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CHAPTER VI: PROVIDER-BASED ENTITIES

OBJECTIVES

The objective of this chapter is to provide participants with an understanding of the Final Rule on provider-based status published in the April 7, 2000, *Federal Register*. At the end of this session, participants obtain an understanding of:

- The general requirements for status as provider-based entity or department of a provider.
- Specific provisions relating to joint ventures and management contracts.
- Responsibilities of the provider for obtaining provider-based determinations.
- Provisions for recovery, as a result of inappropriate treatment of a facility or organization as provider-based.
- Obligations of hospital outpatient departments and hospital-based entities.

BACKGROUND

Medicare has defined various types of providers of services but has never defined in Medicare law the term “provider-based.” However, from the beginning of the Medicare program, some providers have owned and operated other facilities, such as SNFs or HHAs, that were administered financially and clinically by the main provider. The subordinate facilities may have been located on the main provider campus or may have been located away from the main provider.

Past Treatment (Prior to Inpatient PPS)

- **Cost Reimbursement Provided Economies of Scale**
- **No Payment Incentive for Provider-Based vs Free-Standing**

In order to accommodate the financial integration of the two facilities without creating an administrative burden, HCFA has permitted the subordinate facility to be considered provider-based. The determination of provider-based status allowed the main provider to achieve certain economies of scale. To the extent that overhead costs of the main provider, such as administrative, general, housekeeping, etc., were shared by the subsidiary facility, these costs were allowed to flow to the subordinate facility through the cost allocation process in the cost report. This was considered appropriate because these facilities were also operationally integrated, and the provider-based facility was sharing the overhead costs and revenue producing services controlled by the main provider.

Before implementation of the hospital inpatient PPS in 1983, there was little incentive for providers to affiliate with one another merely to increase Medicare revenues or to misrepresent themselves as being provider-based, because at that time each provider was paid primarily on a retrospective, cost-based system. At that time, it was in the best interest of both the Medicare program and the providers to allow the subordinate facilities to claim provider-based status, because the main providers achieved certain economies, primarily on overhead costs, due to the low incremental nature of the additional costs incurred.

PPS Systems Initiated in 1983 Resulted in:

- **Increase in Provider-Based Status**
- **As Additional PPS Systems Implemented Payment Variances Increase**

In the proposed rule, HCFA noted the increase of provider-based facilities and the financial and organizational incentives for that increase since 1983. A variety of factors such as the emergence of integrated delivery systems and the pressure to enhance revenues have combined to create incentives for providers to affiliate with one another and to acquire control of traditionally non-provider treatment settings, such as physician offices.

HCFA noted in the proposed rule that it is essential to make decisions regarding provider-based status appropriately, and that we have clear rules for identifying provider-based entities.

Provider-Based Regulations Incorporated Into OPPS

- **Consistent Definition for Provider-Based Designation**
- **Provider-Based Regulations Effective 10/10/2000**
- **OPD PPS Effective 7/1/2000**

One example given in the proposed rule is a beneficiary treated in a physician's office versus a hospital outpatient clinic. When the beneficiary is treated in a physician's office, the only payment made is Part B payment to the physician for his or her professional services, under the physician fee schedule. The single payment made under the physician fee schedule pays for the physician's work and includes a component for practice expense. The beneficiary's coinsurance is based on 20 percent of the physician fee schedule amount. If the same services is furnished in a hospital outpatient clinic, Medicare Part B payment for a facility fee is also made to the hospital, in addition to the physician's payment (with a reduced practice expense component) and the beneficiary's coinsurance is based on 20 percent of the hospital's charges.

The effective date of the "provider-based" regulations is six months after the publication of the Final Rule, or 10/10/2000.

DEFINITIONS

The Final Rule provides definitions and general requirements for the determination of provider-based status. In addition to provider-based status, the following terms are also defined:

- Main provider
- Campus
- Department of a provider
- Provider-based entity
- Remote location of a hospital
- Free-standing facility

Campus

- **Immediately adjacent**
- **Within 250 Yards**
- **As determined by HCFA**

Campus

A campus means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings. A campus will also include any other areas determined on an individual case basis, by the HCFA regional office, to be part of the provider's campus.

Main Provider

A main provider means a provider that either creates, or acquires ownership of, another entity to deliver additional health care services under its name, ownership, and financial and administrative control.

Department of Provider

- **Under the Name, Ownership and Financial and Administrative Control**
- **Not Licensed in Own Right**
- **Excludes RHC/FQHC**

Department of a Provider

A department of a provider means a facility or organization or a physician office that is either created by, or acquired by, a main provider for the purpose of furnishing health care services under the name, ownership, and financial and administrative control of the main provider.

A department of a provider may not be licensed to provide health care services in its own right, and Medicare conditions of participation do not apply to a department as an independent entity.

The term department of a provider would not include an RHC or FQHC. HCFA has determined that RHCs will be defined as “provider-based” entities. In addition, HCFA has established special provisions for FQHCs that will be addressed later in this chapter .

Provider-Based Entity

- **Services of a Different Type**
- **Under the Name, Ownership and Financial and Administrative Control**

Provider-Based Entity

A provider-based entity is a provider of health care services, or an RHC that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider. A provider-based entity will operate under the name, ownership, and administrative and financial control of the main provider

Remote Location of a Provider

- **Not Licensed in Own Right**
- **Under the Name, Ownership and Financial and Administrative Control**

Remote Location of a Hospital

The term “remote location of a provider” is used to describe a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services. As with a “department of a hospital,” a remote location of a hospital operates under the name, ownership, and financial and administrative control of the main provider.

A remote location of a hospital may not be licensed to provide inpatient hospital services in its own right, and Medicare conditions of participation do not apply to a department as an independent entity. The term “remote location of a hospital” does not include a satellite facility.

Provider-Based Status

The term “provider-based status” will be used to describe the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or satellite facility that complies with the Final Rule.

Free-Standing Facility

The term “free-standing facility” is used to describe an entity that furnishes health care services to Medicare beneficiaries and that is not integrated with any other entity as a main provider, a department of a provider, or a provider-based entity.

Provider-Based Requirements

- **Licensure**
- **Ownership and Control**
- **Administration and Supervision**
- **Clinical Services**
- **Financial Integration**
- **Public Awareness**
- **Location**

Ownership and Control

- **Owned by Provider**
- **Same Governing Body**
- **Same Organizational Documents**
- **Main Provider Has Final Responsibility**

REQUIREMENTS FOR PROVIDER-BASED ENTITY OR DEPARTMENT OF PROVIDER

HCFA has defined specific requirements for provider-based entities or departments of providers. All the defined criteria must be met.

Licensure

The department of the provider, remote location of the hospital, or 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 under a single license.

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, HCFA will determine that the facility or organization does not have provider-based status.

Ownership and Control

The facility or organization seeking provider-based status must be operated under the ownership and control of the main provider. The following requirements must be met:

- The business enterprise that constitutes the facility or organization must be 100 percent owned by the main provider.
- The main provider and the facility or organization seeking status as a department of the provider, remote location or satellite facility must have the same governing body.

- The facility or organization must 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 (such as fringe benefits/code of conduct), and final approval for medical staff appointments in the facility or organization.

Administration and Supervision

Administrative and Supervision

- **Direct Supervision**
- **Monitoring and Oversight**
- **Integrated Administrative Functions**

The reporting relationship between the facility or organization 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 departments, as evidenced by compliance with all of the following requirements:

- The facility or organization is under the direct supervision of the main provider.
- The facility or organization 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 or organization director or individual responsible for daily operations at the entity must maintain a day-to-day reporting relationship with a manager at the main provider, and be accountable to the governing body of the main provider, in the same manner as any department head of the provider.
- The following administrative functions of the facility or organization are integrated with those of the provider where the facility or organization is based:
 - billing services
 - records

- human resources
- payroll
- employee benefit package
- salary structure
- purchasing services

The same employees or group of employees must handle these administrative functions for the facility or organization and the main provider. The administrative functions for either the facility or organization and the entity can 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's billing department.

Clinical Services

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

Integrated Clinical Services

- **Professional Staff Privileges**
- **Monitoring of Clinical Services**
- **Day-to-Day Reporting with Medical Officer**
- **Main Provider Responsible for Medical Activities**
- **Integrated Medical Records**
- **Integrated Patient Services**

- Professional staff of the facility or organization have clinical privileges at the main provider.
- The main provider maintains the same monitoring and oversight of the facility or organization as it does for any other department of the provider.
- The medical director of the facility or organization seeking provider-based status maintains a (day-to-day) 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 director of a department of the main provider and the chief medical officer or other similar officer 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.

- Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility or organization including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility or organization seeking provider-based status and the main provider.
- Medical records for patients treated in the facility or organization are integrated into a unified retrieval system (or cross reference) of the main provider.
- Inpatient and outpatient services of the facility or organization and the main provider are integrated, and patients treated at the facility or organization who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.

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 are reported in a cost center of the main provider and the financial status of the facility or organization is incorporated and readily identified in the main provider's trial balance.

Public Awareness

The facility or organization seeking status as a department of a provider, remote location or satellite facility is held out to the public and other payers as part of the main provider. When patients enter the provider-based facility or organization, they are aware

that they are entering the main provider and are billed accordingly.

Exceptions to Same Campus

- **High Level Integration**
- **Same State**
- **Rural Health Clinic**

Location in Immediate Vicinity

The facility or organization and the main provider are located on the same campus, except as noted below.

High Level Integration

The facility or organization 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 HCFA, and for each subsequent 12-month period:

- At least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider;
- At least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (for example, at least 75 percent of the patients of an RHC seeking provider-based status received inpatient hospital services from the hospital that is the main provider); or
- If the facility or organization is unable to meet the criteria because it was not in operation during all of the 12-month period, the facility or organization is located in a zip code area included among those that, during all of the 12-month period described in the previous sentence, accounted for at least 75 percent of the patients served by the main provider.

Same State or Adjacent States

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 in an adjacent State, if this is not inconsistent with the law of either State and other criteria are met, including those related to services to the same patient population.

Rural Health Clinic

A rural health clinic that is otherwise qualified as a provider-based entity of a hospital that is located in a rural area and has fewer than 50 beds, is not subject to the criterion on services to the same potential patient population as the main provider. However, the clinic is subject to the rule on location in the same state as the main provider or, or in an adjacent State, if this is not inconsistent with the law of either State and other criteria are met.

Additional Provisions

- **Joint Ventures**
- **Management Contracts**

ADDITIONAL PROVISIONS**Joint Ventures**

A facility or organization cannot be considered provider-based if the entity is owned by two or more providers engaged in a joint venture. For example, where a hospital has jointly purchased or jointly created free-standing facilities under joint venture arrangements, neither party to the joint venture arrangement can claim the free-standing facility as a provider-based entity.

Management Contracts

Facilities and organizations operated under management contracts are considered provider-based if all of the following criteria are met:

- The staff of the facility or organization are employed by the provider or by another organization other than the management company, which also employs the staff of the main provider.
- The administrative functions of the facility or organization are integrated with those of the main provider.
- The main provider has significant (day-to-day) control over the operations of the facility or organization.
- The management contract is held by the main provider itself, not by a parent organization that has control over both the main provider and the facility or organization.

RESPONSIBILITY FOR OBTAINING PROVIDER-BASED DETERMINATIONS

Provider-Based Determination Made by HCFA

Provider May Not Bill for Services Until it Notifies HCFA of New Unit

If Not on Campus Assumed Free-Standing

The final regulations state that a facility or organization is not entitled to be treated as provider-based simply because it or the main provider believe it is provider-based. A main provider or a facility or organization must contact HCFA and be determined by HCFA to be provider-based, before they bill for services as if the facility or organization were provider-based, or before it includes costs of those services on its cost report.

Furthermore, a facility that is not located on the campus of a hospital and is used as a site of physician services of the kind ordinarily furnished in physician offices will be presumed to be a free-standing facility, unless it is determined by HCFA to have provider-based status.

Main provider must report any newly created or acquired facility it wishes to report as provider-based if:

- **Located off Campus**
- **Increase in Total Cost**
- **Material Change in Relationship**

A main provider that creates or acquires a facility or organization for which it wishes to claim provider-based status, including any physician offices that a hospital wishes to operate as a hospital outpatient department or clinic, must report the acquisition to HCFA if:

- The facility or organization is located off the campus of the provider.
- The inclusion of the costs of the facility or organization in the provider's cost report would increase the total costs on the provider's cost report by at least 5 percent.

The main provider must furnish all information needed for a determination as to whether the facility or organization meets the requirements for provider-based status.

A material change in the relationship between a main provider and any provider-based facility or organizations must also be reported to HCFA. Material changes could include change in ownership

or entry into a new or different management contract that could affect the provider-based status of the facility or organization.

**Outpatient Department/
Hospital-Based Entity
Obligations**

- **Anti-Dumping Rules**
- **Site of Service**
- **Provider Agreement**
- **All Patients**
- **Payment Window**
- **Notice of Liabilities**
- **Safety Rules**

**OBLIGATIONS OF HOSPITAL OUTPATIENT
DEPARTMENTS AND HOSPITAL-BASED ENTITIES**

Hospital outpatient departments and hospital-based entities must meet the following requirements:

- Hospital outpatient departments located either on or off the main premises of the hospital must comply with anti-dumping rules.
- Physician services furnished in hospital outpatient departments or hospital-based entities (other than RHCs) must be billed with the correct site-of-service indicator, so that applicable site-of-service reductions to physician and practitioner payment amounts can be applied.
- Hospital outpatient departments must comply with all the terms of the hospital's provider agreement.
- Physicians who work in hospital outpatient departments or hospital-based entities are obligated to comply with non-discrimination provisions.
- Hospital outpatient departments (other than RHCs) must hold themselves out to other payers as outpatient departments of that hospital, and must treat all patients, for billing purposes, as hospital outpatients. The department must not treat some patients as hospital outpatients and others as physician office patients.
- Services for a patient admitted to the hospital as an inpatient after receiving treatment in the hospital outpatient department or hospital-based entity, are subject to the payment window provisions applicable to PPS hospitals and to hospitals and units excluded from PPS.

- When a Medicare beneficiary is treated in a hospital outpatient department or hospital-based entity (other than an RHC), the hospital has a duty to notify the beneficiary, prior to the delivery of services, of the beneficiary's potential financial liability (that is, a coinsurance liability for an outpatient visit to the hospital as well as for the physician service).
- Hospital outpatient departments must meet applicable hospital health and safety rules for Medicare-participating hospitals.

INAPPROPRIATE TREATMENT OF A FACILITY OR ORGANIZATION AS PROVIDER-BASED/MAIN PROVIDER PAYMENTS

No Notification of New Provider-Based Main Provider

- **Reviews Requirements for Provider-Based**
- **Reconsider Payments**
- **Recovery/Good Faith Effort**

Determination and Review

If HCFA learns of a provider treating a facility or organization as provider-based without notification to obtain a determination of provider-based status, the following actions will be taken:

- All payments to that provider for all cost reporting periods subject to re-opening will be reconsidered.
- HCFA will investigate and determine whether the requirements for provider-based status were met.

In cases where the facility or organization would not qualify for a provider-based determination, HCFA will recover the difference between the amount of payments that actually were made and the amount of payments that should have been made in the absence of a determination of provider-based status. Recovery will not be made for any period prior to the effective date of final rule, if during all of that period the management of the entity made a good faith effort to operate it as a provider-based facility or organization.

Good Faith Effort

HCFA determines that the management of a facility has made a good faith effort to operate it as a provider-based entity if:

- The requirements regarding licensure and public awareness are met;
- All facility services were billed as if they had been furnished by a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity of the main provider; and
- All professional services of physicians and other practitioners were billed with the correct site-of-service indicator.

Inappropriate Billing

- **Notice to Provider**
- **Adjustment of Payments**
- **Review of Previous Payments**
- **Review determination**
- **Continuation of Payment**

INAPPROPRIATE BILLING

The final rule outlines the actions that will be taken by HCFA where inappropriate billing has occurred or is occurring after a non provider-based determination has been made.

Notice to Provider

HCFA will issue written notice to the provider. The notice will inform the provider that payments for past cost reporting periods may be reviewed and recovered and that future payments will be adjusted.

Adjustment of Payments

Future payments will be adjusted to approximate as closely as possible the amounts that would have been paid, in the absence of a provider-based determination, if all other requirements for billing were met.

Review of Previous Payments

Previous payments will be reviewed and, if necessary, action will be taken in accordance with the rules on inappropriate treatment of a facility or organization as provider-based.

Determination Regarding Provider-Based Status

HCFA will determine whether the facility or organization qualifies for provider-based status. If it is determined that the facility or organization qualifies for provider-based status, future payment for services at or by the facility or organization will be adjusted to reflect that determination. If the facility or organization does not qualify for provider-based status, future

payment for services at or by the facility or organization will be made accordingly.

CONTINUATION OF PAYMENT

The notice of denial of provider-based status sent to the provider will ask the provider to notify HCFA in writing, within 30 days of the date the notice is issued, of whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services in a free-standing facility.

If the provider indicates that the facility, organization, or practitioners will not be seeking to enroll, or if HCFA does not receive a response within 30 days of the date the notice was issued, all payments will end as of the 30th day after the date of notice.

If the provider indicates that the facility will be seeking to meet enrollment and other requirements for billing for services as a free-standing facility:

- Payment for services of the facility will continue, at adjusted amounts for as long as is required for all billing requirements to be met (but not longer than 6 months).
- The facility must submit a enrollment application and provide all other required information within 90 days after the date of notice and furnish all other information needed by HCFA to process the enrollment application and verify that other billing requirements are met.
- If the necessary applications or information are not provided, HCFA will terminate all payments to the provider as of the date HCFA issues notice that necessary applications or information has not been submitted.

Other Issues

- **Correction of Errors**
- **FQHC Facilities**
- **IHS/Tribal Facilities**

OTHER ISSUES**Correction of Errors**

HCFA may review a past determination of provider-based status if it believes that the determination may be inappropriate. If HCFA determines that a previous determination was in error, and the entity should not be considered provider-based, HCFA notifies the main provider. Treatment of the facility or organization as provider-based ceases with the first day of the next cost report period following notification of the redetermination, but not less than 6 months after the publication of the Final Rule.

FQHC Facilities

FQHCs that have furnished services that were billed as if they were a department of the provider, for at least 5 years prior to the issuance of the Final Rule, will continue to be treated as a department of the provider without regard to the provider-based criteria.

This provision applies to FQHCs that received a grant before 1995, is receiving funding under a contract with the recipient of a grant, or based on the recommendation of the public health service, was determined by HCFA before 1995 to meet the requirements

Indian Health Services (IHS) and Tribal Facilities

IHS or tribal facilities will be considered provider-based departments of IHS or Tribal hospitals if on or before April 7, 2000, they furnished only services that were billed as services of an IHS or Tribal hospital.

PHYSICIAN SUPERVISION REQUIREMENTS

Therapeutic Services

Medicare covers outpatient hospital services and supplies furnished incident to a physician service. Outpatient hospital services must be furnished:

Outpatient hospital therapeutic services

- Incident to physician service provision

- By or under arrangements made by a participating hospital, except in the case of an SNF PPS resident
- As an integral though incidental part of a physician's services
- In the hospital or at a location designated by HCFA as a department of a provider, other than a rural health clinic (RHC) or a federally qualified health center (FQHC).

Partial hospitalization services furnished by a hospital to its outpatients must meet these "incident to" requirements.

To be covered as incident to physicians' services, the services and supplies must be furnished on a physician's order by hospital personnel under hospital medical staff supervision in the hospital, or if outside the hospital, under the direct personal supervision of a physician who is treating the patient. For example, if a hospital respiratory therapist goes to a patient's home to give treatment and no physician accompanies him, the therapist's services are not covered.

Definition of "direct supervision"

- On premises
- Available

Definition: Direct Physician Supervision

"Direct supervision" means the physician must be present and on the premises of the location and immediately available to furnish assistance and

direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. The supervising physician does not have to be of the same specialty as the procedure or service that is being performed.

Application

The direct supervision requirement is separate from and independent of the provider-based requirements. Hospitals are already subject to the direct supervision of "incident to" services requirement per the Medicare Hospital Manual, Pub. 10, Section 230.4A. The Final Rule defines this requirement as it relates to departments of hospitals.

Direct supervision

- **On campus department**
- **Off campus department**
- **Provider based entity**

On Campus Department

For outpatient hospital services furnished in a department of a hospital located on the campus of the hospital, the direct supervision requirement is assumed to be met. On the hospital premises, staff physicians are always nearby.

Off Campus Department

When outpatient services are provided at a location off the campus of the hospital, the physician must be present and on the premises of the location and immediately available to furnish assistance and direction. This applies to services furnished at an entity designated as having provider-based status as a department of a hospital.

Provider Based Entity

The direct supervision requirements do not apply to a provider-based entity, such as a skilled nursing facility

or home health agency, regardless of its location. The "incident to" requirement applies only to hospitals.

Diagnostic Services

Outpatient hospital diagnostic services

- **Use 62 FR 59048**
- **FI decision for provider based entity**

In the proposed rule, our model for the physician supervision requirement was the requirement for physician supervision for diagnostic tests payable under the Medicare physician fee schedule that was issued in the October 31, 1997 physician fee schedule final rule for CY 1998 (62 FR 59048). There have been issues raised about the appropriate level of supervision for some specific diagnostic services. These issues have not yet been resolved.

Hospitals and intermediaries should use to use the October 31, 1997 physician fee schedule final rule physician supervision requirements as a guide, pending issuance of updated requirements. Until these are issued, fiscal intermediaries, in consultation with their medical directors, will define appropriate supervision levels for services not listed in the October 31, 1997 final rule when the services are furnished at a provider-based entity in order to determine whether claims for these services are reasonable and necessary.

SPECIAL RESPONSIBILITIES OF MEDICARE HOSPITALS IN EMERGENCY CASES

Hospital EMTALA requirements

- **Entire hospital responsible**

When a person comes alone, or with another person, to the emergency department of a hospital and requests examination or treatment of a medical condition, the hospital must provide an appropriate medical screening examination, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists. Existing regulations define "hospital with an emergency department" to include all hospitals that offer services for emergency medical conditions, not just those that have organized emergency rooms or departments.

The intent of the revised regulation is to ensure that patients who come to the hospital and request examination or treatment for what may be an emergency medical condition are not denied EMTALA (Emergency Medical Treatment and Active Labor Amendment) protection simply because they enter the wrong part of the hospital or fail to make their way to the emergency room. The obligation of a hospital must be met within the entire hospital. However, provider-based entities, such as skilled nursing facilities or home health agencies, located off the hospital campus would not be subject to EMTALA since a patient coming to these entities would not have come to the hospital.

Definition Change

The phrase, “comes to the emergency department,” means that the individual is on the hospital property. “Property” is defined as the entire main hospital campus, including:

- The parking lot
- The sidewalk
- The driveway
- Any facility or organization determined to be a department of the hospital, but located off the main hospital campus
- Ambulances owned and operated by the hospital even if the ambulance is not on hospital grounds
- A non-hospital-owned ambulance on hospital property

A non-hospital owned ambulance off hospital property is not considered to have come to the emergency department even if a member of the ambulance staff contacts the hospital and informs the hospital that they want to transport an individual to the hospital for examination and treatment.

Definition of hospital “property”

Responsibility

- Provide screening
- Provide stabilizing treatment

Hospital Responsibilities

If a person comes to an off-campus department of a hospital and requests examination or treatment of a potential emergency medical condition, the hospital is obligated to provide the individual with an appropriate medical screening examination and any necessary stabilizing treatment. In some cases, the patient may need to be taken back to the main hospital campus for a full screening and or stabilizing treatment. Under these circumstances, the hospital is responsible for moving the patient or arranging his or her safe transport.

This principle does not mean the hospital is required to:

- Locate additional personnel or staff to off-campus locations to be on standby for possible emergencies
- Equip all areas of the hospital to provide emergency care
- Always provide treatment outside the emergency area or department
- Have a fully equipped and staffed emergency department at each location

Protocols

Protocols for off-campus department

- **Direct contact with emergency personnel**
- **May send emergency personnel to off campus site**

The hospital must establish protocols for the handling of possible emergency cases at off-campus departments. These protocols must include provision for direct contact between personnel at the off-campus department and emergency personnel at the main hospital campus and may provide for dispatch of practitioners from the main hospital campus to the off-campus department to provide screening or stabilization services. The intent is to ensure timely exchange of information between the two sites. These protocols must be established prior to the potential emergency situation.

While emergency medical services (EMS) personnel can play a valuable role in transporting patients to appropriate sources of emergency care, they cannot provide the screening and stabilization needed to fulfill a hospital's EMTALA responsibilities. A hospital does not fulfill its EMTALA obligations merely by summoning EMS personnel. However, EMS may be used appropriately in conjunction with the hospital's response.

Department Staffed by Physicians or Nurses

If the off-campus department is an urgent care center, primary care center, or other facility that is routinely staffed by physicians, RNs, or LPNs:

Protocols for a department with an MD, RN, or LPN

- These personnel must be trained, and given appropriate protocols, for the handling of emergency cases.
- At least one individual on duty during the off-campus department its regular hours of operation must be designated as a qualified medical person (as determined by the hospital in its by-laws or rules and regulations).
- The qualified medical person must initiate screening of individuals who come to the off-campus department with a possible emergency medical condition, and **may** be able to complete the screening and provide any necessary stabilizing treatment at the off-campus department.

Other Departments

If the off-campus department is a physical therapy, radiology, or other facility not routinely staffed with physicians, RNs, or LPNs:

Protocols for a department without MD, RN, or LPN

- The department's personnel must be given protocols that direct them to contact emergency

personnel at the main hospital campus for direction.

- Under the direction from the emergency personnel, and in accordance with these protocols, the personnel at the off-campus department must :
 - Describe patient appearance
 - Report symptoms
 - If appropriate, arrange transportation of the individual to the main hospital campus or assist in an appropriate transfer

Movement of the individual to the main campus of the hospital is not considered a transfer, since the individual is being moved from one department of a hospital to another department or facility of the same hospital.

Transfer Provisions

Hospital protocols must provide for the movement of an individual with a possible emergency condition to a facility other than the main hospital campus if that movement is warranted either because:

- The main hospital campus does not have the specialized capabilities or facilities required by the individual, or
- The individual's condition is deteriorating so rapidly that taking the time needed to move the individual to the main hospital campus would significantly jeopardize the life or health of the individual.

The protocols must include procedures and agreements established in advance with other hospitals or medical facilities in the area of the off-campus department to facilitate these transfers. A transfer under this provision does need to meet one of these three existing requirements for transfers:

Protocols for transfer

- **Unable to provide specialized service**
- **Deteriorating condition**

Transfer requirements

- Patient request
- Certification

- The individual, or a legally responsible person, requests the transfer, after being informed of the hospital's obligations related to emergency cases. The request must:
 - Be in writing
 - Indicate the reasons for the request
 - Indicate that the person is aware of the risks and benefits of the transfer
- A physician must sign a certification that, based upon the information available at the time of transfer, the medical benefits of receiving appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the woman or the unborn child. The certification must contain a summary of the risks and benefits upon which it is based.
- If a physician is not physically present at the time an individual is transferred, a qualified medical person (as determined by the hospital in its by-laws or rules and regulations) must:
 - Consult with a physician who agrees with the certification
 - Sign the certification containing the same information required for a physician's certification

The physician must subsequently countersign the certification