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TITLE 42--PUBLIC HEALTH

CHAPTER IV--CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF  
HEALTH AND HUMAN SERVICES

PART 413\_PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE

Subpart E\_Payments to Providers

Sec. 413.65 Requirements for a determination that a facility or an organization has provider-based status.

(a) Scope and definitions. (1) Scope. (i) This section applies to all facilities for which provider-based status is sought, including remote locations of hospitals, as defined in paragraph (a)(2) of this section and satellite facilities as defined in Sec. 412.22(h)(1) and Sec. 412.25(e)(1) of this chapter, other than facilities described in paragraph (a)(1)(ii) of this section.

(ii) The determinations of provider-based status for payment purposes described in this section are not made as to whether the following facilities are provider-based:

- (A) Ambulatory surgical centers (ASCs).
- (B) Comprehensive outpatient rehabilitation facilities (CORFs).
- (C) Home health agencies (HHAs).
- (D) Skilled nursing facilities (SNFs) (determinations for SNFs are made in accordance with the criteria set forth in Sec. 483.5 of this chapter).
- (E) Hospices.
- (F) Inpatient rehabilitation units that are excluded from the inpatient PPS for acute hospital services.
- (G) Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services (as defined in section 1861(jj) of the Act), facilities that furnish only clinical diagnostic laboratory tests, or facilities that furnish only some combination of these services.
- (H) Facilities, other than those operating as parts of CAHs, furnishing only physical, occupational, or speech therapy to ambulatory patients, for as long as the \$1,500 annual cap on coverage of physical, occupational, or speech therapy, as described in section 1833(g)(2) of the Act, remains suspended by the action of subsequent legislation.
- (I) ESRD facilities (determinations for ESRD facilities are made under Sec. 413.174 of this chapter).
- (J) Departments of providers that perform functions necessary for the successful operation of the providers 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).
- (K) Ambulances.
- (L) Rural health clinics (RHCs) affiliated with hospitals having 50

or more beds.

(2) Definitions. In this subpart E, unless the context indicates otherwise--

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

Department of a provider means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A department of a provider may not by itself be qualified to participate in Medicare as a provider under Sec. 489.2 of this chapter, and the Medicare conditions of participation do not apply to a department as an independent entity. For purposes of this part, the term ``department of a provider'' does not include an RHC or, except as specified in paragraph (n) of this section, an FQHC.

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Free-standing facility means 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, remote location of a hospital, satellite facility, or a provider-based entity.

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.

Provider-based entity means a provider of health care services, or an RHC as defined in Sec. 405.2401(b) of this chapter, 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 under the ownership and administrative and financial control of the main provider, in accordance with the provisions of this section. A provider-based entity comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A provider-based entity may, by itself, be qualified to participate in Medicare as a provider under Sec. 489.2 of this chapter, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity.

Provider-based status means 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 provisions of this section.

Remote location of a hospital means 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 under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A

remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term ``remote location of a hospital'' does not include a satellite facility as defined in Sec. 412.22(h)(1) and Sec. 412.25(e)(1) of this chapter.

(b) Provider-based determinations.--(1) 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.

(2) If a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. The requirements, limitations, and exclusions specified in paragraphs (d), (e), (f), (h), and (i) of this section will not apply to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. For purposes of this paragraph (b)(2), a facility is considered as provider-based on October 1, 2000 if, on that date, it either had a written determination from CMS that it was provider-based, or was billing and being paid as a provider-based department or entity of the hospital.

(3)(i) Except as specified in paragraphs (b)(2) and (b)(5) of this section, if a potential main provider seeks a determination of provider-based status for a facility that is located on the campus of the potential main provider, the provider would be required to submit an attestation stating that the facility meets the criteria in paragraph (d) of this section and, if it is a hospital, also attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider seeking such a determination would also be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS and to CMS contractors upon request. If the facility is operated as a joint venture, the provider would also have to

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attest that it will comply with the requirements of paragraph (f) of this section.

(ii) If the facility is not located on the campus of the potential main provider, the provider seeking a determination would be required to submit an attestation stating that the facility meets the criteria in paragraphs (d) and (e) of this section, and if the facility is operated under a management contract, the requirements of paragraph (h) of this section. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider would be required to supply documentation of the basis for its attestations to CMS at the time it submits its attestations.

(iii) Whenever a provider submits an attestation of provider-based status for an on-campus facility or organization, as described in paragraph (b)(3)(i) of this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for

completeness, consistency with the criteria in this section, and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

(iv) Whenever a provider submits an attestation of provider-based status for an off-campus facility or organization, as described in paragraph (b)(3)(ii) of this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, consistency with the documentation submitted with the attestation and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

(4) A facility that is not located on the campus of a hospital and that is used as a site where physician services of the kind ordinarily furnished in physician offices are furnished is presumed as a free-standing facility, unless CMS determines the facility has provider-based status.

(5) A facility that has requested provider-based status in relation to a hospital or CAH on or after October 1, 2000 and before October 1, 2002 will be treated as provider-based in relation to the hospital or CAH from the first date on or after October 1, 2000 on which the facility was licensed (to the extent required by the State), staffed and equipped to treat patients until the date on which CMS determines that the facility does not qualify for provider-based status.

(c) Reporting of material changes in relationships. A main provider that has had one or more facilities or organizations considered provider-based also may report to CMS any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that would affect the provider-based status of the facility or organization.

(d) Requirements applicable to all facilities or organizations. Any facility or organization for which provider-based status is sought, whether located on or off the campus of a potential main provider, must meet all of the following requirements to be determined by CMS to have provider-based status:

(1) Licensure. The department of the provider, the 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 for the department of the provider, the remote location of a hospital, or the satellite facility, or in States where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility 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, CMS will determine that the facility or organization does not have provider-based status.

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(2) 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:

(i) Professional staff of the facility or organization have clinical

privileges at the main provider.

(ii) The main provider maintains the same monitoring and oversight of the facility or organization as it does for any other department of the provider.

(iii) The medical director of the facility or organization seeking provider-based status 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.

(iv) 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.

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

(vi) 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.

(3) Financial integration. The financial operations of the facility or organization 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 or organization. The costs of a facility or organization that is a hospital department are reported in a cost center of the provider, costs of a provider-based facility or organization other than a hospital department are reported in the appropriate cost center or cost centers of the main provider, and the financial status of any provider-based facility or organization is incorporated and readily identified in the main provider's trial balance.

(4) Public awareness. The facility or organization 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 or organization, they are aware that they are entering the main provider and are billed accordingly.

(5) Obligations of hospital outpatient departments and hospital-based entities. In the case of a hospital outpatient department or a hospital-based entity, the facility or organization must fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section.

(e) Additional requirements applicable to off-campus facilities or organizations. Except as described in paragraphs (b)(2) and (b)(5) of this section, any facility or organization for which provider-based status is sought that is not located on the campus of a potential main provider must meet both the requirements in paragraph (d) of this section and all of the following additional requirements, in order to be determined by CMS to have provider-based status.

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

(i) The business enterprise that constitutes the facility or organization is 100 percent owned by the main provider.

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

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(iii) The facility or organization is operated under the same organizational documents as the main provider. For example, the facility or organization seeking provider-based status must be subject to common bylaws and operating decisions of the governing body of the main provider where it is based.

(iv) 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 or organization.

(2) Administration and supervision. 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 existing departments, as evidenced by compliance with all of the following requirements:

(i) The facility or organization is under the direct supervision of the main provider.

(ii) 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--

(A) 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

(B) Is accountable to the governing body of the main provider, in the same manner as any department head of the provider.

(iii) 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, and purchasing services. Either the same employees or group of employees handle these administrative functions for the facility or organization and the main provider, or the administrative functions for both the facility or organization and the entity are--

(A) Contracted out under the same contract agreement; or

(B) Handled under different contract agreements, with the contract of the facility or organization being managed by the main provider.

(3) Location. The facility or organization meets the requirements in paragraph (e)(3)(i), (e)(3)(ii), (e)(3)(iii), (e)(3)(iv), (e)(3)(v), or, in the case of an RHC, paragraph (e)(3)(vi) of this section, and the requirements in paragraph (e)(3)(vii) of this section.

(i) The facility or organization is located within a 35-mile radius of the campus of the hospital or CAH that is the potential main provider.

(ii) The facility or organization is owned and operated by a hospital or CAH that has a disproportionate share adjustment (as determined under Sec. 412.106 of this chapter) greater than 11.75 percent or is described in Sec. 412.106(c)(2) of this chapter implementing section 1886(d)(5)(F)(i)(II) of the Act and is--

(A) Owned or operated by a unit of State or local government;

(B) A public or nonprofit corporation that is formally granted governmental powers by a unit of State or local government; or

(C) A private hospital that has a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan).

(iii) 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

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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--

(A) 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; or

(B) 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).

(iv) If the facility or organization is unable to meet the criteria in paragraph (e)(3)(iii)(A) or paragraph (e)(3)(iii)(B) of this section because it was not in operation during all of the 12-month period described in paragraph (e)(3)(iii) of this section, the facility or organization is located in a zip code area included among those that, during all of the 12-month period described in paragraph (e)(3)(iii) of this section, accounted for at least 75 percent of the patients served by the main provider.

(v) The facility or organization meets all of the following criteria:

(A) The facility or organization is seeking provider-based status with respect to a hospital that meets the criteria in Sec. 412.23(d) for reimbursement under Medicare as a children's hospital;

(B) The facility or organization meets the criteria for identifying intensive care type units set forth in the Medicare reasonable cost reimbursement regulations under Sec. 413.53(d).

(C) The facility or organization accepts only patients who are newborn infants who require intensive care on an inpatient basis.

(D) The hospital in which the facility or organization is physically located is in a rural area as defined in Sec. 412.64(b)(1)(ii)(C) of this chapter.

(E) The facility or organization is located within a 100-mile radius of the children's hospital that is the potential main provider.

(F) The facility or organization is located at least 35 miles from the nearest other neonatal intensive care unit.

(G) The facility or organization meets all other requirements for provider-based status under this section.

(vi) Both of the following criteria are met:

(A) The facility or organization is an RHC that is otherwise qualified as a provider-based entity of a hospital that has fewer than 50 beds, as determined under Sec. 412.105(b) of this chapter; and

(B) The hospital with which the facility or organization has a provider-based relationship is located in a rural area, as defined in Sec. 412.64(b)(1)(ii)(C) of this subchapter.

(vii) A facility or organization may qualify for provider-based status under this section only if the facility or organization and the main provider are located in the same State or, when consistent with the laws of both States, in adjacent States.

(f) Provider-based status for joint ventures. In order for a facility or organization operated as a joint venture to be considered provider-based, the facility or organization must--

(1) Be partially owned by at least one provider'

(2) Be located on the main campus of a provider who is a partial owner;

(3) Be provider-based to that one provider whose campus on which the facility or organization is located; and

(4) Also meet all the requirements applicable to all provider-based facilities and organizations in paragraph (d) of this section. For example, where a provider has jointly purchased or jointly created a facility under joint venture arrangements with one or more other providers, and the facility is not located on the campus of the provider or the campus of any other provider engaged in the joint venture arrangement, no party to the joint venture arrangement can claim the facility as provider-based.

(g) Obligations of hospital outpatient departments and hospital-based entities. To qualify for provider-based status in relation to a hospital, a facility or organization must comply with the following requirements:

(1) The following departments must comply with the antidumping rules of Sec. 489.20(1), (m), (q), and (r) and Sec. 489.24 of this chapter:

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(i) Any facility or organization that is located on the main hospital campus and is treated by Medicare under this section as a department of the hospital; and

(ii) Any facility or organization that is located off the main hospital campus that is treated by Medicare under this section as a department of the hospital and is a dedicated emergency department, as defined in Sec. 489.24(b) of this chapter.

(2) Physician services furnished in hospital outpatient departments or hospital-based entities (other than RHCs) must be billed with the correct site-of-service so that appropriate physician and practitioner payment amounts can be determined under the rules of Part 414 of this chapter.

(3) Hospital outpatient departments must comply with all the terms of the hospital's provider agreement.

(4) Physicians who work in hospital outpatient departments or



hospital-based entities are obligated to comply with the non-discrimination provisions in Sec. 489.10(b) of this chapter.

(5) Hospital outpatient departments (other than RHCs) must treat all Medicare patients, for billing purposes, as hospital outpatients. The department must not treat some Medicare patients as hospital outpatients and others as physician office patients.

(6) In the case of a patient admitted to the hospital as an inpatient after receiving treatment in the hospital outpatient department or hospital-based entity, payments for services 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 set forth at Sec. 412.2(c)(5) of this chapter and at Sec. 413.40(c)(2), respectively.

(7) When a Medicare beneficiary is treated in a hospital outpatient department that is not located on the main provider's campus, the treatment is not required to be provided by the antidumping rules in Sec. 489.24 of this chapter, and the beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the physician service, the following requirements must be met:

(i) The hospital must provide written notice to the beneficiary, before the delivery of services, of--

(A) The amount of the beneficiary's potential financial liability;

or

(B) If the exact type and extent of care needed are not known, an explanation that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based, an estimate based on typical or average charges for visits to the facility, and a statement that the patient's actual liability will depend upon the actual services furnished by the hospital.

(ii) The notice must be one that the beneficiary can read and understand.

(iii) If the beneficiary is unconscious, under great duress, or for any other reason unable to read a written notice and understand and act on his or her own rights, the notice must be provided, before the delivery of services, to the beneficiary's authorized representative.

(iv) In cases where a hospital outpatient department provides examination or treatment that is required to be provided by the antidumping rules of Sec. 489.24 of this chapter, notice, as described in this paragraph (g)(7), must be given as soon as possible after the existence of an emergency has been ruled out or the emergency condition has been stabilized.

(8) Hospital outpatient departments must meet applicable hospital health and safety rules for Medicare-participating hospitals in part 482 of this chapter.

(h) Management contracts. A facility or organization that is not located on the campus of the potential main provider and otherwise meets the requirements of paragraphs (d) and (e) of this section, but is operated under management contracts, must also meet all of the following criteria:

(1) The main provider (or an organization that also employs the staff of the main provider and that is not the management company) employs the staff of the facility or organization 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 at part 414 of this chapter. Other than staff that may be paid under such a Medicare fee schedule, the main provider may not utilize the services of ``leased'' employees (that is, personnel who are actually employed by the management company but provide services for the provider under a staff leasing or similar agreement) that are directly involved in the delivery of patient care.

(2) The administrative functions of the facility or organization are integrated with those of the main provider, as determined under criteria in paragraph (e)(2)(iii) of this section.

(3) The main provider has significant control over the operations of the facility or organization as determined under criteria in paragraph (e)(2)(ii) of this section.

(4) 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.

(i) Furnishing all services under arrangement. A facility or organization may not qualify for provider-based status if all patient care services furnished at the facility or organization are furnished under arrangements.

(j) Inappropriate treatment of a facility or organization as provider-based--(1) Determination and review. If CMS learns that a provider has treated a facility or organization as provider-based and the provider did not request a determination of provider-based status from CMS under paragraph (b)(3) of this section and CMS determines that the facility or organization did not meet the requirements for provider-based status under paragraphs (d) through (i) of this section, as applicable (or, in any period before the effective date of these regulations, the provider-based requirements in effect under Medicare program regulations or instructions), CMS will--

(i) Issue notice to the provider in accordance with paragraph (j)(3) of this section, adjust the amount of future payments to the provider for services of the facility or organization in accordance with paragraph (j)(4) of this section, and continue payments to the provider for services of the facility or organization only in accordance with paragraph (j)(5) of this section; and

(ii) Except as otherwise provided in paragraphs (b)(2), (b)(5), or (j)(2) of this section, recover the difference between the amount of payments that actually was made and the amount of payments that CMS estimates should have been made, in the absence of compliance with the provider-based requirements, to that provider for services at the facility or organization for all cost reporting periods subject to reopening in accordance with Sec. Sec. 405.1885 and 405.1889 of this chapter.

(2) Exception for good faith effort. CMS will not recover any payments for any period before the beginning of the hospital's first cost reporting period beginning on or after January 10, 2001, if, during all of that period--

(i) The requirements regarding licensure and public awareness in paragraphs (d)(1) and (d)(4) of this section were met;

(ii) All facility services were billed as if they had been furnished by a department of a provider, a remote location of a hospital, a satellite facility, or a provider-based entity of the main provider; and

(iii) All professional services of physicians and other practitioners were billed with the correct site-of-service indicator, as described in paragraph (g)(2) of this section.

(3) Notice to provider. If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will issue written notice to the provider that payments for past cost reporting periods may be reviewed and recovered as described in paragraph (j)(1)(ii) of this section, and that future payments for services in or of the facility or organization will be adjusted as described in paragraph (j)(4) of this section.

(4) Adjustment of payments. If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will adjust future payments to the provider or the facility or organization, or both, to estimate the amounts that would be paid for the same services furnished by a freestanding facility.

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(5) Continuation of payment. (i) The notice of denial of provider-based status sent to the provider will ask the provider to notify CMS in writing, within 30 days of the date the notice is issued, of whether the provider intends to seek a determination of provider-based status for the facility or organization under this section or 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 freestanding facility.

(ii) If the provider indicates that it will not be seeking a determination for the facility or organization under this section or that the facility or organization or its practitioners will not be seeking to enroll, or if CMS does not receive a response within 30 days of the date the notice was issued, all payment under this paragraph (j)(5) will end as of the 30th day after the date of notice.

(iii) If the provider indicates that it will be seeking a determination for the facility or organization under this section or that the facility or organization or its practitioners will be seeking to meet enrollment and other requirements for billing for services in a freestanding facility, payment for services of the facility or organization will continue, at the adjusted amounts described in paragraph (j)(4) of this section, for as long as is required for all billing requirements to be met (but not longer than 6 months) if the provider or the facility or organization or its practitioners--

(A) Submits, as applicable, a complete request for a determination of provider-based status or a complete enrollment application and provide all other required information within 90 days after the date of notice; and

(B) Furnishes all other information needed by CMS to make a determination regarding provider-based status or process the enrollment application, as applicable, and verifies that other billing requirements are met.

(v) If the necessary applications or information are not provided, CMS will terminate all payment to the provider, facility, or organization as of the date CMS issues notice that necessary applications or information have not been submitted.

(k) 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 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 provider-based requirements is one that includes all information needed to permit CMS to make a determination under paragraph (b)(3) of this section.

(1) Correction of errors. (1) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section no longer qualifies for provider-based status, and the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did report to CMS under paragraph (c) of this section, treatment of the facility or organization as provider-based ceases with the date that CMS determines that the facility or organization no longer qualifies for provider-based status.

(2) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section no longer qualifies for provider-based status, and if the failure to qualify for provider-based

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status resulted from a material change in the relationship between the provider and the facility or organization that the provider did not report to CMS under paragraph (c) of this section, CMS will take the actions with respect to notice to the provider, adjustment of payments, and continuation of payment described in paragraphs (j)(3), (j)(4), and (j)(5) of this section, and will recover past payments to the provider to the extent described in paragraph (j)(1)(ii) of this section.

(m) Status of Indian Health Service and Tribal facilities and organizations. Facilities and organizations operated by the Indian Health Service or Tribes will be considered to be departments of hospitals operated by the Indian Health Service or Tribes if, on or before April 7, 2000, they furnished only services that were billed as if they had been furnished by a department of a hospital operated by the Indian Health Service or a Tribe and they are:

(1) Owned and operated by the Indian Health Service;

(2) Owned by the Tribe but leased from the Tribe by the IHS under the Indian Self-Determination Act (Pub. L. 93-638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes: or

(3) Owned by the Indian Health Service but leased and operated by the Tribe under the Indian Self-Determination Act (Pub. L. 93-638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes.

(n) FQHCs and ``look alike.'' A facility that has, since April 7, 1995, furnished only services that were billed as if they had been furnished by a department of a provider will continue to be treated, for purposes of this section, as a department of the provider without regard to whether it complies with the criteria for provider-based status in this section, if the facility--

(1) Received a grant on or before April 7, 2000 under section 330 of

the Public Health Service Act and continues to receive funding under such a grant, or is receiving funding from a grant made on or before April 7, 2000 under section 330 of the Public Health Service Act under a contract with the recipient of such a grant, and continues to meet the requirements to receive a grant under section 330 of the Public Health Service Act; or

(2) Based on the recommendation of the Public Health Service, was determined by CMS on or before April 7, 2000 to meet the requirements for receiving a grant under section 330 of the Public Health Service Act, and continues to meet such requirements.

(o) Effective date of provider-based status--(1) General rule. Provider-based status for a facility or organization is effective on the earliest date all of the requirements of this part have been met.

(2) Inappropriate treatment as provider-based or not reporting material change. Effective for any period on or after October 1, 2002 (or, in the case of facilities or organizations described in paragraph (b)(2) of this section, for cost reporting periods starting on or after July 1, 2003), if a facility or organization is found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section for those periods, or previously was determined by CMS to be provider-based but no longer qualifies as provider-based because of a material change occurring during those periods that was not reported to CMS under paragraph (c) of this section, CMS will not treat the facility or organization as provider-based for payment purposes until CMS has determined, based on documentation submitted by the provider, that the facility or organization meets all requirements for provider-based status under this part

[65 FR 18538, Apr. 7, 2000, as amended at 65 FR 58920, Oct. 3, 2000; 66 FR 1599, Jan. 9, 2001; 66 FR 59920, Nov. 30, 2001; 67 FR 50114, Aug. 1, 2002; 68 FR 46070, Aug. 4, 2003; 68 FR 53261, Sept. 9, 2003; 70 FR 47487, Aug. 12, 2005]