

THE PROVIDER-BASED RULES

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Background

- On April 7, 2000, the Centers for Medicare and Medicaid (“CMS”) (then named “HCFA”) issued requirements for provider-based departments and entities as part of the final rule implementing the prospective payment system for outpatient hospital services.

Source: 65 Fed. Reg. 18,433 (April 7, 2000) (codified at 42 C.F.R. § 413.65).

Background continued

- The regulation was later amended at 65 Fed. Reg. 47,670, 47,677 (Aug. 3, 2000), and at 66 Fed. Reg. 59856, 59909-59915 (Nov. 30, 2001), implementing § 404 of the Benefits Improvement and Protection Act of 2000 (Dec. 21, 2000) (“BIPA”).

Background continued

- In addition, CMS has furnished limited guidance in the form of Q&As, found at <http://www.hcfa.gov/medlearn/provqa.htm>. The regulation's standards resemble, but are more stringent than, the prior standards embodied in PM A-96-7 and State Operations Manual § 2004.

Why is Provider-Based Status Important?

- **Payment Ramifications**

- Provider-based status historically meant that the provider-based unit could appear on the hospital's cost report and receive an allocation of the hospital's overhead. This allocation consideration is of dwindling importance.

Why is Provider-Based Status Important? continued

- **Payment Ramifications, continued**
 - Nevertheless, provider-based status can have payment significance. For example, look at services furnished non-provider clinic settings (physician fee schedule) vs. the same services furnished in hospital outpatient setting (APCs).

Why is Provider-Based Status Important?

continued

- **Coverage Ramifications**

- Certain services must be furnished in a particular setting as a condition of coverage. For example, partial hospitalization services must be furnished in a certified Community Mental Health Center (CMHC) or a hospital.

Why is Provider-Based Status Important?

continued

- **Compliance Considerations**

- There are cases in which the providers' alleged failures to satisfy previous criteria have given rise to fraud and abuse charges. Expect significant increase in charges once new rules are fully in place.

To Whom Do the Rules Apply?

- **General Rule**
 - The rules apply to: (i) provider-based entities (such as RHCs); (ii) hospital departments; (iii) remote locations of a hospital, such as a hospital location for specialty services located many miles away from the main provider; and (iv) to satellite facilities.



To Whom Do the Rules Apply? continued

- **Distinct Part Units**

- The provider-based rules apply to cost-reimbursed distinct part units. This means that inpatient psychiatric units must qualify as provider-based. The units will need to file two applications with CMS – one for provider-based status and one for distinct part status.

To Whom Do the Rules Apply? continued

- **Multi-Campus Hospitals**
 - Multi-campus hospitals must meet the provider-based criteria, with one campus being designated as the “main provider.”

To Whom Do the Rules Apply? continued

- **If No Payment Effect**

- Where provider-based versus freestanding status has no payment ramifications and does not affect beneficiary liability, CMS will not apply the provider-based rules and will not require the site to submit an application.

To Whom Do the Rules Apply? continued

- **If No Payment Effect, continued**
 - This applies to:
 - (1) Ambulatory Surgery Centers (ASCs);
 - (2) Comprehensive Outpatient Rehabilitation Facilities (CORFs);
 - (3) Home Health Agencies (HHAs);
 - (4) Skilled Nursing Facilities (SNFs);
 - (5) Hospices;
 - (6) Inpatient Rehabilitation Units paid under the new Rehab PPS;

To Whom Do the Rules Apply? continued

- **If No Payment Effect, continued**
 - (7) Facilities that furnish only clinical diagnostic laboratory tests;
 - (8) End-Stage Renal Disease (ESRD) facilities; and
 - (9) Facilities that furnish only outpatient physical, occupational and speech therapy as long as the \$1,500.00 annual cap on those services is suspended.

What Are the Regulation's Effective Dates?



- **General Rule**

- CMS originally directed that the requirements become effective October 10, 2000, but, at the urging of Congress and the public, later delayed the effective date of the requirements until January 10, 2001. In Section 404 of BIPA, Congress further delayed the effective date for certain aspects of the regulation.

What Are the Regulation's Effective Dates?

continued

- **Grandfathering Provision – What Is Further Delayed under BIPA?**
 - Facilities and organizations “treated as provider-based in relation” to a hospital as of October 1, 2000 are “grandfathered” until October 1, 2002. These grandfathered facilities are not required to meet the new requirements applicable to qualifying as provider-based or the limitations applicable to joint ventures, management contracts, and “under arrangement” services until that date.

What Are the Regulation's Effective Dates?

continued

- **Grandfather Provision – What Is Not Further Delayed?**
 - Section 404 does not delay all of the provider-based rules for “grandfathered” facilities. Notably, the provider-based rules applicable to EMTALA and to the obligations of provider-based entities became effective on the first day of the hospital’s cost reporting period beginning on or after January 10, 2001. Similarly, the rules regarding physician supervision are not delayed.

What Are the Regulation's Effective Dates? continued

- **Facilities That Are Not “Grandfathered”**
 - Facilities and organizations that were not “grandfathered” were required to meet all provider-based requirements and obligations effective with the first day of the facility’s cost reporting period beginning on or after January 10, 2001.

The Regulation's Primary Requirements



- The provider-based regulation requires provider-based entities to satisfy all of the following requirements:

The Regulation's Primary Requirements

- **Licensure**

- The department of the provider, a remote location of a hospital, or a satellite facility must be operated under the same license as the main provider, except in areas where the state requires a separate license for the department, remote location, or satellite facility. If the state does not require licensure for the particular type of facility, CMS will not require that licensure standard be met.

The Regulation's Primary Requirements continued

- **Licensure, continued**

- If a state health facilities' cost review commission or other agency that has authority to regulate the rates charged by hospitals or other providers in a state “finds that a particular facility or organization is not part of a provider,” CMS will determine that the facility or organization does not have provider-based status. This is applicable primarily to Maryland facilities.

The Regulation's Primary Requirements continued

- **Licensure, continued**

- Although accreditation as part of the hospital is required for provider-based status under SOM 2004 and PM A-96-7, this requirement was dropped in the regulation.

The Regulation's Primary Requirements continued

- **Operation Must Be under Ownership and Control of the Main Provider**

The facility or organization must:

- Be 100 percent owned by the provider.
- Have the same governing body.

The Regulation's Primary Requirements continued

- **Operation under Ownership and Control of the Main Provider, continued**
 - Be operated under the same organizational documents as the main provider.
 - The main provider must have final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies and final approval for medical staff appointments in the facility or organization.

The Regulation's Primary Requirements continued

- **Operation under Ownership and Control of the Main Provider, continued**
 - Note that CMS has said that “common control of two separate entities by the same parent organization . . . [is not] sufficient to meet a requirement for ownership and control by the main provider.” 65 Fed. Reg. 18,514. This is consistent with the practice of a number of Regional Offices over the past several years.

The Regulation's Primary Requirements continued

- **Operation under Ownership and Control of the Main Provider, continued**

- The ownership requirement applies to the business entity; physical assets do not have to be owned and may be leased.

Source: 65 Fed. Reg. 18,514

- Joint ventures are not allowable because they do not amount to 100% ownership and control.

Source: 42 C.F.R. § 413.65 (e)

The Regulation's Primary Requirements continued

- **Administration and Supervision**

- The facility or organization must be under the direct supervision of the provider where it is located.
- It must be operated under the same monitoring and oversight by the provider as any other department of the provider, and it must be operated just as any other department of the provider with regard to supervision and accountability.

The Regulation's Primary Requirements continued

- **Administration and Supervision, continued**
 - The facility or organization director or individual responsible for daily operations at the entity must:
 - Maintain a reporting relationship with a manager at the main provider; and
 - Be accountable to the governing body of the main provider.
 - Relationship here must be the same as exists between the main provider and other departments, with same degree of accountability, frequency of reporting, and the like.

The Regulation's Primary Requirements continued

- **Administration and Supervision, continued**
 - Administrative functions — billing records, records, human resources, payroll, employee benefits, salary structure, and purchasing services — of the facility or organization must be integrated with the main provider's. The same employees or group of employees must handle these administrative functions for the facility or organization and the main provider.

The Regulation's Primary Requirements continued

- **Administration and Supervision, continued**
 - The administrative functions for both the facility or organization and the entity must be:
 - Contracted out under the same contract agreement; or
 - Handled under different contract agreements, with the contract of the facility or organization being managed by the main provider.

The Regulation's Primary Requirements continued

- **Integration of Clinical Services**

- The professional staff of the facility or organization must have clinical privileges at the main provider.
- The main provider must maintain the same monitoring and oversight of the facility or organization as exists with any other department.

The Regulation's Primary Requirements continued

- **Integration of Clinical Services, continued**
 - The medical director of the facility or organization seeking provider-based status must maintain a reporting relationship with the Chief Medical Officer or other similar official of the main provider. It must be of the same frequency, intensity and level of accountability as exists with directors of other hospital departments.

The Regulation's Primary Requirements continued

- **Integration of Clinical Services, continued**
 - Medical staff committees or other professional committees at the main provider must be responsible for the medical activities in the facility or organization, including quality assurance, utilization review, and coordination and integration of services between the facility or organization seeking provider-based status and the main provider.

The Regulation's Primary Requirements continued

- **Integration of Clinical Services, continued**
 - Medical records for patients treated in the facility or organization will be integrated into a unified retrieval system of the main provider. Professionals practicing at either the main provider or the provider-based site must be able to “obtain relevant medical information about care in the other setting.”

The Regulation's Primary Requirements continued

- **Integration of Clinical Services, continued**
 - Inpatient and outpatient services of the facility or organization and the main provider must be integrated. Patients treated at the facility or organization who require further care must have full access to all services of the main provider and be referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.

The Regulation's Primary Requirements continued

- **Financial Integration**

- The financial operations of the facility or organization must be fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization.
- The costs of the facility or organization must be reported in a cost center of the provider, and the financial status of the facility or organization must be incorporated and readily identified in the main provider's trial balance.

The Regulation's Primary Requirements continued

- **Public Awareness**

- The facility or organization seeking status as a department of a provider, remote location, or satellite facility must be held out to the public and other payers as part of the main provider. How much the names must match is open to question.
- When patients enter the provider-based facility or organization, they must be aware that they are entering the main provider and will be billed accordingly.

The Regulation's Primary Requirements continued

- **Location in Immediate Vicinity**

- The facility or organization and the main provider must be located on the same campus.
- Alternatively, it must demonstrate a high level of integration with the main provider by showing that it meets all of the other provider-based criteria, and by demonstrating as well that it serves the same patient population as the main provider (75% zip code tests).

The Regulation's Primary Requirements continued

- **Location in Immediate Vicinity, continued**
 - Alternatively, it must be located not more than 35 miles from the main campus of the hospital or critical access hospital.
 - A facility or organization is not considered to be in the “immediate vicinity” of the main provider unless the facility or organization and the main provider are located in the same state or, where consistent with the laws of both states, adjacent states.

The Regulation's Primary Requirements continued

- **Location in Immediate Vicinity, continued**

Immediate vicinity criterion is waived in two cases:

First — If the main provider has a disproportionate share adjustment percentage greater than 11.75% and is (1) a government owned or operated hospital, (2) a public or private nonprofit corporation that is formally granted governmental powers by a unit of state or local government, or

The Regulation's Primary Requirements continued

- **Location in Immediate Vicinity, continued**

(3) a private hospital that has a contract with a state or local government that includes the operation of clinics of the hospital to ensure access in a well-defined service area to health care services for low-income individuals who are not entitled to Medicare or Medicaid, the facilities are deemed to comply with the “immediate vicinity” requirements of the provider-based rules.

The Regulation's Primary Requirements continued

- **Location in Immediate Vicinity, continued**

Second — there is an RHC exception for rural health clinics that are otherwise qualified as provider-based entities of a hospital that is located in a rural area and has fewer than 50 beds.

The Regulation's Primary Requirements continued

- **Exception to Provider-based Rules for FQHCs and “Look Alikes”**
 - A facility that, since April 7, 1995, has furnished only services that were billed as if they had been furnished by a department of a provider, does not have to satisfy the provider-based criteria if: (1) before April 7, 2000, it received a § 330 Public Health Service Act grant; or is receiving funding from such a grant under a contract with the grant's recipient and meets the requirements to receive such a grant; or, based on a recommendation from PHS, was determined by HCFA before April 7, 2000 to meet the requirement for receiving such a grant; and (2) since April 7, 2000, furnished only services that were billed as if they had been furnished by a department of the provider.

Additional Standards

In addition, the final rule adds new limitations on obtaining provider-based status, as well as new standards applicable to entities that obtain provider-based status.



Management Contracts

- **Management contracts must meet the following:**
 - The staff (except managers) must be employees of the main provider or the entity that employs the main provider's staff
 - Integration of administrative functions with the main provider (billing; records; human resources; payroll; employee benefits; salary structure; and purchasing)
 - The main provider has significant control over the service (final administrative decisions, contracts with outside parties, personnel actions and policies and medical staff appointments)
 - The management contract is held by the main provider

Source: 42 C.F.R. § 413.65(f)

“Under Arrangements” and “Joint Ventures”

- A facility or organization may not qualify for provider-based status if
 - all patient services at the facility are furnished under arrangements; or
 - the entity is owned by two or more providers in a joint venture

Source: 42 C.F.R. § 413.65(e) and (h)

- Question: is a joint ventured under arrangement permitted in the main facility?

Provider-Based and Medicaid

- Preamble — hospitals under Medicaid must meet the same standards as Medicare facilities
- October 2000: States have considerable flexibility to determine payment rates, and could adopt higher rates for services affiliated with a provider even if free-standing for Medicare purposes
- Issue: can a free-standing service of a hospital be certified for Medicaid purposes?
- Effect: regional pediatric hospital services

Outpatient Department Additional Rules

- **Outpatient departments must --**
 - Comply with the hospital's Medicare provider agreement
 - Ensure the physicians and staff comply with Medicare non-discrimination rules
 - Meet hospital health and safety rules
 - Ensure that physicians billing professional services in the departments use the correct site-of-service indicator
 - Meet the “incident to” rules for services/supplies furnished to patients; a physician must be on the premises and immediately available to assist and direct when patients are receiving “incident to” services

Source: 42 C.F.R. §§ 410.27; 413.65(g)(2)-(4) and (8)

Outpatient Department Additional Rules

- **Outpatient departments must --**
 - Treat all Medicare patients alike (i.e., cannot treat some Medicare patients as hospital-based and some as physician office patients)
 - Split bill technical and professional components for Medicare patients; but may globally bill other payors
 - Inform beneficiaries in writing of potential financial liability

Source: 42 C.F.R. § 413.65(g)(5) and (7)



EMTALA



New Requirements for On-Campus and Off-Campus Services

On-Campus Issues

- **Rule:** EMTALA applies to any person who is on the hospital campus who is seeking emergency services.
- **Definition:** the hospital “campus” is
 - The main hospital buildings, and
 - Other areas and structures that are located within 250 yards of the main buildings, and
 - May include other areas determined by the CMS regional office to be part of the hospital campus.

Source: 42 C.F.R. § 413.65(a)

On-Campus Issues

The 250-Yard Test

- **Rule:** Applies to buildings and structures located within 250 yards of the main buildings that are part of the hospital.
- **Guidance:** “The parameters of a hospital’s campus are not determined by drawing a circle 250 yards around a hospital’s main buildings and concluding that every building, area and structure that happens to be located within those boundaries is part of the hospital campus.”

On-Campus Issues

The 250-Yard Test

- **Examples of what is covered:** provider-based departments, parking lots, sidewalks, driveways and buildings that are part of the hospital.
- **Examples of what is not covered:** privately-owned businesses (e.g., gas stations, restaurants), private residences, private physician offices.
- **The gray areas:** public streets, public areas within hospital-owned medical office buildings, privately-owned parking lots.

Source: CMS EMTALA Guidance (Q/A 1)

On-Campus Issues

Moving Patients within the Campus

- **Service must be on-campus and operated by the hospital --**
 - MSE must be provided under EMTALA policies by staff designated to perform medical screenings
 - Patients who are moved within the campus have similar medical conditions (e.g., occupational medicine, non-urgent patients)
 - There are bona fide reasons to move patients
 - Patients are provided an escort or assistance, as needed

Source: EMTALA Interpretive Guidelines, Tag No. A406

Off-Campus Departments

- If *provider-based*, must meet EMTALA requirements —
 - Capability of an off-campus service is the capability of the entire hospital, but “...the hospital is not required to locate additional personnel or staff to off-campus departments to be on standby for possible emergencies.”

Off-Campus Departments

- **Every off-campus department must have --**
 - Protocols for handling patients with potential emergency conditions
 - Direct contact with emergency personnel at hospital in the event that a patient presents with an emergency medical condition; and
 - Transfer agreements with other area hospitals
 - Central log recording of emergency patients
 - EMTALA signage

Source: 42 C.F.R. § 489.24(i); CMS EMTALA Guidance (Q/A 6, 17-20, 23-4)

Off-Campus Departments Staffing Requirements

- Off-campus urgent care, primary care and other services routinely staffed by physicians and nurses must have at least one person on duty during regular hours of operation to provide medical screening examinations and stabilizing treatment
- Off-campus services that are NOT routinely staffed by physicians and nurses must have protocols for contacting emergency personnel at the main hospital and arranging either transport of a potential emergency to the hospital or transfer to another hospital

Source: 42 C.F.R. § 489.24(i)

Off-Campus Departments Staffing and the MSE

- The hospital may use less stringent criteria for designation of personnel to perform the MSE in an off-campus department
- Regular hours of operation do not include periods when the department is closed (e.g., lunch time)
- Hospitals may dispatch emergency personnel to off-site locations but are not required to do so
- Department must prioritize the screening based upon the individuals presenting at that location ...cannot delay due to non-emergency caseload

Source: CMS EMTALA Guidance, 7/20/01 (Q/A 9-12)

Off-Campus Departments

Scope of the MSE

- **Rule:** An off-campus department routinely staffed by physicians and nurses must provide an MSE to an individual seeking or needing emergency services
- **Question:** Must the MSE in an off-campus department be conducted in the same manner as the emergency department?

Off-Campus Departments Scope of the MSE (continued)

- **Answer:** “We expect that the type and extent of the screening will be dependent upon the conditions that the patient presents. Depending on the presenting conditions and the capabilities and capacity available at an off-campus department, the personnel at that off-campus department may be able to complete the screening, or may need to arrange transport of the individual to the main hospital’s emergency department for completion of the screening and any necessary stabilization.”

Source: CMS EMTALA Guidance (Q/A7)

Off-Campus Departments Communication with the Hospital

- **Rule:** An off-campus department must contact the hospital E.D. if an individual has an emergency medical condition
- **CMS Guidance:** The communication “should be reliable for its intended purpose, which is to provide timely direction to the off-campus department. It should link the off-campus department directly to the main campus emergency department, and protocols should ensure that calls from the off-campus department to the main campus emergency department will be answered in person and responded to promptly, within the capability of the main campus emergency department.”
 - “Contact may be delayed ... if the contact would endanger a patient subject to EMTALA protection.”

Source: CMS EMTALA Guidance, 7/20/01 (Q/A 7 and 13)

Off-Campus Departments Moving the Patient

- **Rules:**

- All off-campus services must transport an emergency patient needing a higher level of care to the main hospital. This is NOT considered a transfer as defined by EMTALA
- Must make an EMTALA-appropriate transfer to another hospital if —
 - The main hospital cannot provide the care, or
 - The patient requests a transfer to another facility; or
 - Transporting of the patient to the main hospital will significantly jeopardize the life or health of the patient

Source: 42 C.F.R. § 489.24(i)

Off-Campus Departments Calling 911

- **Question:** What is the appropriate use of 911?
- **Guidance:** “If a patient presents to a provider-based off-campus department with an emergency medical condition, CMS expects the off-campus staff to initiate care within their capability. However, if it is evident that the staff’s best efforts will be insufficient to stabilize the patient’s emergency medical condition, or the patient’s condition rapidly deteriorates, and the instability of the patient’s condition does not permit hospital staff to move the patient to the main hospital safely because doing so would significantly jeopardize the patient’s life or health, it would be appropriate to activate the EMS to facilitate an appropriate transfer consistent with ...” EMTALA standards.

Source: CMS EMTALA Guidance (Q/A 14)

Off-Campus Departments Calling 911 (continued)

- Activating 911 does not excuse the off-campus staff from providing screening and stabilization care within their capabilities pending the arrival of EMS
- Even if EMS is activated, the off-campus department must contact the hospital E.D. to report the situation. Contact may be delayed if to do so would endanger the patient.
- The decision to call 911 and patient disposition will be based on the capabilities of the personnel staffing the off-campus department. Each department must have protocols for handling emergency situations.
- If the off-campus personnel call 911, the patient must still be entered in the central log.

Source: CMS EMTALA Guidance (Q/A 14-16)

EMTALA Compliance Tips

- Hospital property policies for EMTALA compliance
- Policies and procedures for off-campus departments
- Designation of personnel to perform medical screening examinations
- Transfer agreements
- Policies and procedures for E.D. to handle calls from off-campus departments
- Post signage
- In-service training
- Quality management



Provider-Based Applications

Reporting and Approval

- **Who Must Seek Approval?**

- As a general matter, a main provider or a provider-based facility or organization must contact CMS, and the facility or organization must be determined by CMS to be provider-based, before the main provider bills for services of the facility or organization as if the facility or organization were provider-based, or before it includes costs of those services on its cost report.

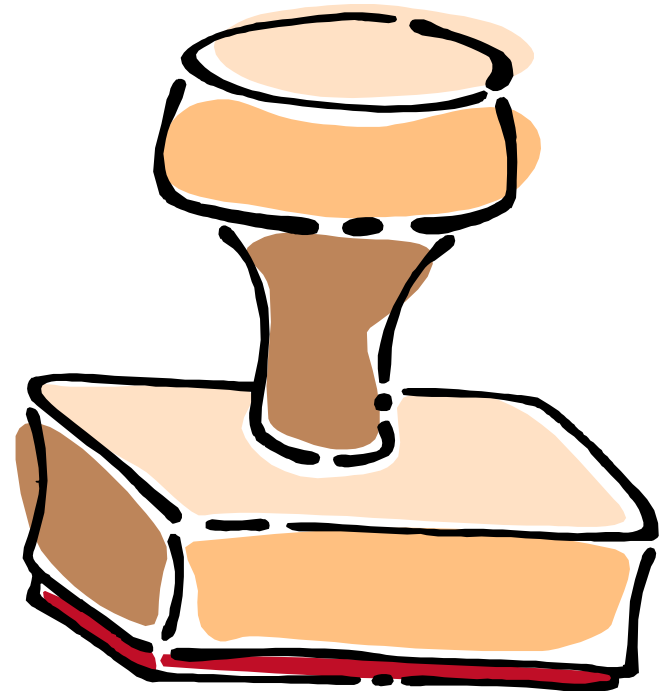
Source: 42 C.F.R. § 413.65(b)(3).

Who Must Apply

- **Who must apply --**
 - Any new or acquired off-campus facility or department (regardless of size or complexity)
 - Any material change in an existing provider-based facility (e.g., change of ownership, change in financial operations, or a new or different management contract that could affect provider-based status)
 - Applications for entities/departments currently treated as provider-based under BIPA, but no prior formal determination for the entity/department has been made

Reporting and Approval

- **CMS's Plans to Review**
 - CMS states that it plans to review all new referrals for provider-based status. It does not intend, at present, to review all providers to determine whether they may be claiming provider-based status inappropriately.



Reporting and Approval continued

- **Application Process**

- CMS has said that it is developing an application process that should be in place “soon.” In the meantime, many Regional Offices have developed their own application forms. The CMS Regional Offices will make the provider-based determinations presumably after consultation with the provider’s intermediary. If a facility seeks provider-based status prior to the application being developed, the facility should send a detailed letter to the Regional Office explaining why it meets all of the provider-based criteria, together with supporting documentation.

What Happens in the Event of Failure to Satisfy Provider-Based Criteria – Exceptions to the General Rule



- **If No Prior “Formal” Approval of Provider-Based Status**
 - Section 404 of BIPA specifies that entities that were paid as provider-based as of October 1, 2000 will continue to be treated as provider-based until October 1, 2002, irrespective of whether the entity meets the new rules. Until that date, these entities are “grandfathered” and are not penalized in the absence of formal approval from CMS of provider-based status.

What Happens in the Event of Failure to Satisfy Provider-Based Criteria continued

- **If No Prior “Formal” Approval of Provider-Based Status, continued**
 - Moreover, as long as the facility or organization makes application for provider-based status on or after October 1, 2000, and before October 1, 2002, it is to be treated as provider-based until a determination is made with respect to its status. If status is denied, the denial will be prospective only.

Sources: BIPA § 404; 42 C.F.R. § 413.65(b)(2).

What Happens in the Event of Failure to Satisfy Provider-Based Criteria continued

- **If Past Favorable Provider-Based Determination Was Mistaken**
 - If CMS has previously determined that an entity is provider-based, CMS may nonetheless review that determination to correct errors made in reaching it. If CMS reverses a past favorable determination, provider-based status ceases with the first day of the next cost reporting period following notice of redetermination, but in no case prior to six months after the date on which CMS notifies the provider of the reversal.

Compliance Tips

- Inventory all hospital services (including inpatient) on and off campus that are billed to the Medicare Program
- Determine whether any services are under arrangements or joint ventures
- Apply the seven provider-based criteria to each service
- Review all management contracts, and apply the four management criteria to each managed service
- Determine what services have CMS letters confirming provider-based designation

Provider-Based Compliance Tips

- Determine what departments/entities have CMS letters confirming provider-based designation
 - Are there material changes since the date of the letter?
- Compile documents for departments/entities that do not have letters confirming provider-based designation
- Develop strategies for non-complying departments/entities
- Review projects in the pipeline for compliance
- Review compliance with billing, cost reporting and other rules for provider-based departments