location where hospital outpatient services are being furnished that he or she could not intervene right away. The hospital or supervisory physician must judge the supervisory physician’s relative location to ensure that he or she is immediately available.” Medicare Benefit Policy Manual, Chapter 6, § 20.4.4.
7. “The supervisory physician 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 diagnostic testing equipment, and while in such cases CMS does not expect the supervisory physician to operate this equipment instead of a technician, the physician who supervises the provision of the diagnostic service must be knowledgeable about the test and clinically able to furnish the test.” Medicare Benefit Policy Manual, Chapter 6, § 20.4.4.

8. “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 would make all decisions unilaterally without informing or consulting the patient’s treating physician or . . . [NPP]. In summary, the supervisory physician must be clinically appropriate to supervise the service or procedure.” Medicare Benefit Policy Manual, Chapter 6, § 20.4.4.

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, not just respond to an emergency.

3. Nonsurgical extended duration therapeutic services.
a. Personnel understand what are nonsurgical extended duration therapeutic services.

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).

   a. The Fraud Enforcement and Recovery Act of 2009 (“FERA”) amends the FCA to provide that the knowing retention of an overpayment constitutes a violation, resulting in a civil penalty of
not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages that the government sustains resulting from the violation. Further, in PPACA, § 6402, Congress amended the Medicare and Medicaid program integrity provisions (codified at 42 U.S.C. § 1320a-7k) to provide that if a person/entity has received an overpayment, the person/entity shall “report and return the overpayment” and include a description of the reason for the overpayment. “Overpayment” is defined as “any funds that a person receives or retains under [Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled under such title.” The deadline for reporting and returning overpayments is the later of: (a) 60 days after the date on which the overpayment was identified; or (b) the date any corresponding cost report is due (if applicable). Retention of an overpayment after the deadline for reporting and returning the overpayment is considered a false claim.

b. In early February 2012, CMS issued a proposed rule implementing PPACA, § 6402. The proposed rule was published in the February 16, 2012 Federal Register (77 Fed. Reg. 9179). CMS proposes that a person has identified an overpayment if the person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment. If an overpayment is claims related, the provider/supplier would be required to report and return the overpayment within 60 days of identification. For providers that submit cost reports, if the overpayment is such that it would generally reconciled on the cost report by the provider, the provider would be permitted to report and return the overpayment either 60 days from the identification of the overpayment or on the date the cost report is due, whichever is later. A provider/supplier may receive information concerning a potential overpayment that creates an obligation to make a reasonable inquiry in order to determine whether an overpayment exists. If the reasonable inquiry reveals an overpayment, the provider then has 60 days to report and return the overpayment. Failure to make a reasonable inquiry, including failure to conduct such inquiry with all deliberate speed after obtaining the information, could result in the provider knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance of whether it received such an overpayment. See proposed 42 C.F.R. §§ 401.301 through 401.305.

XI. RECENT SIGNIFICANT DEVELOPMENTS.

A. Survey & Certification Memorandum S&C-12-17-Hospitals (Feb. 17, 2012), describes a new CMS policy for practitioners ordering hospital outpatient services. See Section II.A.2.
B. Congress extends the therapy caps to therapy services furnished in hospital outpatient departments, effective January 1, 2012. See Section II.B.3.

C. In the HHS OIG Work Plan for FY 2012, the OIG describes that it is reviewing physician coding for professional services furnished in hospital outpatient departments in order to determine whether POS 22 is properly being used rather than POS 11. 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. See Section VI.B.

D. Congress and CMS revise and clarify application of the Medicare three-day payment window rule. See Section VI.F.


G. The Joint Commission now accredits hospitals in accordance with their CCNs, requiring a multi-campus hospital operating under one CCN to have one governing body, one unified medical staff and a common nursing staff for all campus locations. In addition, CMS has proposed revising the Medicare CoP for hospital governing bodies to enable a hospital system with multiple hospitals operating under separate CCNs to have a single governing body. See Section VIII.E.

H. In its FY 2012 OPPS Final Rule, 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. See Section X.B.5.

I. CMS issued a proposed rule that would require providers and suppliers receiving funds under the Medicare program to report and return overpayments by the later of the date: (i) which is 60 days after the date on which the overpayment was identified; or (ii) any corresponding cost report is due, if applicable. See Section X.E.3.b. above.

J. In a July 22, 2011 letter, the CMS Chicago Regional Office denied provider-based status to a prospective hospital outpatient department that would furnish radiology services. The Regional Office premised its negative determination in part on the fact that the facility shared certain space with a freestanding facility (“CMS does not recognize facilities that share space with freestanding facilities to meet the definition of a ‘department’ of a hospital. A facility that shares space
with a freestanding facility cannot have provider-based status as a department of a hospital. . . . Hospitals are not permitted to ‘carve out’ areas as non-hospital spaces. . . . Certain features, such as shared entryways, interior hallways, bathroom facilities, treatment rooms, waiting rooms, and registration areas are all indications that a purported hospital space may instead be a part of a larger component.

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. Regulations implementing the Stark Law (as it initially applied to clinical laboratory services) were issued by CMS (HCFA at the time of issuance) in 1995. 60 Fed. Reg. 41914 (Aug. 14, 1995). Proposed Regulations implementing the Stark Law (as expanded to include all DHS) were issued by HCFA in 1998 (the "Phase I Proposed Regulations"). 63 Fed. Reg. 1659 (Jan. 9, 1998). Additional regulations were issued in 2001, in the phase I final Stark regulations (the "Phase I Final Regulations"). 66 Fed. Reg. 856 (Jan. 4, 2001). The second phase of the Stark Law regulations was released in the form of an interim final rule and became effective on July 26, 2004 ("Phase II Interim Final Regulations"). 69 Fed. Reg. 16054 (March 26, 2004). The third and final phase of these final regulations became effective on December 4, 2007 (the "Phase III Regulations"). 72 Fed. Reg. 51012 (Sept. 5, 2007). Recently, revisions to the Stark Law regulations have been promulgated with the physician fee schedule and the OPPS and IPPS regulations. Many changes were

3. 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 in, or compensation relationship with, the service provider.

B. Application to Under Arrangements Relationships - Definition of “Entity.”

1. In 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 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 will 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 2010 MPFS Rule, 74 Fed. Reg. 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.

6. 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. Specific areas for which comments were solicited include the following:

a. Whether performance of services should be analyzed the same for inpatient and outpatient services;

b. Whether performance of services should be analyzed based on how many of the following are provided: (i) space, (ii) equipment, (iii) supplies, (iv) management services, (v) billing services, and (vi) nonphysician services that are not separately billable;

c. Whether an interpretation of “medical work” was relied upon in restructuring under arrangements relationships and if so, how; and

d. The degree to which the amount and nature of services by physician and nonphysician personnel should influence the determination.

CMS also welcomed comments on how the definition of entity has been interpreted and applied, and how arrangements were restructured to achieve compliance.

7. Litigation by the Council for Urological Interests challenging the changes in the Stark law affecting under arrangements relationships is in process. In December 2011, the U.S. Court of Appeals for the District of Columbia Circuit held that exhaustion of administrative remedies was not required and remanded the case to the District Court for further proceedings. Council for Urological Interests v. Sebelius, D.C. Cir., No. 11-5030, Dec. 23, 2011.

C. Per-Unit and Percentage Payment Arrangements.

1. Under the special compensation rules of 42 C.F.R. § 411.354(d)(1), time-based or per-unit-of-service-based compensation is considered set in advance. These rules also provide that percentage compensation is considered set in advance if the formula is set forth in sufficient detail to be objectively verifiable, and does not change in any manner that reflects the volume or value of referrals or other business generated between the parties. Further, 42 C.F.R. § 411.354(d)(2) and (3) deem unit-based compensation arrangements not to take into account the volume or value of referrals or other business generated if the compensation is fair market
value and does not vary during the course of the compensation arrangement in a manner that takes referrals of DHS into account. Percentage compensation is not included in the language of these provisions. In the preamble to the Phase III Regulations, CMS indicated it was not persuaded that percentage compensation should be included within the scope of 42 C.F.R. § 411.354(d)(2) and (3). 72 Fed. Reg. at 51030-31.

2. In the 2009 IPPS Final Rule, the exceptions for space leases, equipment leases, fair market value compensation and indirect compensation arrangements were revised to prohibit rental charges based on per-unit-of-service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. (The language was changed from “between the parties” to “by the lessor to the lessee” in a technical correction published at 73 Fed. Reg. 57541 (October 3, 2008).) The same exceptions were also revised to prohibit rental charges based on a “percentage of the revenue raised, earned, billed, collected or otherwise attributable to the services performed or business generated” through use of the space or equipment. 42 C.F.R. §§ 411.357(a)(5), (b)(4), (l)(3) and (p)(1). The prohibition on percentage compensation is broader than that on unit-based compensation because it is not limited to circumstances in which the charges reflect referrals between the parties. Like the change in the definition of “entity”, the effective date for these revisions was delayed until October 1, 2009.

3. As noted in the preamble, per-unit leases continue to be permitted if referrals from the lessor are not included in the number of units charged. Thus, a lease could be structured that charges on a per-unit basis only for services not referred by the lessor, but compliance with the requirement that the lease be consistent with fair market value and commercially reasonable could make such a structure difficult to design. See 73 Fed. Reg. at 48717.

4. CMS also discussed time-based rental arrangements, and concluded that “on demand” rental arrangements are essentially a per-click type of arrangement covered by the final rule. CMS recognized that block leases may be structured to meet the requirements of the exception, but indicated that it intends to study them and may propose rulemaking in the future. 73 Fed. Reg. at 48719. CMS personnel have informally indicated that a lease without a per-click fee structure, but with “as needed” scheduling for usage, is permitted.

5. Many had concerns about application of the revised rules to arrangements in which a package of services and equipment is provided. CMS posted an answer to the following question on its website on January 22, 2009 (which was updated January 6, 2010): “Where a physician-owned lithotripsy partnership contracts with a hospital to provide a lithotripter and skilled technician "under arrangements," may the hospital pay for such services using a per-use or percentage-based compensation formula without violating the physician self-referral law?” In its answer, CMS indicates that such a formula is permissible if “a
The lithotripsy partnership is actually furnishing a service (or a package of services) to the hospital, and not merely leasing equipment over which the hospital would have dominion and control.” In reaching this conclusion, CMS references its discussion in the Phase II Regulations recognizing that contractors may provide the “tools of their trade” in connection with service contracts. 69 Fed. Reg. at 16090-91. (This question is accessible by clicking on “Frequently Asked Questions” at http://www.cms.hhs.gov/PhysicianSelfReferral/ and clicking through to this question, which has identification number 9556.)

D. Indirect Compensation.

1. An indirect compensation arrangement exists if: (a) there exists between the referring physician and the designated health services entity an unbroken chain of persons or entities that have financial relationships between them; (b) the aggregate compensation received by the referring physician varies with, or takes into account, the volume or value of referrals or other business generated by the physician for the DHS entity; and (c) the designated health services entity has actual knowledge that the aggregate compensation received by the referring physician varies with, or takes into account, the volume or value or referrals or other business, or acts in reckless disregard or deliberate ignorance of the existence of such relationship. 42 C.F.R. § 411.354(c)(2).

   a. The compensation relationship closest to the individual physicians is the financial relationship to analyze for purposes of applying the indirect compensation definition. In assessing a relationship with a supplier owned in part by physicians, the financial relationship between the hospital and the supplier must be analyzed. In assessing a relationship with a supplier that has a compensation relationship with physicians, that compensation relationship must be analyzed.

2. CMS has expressed concern about whether parties are reading the definition of “indirect compensation” too narrowly. In the preamble to the 2009 IPPS proposed rule, 73 Fed. Reg. 23527 (April 30, 2008), CMS indicated that the second prong of the test for an indirect compensation relationship may be met in a “wide range of circumstances, including, without limitation, arrangements involving: variable, per-click or percentage-based compensation; exclusive contracts; inflated fixed payments; or explicit or implicit tying of compensation to other referrals.” 73 Fed. Reg. at 23687.

   a. Recently, in United States ex rel. Singh v. Bradford Reg’l Med. Ctr., No. 04-186, 2010 U.S. Dist. WL 4687739 (W.D. Pa. Nov. 10, 2010), the court found that the circumstances surrounding a fixed-fee equipment sublease between a hospital and physicians established that the aggregate compensation took into account the value or volume of anticipated referrals. Among other things, the hospital’s consultant placed a value on the covenant not to compete that was included in the sublease based on the revenues
the hospital would receive, assuming that the physicians would be likely to refer to the hospital for the services.

3. If an indirect compensation arrangement is found to exist, the parties will need to structure the relationship to meet the applicable exception. The exception for indirect compensation arrangements requires compliance with the following conditions: (a) the compensation received by the referring physician (or an immediate family member) is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnished the designated health service; (b) the compensation arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment arrangement in which case the arrangement need not be in writing but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer; and (c) the compensation arrangement does not violate the Anti-Kickback Statute or any federal or state law/regulation governing billing or claims submission. 42 C.F.R. § 411.357(p). As discussed above, as a result of the revisions adopted in the 2009 IPPS Final Rule, certain percentage and per-unit rental arrangements were prohibited effective October 1, 2009.

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. In addition, it is often useful to consider the questions that would need to be answered in submitting an advisory opinion request to the OIG. See the suggested questions in Attachment A posted at http://oig.hhs.gov/fraud/docs/advisoryopinions/prequestions.htm.

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
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 (Nov. 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 (Nov. 23, 1999). Also see OIG Advisory Opinion 09-17 (Oct. 7, 2009), OIG Advisory Opinion 10-14 (Aug. 30, 2010), OIG Advisory Opinion 10-23 (Oct. 28, 2010) and OIG Advisory Opinion 10-24 (Oct. 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. Equity Joint Venture Analysis.

1. If a hospital and physicians form a joint venture that will provide under arrangements services, the small entity investment safe harbor will also be relevant. 42 C.F.R. § 1001.952(a)(2). In analyzing a joint venture formed to provide services under arrangements to a hospital, both the investing physicians and the hospital would be considered referral sources for purposes of applying this safe harbor, making satisfaction of the safe harbor criteria limiting the extent of investment by referral sources and percentage of revenue derived from referral sources difficult.

D. 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 (Jan. 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.

E. OIG Advisory Opinion 09-17 (Oct. 7. 2009).

1. In this Advisory Opinion, the OIG considered a joint venture ambulance company (the “Ambulance Company”) with four owners, including a hospital that contracted for the services of the Ambulance Company under arrangements (the “Hospital Owner”) and a competitor that provided management services to the Ambulance Company for a management fee equal to a percentage of the Ambulance Company’s revenues (the “Management Company”).

2. The OIG noted that the Ambulance Company raised concerns of a problematic joint venture, citing both its alert on joint ventures and its bulletin on contractual joint ventures. The OIG analyzed the relationship under the small entity safe harbor, concluding that this safe harbor was
not satisfied because the Hospital Owner and Management Company together owned more than 40% of the equity in the joint venture. It also analyzed the agreement with the Management Company under the safe harbor for personal services and management contracts, concluding that this safe harbor was not met because the aggregate fee to the Management Company was not set in advance.

3. Despite indicating that the arrangement was “highly prone to fraud and abuse because of the multiple streams of remuneration flowing between parties that can make referrals and parties that can profit from those referrals,” the OIG concluded that it would not impose sanctions under the specific facts and circumstances of this arrangement.

4. The OIG concluded that there was low risk that the return on investment to the owners of the Ambulance Company was in exchange for referrals to the Ambulance Company or the other owners for the following reasons:
   
a. The substantial majority of the revenues of the Ambulance Company were from a contract with a county’s emergency medical authority to respond to calls dispatched through the county’s 911 system. The owners of the Ambulance Company could not influence the volume of these revenues.
   
b. The Ambulance Company promoted a public benefit by providing needed services to the county.
   
c. The revenue of the Ambulance Company attributable to referrals from its owners was well below the 40% threshold of the small entity investment safe harbor.
   
d. Distribution of income to the owners of the Ambulance Company was strictly in proportion to their ownership interests (25% each).
   
e. The owners of the Ambulance Company “assumed genuine business risk by committing financial resources.”

5. The OIG concluded that the agreement for services between the Hospital Owner and the Ambulance Company, while meriting careful scrutiny, did not appear to pose an undue risk for the following reasons:
   
a. There was no substantial risk that the Ambulance Company was swapping a discount on the services billed by the Hospital Owner under arrangements for the referral of Medicare business billed directly by the Ambulance Company. Pricing to the Hospital Owner was represented to be at fair market value, the Ambulance Company was required to provide services to all patients, including uninsured patients, and while the Ambulance Company was a preferred provider of ambulance services for the Hospital Owner, a patient’s preference for a different provider would be honored.
b. The arrangement did not pose a significant risk of over-utilization. The arrangement covered discharge transports and inter-facility transports, and the Owner Hospital had a countervailing incentive to limit its costs for the services.

6. Last, the OIG concluded that the management agreement posed an acceptably low level of risk for the following reasons:

a. The Management Company made referrals to the Ambulance Company only in limited circumstances when the Ambulance Company had the closest ambulance to an area that the Management Company was under contract to cover. Because the Management Company would achieve greater profit from providing such services itself than from referring them to the Ambulance Company, it had a strong financial incentive not to refer to the Ambulance Company.

b. The parties certified that the management fee was consistent with fair market value.

c. The management agreement appeared to meet all conditions of the safe harbor for personal services and management contracts other than the requirement that the aggregate compensation be set in advance.

F. OIG Advisory Opinions Addressing Sleep Lab 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 (Aug. 30, 2010), 10-23 (Oct. 28, 2010 and 10-24 (Oct. 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 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.

XIV. ANALYTIC FRAMEWORK.

A. Purpose of Arrangement.
   
1. Will Medicare/Medicaid payment be affected by whether or not the service is billed as a hospital service?
   
2. If an equity venture or contractual joint venture is being pursued, what is the purpose of the venture, and what role do the participants play?

B. Stark Law (See discussion at Section XII above).
   
1. Does a physician have an ownership or compensation relationship with a party to the venture?
   
2. If so, what exception is available?

C. Medicare Coverage – Location and Physician Supervision (See discussions at Section II and Section X above).
   
1. Is the service covered only if performed in a hospital or hospital-based department?
   
2. What level of practitioner supervision is required for the service? If direct supervision, is the physician (or certain other practitioner for therapeutic services) immediately available?
   
3. What qualifications must the supervisory practitioner have?
D. Basis for Billing Service as a Hospital Service.

1. Satisfaction of provider-based status requirements (See Sections III, V, VI and VII above).

2. Ability to obtain and bill for services under arrangements (See Section IV above).

E. Medicare Conditions of Participation (See Section II.E. and Section IV.E. above).

F. Satisfaction of Joint Commission or Other Accreditation Requirements (See Sections IV.F. and IV.G. above).

G. Compliance with Anti-Kickback Statute (See Section XIII above).

H. Compliance with State Self-Referral Prohibitions and Anti-Kickback Laws.

I. Compliance with State Licensure Law and Other State Law Requirements.

J. Compliance with Federal and State Tax Laws.