payment amount associated with particular devices, drugs, or biologicals, and any pro rata reduction. Section 202(a) of the BBRA 1999 further redesignates section 1833(t)(11) as section 1833(t)(12).

IV. Provider-Based Status

A. Background

The Medicare law (section 1861(u) of the Act) lists the types of facilities that are regarded as providers of services, but does not use or define the term ''provider-based.'' However, from the beginning of the Medicare program, some providers, which we refer to in this section as ''main 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. In order to accommodate the financial integration of the two facilities without creating an administrative burden, we have 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.

In the proposed rule, we pointed out 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 nonprovider treatment settings, such as physician offices.

We noted in the proposed rule that it is essential that we make decisions regarding provider-based status appropriately, and that we have clear rules for identifying provider-based entities. By failing to distinguish properly between provider-based and free-standing facilities or organizations, we risk increasing program payments and beneficiary coinsurance with no commensurate benefit to the Medicare program or its beneficiaries and we jeopardize the delivery of safe and appropriate health care services to our beneficiaries.

Although there is no direct statutory requirement to maintain explicit criteria for determination of provider-based status, there are statutory references acknowledging the existence of this payment outcome. For example, section 1881(b) of the Act provides for separate payment rates for hospital-based ESRD facilities. There is currently no general definition of ''provider-based facility'' in the CFR. However, in the proposed rule, we cited issuances that do contain provisions for recognition of specific types of entities as provider-based, including Program Memorandum A–96–7, published on August 27, 1996, which pulled together instructions for specific entity types from previously published documents and consolidated them into a general instruction for the designation of provider-based status for all facilities or organizations. That Program Memorandum was subsequently reissued, without substantive change, as Program Memoranda A–98–15 and A–99–24 and, in October 1999, was manualized by the Provider Reimbursement Manual, Part I, Transmittal 411 (adding new section 2446), and the State Operations Manual, Transmittal 11 (replacing previous section 2003 and adding new section 2004). Our policy will continue to follow the principles we articulated in Program Memorandum A–96–7 and the Provider Reimbursement Manual and State Operations Manual sections cited above until October 10, 2000. After that date, we shall apply the policies set forth in these final regulations.

B. Provisions of the Proposed Rule

We announced our intention to implement §§ 413.24(d)(6)(i) and (ii), 413.65, 489.24(b), and 498.3, as revised based on our consideration of public comments, with respect to services furnished on or after 30 days following publication of a final rule. We describe these sections below and explain that we have now provided a 6-month delay in the effective date of the regulations on provider-based status.

We proposed to add a new § 413.65 on the determination of provider-based status. In paragraph (a), we proposed to define the following terms: department of a provider, free-standing facility, main provider, provider-based entity, and provider-based status. In paragraph (b), we proposed that a facility or organization would not be entitled to be treated as provider-based simply because it or the provider believe it to be provider-based. The facility or organization, or the provider, would have to contact HCFA and obtain an affirmative provider-based determination before billing of the facility's or organization's costs through the main provider, or inclusion of those costs on the main provider's cost report, is initiated. Further, we proposed to presume a facility not located on the campus of a hospital and used as a site of physician services of the kind ordinarily furnished in physician offices to be a free-standing facility unless we determined it to have provider-based status.

We proposed to require, in paragraph (c), that a main provider that acquires a facility or organization for which it wishes to claim provider-based status must report its acquisition of the facility or organization to us if the facility or organization is off the campus of the main provider, or is located on the campus of the main provider and, if acquired, would increase the main provider's costs by 5 percent or more. The main provider must also furnish all information needed for a determination as to whether the facility or organization meets the criteria in this section for provider-based status. A main provider that has had one or more facilities or organizations determined to have provider-based status also must report to us any material change in the relationship between it and any department or provider-based entity, such as a change in ownership of the entity or entry into a new or different management contract, that could affect the provider-based status of the department or entity.

In paragraph (d), we proposed the requirements for a determination of provider-based status. In paragraph (d)(1), we proposed to set forth licensure requirements for facilities or organizations seeking provider-based status.

In paragraph (d)(2), we proposed to require that a facility or organization be

under the ownership and control of the main provider.

In paragraph (d)(3), with respect to administration and direct supervision of the main provider, we proposed to require that a facility or organization seeking provider-based status have a reporting relationship to the main provider that is characterized by the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its departments.

In paragraph (d)(4), we proposed that a facility or organization seeking provider-based status and the main provider share integrated clinical services, as evidenced by privileging of the professional staff of the department or entity at the main provider, and the main provider's maintenance of the same monitoring and oversight of the department or entity as of other departments. Also, the medical director of the department or entity would be required to maintain a day-to-day reporting relationship with the chief medical officer (or equivalent) of the main provider, and be under the same supervision as any other director of the main provider.

In paragraph (d)(5), we proposed to require that the department or entity and the main provider be fully financially integrated within the main provider's financial system, as evidenced by the sharing of income and expenses. The department's or entity's costs should be reported in a cost center of the provider, and the department's or entity's financial status should be incorporated into, and readily identifiable in, the main provider's trial balance.

In paragraph (d)(6), we proposed to require that the main provider and the facility seeking status as a department of the provider be held out to the public as a single entity, so that when patients enter the department they are aware that they are entering the provider and will be billed accordingly. (This requirement would not apply to a provider-based entity that is itself a provider, such as a SNF.)

In paragraph (d)(7), we proposed to require that the department of a provider or provider-based entity and the main provider be located on the same campus, except where requirements relating to service to the same patient population are met.

Paragraph (e) would specifically prohibit the approval of provider-based status for any proposed department or entity that is owned by two or more providers engaged in a joint venture.

In proposed paragraph (f), we proposed to state that facilities or organizations operated under management contracts would be considered provider-based only if specific requirements are met related to: Staff employment, administrative functions, day-to-day control of operations, and holding of the management contract by the provider itself rather than by a parent organization.

In proposed paragraph (g), we proposed to specify nine obligations of hospital outpatient departments and hospital-based entities. We explained that these obligations ensure that facilities seeking recognition as hospital outpatient departments or hospital-based entities are in fact what they represent themselves to be, and are not simply the private offices of individual physicians or of physicians in group practices.

We also proposed to preclude any facility or organization that furnishes all services under arrangements from qualifying as provider-based. We believe the provision of services under arrangement was intended to be allowed only to a limited extent, in situations where cost-effectiveness or clinical considerations, or both, necessitate the provision of services by someone other than the provider's own staff. The ''under arrangement'' provision in section 1861(w)(1) of the Act and § 409.3 is not intended to allow a facility merely to act as a billing agent for another.

Proposed paragraph (h) states that, if we learn of a provider that has inappropriately treated a facility or organization as provider-based, before obtaining our determination of provider-based status, we would reconsider all payments to that main provider for those periods subject to reopening, and we would investigate to determine whether the designation was appropriate.

In proposed paragraph (i), we would apply the principles in paragraph (h) to situations involving inappropriate billing for services furnished in a physician's office or other facility or organization as if they had been furnished in a hospital outpatient or other department of a provider or in a provider-based entity.

We also proposed to add a new paragraph (j) that would allow us to review past determinations. If we find that a designation was in error, and the facility or organization in question does not meet the requirements of this section, we will notify the main provider that the provider-based status will cease as of the first day of the next cost report period following notification of the redetermination.

In addition, we proposed to add to § 413.24(d) new paragraphs (6)(i) and (6)(ii) to clarify that main providers, in completing their Medicare cost reports, may not allocate overhead costs to the provider-based or other cost centers that incur similar costs directly through management contracts or other arrangements. These changes are needed to prevent misallocation of management costs, which would result in excessive payment to those types of providers paid on a reasonable cost basis.

To provide an administrative appeals process for entities that have been denied provider-based status, we proposed to revise the regulations on provider appeals at § 498.3. As revised, these rules would specify that a provider seeking a determination that a facility or an organization is a department of the provider or a provider-based entity under proposed § 413.65 would be included in the definition of ''prospective provider'' for purposes of part 498, and would be afforded the same appeal rights as a prospective provider, such as a hospital or SNF, that we have found not to qualify for participation as a provider.

C. Comments and Responses

In response to our proposals, we received approximately 120 letters of comment, most of which raised a number of issues. Included among the commenters were hospitals and hospital and other provider associations, physicians, attorneys, and other individuals. Here we respond to comments submitted on the proposed rule.

General Comments

Many comments were not directed to a specific provision or criterion, but concerned the implementation of the regulations or the application of provider-based criteria to specific types of facilities. These are summarized below.

Effective Date

Comment: A commenter requested clarification as to when the parts of the final rule setting forth criteria for provider-based status would be effective, and a number of commenters requested an extended grace period or a delay in effective date of the final rules, with some commenters requesting delays as long as 12 to 18 months. Various reasons were cited, including the pressures on providers to prepare their systems and staff for the outpatient PPS, the need to bring operations into compliance with the provider-based criteria, and the anticipated workloads of HCFA regional offices that may

receive a large number of requests for provider-based determinations. Commenters argued that it is unrealistic to expect that a hospital would engage in a full-blown analysis of its provider-based arrangements and modify each arrangement until it knows against which exact criteria it is measuring those arrangements. Any changes in status will require hospitals to implement billing and other operational changes. Thus, commenters argued that it is not reasonable to expect hospitals to complete such steps within a 30-day period.

Response: We agree, and are providing a delay in the effective date until October 10, 2000. Moreover, as stated in our response to comments on proposed § 413.65(j) below, any redetermination of provider-based status that finds the facility or organization not to be provider-based will not take effect for at least 6 months after the date the provider is notified of the redetermination.

Application to Specific Facilities

Comment: One commenter stated that under the Balanced Budget Act of 1997 (the BBA 1997) long-term hospitals established on or before September 30, 1995 are entitled to retain their long-term hospital classification notwithstanding their location in the same building or campus of another hospital. In the commenter's view, these hospitals should not now have this classification revoked by this proposed regulation.

Response: The provision referred to by the commenter, section 4417(a) of the BBA 1997, is codified in section 1886(d)(1)(B) of the Act and is implemented under regulations at § 412.22(f). That provision authorizes certain hospitals to continue being excluded from the Medicare hospital inpatient prospective payment system (PPS) based on their exclusion status and configuration on or before September 30, 1995, even though they would not otherwise qualify for this exclusion. The criteria for provider-based status do not conflict with or even directly relate to the section 4417(a) provision, and we have therefore not made any change in the regulations based on this comment.

Comment: The commenter believes that rural health clinics (RHCs) should be exempted from provider-based designation requirements if they meet the intent of the enabling regulation. The commenter requested that an RHC be granted provider-based status if it meets one of the following criteria: Is the sole source of primary care for the community; has traditionally served the community with an open door policy; or treats a disproportionate share of the community's Medicare and Medicaid population.

Response: We share the commenter's concern, but believe the criteria suggested are overly inclusive and could lead to a proliferation of RHCs in areas where there are no true shortages of care. While we do not believe a blanket exemption from the criteria is warranted, we have developed a special provision for RHCs affiliated with small rural hospitals, as described below in our responses to comments on § *415.65(d)(7), Location in immediate vicinity.*

Comment: A commenter stated that there may be instances where the Medicare regulations related to provider-based definitions conflict with the Medicaid provider-based regulations, and asked whether Medicaid will be required to comply with the new Medicare provider-based regulations.

Response: Because hospitals under Medicaid are required to meet the same standards as Medicare facilities, these final rules would affect the Medicaid definition of these facilities as well as the Medicare definitions.

Comment: Commenters stated that the reasons cited for establishing provider-based requirements that are found in the preamble do not apply to clinical laboratories and thus these requirements should not apply. The commenters asked that we explicitly state in the final regulations that the provider-based requirements are not applicable to clinical laboratories. They believe the regulations have little bearing where, as with clinical laboratory services, reimbursement is under a fee schedule amount, and neither the Medicare program nor the beneficiary will pay anyone differently as a result of the treatment of the laboratory in the manner proposed.

Response: As explained more fully in the preamble to the proposed rule, our objective in issuing specific criteria for provider-based status is to ensure that higher levels of Medicare payment and increases in beneficiary liability for deductibles or coinsurance (which can all be associated with provider-based status) are limited to situations where the facility or organization is clearly and unequivocally an integral and subordinate part of a provider. Under this principle, we agree with the commenter's view that it would not be either necessary or appropriate to make provider-based determinations with respect to facilities or organizations if by law their status (that is, provider-based or free-standing) would not affect either Medicare payment levels or beneficiary liability. However, we believe that it is not necessary to specify in the regulations that specific facility types are excluded, since these facilities or organizations are unlikely to seek a provider-based determination. We will be careful to clarify this policy in program operating instructions.

Comment: A commenter stated that the proposed provider-based requirements seem to preclude the possibility of a Comprehensive Outpatient Rehabilitation Facility (CORF) meeting these new requirements. The commenter believes that in the past, CORFs have been permitted to be either provider-based or free-standing and asked whether the final rules will give CORFs the option of being either free-standing or provider-based.

Response: As explained more fully in the preamble to the proposed rule, our objective in issuing specific criteria for provider-based status is to ensure that higher levels of Medicare payment and increases in beneficiary liability for deductibles or coinsurance (which can all be associated with provider-based status) are limited to situations where the facility or organization is clearly and unequivocally an integral and subordinate part of a provider. We are aware that, under the cost-based payment system that applied to CORFs prior to January 1, 1999, approximately 17 percent of participating CORFs claimed provider-based status. However, effective January 1, 1999, in accordance with the BBA 1997, payment for all CORF services is made no longer on the basis of cost reimbursement but on the basis of the physician fee schedule. Beneficiary liability is also determined under the fee schedule, regardless of the organizational structure or affiliations of the CORF. The switch to fee schedule payment from a cost-based system eliminates or removes any payment incentives to be a provider-based rather than a free-standing CORF. Thus, as in the case of the preceding comment, we agree with the commenter's view that it would not be either necessary or appropriate to make provider-based determinations with respect to facilities or organizations if by law their status (that is, provider-based or free-standing) would not affect either Medicare payment levels or beneficiary liability. We also note that existing regulations at § 413.174 specify rules for determining whether ESRD facilities are independent or hospital-based, and we have revised § 413.65(a) to state that determinations with respect to ESRD facilities will continue to be made under § 413.174,

not § 413.65. However, we believe that it is not necessary to specify in the regulations that most specific facility types are excluded, since these facilities or organizations are unlikely to seek a provider-based determination. We will be careful to clarify this policy in program operating instructions.

Application to Specific Facilities—Indian Health Service (IHS)

Comment: Several commenters requested an exception or exemption from the rules for IHS and tribal facilities. One commenter was concerned that the implementation of these proposed regulations will have the effect of denying Medicare participation as provider-based entities to a number of IHS facilities that are currently operated by Indian tribes under the auspices of Public Law 93–638. They will also cause a disruption of the coordinated health care delivery system(s) that exist between IHS and numerous tribes, and jeopardize statutorily authorized contracting and compacting relationships between the IHS and these tribes due to the conflict between these proposed regulations and the statutory opportunities for self-determination by the Indian tribes. The IHS strongly recommended that these proposed regulations not apply to IHS and tribal health systems as written. Recommendations were also made to deem satellite facilities within a discrete Indian reservation as meeting the definition of a provider-based entity as well as satellite facilities within a historical service unit. Finally, the IHS recommended that the current system be ''grandfathered'' to meet the definition of provider-based entity.

Response: We share many of these concerns and have provided special treatment for IHS and tribal facilities as described below.

Comment: A commenter was concerned that the proposed regulations would severely restrict a number of IHS satellite clinics from receiving reimbursement for the provision of Medicare Part B services. The commenter believes that a number of the requirements that must be met before an entity can be designated as provider-based for Medicare payment purposes are unrealistic for IHS satellite clinics, which are often the only Medicare providers on remote tribal lands. The commenter recommended that HCFA provide for an exemption for IHS satellite facilities that are generally located on a main hospital campus or within a short distance of a hospital. Also, the commenter recommended that the final rule clarify that IHS and tribal outpatient departments or satellite clinics are eligible to receive designation as a department of a provider or a provider-based entity and are eligible for Part B reimbursement.

Response: We share many of these concerns and have provided special treatment for IHS and tribal facilities as described below.

Comment: Many tribes have acquired operations of outpatient facilities and are in the process of acquiring the affiliated hospitals. The commenter stated that this trend, coupled with the complexities of the Indian Self-Determination Act (Pub. L. 93–638), the Indian Health Care Improvement Act (Pub. L. 94–437), and a moratorium on tribal compacting and contracting, requires special consideration by HCFA. The commenter requested that facilities be recognized as provider-based if—

(1) The outpatient facility is owned and operated by the tribe that owns the majority of the tribal shares utilized in funding the main hospital;

(2) The tribe has previously compacted programs that were historically administered by the hospital and are now administered through a committee or board comprised of medical staff of both facilities;

(3) The outpatient facility is in the same State as the hospital;

(4) There is coordination and integration of services, to the extent practicable, between the outpatient facility seeking provider-based status and the main provider.

Response: We recognize that the provision of health services to members of Federally recognized Tribes is based on a special and legally recognized relationship between Indian tribes and the United States Government. To address this relationship, the IHS has developed an integrated system to provide care that has its foundation in IHS hospitals. Because of these special circumstances, not present in the case of private, non-Federal facilities and organizations that serve patients generally, we agree that it would not be appropriate to apply the provider-based criteria to IHS facilities or organizations or to most tribal facilities or organizations. Therefore, we have revised the final rule to state that facilities and organizations operated by the IHS 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 IHS; (2) owned by the Tribe but leased from the Tribe by the IHS under the Indian Self-Determination Act in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes: or (3) owned by the IHS but leased and operated by the Tribe under the Indian Self-Determination Act in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes. Facilities or organizations that are neither leased nor owned by the IHS would not be eligible for this special treatment, even if operated on Tribal land by members of the Tribe. These facilities would, of course, be eligible to participate in Medicare as FQHCs if applicable requirements in our regulations at 42 CFR part 405, subpart X are met. We did not adopt the conditions recommended by one commenter because we believe they may not apply to all Tribes.

Application to Specific Facilities—Federally Qualified Health Centers (FQHCs)

Comment: A commenter stated that despite specific acknowledgment of the eligibility of FQHCs to qualify as provider-based entities, certain proposed ownership, governance, and supervision criteria in connection with the determination of provider-based status would effectively prohibit entities from maintaining concurrent provider-based and FQHC designations. The commenter believe the criteria should be modified, or some other special provision created, to allow FQHCs to be departments of a provider.

Response: We understand the commenter's concerns and have provided special treatment for FQHCs as described below.

Comment: The commenter, a hospital that is affiliated with a number of off-site community health centers, believes the criteria in the proposed rule would deny provider-based status to community controlled, urban tax-exempt health centers operated under the license of a ''main provider.'' Several of the commenter's health centers are FQHCs that must fulfill certain criteria to maintain this status. In the commenter's view, it is not feasible to require the ''main provider'' to own and control these health centers or to require that the health centers and the ''main provider'' strictly meet all of the requirements set forth in the proposed rule. The commenter asked that the final rule be revised to take into account these historical relationships and ''grandfather'' the provider-based status of health centers that have been on the license of a disproportionate share hospital for at least 10 years. The recommended ''grandfathering''

provisions also could, in the commenter's view, require common Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation, integration of clinical care committees, main provider approval of clinical guidelines and protocols, and financial oversight and review by the main provider.

Response: We share many of these concerns and have provided special treatment for FQHCs as described below.

Comment: A commenter requested that we provide a transition period of at least five years for health centers that have been treated as provider-based entities for a significant period of time (for example, 10 years or more), so that the centers will have adequate time to achieve compliance with the provider-based criteria. In the commenter's view, an extended time period for compliance would permit continuity of care to the populations served by the health centers while granting the affected health centers an opportunity to find alternative funding streams.

Response: We recognize that FQHC qualification criteria effectively require these facilities to be governed by community-based boards independent of hospitals and other providers, while our provider-based criteria require facilities seeking provider-based status to be operated under the ownership and control of the main provider, and to be under the direct supervision of that provider. This does not preclude an FQHC from participating in Medicare as a free-standing entity; on the contrary, this participation is entirely appropriate. However, it does preclude the facility from qualifying as a department of a hospital or other provider under our criteria.

Despite the difference between HRSA and HCFA requirements, we are aware that some FQHCs may have been treated by hospitals as departments for purposes of Medicare and Medicaid billing, and we are concerned that an abrupt change in status for them could force some or all to close, leading to shortages of care in some areas. Therefore, we plan to establish special provisions for FQHCs and FQHC ''look-alikes'' (facilities that are structured like FQHCs and meet all requirements for grant funding, but have not actually received these grants). Specifically, we have revised the regulations to state that if a facility has since April 7, 1995 furnished only services that were billed as if they had been furnished by a department of a provider and either (1) received a grant before 1995 under section 330 of the Public Health Service Act or, before 1995, received funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 330 of the Public Health Service Act; or (2) based on the recommendation of the PHS, was determined by HCFA before 1995 to meet the requirements for receiving such a grant, the facility 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 § 413.65. We note that both types of facilities would be obligated, for as long as they are treated as a department of a provider, to comply with the applicable requirements for departments of providers as stated in § 413.65(g).

Application of Standards

Comment: One commenter believes that the proposed rule did not make clear how it would apply to existing entities, because some language in the rule could be read to require that existing entities would not receive provider-based status until we have issued a determination letter. Another commenter requested that we clarify whether we expect to review all clinics prospectively or just new clinics. The commenter stated that requirements that only new clinics seek designation does not preclude us from auditing currently designated clinics. Another commenter asked if there will be a set time frame during which current providers with provider-based departments or entities under Program Memorandum A–96–7 must contact us and receive an official designation in order to continue billing as they currently do. More specifically, the commenter asked whether, if there is such a time frame, compliance with the criteria in the Program Memorandum would constitute a good faith effort as referred to in § 413.65(i)(2). Additional guidance was also requested as to what providers should do now to demonstrate that they have made a good faith effort.

Response: We plan to review all new requests for provider-based status. At present, we have no plans to systematically review all providers to determine whether they may be claiming provider-based status for some facilities or organizations inappropriately. However, we will review the status of specific facilities or organizations in response to complaints or any other credible information that indicates that provider-based status requirements are not being met. If the regional office determines that this is the case, it will take action in accordance with the rules in new § 413.65(h) and (i). In response to the comment about possible retroactive application of the new regulations, we note that they will apply only on or after their effective date of October 10, 2000. We will not apply the provider-based criteria in the new regulations to periods prior to that date; on the contrary, decisions for such periods will be reviewed only under the criteria in effect at the time, as stated in Program Memoranda and the Provider Reimbursement Manual and State Operations Manual.

Comment: Two commenters pointed out the proposed rules do not state whether the required approval status is retroactive to when the provider applied or to when we granted approval. These commenters believe it should be retroactive to the date of the provider's application for the determination.

Response: We plan to make provider-based status applicable as of the earliest date on which a request for provider-based status has been made and all requirements for provider-based status are shown to have been met, not on the date of our determination. Thus, if a provider requests provider-based status for a facility on May 1 and demonstrates that applicable criteria were met on that date, but the regional office did not make a formal determination until June 1, the determination would be effective on May 1.

Comment: The commenter stated that we should not have published important provider-based policies in a **Federal Register** document that some providers, such as skilled nursing facilities and home health agencies, may not have read. The commenter recommended that we re-issue these proposed rules separately from the proposed hospital outpatient prospective payment rules.

Response: We do not agree that the proposed rules were published in an obscure location. On the contrary, the number of written comments received, many of them from providers other than hospitals, indicates that our proposals were widely known among providers that could be affected. Therefore, we do not intend to republish the proposed rules.

Comment: A commenter expressed concern that these provider-based provisions are unnecessarily restrictive and will unreasonably limit practice arrangements. The commenter went on to state that in the current health care environment, physicians and hospitals need flexibility to adapt to local market conditions and participate in a variety of practice arrangements to provide cost effective, high quality care. An unnecessary strict definition of

''provider-based entity'' could have a chilling effect on the evolution of new care delivery structures that would expand access to care, especially in rural areas.

Response: We share the commenter's concern with preserving Medicare beneficiaries' access to care, but do not agree that the provider-based rules will limit access. We note that the rules do not prohibit hospitals from purchasing physician practices or taking other actions to enhance access to care in remote rural areas; they only set minimum standards for the type of affiliations that will be recognized for provider-based designation.

For example, an institutional provider such as a hospital or SNF may elect to use part of its institutional complex to house physician offices or other facilities that provide services complementing those of the provider. Those facilities'costs will have to be included in the trial balance of the institutional complex, in order to allow costs to be allocated accurately to all parts of the complex, and permit the costs of the provider to be determined. However, inclusion of such facilities' costs on the institutional complex trial balance does not make the facilities provider-based. On the contrary such facilities would have to meet the criteria in § 413.65 to qualify for provider-based status.

Comment: Different views were expressed on how much

discretion regional offices should have in applying the provider-based criteria. One commenter asked that we make the rules as clear and concise as possible. The commenter argued that rules allowing for great latitude in interpretation could be dangerous for the provider community. On the other hand, another commenter stated that we should allow Medicare regional offices greater latitude for determining when sufficient integration exists for a facility to qualify as provider-based, and should avoid adopting regulations that ''micro-manage'' a hospital's operations. Another commenter suggested that rather than requiring that *all* criteria must be met to achieve provider-based status, we change the test to *substantially all.* There may be circumstances where criteria are not fully met, but an overall assessment supports a provider-based determination. This same commenter recommended that a ''pending'' status be incorporated into the evaluation process, whereby hospitals not meeting the criteria for provider-based status would be afforded an opportunity to make the modifications necessary. Another commenter asked that instead of meeting all criteria, we permit the regional offices to evaluate a facility's status with respect to the main provider with input from local government and the fiscal intermediary. Another commenter also suggested that the standards only be enforced to the extent that they are applicable and relevant, consistent with state laws, and relate to practices that are subject to the control of the particular provider.

Response: We have tried to balance the need to apply standards that can be adapted to fit particular circumstances, and agree that the standards should not be overly prescriptive, but rely on regional judgment to ensure appropriate decision making. Because provider-based status is a matter of extreme importance to many facilities, published standards provide a basis for advance assessment and planning of particular organizational and financial arrangements. Therefore, we have decided that a facility or organization will be found to be provider-based only when it is in compliance with *all* standards set forth in these final rules.

With respect to the comment regarding situations in which all but a few criteria for provider-based status are met, we note that nothing prohibits the main provider from re-applying for approval of provider-based status for a facility or organization after having made the changes necessary to come into compliance. Regional offices would in such cases only need to verify compliance with whatever criteria had not been previously met, unless the amount of time that elapses between requests, or other factors, make a full re-evaluation necessary. Because facilities have this flexibility under the rules as proposed, we did not make any changes based on this comment.

Comment: One commenter believes that we had not fully addressed the impact of these rules on service delivery. The commenter suggested that changes would affect deemed status, survey and certification requirements, state licensure requirements, physician referral requirements, and a host of related issues. Another commenter stated that the new requirement regarding administration and supervision found in § 413.65(d)(3) could impact more than our estimated 105 providers. The commenter believes that if providers are required to convert management firm employees to hospital employees and then revert back when outpatient PPS becomes effective, this could impact 5,000 inpatient PPS hospitals.

Response: We again reviewed our requirements, but do not believe they will have the far-reaching effects envisioned by these commenters. In particular, to the extent a facility or organization that claims to be a department of a provider must be accredited, surveyed, or licensed as a part of that provider, or must adapt to the physician referral requirements of the main provider, that result does not flow from the existence of criteria for provider-based status, but instead is a direct result of the provider's decision to claim the facility or entity as a department. We also do not think it is reasonable to assume that any significant number of hospitals will restructure themselves repeatedly because of the final rules set forth below. As noted earlier, both the proposed and final rules closely parallel policies that have been stated explicitly on program instructions since 1996, and we are providing a 6-month delay in effective date for the final rule. Thus, hospitals and other providers have had ample time to assess the impact of any changes and to make necessary adjustments in an orderly way.

Comment: A commenter requested clarification as to how the proposed rules would apply to two hospitals seeking consolidation into a single provider. The commenter also asked whether two small PPS hospitals located approximately 15 to 25 miles apart in separate towns within a metropolitan statistical area (MSA) who wish to consolidate would be prohibited from doing so because of patient population or licensure requirements. Furthermore, if these two hospitals are already certified as a single provider, would the proposed rules require them to separate and create separate providers? Another commenter requested that the final regulatory text state that the provider-based requirements do not apply to any facility where there are inpatient beds since such a facility would be viewed as a ''main provider.'' The provider-based requirements should apply only to facilities or organizations other than main providers.

Response: Although the Program Memorandum and proposed rules were issued in response to situations primarily involving outpatient facilities, we believe the policies set forth in these documents are equally applicable to inpatient facilities, and should be applied in the many cases in which a determination about inpatient facilities must be made. The rules would not prohibit two previously separate hospitals from merging to become a single provider. However, for either facility to be considered provider-based with respect to the main provider, the facility would have to meet the criteria

in this final rule. To clarify the scope of application of these regulations, we have added a definition of ''remote location of a hospital'' and a reference to hospital satellite facilities to § 413.65(a) Definitions, and have clarified the wording of several later sections by including references to remote locations and satellites. We have defined a ''remote location of a hospital'' as 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 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 as defined in § 412.22(h)(1) and § 412.25(e)(1). Hospitals may acquire remote locations by various means, but often do so by mergers or acquisitions, in which a single hospital purchases other, previously separate hospitals, and operates them as remote locations that are not separately organized as departments, but instead furnish the same types of services as the original hospital. For example, a long-term care or other specialty hospital might acquire one or more other hospitals, terminate their separate participation in Medicare, but continue to use them as sites of the same type of care as the original hospital. Satellite facilities are currently defined in our regulations at § 412.22(h)(1) (for hospitals) and § 412.25(e)(1) (for units). In general, a satellite facility is a part of a hospital (or of a hospital unit) that provides services in a building also used by another hospital, or in one or more buildings on the same campus as buildings also used by another hospital. Satellite status always involves co-location with another hospital, while remote locations are not co-located with other hospitals' facilities.

Comment: A commenter requested clarification that the provider-based requirements apply only to providers who are paid under the reasonable cost methodology. The preamble language in section VI implies that these requirements would also apply to providers under the outpatient PPS. The commenter believe that if this were the case, the requirements found in §§ 413.24(d)(6) and 413.65 would be appropriately placed in Subchapter E (for example, Part 482, Conditions of Participation for Hospitals).

Response: The rules set forth below are not limited in their scope to providers paid on a reasonable cost basis but, except where specifically stated in the text of the rules, apply to all providers and facilities seeking Medicare payment. While many of the problems associated with inappropriate accordance of provider-based status relate to cost reimbursement, the different payment systems used for various providers may produce some unintended incentives for one type of facility to gain an unfair payment advantage by misrepresenting itself. The specific requirements cited do not, like the Medicare conditions of participation, implement section 1861(e) of the Act, nor do they primarily concern patient health and safety. Therefore, we did not adopt the suggestion that the section be relocated to part 482.

Comment: A commenter would support a provision that prohibits hospitals from acquiring free-standing physician practices and converting them to hospital-based entities.

Response: We understand the commenter's concern, but do not have authority under the Medicare law to prohibit this practice. We do believe that the rules set forth below will keep hospitals from misrepresenting physicians' practices as hospital outpatient departments.

Section 413.24(d)(6) Adequate cost data and cost finding: Management contracts

Comment: The proposed cost reporting requirements state that if an overhead administrative cost center does not perform services for the off-site clinic or department, no costs should be allocated to that function. The commenter pointed out that this contradicts generally established Medicare cost reporting principles that have always required that the administrative costs be allocated to allowed and nonallowed cost centers.

Response: Our position, as expressed in the Provider Reimbursement Manual, Part II, Chapter 36 for hospitals, is to allow the provider to bypass the allocation of overhead through the cost report to avoid inappropriate allocations. An example of this would be lab services under arrangement, where there is obviously no administrative activity by the main provider. Our electronic cost report systems are set up to ''skip'' that particular cost center and to re-allocate the costs to the remaining cost centers. Likewise, where administrative costs such as billing are performed by the subordinate provider, no billing cost from the main provider should be allocated to that cost center from the main provider.

Comment: Several commenters suggested clarification of ''like'' costs by adding a definition or providing examples. Also, a commenter stated that since the main concern is costs, this provision should be applied when management costs exceed the hospital's operating costs of the department by 10 percent on a comparable basis. Another commenter stated that: (1) Management services benefit only the specific department to which they are expensed, and provide no direct services to other hospital departments; (2) A department under the management contract receives necessary services from other hospital overhead departments; (3) such overhead departments do not represent duplicate services provided under the management contract. Since management agreements can be drastically diverse, the commenter believes this clarification would assist in avoiding any confusion, as well as allow for consistency with generally accepted cost finding principles. Another commenter stated that most entities that contract to manage an area of a hospital manage just that area. Therefore, if they offer assistance with a particular function, it is only for that area and not for the whole hospital. The commenter believes the same principles of reimbursement should be applied whether the hospital provides the service directly or contracts for the service to be provided.

Response: Examples of similar costs when management contracts provide services also available through the main provider are the following: billing services, computer services, accounting services, and, possibly, general administrative staff. When the same services are included in the administrative and general costs of the main provider, and allocated down to subordinate cost centers or providers incurring and reporting these same costs in the trial balance, the result is a duplication of costs to the subordinate cost center or provider. As long as the main provider has the ability to identify these ''like'' service costs, these costs should be re-allocated to the remaining reimbursable and non-reimbursable cost centers in proportion to each cost center's total costs as prescribed in the Provider Reimbursement Manual, Part II, Chapter 36. However, if the main provider is not able to identify the costs of these same services to permit the exclusion of allocation to the subordinate providers or cost centers,

the cost of the management contract of the subordinate provider or cost center must be reclassified to the main provider's administrative and general cost center, and allocated down to *all* reimbursable and non-reimbursable cost centers in proportion to each cost center's total cost.

Comment: With regard to the language in paragraph (d)(6)(ii), Medicare principles of reimbursement require that, when two entities are related, and one contracts from the other, reimbursement for these services is at cost due to the ''related party principle.'' The commenter stated that the cost of a service is both direct and indirect; Medicare reimbursement has a longstanding methodology concerning nonrevenue producing costs and their allocation on a provider's cost report. A separate work paper should not be required. The appropriate methodology for stepping down administrative costs should be based on the cost of the entity utilizing the service. The cost of the free-standing entity must be placed on the main provider's cost report to step down cost appropriately. Additional work papers would allow room for error and would delay any necessary adjustments.

Response: The intent of § 413.24(d)(6)(ii) was to require the main provider to report costs of related party entities that would not be reported through their accounting system on the main provider's books and records, for example, trial balance. Consequently, when there is a sharing of administrative services, for example, managerial staff, the related entity escapes any administrative overhead allocation when that same related entity is not reported on the main provider's trial balance of the cost report. While the commenter is correct regarding the proper reporting of related transactions at cost of the related entity, this regulation section goes further to require the main provider to develop the total cost of the related entity, utilizing and maintaining workpapers to justify the amount to be reported, and to report those costs by the main provider on the cost report trial balance.

Section 413.65(a) Definitions (retitled in this final rule as Section 413.65(a) Scope and definitions)

Comment: Two commenters requested that a definition be provided for ''a provider's campus.'' A definition would be important since the proposed regulation specifies additional requirements for off-campus locations.

Response: We agree that location on or off a hospital's campus is important. To provide a clear standard, we have revised the final rule to define ''campus'' as ''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 our regional office, to be part of the provider's campus.'' This definition would encompass not only institutions that are located in self-contained, well-defined settings, but other locations, such as in central city areas, where there may be a group of buildings that function as a campus but are not strictly contiguous and may even be crossed by public streets. This would also allow the regional offices to determine, on a case-by-case basis, what comprises a hospital's campus. We believe allowing regional office discretion to make these determinations will allow us to take a flexible and realistic approach to the many physical configurations that hospitals and other providers can adopt.

Comment: The commenter expressed concern regarding the definition of provider-based facilities as many hospital-owned outpatient services are often provided with leased employees with ambulatory care experience. It is not clear that such an arrangement would satisfy the intent of the regulation.

Response: The regulations do not explicitly prohibit the use of leased employees, and each situation will be evaluated relative to the criteria in the regulations set forth below.

Comment: One commenter stated that the difference between ''department of a provider'' and ''provider-based entity'' is not clear from the definitions given of those terms. The commenter requested that we clarify in the regulations text whether a provider-based entity must be certified in its own right, and what type of certification this encompasses. The commenter also requested clarification in the regulations text concerning whether the term ''provider'' in the definition is intended to mean only entities that satisfy the Medicare definition of ''provider'' contained in § 400.202.

Response: We have clarified § 413.65(a) to state that a ''department of a provider'' is a facility or organization that could not by itself be qualified to participate in Medicare as a provider under § 489.2, while a ''provider-based entity'' could be so qualified. For example, a skilled nursing facility (SNF) could be a ''provider-based entity,'' whereas an entity that furnishes ambulatory surgical services could not be a provider-based entity, and could participate in Medicare (for example, receive Medicare payment for services furnished to beneficiaries), only as a department of a provider, as a physician office, or as an ambulatory surgical center approved by Medicare under part 416, if at all. We have further revised the final rule to clarify that a department of a provider furnishes services of the same type as the main provider (for example, a department of a hospital furnishes hospital services), while a provider-based entity furnishes services of a different type from those of the main provider (for example, a hospital-based RHC furnishes RHC services, not hospital services).

Comment: A commenter believes the proposed rule should be revised for medically underserved populations and health manpower shortage areas to allow the referral of beneficiaries back to their community for treatment of community-based therapy providers. Therapy services provided under such a referral would be included under the provider-based designation.

Response: We do not oppose use of such referrals where they are medically appropriate, but believe that referral arrangements should not be equated to provider-based status.

Comment: A commenter questioned the requirement that services be furnished ''under the name'' of the main provider entity. The commenter argued that the requirement is inconsistent with the commenter's view that health care in the late 1990s is, and in many markets must be, ''marketed'' in a highly competitive environment. The commenter's view is that having provider-based status turn on the names used will inevitably invite micro-management of the way the main provider's name is used by the department or other hospital-based entity.

Response: We disagree with any suggestion that health care is merely a generic commodity that can be repackaged under another name for marketing purposes. On the contrary, we believe that operating under the name of the main provider, and holding oneself forward to patients under that name, is an important indicator of status as an integral and subordinate part of that provider. Therefore, we did not make any changes in the regulation based on this comment.

Section 413.65(b) Responsibility for obtaining provider-based determinations

Comment: A commenter stated that the proposed rule does not state clearly enough whether our approval is required in order to permit billing each

time a provider sets up a new service, regardless of whether the service is acquired, managed, new, located on the main campus, or off the main campus. Some commenters stated that if approval is required in all instances, it will cause a significant paperwork backlog and will be quite costly to administer.

Response: Section 413.65(b) states explicitly that a determination by us that a facility or organization is provider-based is required before the main provider may treat the facility or organization as provider-based for billing or cost reporting purposes. We recognize that this may generate some administrative cost, but believe the cost will be much less than the amounts that would be spent improperly if payment were made to a free-standing facility as if it were provider-based.

Comment: A commenter urged that the new determination process be applied to all current as well as new hospital-based services.

Response: We have no plans at present to review all hospitals and other providers with respect to provider-based criteria, but will look into any situations that come to our attention in which it appears that a facility does not meet the requirements of the new regulations but is being treated as provider-based. If the facility or organization does not qualify as provider-based, action will be taken as described later in this preamble and in § 413.65(i).

Comment: A commenter stated that there should be some mechanism in place for a long-term hospital (LTH) to seek an advance determination or advisory ruling that a proposed LTH satellite will be granted provider-based status. Because establishing an LTH requires a huge expenditure of time and human resources, an LTH main provider needs to know in advance whether or not its proposed satellite will receive a favorable provider-based determination. It is suggested that we institute a system by which advance rulings or determinations are available before the satellite is established.

Response: We understand the commenter's concern, but do not have the staff or facilities to provide advance approvals of restructuring proposals. We suggest that providers review the new criteria carefully and avoid forms of organization that are not clearly in compliance with them.

Comment: Two commenters suggested that we provide guidance on the application process providers must complete in order to receive a provider-based determination. In addition, time limits for approval of these determinations should be established. Furthermore, existing provider-based entities should not be required to change their billing and accounting procedures. A commenter also asked for clarification as to whether the intermediary and regional office is to be the contact, and who will make the actual determination of provider-based status.

Response: We are developing an application process and intend to have it in place and ready for use before the effective date of the regulation. We expect that determinations of provider-based status will be made by our regional offices. Involvement by other entities, such as fiscal intermediaries or State survey agencies, will be for information-gathering purposes and under the direction of the regional office.

Comment: A commenter suggested that if a determination goes against the provider, the provider should be given the option to come into compliance with the requirements or file an appeal.

Response: As noted earlier, the regulations do not prohibit a provider that meets most but not all criteria from taking action to fully meet the criteria, thus qualifying a facility or organization for provider-based status. In the case of a provider that believes that the determination of the regional office is incorrect, an appeals process is provided under part 498.

Comment: A commenter stated that the requirement in paragraph (b)(3) establishes an adverse presumption against provider status for ''off-campus'' physician practice sites, and that the focus on ''campus'' boundaries will prove elusive, and serve no real policy purpose.

Response: As explained later, we believe location in the immediate vicinity is an important indicator of provider-based status, and that location can be a good basis for identifying facilities for further scrutiny.

Section 413.65(c) Reporting

Comment: Several commenters pointed out that the regulatory language does not reflect the preamble language regarding off-campus entities and the five percent increase in a provider's costs.

Response: We have revised the final rule to correct this oversight.

Comment: One commenter asked whether this language applies only to entities that are applying for provider-based status, or also applies to entities that have already achieved provider-based status.

Response: The requirement applies to both types of providers, but providers that have entities with provider-based status are required to report only newly created or acquired facilities or organizations.

Comment: Two commenters stated that the five percent and off-campus criteria with regard to provider-based status do not take into account the characteristics of rural and frontier areas, and could lead to lower payments to some facilities, thus reducing the flow of Federal money into rural areas and possibly creating a shortage of care. In addition, considering the small budget of RHCs and other rural facilities, 5 percent is an inappropriately low and unreasonable growth limit.

Response: We understand the commenter's concern but do not agree that a 5 percent threshold for reporting is too low. Therefore, we made no change based on this comment.

Comment: A commenter asked whether this reporting requirement also applies to all newly developed services (that is, department on the campus of the hospital).

Response: The requirement applies to all newly developed on-campus services that could increase the costs of the provider by 5 percent or more.

Comment: A commenter requested clarification that a main provider that ''creates'' as well as ''acquires'' a facility or organization is responsible for reporting to us. The commenter also suggested specific items to be included in the reporting and approval process. These include specific data elements to be reported by the main provider, specifying our component with primary responsibility; specifying our approval process; adding a preliminary conditional approval process; adding a specific time period for our approval; and adding requirements for the effective date that the costs of the provider-based entity can be included on the main provider's cost report.

Response: We have revised the regulation to clarify that it applies to facilities or organizations created by the main provider, as well as those ongoing operations acquired by purchase or other means. We have not included the procedural detail requested by the commenter in regulations, but will consider including it in program instructions.

Comment: A commenter stated that the use of the phrase ''any material change'' in paragraph (c)(2) of this section is too vague and open to interpretation. It is suggested that the section be revised to clearly designate changes of ownership and new management agreements as the only two material changes that require reporting by provider-based entities.

Response: We do not agree that the range of reportable events should be limited in this way. On the contrary, we intend to require reporting of any change that could have a significant (''material'') effect on compliance with the provider-based criteria.

Comment: A commenter asked if the reporting requirements are coordinated with the notification of change of ownership requirements at § 489.18(b), where notice is to be given in advance, and whether there should be a cross reference or clarification with respect to the change in ownership regulation and this proposed regulation.

Response: We believe this suggestion has merit, and will consider revising our program instructions to specify that a report under § 489.18(b) should be reviewed for its applicability to provider-based determinations.

Section 413.65(d) Requirements

Comment: A commenter suggested that we clarify whether all requirements, or only a majority of the requirements, must be met to obtain provider-based status.

Response: We have revised the first sentence of paragraph (d) to state that all of the stated requirements must be met by a facility or organization that wishes to be classified as provider-based.

Section 413.65(d)(1) Licensure

Comment: Many commenters objected to the requirement that provider-based facilities share a common license with the main provider unless the State requires separate licensure for the subordinate facility. One commenter listed several reasons for this concern. First, in the commenter's opinion, licensure determinations may be made based on factors that are different from those that would be important for provider-based determinations. Another reason cited by the commenter is that State licensure laws may vary from State to State. Some State hospital licensure definitions are building specific, and do not include off-site outpatient facilities, thus giving what the commenter argues is undue weight to physical location in evaluating provider-based status. Finally, the commenter believes that requiring common licensure will create a situation where some States may have a large number of provider-based entities and others will have few or none, thus leading to inconsistent application of our rules. One commenter recommended that the same licensure requirement be waived for States with idiosyncratic licensure requirements. An alternative would be accreditation with the provider as a deemed status for meeting a common license requirement. The commenter suggested that the proposed language could be reworded to clarify that offsite clinics would not have to be licensed or operated under the same license as the provider in those States that do not license them.

Response: We recognize that licensure may not be an appropriate indicator of provider-based status in all States, and have therefore revised the regulations to require common licensure only in States with laws that permit common licensure of the provider and the prospective provider-based department under a single license. This means that in States that do not allow licensure of certain types of facilities, such as those providing ambulatory care or those located off the provider's main campus, the licensure criterion would not be applied. We do not agree that JCAHO or other accreditation should be accepted in lieu of licensure, since such accreditation may not necessarily reflect an on-site evaluation of the prospective provider-based department. In recognition of the fact that some hospitals are not licensed by the State because they are Indian Health Service (Federal) hospitals or are located on Tribal lands, we also will not apply the licensure requirement to departments of those hospitals.

Comment: Under paragraph (d)(1) as proposed, clinics in another State from the main provider could not be under the hospital's license. Several commenters argued that this requirement would arbitrarily affect rural and urban health care delivery, where the main provider is close to a State line. A commenter recommended that close proximity be used instead, where a hospital-based clinic is in another State from the main provider. For urban hospitals in large metropolitan statistical areas that cross State boundaries, the commenter believes that the market area of the main provider should be the primary determinant of the potential for integration with the main provider.

Response: Under the regulations as revised based on the comments summarized above, common licensure would not be required of facilities located across State lines if the law of the State in which the main provider is located does not allow such licensing. However, see the discussion, later in this preamble, of § 413.65(d)(7)(ii).

Comment: A commenter pointed out that the proposed rule appears to limit the licensure requirement to ''departments'' of the main provider. The commenter asked whether this requirement only applied to ''provider-based entities.'' The commenter also suggested that where a State has two licensure schemes for the same type of facility, we should not prefer one licensure scheme over the other for purposes of determining the provider-based status of the facility.

Response: The commenter is correct in noting that the common licensure requirement in the proposed rule would have applied only to provider-based departments. We did not propose to apply a common licensure requirement to provider-based entities such as SNFs and HHAs, because they are providers of services in their own right, and typically would be separately licensed without regard to their affiliation with the provider. We disagree with the commenter's view that licensure should not be viewed as an indicator of integration. On the contrary, our view is that if a facility could be licensed as part of a main provider but chooses not to be, the facility cannot reasonably be seen as an integral and subordinate part of that provider.

Comment: With regard to the proposed requirement that states that our determination regarding provider-based status will be based on a State health facilities' review commission, one commenter argued that relying on the commission's criteria for purposes of making provider-based determinations is arbitrary and inappropriate. The commenter believes imposing this criterion could disadvantage providers and discourage expansion to off-site locations, thus indirectly leading to shortages of care. Another commenter requested that there be a delay in implementation during which time changes can be made to the commission's definition of what rates it can regulate.

Response: We continue to believe it would be inappropriate for a facility to claim to be separate from the provider for State rate-setting purposes while also claiming to be an integral and subordinate part of the provider for Medicare purposes. To allow this practice would authorize providers to misrepresent their structures and affiliations in whatever way will yield the highest payment. Thus, we did not make changes to reflect the comment.

Section 413.65(d)(2) Operation under the ownership and control of the main provider

Comment: Regarding § 413.65(d)(2), the commenter suggested that the regulations provide a separate set of criteria that would allow a provider that is operated within one legal entity to be provider-based to a provider that is operated within another legal entity, as long as the two entities are under common control. Another commenter

stated that this ownership and control requirement is unnecessarily rigid, since a hospital-based clinic, which was strictly an administrative division of the hospital, might qualify while another similar clinic, wholly owned by the hospital with slightly different governing bodies and documents, would not be eligible.

Response: We do not agree that common control of two separate entities by the same parent organization should be sufficient to meet a requirement for ownership and control by the main provider. While this arrangement may be an appropriate way to manage two separate entities, it does not establish provider-based status for either. With respect to the second comment, we agree that the form of administration of an entity can determine whether or not the entity is found to be provider-based. We believe this would be an appropriate result, since it would help ensure that only facilities that are organized as provider-based entities or departments of a provider are given this status.

Comment: One commenter believes it is unrealistic to require a potential provider-based facility or organization to be owned by the main provider and share bylaws and an identical governing body. The commenter stated that in the present business climate an entity can operate as a provider-based entity without meeting these criteria. It is recommended that we replace the proposed 100 percent ownership standard with a majority standard, require only overlapping governing bodies, and eliminate the requirement for organization under the same organizational documents. Another commenter believes that the key consideration should be whether the provider is in control of the day-to-day operations of that portion of the facility in which the provider seeks provider-based status, and not necessarily whether the building is 100 percent owned by the provider. The commenter believes we should rephrase this provision to require that the operations of that portion of the facility or organization in which the provider is seeking provider-based status be controlled by the provider.

Response: In response to the first comment, we recognize that many organizations enter into business relationships that involve overlapping of ownership, governance, and applicability of bylaws. However, this degree of collaboration does not mean that one facility is an integral and subordinate part of another. Therefore, we made no change based on this comment. Regarding the second comment, we wish to clarify that it is ownership of the business enterprise, not of the buildings or other physical assets of the enterprise, that is required under paragraph (b)(1). We have therefore revised the regulation text to refer to ownership of the business enterprise.

Comment: A commenter stated that the requirements contained in paragraph (d)(2) would preclude entities that are jointly owned through legitimate joint ventures or those separately organized subordinate facilities from qualifying for provider-based status. Additionally, to require the level of integration suggested by our proposed rule would prevent providers from establishing efficient systems of delegation and management, solely to qualify for provider-based status.

Response: We agree that this criterion would have the stated effect. As explained further in our discussion of comments on proposed § 413.65(e), facilities operated jointly by two or more providers cannot appropriately be considered integral and subordinate parts of either provider. With respect to the second comment, we do not oppose systems of operation that stress separate, decentralized operation where this leads to greater efficiency. However, we believe such facilities or organizations should be recognized as the separate enterprises that they are, not considered integral and subordinate parts of another institution.

Comment: A commenter suggested that the requirement under paragraph (d)(2) be modified for medically underserved populations and health manpower shortage areas.

Response: We are also concerned that our criteria not limit access to care for any vulnerable populations and have, to avoid this potential problem, created special provisions for FQHCs and IHS and tribal facilities. As described later in this preamble, we have also created an exception to the location requirements in paragraph (d)(7), which is designed to help avoid restricting access to primary care furnished by RHCs in remote, underserved areas. In view of these provisions, we do not believe it is necessary to also modify our requirement relating to ownership of the facility or organization.

Comment: A commenter stated that the proposed requirements in paragraph (d)(2) are inherently inconsistent with section 330 of the Public Health Service Act statutory and regulatory requirements and the Bureau of Primary Health Care expectations necessary to obtain and maintain section 330 funding (and FQHC status). The commenter believes HCFA should not require FQHCs to be 100 percent owned by the main provider or share a common governing body and common bylaws with the main provider. The commenter also suggested that we accept appropriate reporting relationships and satisfaction of other criteria (for example, licensure, quality assurance, integration of certain administrative and clinical functions, such as billing, purchasing, retention of medical records, quality assurance and utilization review procedures; and public awareness of the relationship between the health center and the main provider) as a sufficient basis for provider-based status.

Response: As described earlier, we have provided a special transition period for FQHCs. We believe this period will be adequate to avoid the problems envisioned in this comment.

Section 413.65(d)(3) Administration and supervision

Comment: A commenter recommended that the daily reporting relationship stated in § 413.65(d)(3) should be replaced with the standard of having the reporting relationships have the same intensity as on-site departments. The commenter stated that in practice at the hospital, there may be very little day-to-day contact between medical directors of various hospital services. Also, the commenter believes it is unlikely that departmental directors report directly to the chief executive officer, but rather to a chief operating officer or other designee. Finally, the commenter argued that under the common governance requirement, while all hospital employees are theoretically accountable to the governing body, the accountability may be directed through the CEO, and multiple executives may not have an independent reporting with the board. Another commenter also believes that the standards for the provider-based entity should mirror those of the main facility; personnel reporting structure needs to be respected within the regulations. Still another commenter found ''intensity'' to be a subjective standard and asked how it will be measured.

Response: We agree that reporting need not be daily in all cases, and have revised the final rule to state that 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. We agree with the commenter that the intensity of supervision will have to be assessed on a case-by-case basis, but do not believe

this will lead to imprecise or poorly reasoned decisions.

Comment: Several commenters believe that this requirement limits the flexibility of the entity to operate efficiently and effectively in the current environment, since hospitals frequently turn to many specialized management companies to operate more efficiently and effectively than with hospital resources. Another commenter stated that whether the administrative department utilizes employees at one location and contracts at another location should be irrelevant as long as the function is integrated with the main provider, follows the policies and procedures of the main provider, and is accountable to the governing body of the main provider as is any other department. Still another disagreed, and believes that it may be appropriate to require that the main provider manage such contracts.

Response: We do not agree that the provision unreasonably limits hospital flexibility. Paragraph (3)(iii)(B) explicitly allows different management contracts to be used for the facility or organization and the main provider, as long as the provider manages the contracts. Thus, we did not make any changes in the proposal based on these comments.

Comment: A commenter asked whether the administrative functions listed in paragraph (d)(3)(iii) are the only services that must be integrated between the main provider and the subordinate facility.

Response: The commenter was correct in understanding that the functions listed are the only administrative functions that must be integrated. There are also requirements for integration of certain financial functions, as described below.

Comment: One commenter posed several questions concerning this proposed requirement. First, in a certain situation, the facility fee is billed to the intermediary by the hospital billing department using the provider number, while the professional fee is billed to the Part B carrier by the faculty practice billing organization under its physician group number. The commenter asked if the different provider number and tax identification impact on the provider-based status, and if there is a more appropriate way to obtain billing numbers for hospital-based clinics. Also, the commenter asked if clinic space can be shared by two clinics, when one is provider-based and one is free-standing, without impacting the provider-based status of the first clinic.

Response: In the circumstances described, the use of separate billing and tax identification numbers for provider and physician services would not adversely affect a facility's request for provider-based status, since such billings are required under Medicare to be separate in the case of services in hospitals. The question regarding sharing of space, however, can be answered only in the context of a specific case, and we expect that such decisions will be made by our regional offices.

Comment: With respect to the oversight of contracts under paragraph (3)(B)(iii)(B), several commenters stated that it is common for hospitals to subcontract out the billing for different departments, especially the hospital outpatient department, due to the complexity and number of claims. These commenters stated that while it may be appropriate to require the main provider to manage such contracts, departments other than the billing department should be permitted to perform this management function. One commenter suggested revising the criterion on billing under the integration of administrative functions to state, ''common billing or the contract for billing services is held by the provider where it is based.''

Response: We agree that departments other than the main provider's billing department may appropriately manage billing contracts, and have revised the criterion to state that the contract for a provider-based facility or organization must be managed by the main provider.

Section 413.65(d)(4) Clinical services

Comment: A commenter asked for clarification of paragraph (4)(iv) of this section, specifically concerning whether this language would require a Medicare certified HHA's improvement activities to be overseen by hospital medical staff, rather than the advisory committee as is now being done. The commenter believes that having the hospital medical staff overseeing the quality assurance activities of a HHA may not be appropriate or cost effective and may even slow the process of performance changes.

Response: The commenter is correct in understanding that compliance with this criterion would require oversight of a hospital-based HHA's quality improvement activities by the hospital's medical staff. We do not agree with the commenter that the outcome would be to substitute the judgment of the hospital for the HHA's own committee or that it would be inappropriate. The hospital conditions of participation contain a number of separate requirements that must be read together to make complete sense of this provision. Conditions spelled out at § 482.12 (Governing body), § 482.21 (Quality assurance), and § 482.22 (Medical staff) establish a chain of accountability in a hospital for the quality of care it provides. The requirements are clearly applicable to any activity (for example, provider-based entity) that is an integral part of the hospital. Thus, a quality improvement activity of the HHA is likely to be firmly grounded in the hospital's operating and governance fabric even when the group is ''established'' by the HHA, and staffed by employees and physicians who work primarily in home health. We would expect the linkages to be formal (that is, known to the governing bodies and medical staffs of both providers), and the quality assurance mechanisms interrelated to the extent that shared patients are the subject of the effort.

Comment: Regarding paragraph (d)(4)(v) of this provision, some commenters requested clarification of what is meant by a ''unified retrieval system,'' or for guidance as to what types of cross referencing are acceptable. Another commenter asked for an explanation of the practical expectations regarding the maintenance of medical records. Finally, a commenter expressed support for the requirement for a unified retrieval system (or cross references), saying the latter system would be used in States that mandate a unified system.

Response: We would like to clarify that what is intended is that a system be maintained under which both the potential provider-based entity or department of a provider and the main provider have access to the beneficiary's record, so that practitioners in either location can obtain relevant medical information about care in the other setting. We did not, however, make any changes in the requirement based on these comments.

Comment: A commenter believes that functions of operations should not be regulated to dissuade cost efficiency, and that laundry and housekeeping would be examples where shared services may not be the most effective manner of operation.

Response: We agree that in some cases it may be less expensive for a facility to obtain services independently, but continue to believe such separateness is an indicator that the facility is not an integral and subordinate part of a provider.

Comment: With regard to paragraph (d)(4)(vi) requiring integration of services of the main and provider-based entity, the commenter expressed concern about the potential impact of

this section on a patient's freedom of choice. The commenter believes that the entity's efforts to meet this standard would limit a patient's freedom of choice. The commenter suggested that we clarify our position so that providers acting in good faith will not be sanctioned for attempting to comply with this requirement.

Response: Paragraph (d)(4)(vi) requires only that patients have access to the services of the main provider and that they be referred to it where the referral is appropriate. We wish to clarify that these criteria are not intended to restrict patient freedom of choice or the practitioner's freedom to refer patients to other locations, where doing so will result in better care for the patient.

Section 413.65(d)(5) Financial integration

Comment: A commenter believes that § 413.65(d)(5), which requires full integration of financial operations, is too rigid. An alternative approach is suggested that would allow managers of provider-based entities to retain some control over both the resources and information required to administer these units.

Response: Section 413.65(d)(5) requires that there be financial integration of the potential provider-based facility or organization and the main provider, but does not preclude normal management control of resources. Thus, we made no change in the regulation based on this comment.

Comment: A commenter stated that the criteria for common resource usage of building, equipment, and service personnel is not even relevant for multi-campus systems or even buildings that are across the street from each other, much less off-site hospital outpatient departments.

Response: Although the provider-based program memoranda required that there be significant common resource usage of buildings, equipment, and service personnel on a daily basis, this requirement does not appear in the proposed rule. Thus, we made no change in the regulation based on this comment.

Comment: One commenter stated that the requirement for financial integration seems unnecessary in light of the requirement for 100 percent ownership by the main provider. The commenter stated that some providers may wish to segregate the operations of certain departments in their financial systems, and expressed the view that as long as the costs of a department can be adequately identified on the cost report, the practice should be acceptable.

Response: We do not believe that these two requirements are duplicative. On the contrary, in some cases a provider may own 100 percent of another facility or organization, but not be financially integrated with it, either because the other facility or organization is engaged in a different, non-health care activity, or because it is organized and operated separately from the main provider. In these circumstances, we believe the criteria on financial integration apply appropriately to deny provider-based status to separate facilities or organizations.

Section 413.65(d)(6) Public awareness

Comment: Section 413.65(d)(6) requires that provider-based entities be identified as part of the main provider organization. The commenter did not understand the importance of this criterion, particularly when the provider-based organization is licensed and Medicare certified separately from the main provider.

Response: The proposed rule would not apply this criterion to provider-based entities (which may participate separately as providers), but only to provider-based departments. In the latter case, we think it is not unreasonable for such a department to be expected to identify itself with the provider of which it claims to be a part.

Section 413.65(d)(7) Location in immediate vicinity

Comment: A commenter stated that if off-site RHCs cannot be considered provider-based, it will be much harder to deliver care in rural areas. The commenter asked that RHCs be allowed to continue as provider-based RHCs even though they are off campus.

Response: We continue to believe close physical proximity is an important indicator of provider-based status. We note, however, that paragraph (d)(7) does allow off-campus facilities to be treated as provider-based if they meet the criterion relating to service to the same patient population.

Comment: Many commenters believe that more specific tests of service to the same patient population are needed. One commenter suggested that an appropriate criterion would be that the proposed provider-based facility or organization be located within the same geographic area that accounts for a high percentage of patients in the main provider. The commenter believes this test is consistent with Program Memorandum No. 96–7 and with the qualification requirements for sole community hospitals. Other commenters suggested that the main provider's geographical service area be considered the area from which the main provider drew 80 percent of its Medicare inpatients for the previous three years.

Response: We agree that more precise criteria are needed. Therefore, we have revised the regulations to provide that a prospective provider-based facility or organization will be considered to serve the same patient population as the main provider if, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with us, at least 75 percent of the patients served by the facility or organization seeking provider-based status reside in the same zip code areas as at least 75 percent of the patients served by the main provider. As an alternative, we would consider a facility or organization to serve the same patient population if, during the same 12-month period described above, at least 75 percent of the patients served by the prospective provider-based facility or organization who required the type of care furnished by the main provider received that care from the main provider. We require this ''same patient population'' test to be met for the 12-month period used to support an initial determination of provider-based status, and it must continue to be met for each subsequent 12-month period to justify a continuation of provider-based status. Application of population/geographic standards to newly established facilities or organizations is discussed below.

Comment: Commenters suggested we show some flexibility with regard to the definition of patient population for teaching hospitals. The commenter stated that it will not always be the case that the patient populations for the teaching program will be the same as the overall mix or patient population for the main provider.

Response: We recognize that patient populations will not be identical in all cases, and thus have adopted a patient population criterion under which there may be a divergence of up to 25 percent between the main provider and the facility or organization seeking provider-based status. We believe this provides a reasonable allowance for differences in patient population. Moreover, we note that under section 1886 of the Act, Medicare provides much flexibility for teaching hospitals in other ways, for example, under section 1886(h)(4)(E), permitting the counting of residents for purposes of payment to teaching hospitals for the time the residents spend in nonhospital settings.

Comment: Two commenters suggested that the criterion on service to the same patient population be dropped. One commenter believes the criterion is overly vague, could limit access to care as facilities seek to control their service patterns, and, in general, represents a geographically based approach that is out of keeping with modern technology and communications. Another commenter stated that the criterion is unclear, and providers could find it burdensome to assemble the data to show compliance. Other commenters shared the second commenter's concern, but instead of recommending elimination of the criterion, they suggested that a more administrable solution would be to use regional or state standards to define ''same geographic area,'' such as, health systems area, a specified mileage amount, or our wage area.

Response: As described above, we have developed a more precisely stated test of service to the same patient population. We believe that test will be clear and understandable, not impose unrealistic burdens on providers, and allow provider-based designations that parallel service patterns.

Comment: With respect to paragraph (d)(7)(i), a commenter asserted that many currently operating facilities that are treated as provider-based by us provide types of service that are the same as those of the main provider, but serve patient populations from different geographic areas. The commenter believes these entities provide care under the direction of, and utilize substantial services from, the main provider. An example would be the geographically separate campuses of a single parent hospital that are located at various sites throughout a region. The commenter suggested that such campuses be presumed to be provider-based if they provide substantially the same services as the main provider, do not exceed the size of the main provider, and comply with all other provider-based requirements. Another commenter stated that the ''same patient population'' requirement should not apply to multi-campus long term care hospital locations. These locations are fundamentally different from other provider-based entities that the regulation addresses, since a long-term care hospital main provider and its remote campus furnish the same services, and offer the same programs of care, but operate in slightly different geographic areas. The commenter suggested that so long as all of the strict financial and administrative integration requirements of the proposed provider-based regulation are satisfied, the ''same patient population'' requirements should not apply to long-term care hospitals. The result of this criterion would be that satellites will not be established in many underserved areas where long term services are needed. Another commenter believes a specialty facility, such as a long-term care hospital, should be exempt from the geographic proximity requirement if it can demonstrate that it will improve the quality of patient care, and offer services that are not otherwise provided in that area.

Response: We recognize that there may be some cases in which a hospital and another facility seeking provider-based status as a remote location of that hospital may meet most or all other criteria in § 413.65, yet not qualify because the two facilities serve different patient populations. However, we do not agree that this result should lead us to abandon the ''same patient population'' test. On the contrary, we continue to believe that criterion is a valid indicator of provider-based status. Thus, we did not revise the regulation based on this comment. In this context, we note that there is no Medicare rule that would prohibit a hospital from setting up another hospital in another area. We do not agree with the commenter's assumption that because the program memorandum and proposed rule were issued in response to situations primarily involving outpatient facilities, they can apply only to such facilities. On the contrary, we believe the policies set forth in these documents are equally applicable to inpatient facilities, and should be applied in the many cases in which a determination about inpatient facilities must be made. In particular, the rules apply to remote locations of long-term care and other hospitals that are main providers, as well as to satellite facilities of hospitals and hospital units that are excluded from the hospital inpatient prospective payment system. Remote locations and satellite facilities are discussed more fully earlier in this preamble, and ''satellite facilities'' are specifically described in our regulations in §§ 412.22(h) and 412.25(e). (As explained in that document, we are concerned that establishment of satellites by hospitals and units excluded from the inpatient PPS could lead to payment abuses, such as circumvention of certain payment caps mandated by section 4414 of the Balanced Budget Act of 1997, and we have therefore established special payment rules for those facilities. Facilities seeking to qualify as ''satellites'' under the inpatient payment criteria in §§ 412.22(h) and 412.25(e) would first need to comply with the provider-based requirements before being eligible for satellite status.) We have revised the final rule to clarify its application to remote locations of hospitals and satellite facilities.

Comment: The commenter believes that flexibility in the definition of ''located in the immediate vicinity'' needs to be met with additional considerations when viewing rural and underserved areas; for example, it should not be our intention to eliminate the provider-based designation of a rural health clinic (RHC), when the purpose of the RHC is to be an outreach to geographically isolated areas.

Response: We share the commenter's concern and have developed a special provision for RHCs, as described below.

Comment: A commenter believes that the requirement that provider-based entities serve the same population as the main provider could cause significant problems for RHCs. The unique situations addressed by hospital-based RHCs attempting to satisfy the health care needs of medically underserved areas should be considered as exceptions to the proposed rule.

Response: We continue to believe close physical proximity is an important indicator of provider-based status; however, we recognize that small rural hospitals and their RHCs may not be able to demonstrate that a substantial number of clinic patients receive services from the main provider. Small rural hospitals typically provide limited inpatient care compared to their urban counterparts, which may cause the RHC patients to seek inpatient service from other providers. In light of this, we believe small rural hospitals (less than 50 beds) that own and operate RHCs should not be expected to demonstrate that they serve the same patient population as the main provider. Therefore, we are revising the regulation to allow off-campus RHCs affiliated with small rural hospitals (less than 50 beds) to retain their provider-based status without satisfying that requirement.

Comment: Several commenters opposed the inclusion of paragraph (d)(7)(ii), since they view a State border as an arbitrary boundary inhibiting a hospital's ability to serve patients, which seems counterproductive. They also argued that a regulation that fails to recognize the operation of health care systems that function across State lines is unrealistic. Another commenter suggested that we rely on the proposal concerning serving the same patient population. It was also stated that in one case a provider can be located in a city

split by the State border with its related facility located one mile away, but in another state, while in another case, the provider and its subordinate facility can be a mile apart and in the same State. Another commenter believes that, since Medicare beneficiaries often cross borders for health care services, disallowing hospitals in these areas from establishing provider-based entities eliminates choices and prohibits the development of new services. The commenter recommended that we revise or eliminate this criterion. Another commenter suggested that LTHs and their satellites not be subject to this requirement if the main provider and its satellite are located in two contiguous States. Alternatively, the commenter suggested that we consider using the wage index areas as guidelines for the areas to be served by provider-based entities even if that area crosses State lines.

Response: After reviewing these comments, we have decided to revise the regulations to allow providers in one State to have provider-based facilities in an adjacent State, if doing so is not inconsistent with the law of either State, and other criteria are met, including those related to service to the same patient population.

Comment: With regard to paragraph (d)(7)(i), while the proposed rule permits a provider to show that a ''high percentage'' of patients of the main provider and the facility come from the same geographic region, new facilities would not have any historical data upon which to base this assertion, and therefore would fail to be able to demonstrate the criteria prior to operation. Another commenter believes the requirement may pose an impediment to new facilities being located in underserved or outlying areas. Thus, the commenters believe the same patient population requirement should not apply to new facilities, including new long-term care hospital satellites.

Response: We agree that it would be appropriate to establish a criterion that could be met by new facilities or organizations, and therefore have revised the final rule to include a special provision for new facilities or organizations. Under this revision, a new facility or organization, (one that has not been in operation for all of the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with us), may be considered to meet the criterion on service to the same patient population, if it is located in a zip code area included among those that (during the 12-month period described above) accounted for at least 75 percent of the patients served by the main provider. We note that this provision would not be limited to long-term care hospitals' satellites or their remote locations, but would be available to all new facilities or organizations.

Section 413.65(e) Provider-based status not applicable to joint ventures

Comment: Several commenters expressed concern that this criterion would prohibit the use of joint ventures for entities that want to participate as provider-based entities, and argued that such a prohibition would unnecessarily restrict hospital flexibility. One believes this provision should be eliminated. Another commenter suggested modification of paragraph (d)(2) of the rule to establish majority ownership as the standard rather than 100 percent ownership. Still other commenters suggested that provider-based status for facilities or organizations run as joint ventures should be permitted, as long as the hospital at which the facility is located has the equipment or service under its control.

Response: We reviewed these comments carefully, but did not make any changes in the regulations based on them. When a facility or organization is run as a joint venture of two or more providers, it is by definition under their joint control, and therefore cannot be an integral and subordinate part of any individual provider. We have no interest in discouraging such ventures, but continue to believe they do not qualify as provider-based.

Section 413.65(f) Management contracts

Comment: Several commenters expressed the view that the criterion under which the staff of the facility or organization must be employed by the provider or another organization other than a management company is too restrictive, and should be deleted. One commenter argued that, if the written contract maintains the responsibility and control for services in the hands of the main provider, the employer of the staff working at the site is not relevant. Another believes the criterion will discourage economic efficiencies. If a provider is able to demonstrate integration and subordination of the off-site facility based upon other provider-based criteria, the fact that a hospital chooses to provide certain services either directly through its own employees or indirectly through an independent contractor/management arrangements is irrelevant. Another commenter argued that the proposed criterion is inconsistent with: the provision of the Medicare statute that expressly permits coverage of ''services under arrangement''; with the hospital conditions of participation that recognize that contractors may be used to furnish patient care services; and with the Provider Reimbursement Manual, which recognizes that providers commonly contract for management services and the costs of the contract services may be allowed under Medicare principles of reimbursement. Still another commenter believes the proposed criterion would negatively impact the therapy profession, and could impact the health and safety of Medicare beneficiaries.

Response: We do not believe the criterion is overly restrictive, nor do we agree that employment of the staff of a facility or organization is irrelevant to the question of whether that facility or organization is an integral and subordinate part of a provider. On the contrary, employment of the staff of such a facility or organization will normally give the provider significant control over it, thus promoting integration. Conversely, if a facility or organization is staffed by personnel who are employed by another entity that has only a contractual relationship with the provider, the facility or organization may well be an integral and subordinate part of the management company, not of the provider.

We also do not agree that the criterion is inconsistent with section 1861(w)(1) of the Act, which permits providers to make arrangements for the provision of specific health services, nor do we believe adopting this criterion will undercut the ability of providers to have selective services provided under arrangements. In this regard, we point out that existing Medicare policy, stated in section 207 of the Medicare Hospital Manual (HCFA Publication 10), emphasizes the need for the hospital to exercise professional responsibility for the arranged-for services, not merely to serve as a billing mechanism for the other party. This is consistent with our view that section 1861(w)(1) was intended to allow specific health care services to be furnished under arrangements, but was never meant to be a vehicle by which a provider could nominally operate a facility or organization, but, in fact, contract out its operation to another entity. Finally, we note that while there are various sections of the hospital conditions of participation and the Provider Reimbursement Manual that recognize the possibility that specialized health care services or management services may be provided under contract, this does not indicate that providers may

contract out entire departments or services while claiming them as provider-based. To clarify the scope of the requirement on contracted services, we have revised it to state that management staff of the facility or organization (rather than health care or support staff) need not be employed directly by the provider. We have also revised the rule to clarify that if staff of the facility or organization (other than management staff) are employed by an organization other than the management company or the provider, it must be the same organization that also employs the staff of the main provider.

Section 413.65(g) Obligations of hospital outpatient departments and hospital-based entities

Section 413.65(g)(1)

Because of the direct relationship between the proposed changes in this section and those in § 489.24(b), comments on both proposals are discussed later, under § 489.24(b), ''Special responsibilities of Medicare hospitals in emergency cases.''

Comment: A commenter requested clarification as to the application of the anti-dumping requirement in the home health setting.

Response: Section 413.65(g)(1) states that the EMTALA requirements apply to hospital outpatient departments. EMTALA requirements would not apply to off-campus provider-based entities that are not hospital departments, such as home health agencies.

Section 413.65(g)(2)

Comment: While one commenter agreed with the requirement under § 413.65(g)(2) for billing of physician services with the appropriate site-of-service indicator, another commenter also believes there should be clarification that correct billing is the responsibility of the entity performing the billing function. Both commenters suggested that the hospital notify physicians who do their own billing that they must use the correct indicator; they agree that it should not be the responsibility of the hospital.

Response: We agree that physicians (or those to whom they assign their billing privileges) are responsible for appropriate billing, but note that physicians who practice in hospitals, including off-site hospital departments, do so under privileges granted by the hospital. Thus, we believe the hospital has a role in ensuring proper billing.

Section 413.65(g)(5)

Comment: Presently, provider-based clinics bill Medicare for the facility charge on a UB–92 form, and the physician fee is billed separately on a HCFA–1500 form, while other payers may accept a single bill for both charges. A commenter believes it is inappropriate to mandate that two bills be submitted for all patients, as long as charges for similar services are uniform regardless of payer.

Response: As explained further below, we have revised the final rule to eliminate the part of this criterion relating to billing of services to non-Medicare patients. We believe this responds to this commenter's concern.

Comment: Many commenters stated that Medicare should treat a facility that claims a facility fee as being provider-based even when other payers do not do so, reasoning that as long as the hospital claims that the patient is an outpatient for Medicare purposes, the practices of other payers, with respect to similar patients, are not significant, and should be ignored. Another commenter believes this requirement should be eliminated, because, in the commenter's view, it has no bearing on the outpatient services delivered to Medicare beneficiaries, and therefore does not affect Medicare reimbursement. To illustrate, a large commercial insurer does not have the capability to accept certain types of outpatient claims from hospitals; therefore, it requires claims for those services to be billed on a physician claim form, so hospitals will receive the proper reimbursement. If this criteria is retained as proposed, many hospital-based departments would not meet our criteria due to the nuances of other payers' policies, that are often contractual issues with providers. Still another commenter believes that we should reexamine the proposal made in paragraph (g)(5), and at a minimum, clarify what it means by its proposal mandating uniform ''treatment of all patients, for billing purposes, as hospital outpatients.'' If we are proposing to mandate that all outpatients be billed on the same basis, this would effectively extend Medicare direct billing or rebundling rules to all payers. In addition, this proposed requirement would not only be contrary to past policy and practice, but would affect departments that have differentiated billing practices. Another commenter stated that payers typically determine payments based upon how they define a particular service or their individual market power; Medicare certification of outpatient departments should not be influenced by how unrelated third parties pay for services to the patients they cover at these sites. Moreover, this criterion would be very difficult to implement, because hospitals can have hundreds of contracts with insurance companies and the providers that subcontract for part of the risk for plans.

Response: After review of the comments on this section, we have decided to revise it to restrict the requirement for uniform billing to Medicare patients only, thus allowing hospitals to bill other payers in whatever manner is appropriate under those payers' rules. As revised, § 413.65(g)(6) states that 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.

Comment: A commenter stated that there appears to be some confusion as to whether this requirement applies to ''departments'' or all facilities and organizations seeking provider-based status. Also, the commenter asked if there is a provision of the proposed rule that mandates that a facility fee be charged to patients of facilities and organizations receiving provider-based status.

Response: As noted earlier, the proposed rule would not apply this criterion to provider-based entities (which may participate separately as providers) but only to provider-based departments. Regarding the second issue, we have, as described in response to the preceding comment, revised the final rule to eliminate the criterion regarding billing of payers other than Medicare.

Section 413.65(g)(7)

Comment: A commenter stated that requiring written notice for each patient (presumably signed by the patient), would be an overly burdensome requirement, and requested that the requirement allow for a clear, prominently displayed sign in lieu of individual notice. Another commenter believes that the proposed requirement would apply a standard to hospital outpatient departments that is not applied to any other site of service.

Response: First, we emphasize that notice is required only for Medicare beneficiaries, not for all patients. We recognize that providing notice will generate some burden for the provider, but believe that the protection it affords to patients warrants the requirement. We considered allowing the notice requirement to be satisfied through the posting of signs, as recommended by one commenter, but concluded that use of individual written notices would more effectively ensure that each

beneficiary receives the necessary information. In response to the comment concerning settings other than hospital outpatient departments, we note that in other settings, a patient is unlikely to be misled as to what type of facility is the site of treatment, so provision of notice is not required. To avoid confusion as to when the requirement applies, we have revised the final rule to state that notice is required only if the hospital outpatient department or provider-based entity is not located on the campus of the hospital that is the main provider. We have revised this final rule to specify that the notice must be in writing, must be one the beneficiary can read and understand, and must be given to the beneficiary's authorized representative 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.

Section 413.65(g)(9) (redesignated in this final rule as Section 413.65(h), Furnishing all services under arrangement)

Comment: A commenter observed that § 413.65(g)(9) does not preclude an outpatient facility from obtaining a certain type of service from an off-site supplier. If this is correct, if the service is provided on-site in the hospital's outpatient facility, it is not clear how the proposed regulations are intended to be applied. It would appear that if the facility is looked at as a whole, all services are not provided ''under arrangements''; therefore, paragraph (g)(9) of this section would not preclude the facility from being recognized as provider-based. However, in this case, the commenter stated that both licensure and ownership requirements would be difficult to satisfy. In most cases, that portion of the facility that is operated ''under arrangements'' with the hospital will not be on the hospital's license, nor will that portion necessarily be owned by the hospital. Thus, the commenter urged that the ''under arrangements'' portion of an outpatient facility be excluded from the licensure and ownership analyses.

Response: We agree that where a facility offers a variety of services, provision of a single type of service under arrangement would not prevent the facility from meeting this criterion. The criterion could not, of course, be met by a facility that furnished only a specific type of service (such as physical therapy), and provided that service only under arrangement. In the case envisioned by the second commenter, the facility would be out of compliance with licensure and ownership requirements, as well as the requirement involving services under arrangement, and we would agree that it could not be provider-based.

Comment: A commenter asked for clarification of ''under arrangements'', in reference to our other regulations that contain these terms. Also, the commenter requested clarification on the types of services to which this standard applies, that is, direct patient care as opposed to facility related services.

Response: The term ''arrangements'' is defined in section 1861(w)(1) of the Act and the Medicare regulations § 409.3, in that ''arrangements'' refers to arrangements that provide that Medicare payment made to the provider that arranged for the services discharges the liability of the beneficiary or any other person to pay for the services. We wish to emphasize that the provision will apply to patient care services, not housekeeping, security, billing, or other services that are not patient care services but are needed to support their provision.

Section 413.65(h) Inappropriate treatment of a facility or organization as provider-based (redesignated in this final rule as paragraph (i))

Comment: This section establishes sanctions that may be used to address a main provider that has treated an entity as provider-based without our review and approval. A commenter believes that the investigation phase should precede the review of payments to the main provider. A commenter was also concerned that the individuals involved in these reviews and investigations are properly trained to make the required determinations.

Response: We believe review of payments will encompass two activities—investigation to determine whether applicable provider-based requirements were met, and a calculation of the amount of overpayment if they were not. Thus, investigation necessarily precedes recovery, but is a part of the overall effort, which is to reconsider payment amounts. To respond more effectively to concerns about how the review and recovery activities will occur, and to clarify the specific actions we will take in cases of inappropriate billing, we have reorganized paragraph (i) to deal separately with the processes of determination and review, recovery of overpayments, and the good faith effort exception. With respect to determination and review, we state that if we learn that a provider has treated a facility or organization as provider-based and the provider had not obtained a determination of provider-based status under this section, we will review current payments and, if necessary, take action in accordance with the rules on inappropriate billing in paragraph (j), investigate and determine whether the requirements for provider-based status in paragraph (d) of § 413.65 (or, for periods prior to October 10, 2000, the requirements in applicable program instructions) were met, and review all previous payments to that provider for all cost reporting periods subject to re-opening in accordance with § 405.1885 and § 405.1889 of this chapter. With respect to recovery of overpayments and the good faith exception, we have clarified that we will recover only the difference between the amount of payments that actually were made and the amount of payments that we estimate should have been made in the absence of a determination of provider-based status, and that recovery will not be made for any period prior to the effective date of these final rules 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, as described in paragraph (h)(3) of § 413.65. In response to the comment about the competence of individuals involved in these activities, we wish to emphasize that we will ensure that staff involved in these activities have the necessary expertise.

Comment: A commenter believes that it would be unfair to apply the proposed regulations retroactively, that is, to periods before the effective date of the final rule. Even though paragraphs (h) and (i) provide for a good faith exception, it is still unfair to provide that the conditions for this exception will apply prior to the effective date of the final regulation. The commenter requested that these sections be revised to provide that the period of recovery will not extend to any period prior to the effective date of the final regulations. Another commenter also believes that any payment changes be prospective (unless the hospital did not make a good faith effort to operate the site as provider-based).

Response: We agree that it would be inappropriate to apply the rules in paragraph (h) to any period prior to their effective date, and have revised the final rule to clarify that for such periods, we will make determinations based on the program memoranda or other instructions in effect at the time. However, the criteria in paragraph (i) that form the basis for a good faith exception were in effect prior to the issuance of these regulations. Regarding

the last comment, we cannot agree to ignore possible overpayments resulting from noncompliance with published criteria in effect at that time.

Comment: A commenter believes that the term ''good faith effort'' should be defined to provide more direction and opportunity to comply. Also, entities making ''good faith efforts'' should be given an opportunity to correct those factors or criteria that render it out of compliance with the provider-based requirements.

Response: The conditions under which a provider will be found to have made a good faith effort were clarified in § 413.65(i)(2), and have been restated in the final rule.

Section 413.65(i) Inappropriate billing (redesignated in this final rule as paragraph (j))

Comment: A commenter believes that suspending all payments for outpatient services to facilities that have billed inappropriately as provider-based entities until the provider can demonstrate that payments are proper is too onerous. Instead, the commenter suggested that we consider suspending the reimbursement differential between a provider-based entity and a nonprovider-based entity until a determination is made or the facility has had a reasonable opportunity to comply.

Response: We understand the commenter's concern and have revised the final rule to authorize partial suspension of payment (that is, a reduction in payment) to the extent needed to prevent creation of an overpayment to the provider. This rule will allow payment to continue at a reduced rate, thus avoiding creation of financial hardship for the provider. To describe more clearly how we will deal with instances of inappropriate billing, we have reorganized paragraph (j) of § 413.65 to spell out more clearly the actions we will take, and the extent to which payment will be adjusted. Specifically, we state that if we find that a facility or organization is being treated as provider-based without having obtained a determination of provider-based status under this section, we will notify the provider, adjust future payments, review previous payments, determine whether the facility or organization qualifies for provider-based status under this paragraph, and continue payments only under specific conditions. The notice to the provider will explain that payments for past cost reporting periods may be reviewed and recovered, that future payments for services in or of the facility or organization will be adjusted, and that a determination of provider-based status will be made.

We further state that we will not stop all payment in such cases, but instead, will adjust future payments to approximate as closely as possible the amounts that would be paid in the absence of a provider-based determination, if all other requirements for billing were met. We also explain that we will review previous payments and, if necessary, take action in accordance with the rules on inappropriate treatment of a facility or organization described above. The regulation states that we will determine whether the facility or organization qualifies for provider-based status under the criteria in this section. If we determine 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. Even if the facility or organization does not qualify for provider-based status, however, we will continue paying, at an appropriately adjusted level, for a limited time period in order to avoid disruption of services to program beneficiaries at that site and to allow an orderly transition to freestanding status.

The notice of denial of provider-based status sent to the provider will ask the provider to notify us in writing, within 30 days of the date the notice is issued, as to 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 we do not receive a response within 30 days of the date the notice was issued, all payment will end as of the 30th day after the date of notice. If the provider indicates that the facility or organization, or its practitioners, will be seeking to enroll and meet other requirements for billing for services in a free-standing facility, payment for services of the facility or organization will continue, at the adjusted amounts described in paragraph (j)(2) of this section for as long as is required for all billing requirements to be met (but not longer than 6 months) if—

- The facility or organization, or its practitioners, submit a complete enrollment application and provide all other required information within 90 days after the date of notice, and
- The facility or organization, or its practitioners, furnish all other information we need to process the enrollment application and verify that other billing requirements are met.

If the necessary applications or information are not provided, we will terminate all payment to the provider, facility, or organization as of the date we issue notice that necessary applications or information have not been submitted. We have clarified the final rule to state that these reductions will occur where inappropriate billing is or has been taking place.

Comment: A commenter believes that there are already existing mechanisms for overpayment and recoupment that may be used in the situations described in this section. At the very least, administrative actions of this type should be subject to time frames in order to protect providers from the impact of extended investigations.

Response: We plan to conduct any recovery efforts in accordance with applicable law and regulations on overpayment recovery. However, investigations may be complex and require examination of many records, and we do not agree that they should be limited by additional, self-imposed restrictions.

Comment: A commenter stated that a facility or organization that requests a provider-based determination prior to the effective date of the final rule, and meets the good faith requirements, should not be subject to recovery of overpayment for periods either before or after the effective date of the final rule. This will prevent disruptions to existing arrangements that meet the good faith exception during the time that the request is being processed.

Response: If we were to adopt this proposal, we would be guaranteeing an overpayment to providers who, for a specific time period, knowingly billed for services as those of provider-based entities, even though they met only a few of the provider-based criteria. Thus, we did not adopt this comment.

Comment: A commenter requested that the requirement found at paragraph (i)(2)(iii) be clarified to state that management is only responsible for professional services billed by the hospital.

Response: As explained earlier, we believe hospitals' privileging mechanisms give them adequate leverage to prevent inappropriate billing by practitioners using their facilities. Therefore, we did not adopt this comment.

Comment: As to the good faith criteria found in paragraph (i)(2), a commenter questioned why requirements related to public awareness were chosen for inclusion. An organization can represent itself to the public in any number of inaccurate ways in order to mislead our officials and others. The

commenter believes that we should focus our attention on more tangible expressions of good faith efforts to operate a provider based entity.

Response: We believe inclusion of this requirement is needed to help ensure that beneficiaries are protected from unexpected deductible and coinsurance liability. While we agree with the commenter that some providers may misrepresent the status of off-site facilities, we believe such providers cannot reasonably be said to have acted in good faith, and should not receive favorable treatment with respect to past overpayments.

Section 413.65(j) Correction of errors (redesignated in this final rule as paragraph (k))

Comment: A commenter disagreed with the language in this subsection that would allow us to review and rescind, if appropriate, any past determinations. The commenter believes that this subsection should be removed and any previous determinations should be grandfathered in under the new regulations. Other commenters recommended that we grandfather facilities or organizations that had previously been determined by the regional office to be provider-based, or that have not received such a determination but have been billing as provider-based without a determination for a period of at least ten years, so that those facilities or organizations could retain provider-based status even though they do not meet the criteria in the regulations.

Response: We do not agree that it would be appropriate to grandfather existing facilities or organizations, since this would in effect create an ongoing double standard, under which some facilities or organizations are held to higher standards than others. Moreover, the fact that improper billing may have continued undetected for a long period is not a reason to continue to permit such billing. As explained in the response to the following comment, however, any adverse determination regarding provider-based status of facilities or organizations which we previously determined were provider-based will not be effective until the start of the cost reporting period after the period in which the provider is notified of the redetermination, or for at least 6 months, whichever date is later.

Comment: A commenter believes that our proposal that we may review past provider-based determinations inserts needless uncertainty into the process for making provider-based designations. The commenter is concerned that providers may file before the final rule is published in order to avoid a crush of applications and subsequent disruption in payment, if they do not have a determination within 30 days of the rule becoming final. The commenter stated that providers need to be able to receive prompt determinations on which they can rely.

Response: We understand the concern about avoiding the need to process a large number of applications in a short time, and agree that it would not be appropriate to make abrupt changes in provider-based status. To avoid a possible crush of applications within a 30-day period, as envisioned by the commenter, we are providing the delayed effective date described earlier in this document. In addition, under § 413.65(j) of these regulations, when a facility or organization that previously was determined to be provider-based is found to no longer qualify for provider-based status, treatment of the facility or organization as provider-based will not cease until the first day of the first cost reporting period following notification of the redetermination, but not less than 6 months after the date the provider is notified of the redetermination. If there has been no prior determination of provider-based status, and a facility or organization is later found not to meet the criteria, that determination may be effective up to 6 months after the date the provider is notified of the determination, if within 30 days of the determination, the provider indicates that the facility or organization, or its practitioners, will enroll separately and, within 90 days, the facility or organization, or its practitioners, take other necessary action to enroll.

Section 489.24(b) Special responsibilities of Medicare hospitals in emergency cases

Comment: One commenter disagreed strongly with the proposed revisions to the regulation defining ''comes to the emergency department,'' and in particular expressed the view that patients arriving on the campus, sidewalk, driveway, or parking lot of hospital facilities should not be considered to have come to the emergency department. The commenter stated the view that an obligation under section 1867 of the Act (sometimes referred to as the Emergency Medical Treatment and Active Labor Act (EMTALA), after the original title of the legislation adding section 1867) and our regulations at §§ 489.20(l), (m), (q), and (r), and § 489.24 should be triggered only by a presentation to the emergency department, and that only in exceptional situations should EMTALA apply to someone not technically in the emergency department. The commenter recommended that the regulations be revised to state that in these cases, the hospital may rely on a variety of transport options, consistent with the individual's condition and established policies that are applied in a nondiscriminatory manner. The commenter also recommended that the statute be interpreted as requiring only that hospitals with emergency departments have policies and procedures to assure that a person who presents to the hospital requesting emergency services is provided a medical screening examination and, if needed, stabilization or an appropriate transfer.

Another commenter raised several arguments against the proposed change. The commenter stated that there is a legal and ethical conflict in requiring hospital personnel to leave an area of patient care and furnish assistance to another patient in a remote area of the hospital. The commenter also believes that ED personnel are not well-trained or practiced in immobilization or scene safety, and patients and staff may be put at risk if staff are asked to go into the field and render aid to a victim who needs the expert care and experience for which field emergency medical services (EMS) personnel are trained. Finally, the commenter expressed concern about possible increases in the liability insurance cost to hospitals as a result of the proposed change.

Response: We do not agree that the proposed language inappropriately extends the scope of hospitals' EMTALA responsibilities. On the contrary, existing regulations at § 489.24 make it clear that EMTALA applies to hospitals that offer services for emergency medical conditions, and we believe it would defeat the purpose of EMTALA if we were to allow hospitals to rely on narrow, legalistic definitions of ''comes to the emergency department'' or of ''emergency department'' to escape their EMTALA obligations. We would also note, as discussed further below, that there is no requirement that all areas of the hospital be equipped to provide emergency care or that treatment always be provided outside the emergency area or department. Similarly, there is no prohibition of appropriate transfers to other facilities where such a transfer is conducted in accordance with § 489.24. On the contrary, 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 protection simply because they enter the

wrong part of the hospital or fail to make their way to the emergency room.

Comment: Two commenters recommended clarification of the applicability of section 1867 of the Act regarding transfer requirements to scheduled patients at an ''off-campus'' hospital site, to ensure that the movement of scheduled patients unexpectedly requiring a higher level of care to another site of the same hospital is not construed as a ''transfer'' under the emergency access law, and that only those patients taken from one hospital's off-campus facility to another hospital's emergency department or inpatient unit be considered ''transfers'' that must be in accordance with the requirements of section 1867.

Response: We agree that movement of a patient from one part of a hospital to another, including movement from a remote location to a main hospital campus, does not constitute a ''transfer'' for EMTALA purposes, nor does it require compliance with the appropriate transfer requirements in § 489.24(d). The final regulations at § 489.24(i)(3)(i) clarify this policy.

Comment: A commenter expressed the view that the proposed revision to § 489.24 does not recognize the role that EMS personnel play in emergency situations and the true medical benefit provided by EMS personnel to patients in emergency situations. The commenter recommended that language be included in the regulation to authorize hospitals' use of EMS in responding to emergency situations on hospital grounds.

Response: We agree that EMS personnel can play a valuable role in transporting patients to appropriate sources of emergency care. A hospital may not, however, meet its EMTALA obligations merely by summoning EMS personnel. EMS may be used appropriately in conjunction with an appropriate hospital response to treat and move an individual who is already on hospital property. We therefore did not make any change to these regulations to authorize exclusive use of EMS to respond to emergency situations on hospital property.

Comment: A number of commenters stated that the anti-dumping rules implemented under section 1867 of the Act (EMTALA requirements) and our regulations at §§ 489.20(l), (m), (q), and (r), and § 489.24 should apply to the hospital's main campus and to all emergency departments. However, they argued that it is not reasonable to apply these rules to outpatient departments located off-campus that would not be set up to provide emergency services. In the commenters' view, it should suffice that patients in an emergency situation be directed to the hospital's emergency room. Another commenter stated that EMTALA obligations should be limited to those hospital entities that hold themselves out as providing emergency services, and should not be enforceable anywhere outside the emergency department or anywhere on hospital property, including an outpatient department or provider-based entity. Another commenter stated that the enforcement of this requirement would lead to the elimination of service-specific outpatient departments located off a main campus, and asked that we reconsider our policy. One commenter expressed concern that patients identifying a facility as a hospital-based department could mistakenly assume it is equipped to handle emergency cases. Another commenter believes that hospitals should be required to have policies and procedures in place to assure that all parts of the hospital are prepared to deal with getting an individual the appropriate medical screening.

Response: Existing regulations at § 489.24(b) 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. To the extent a hospital acquires or creates an off-campus location, identifies it to us and to the public as a part of that hospital, and claims payment for services at that location as hospital services, we believe it is not unreasonable to expect that hospital also to assume the obligations, including compliance with EMTALA requirements, which flow from hospital status. This principle does not mean, of course, that a hospital must have a fully equipped and staffed emergency department at each location. It also does not mean that every appearance by an individual at an off-campus hospital department that does not offer services for emergency medical conditions will necessarily trigger an EMTALA obligation on the part of the hospital. Individuals come to these departments for many medical purposes which may not involve potential emergency medical conditions. Under these circumstances, the hospital would not have an EMTALA obligation with respect to that individual. This principle does mean, however, that if an individual comes to an off-campus department of a hospital and a request is made for examination or treatment for a potential emergency medical condition, the hospital incurs an obligation to provide, *within its capability,* an appropriate medical screening examination and 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, but this movement would not be considered a ''transfer'' under § 489.24(b), since the patient is merely going from one part of the hospital to another. If it is necessary to transfer the patient to another medical facility, the hospital must provide an appropriate transfer in accordance with § 489.24(d).

After review of the comments on this issue, we have decided to revise the regulations to state more clearly the extent of a hospital's EMTALA obligations with respect to patients who come to a hospital department located off the hospital's main campus. Provider-based entities, such as SNFs or HHAs, located off the hospital campus would not, of course, be subject to EMTALA since a patient coming to such an entity would not have come to the hospital. We will require that each off-campus hospital department, during its regular hours of operation, have in effect procedures for: (1) assessing the possibility that an emergency medical condition exists, and providing such screening (as defined in § 489.24(a) and (b)) and necessary stabilization (as defined in § 489.24(c)) at the off-campus site); (2) transporting the patient to the hospital's emergency room or department for screening and necessary stabilization meeting the requirements of § 489.24; or (3) providing an appropriate transfer to another facility in accordance with the requirements in § 489.24(c). To meet these requirements, the hospital will need to develop procedures that permit staff of the off-campus department to contact emergency physicians or other qualified emergency practitioners at the main hospital campus, to obtain advice and direction regarding the handling of any potential emergencies, and to obtain prompt medical transport, by hospital-owned or other ambulance or other appropriate vehicle, either to the main hospital campus or, where an appropriate transfer is being provided, to another medical facility.

Specifically, we are adding new paragraph (i) to § 489.24 to describe a hospital's obligations. The paragraph states that, if an individual comes to a facility or organization that is located off the main hospital campus as defined in § 413.65(b), but has been determined under § 413.65 of this chapter to be a department of the hospital, and a

request is made on the individual's behalf for examination or treatment of a potential emergency medical condition as otherwise described in paragraph (a) of § 489.24, the hospital is obligated to provide the individual with an appropriate medical screening examination and any necessary stabilizing treatment.

The capability of the hospital includes that of the hospital as a whole, not just the capability of the off-campus facility or organization. Except for cases described in paragraph (i)(3)(iii) (those in which the main hospital campus does not have the specialized capability or facilities needed to treat the individual, or the individual's condition is deteriorating so rapidly that transport to the main campus would significantly jeopardize the life or health of the individual), the obligation of a hospital under this section must be discharged within the hospital as a whole. However, the hospital is not required to locate additional personnel or staff to off-site locations to be on standby for possible emergencies.

In § 489.24(i)(2), Protocols for off-campus departments, we further state that the hospital must establish protocols for the handling of potential 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, when appropriate, from the main hospital campus to the off-campus department to provide screening or stabilization services. The intent of these requirements is to ensure timely exchange of information between the two sites, and to allow the hospital the flexibility to bring emergency personnel to the patient, rather than the opposite, where doing so is the best medical approach to meeting the patient's needs.

Under the final rule, 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, these personnel must be trained, and given appropriate protocols, for the handling of emergency cases. At least one individual on duty at the off-campus department during its regular hours of operation must be designated as a qualified medical person as described in paragraph (d). The qualified medical person must initiate screening of individuals who come to the off-campus department with a potential emergency medical condition, and may be able to complete the screening and provide any necessary stabilizing treatment at the off-campus department, or to arrange an appropriate transfer.

The final rule further states that if the off-campus department is a physical therapy, radiology, or other facility not routinely staffed with physicians, RNs, or LPNs, the department's personnel must be given protocols that direct them to contact emergency personnel at the main hospital campus for direction. Under this direction, and in accordance with protocols established in advance by the hospital, the personnel at the off-campus department must describe patient appearance and reported symptoms and, if appropriate, arrange transportation of the individual to the main hospital campus (if the main hospital campus has the capability required by the individual, and movement to the main campus would not significantly jeopardize the individual's life or health), or assist in an appropriate transfer. Movement of the individual to the main campus of the hospital is not considered a transfer under this section, since the individual is simply being moved from one department of a hospital to another department or facility of the same hospital.

Finally, specific rules apply if the individual's condition warrants movement to a facility other than the main hospital campus, either because the main hospital campus does not have the specialized capability or facilities required by the individual, or because the individual's condition is deteriorating so quickly that taking the time required to move the individual to the main hospital campus could place the life or health of the individual in significant jeopardy. Under these circumstances, personnel at the off-campus department must, in accordance with protocols established in advance by the hospital, assist in arranging an appropriate transfer of the individual to a medical facility other than the main hospital. The hospital must have protocols to ensure that the movement is an appropriate transfer in accordance with paragraph (d)(2) of this section. The protocol 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 anticipated transfers. We note that the interpretive guidelines for enforcement of EMTALA requirements will be revised to conform to these new rules.

Section 498.3 Scope and applicability

Comment: A commenter asked for clarification as to whether appeal rights would be available in the event of revocation by us of provider-based status.

Response: We have revised § 489.3(b)(2) to specify that a determination that a facility or organization no longer qualifies for provider-based status is an initial determination, thus providing an administrative appeals mechanism for these decisions.

D. Requirements for Payment

We proposed to revise § 410.27, Outpatient Hospital Services and Supplies Incident to a Physician Service: Conditions, to require that services furnished at a location other than an RHC or an FQHC that we designate as having provider-based status under § 413.65 must be under the direct supervision of a physician as defined in § 410.32(b)(3)(ii).

Comment: Several commenters requested clarification of what we mean by ''direct supervision.'' One commenter asked that we further define the nature and extent of the supervision needed to comply with our proposal. One commenter asked whether the supervision requirement would be met if a physician is in the hospital or whether the physician must be in the department while the procedure is being performed. The same commenter asked whether the physician billing for the incident to services must be of the same specialty as the procedure being performed. A large trade association stated that we appear to be replacing our current policy in section 3112.4(A) of the Intermediary Manual, which states that we assume the physician supervision requirement to be met when incident to services are furnished on hospital premises, with a policy requiring direct physician supervision at all times, in all outpatient departments, regardless of whether or not they are located on the hospital campus. The commenter recommended that if we retain a direct supervision requirement, it should be limited to outpatient departments located off-site of the main provider. One commenter stated that facilities and organizations accorded provider-based status that are located on the main provider's campus should be subject to the same physician supervision requirements that apply to ''incident to'' services provided elsewhere on the campus.

Response: We regret that our proposal to define ''direct supervision'' by referring to the definition of ''direct supervision of a physician'' given at § 410.32(b)(3)(ii) may have been confusing to some commenters. Section 410.32(b)(3)(ii) defines ''direct supervision'' within (a physician) office

setting as meaning that the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. The definition at § 410.32(b)(3)(ii) goes on to state that ''direct supervision'' does not mean that the physician must be present in the room when the procedure is performed.

Our intention in the proposed rule was to define ''direct supervision'' of hospital outpatient services incident to physician services when they are furnished at a department of a hospital to mean that a physician must be present on the premises of the entity accorded status as a department of the hospital and, therefore, immediately available to furnish assistance and direction for as long as patients are being treated at the site. By ''direct supervision'' we do not mean that the physician must physically be in the room where a procedure or service is furnished. Nor does the supervising physician necessarily have to be of the same specialty as the procedure or service that is being performed. We emphasize that our proposed amendment of § 410.27 to require direct supervision of hospital services furnished incident to a physician service to outpatients applies to services furnished at an entity that is located off the campus of a hospital that we designate as having provider-based status as a department of a hospital in accordance with the provisions of § 413.65. Our proposed amendment of § 410.27 to require direct supervision of hospital services furnished incident to a physician service to outpatients does not apply to services furnished in a department of a hospital that is located on the campus of that hospital. For hospital services furnished incident to a physician service to outpatients in a department of a hospital that is located on the campus of the hospital, we assume the direct supervision requirement to be met as we explain in section 3112.4(A) of the Intermediary Manual. The requirement at § 410.27 does not affect the definition of physician supervision in section 3112.4(A) of the Intermediary Manual. In response to these comments, we have revised our definition of ''direct supervision by a physician'' in the final regulation.

Comment: A major trade association asserted that requiring a physician to be on-site at a provider-based entity throughout the performance of all ''incident to'' services would be burdensome and costly for hospitals where there are a limited number of physicians available to provide coverage, particularly in rural settings. Another commenter believes that entities with provider-based status should not be subject to physician supervision requirements that are more stringent than those applicable to free-standing facilities. A third commenter believes that this requirement is unnecessary because the requirements for integration with the hospital and other requirements for provider-based status include adequate checks and balances to ensure quality care. The commenter recommended that this proposal be omitted from the final rule with the potential for a separate, better defined, proposal at a later date.

Response: We disagree with commenters who believe the proposed supervision requirement is not necessary or that it would be burdensome to the hospital. First, the supervision requirement is separate from and independent of the provider-based requirements, and hospitals and physicians already have to meet a direct supervision of ''incident to'' services requirement that is unrelated to provider-based issues. That is, we require that hospital services and supplies furnished to outpatients that are incident to physician services be furnished on a physician's order by hospital personnel and under a physician's supervision (Intermediary Manual, section 3112.4(A)). We assume the physician supervision requirement is met on hospital premises because staff physicians would always be nearby within the hospital. The effect of the regulations in this final rule is to extend this assumption to a department of a provider that is located on the campus of a hospital. However, the regulation *does not* extend the assumption of supervision to a department of a hospital that is located off the campus of the hospital. We would not extend this assumption to a provider-based entity, regardless of its location, because the ''incident to'' requirement in § 410.27(a)(1)(iii) applies only to hospitals. Also, as we state above, satisfying the requirements to be designated provider-based is unrelated to our requirement that hospital services furnished incident to a physician service to outpatients at an entity that has provider-based status be under the direct supervision of a physician. Finally, this supervision requirement is entirely consistent with the direct supervision requirements currently set forth in the Medicare Carriers Manual, Part 3, section 2050.1(B).

Comment: One commenter suggested that partial hospitalization services furnished by a hospital to its outpatients be exempt from the outpatient department ''incident to'' requirements, or that other requirements be drafted that would, in the commenter's opinion, be more appropriate to the nature of this care.

Response: Section 1861(s)(2)(B) restricts coverage of partial hospitalization services furnished by a hospital to its outpatients to services that meet ''incident to'' requirements. We do not have the discretion to ignore this statutory restriction.

Comment: One commenter asked that we provide an exception to the direct supervision requirement in the case of physical therapy services. The commenter questioned why therapists who furnish the same services in a provider-based entity that they would furnish in an independent practice should be subject to direct physician supervision in one setting and not the other.

Response: The provision on coverage for outpatient physical therapy and occupational therapy services does not require that they be ''incident to'' physician services (see section 1861(s)(2)(D) of the Act). Therefore, there is no need to exempt them from the supervision requirement for outpatient hospital services incident to a physician service that is furnished at a provider-based entity. We therefore made no change in the final regulation based on this comment.

Comment: One commenter suggested that we modify our proposed regulation to waive the direct supervision requirement in entities with provider-based status for certain procedures for which we already waive the direct supervision requirement when the procedures are performed on homebound patients, as set forth in section 2051 of the Medicare Carriers Manual. The commenter believes that general supervision is sufficient for these waived services, for example, the physician need not be present, but the services must be performed under a physician's overall supervision and control, and ordered by a physician.

Response: Under section 2050.2 of the Medicare Carriers Manual, subject to certain requirements, we waive the direct supervision requirement when the following services are furnished to homebound patients: injections; venipuncture; EKGs; therapeutic exercises; insertion and sterile irrigation of a catheter; changing of catheters and collection of catheterized specimen for urinalysis and culture; dressing changes, for example, the most common chronic conditions that may need dressing changes are decubitus care and gangrene; replacement and/or insertion of nasogastric tubes; removal of fecal