

about the individual's payment method or insurance status. Section 1867 of the Act also provides for the imposition of civil monetary penalties on hospitals and physicians responsible for the following: (a) Negligently failing to appropriately screen a patient seeking emergency medical care; (b) negligently failing to provide stabilizing treatment to an individual with an emergency medical condition; or (c) negligently transferring a patient in an inappropriate manner. (Section 1867(e)(4) of the Act defines "transfer" to include both transfers to other health care facilities and cases in which the patient is released from the care of the hospital without being moved to another health care facility.)

These provisions, taken together, are frequently referred to as the Emergency Medical Treatment and Labor Act (EMTALA), also known as the patient antidumping statute. EMTALA was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA). As a result, many people initially referred to EMTALA as "COBRA" or the "COBRA antidumping" statute. Congress enacted these antidumping provisions in the Social Security Act because of its concern with an "increasing number of reports" that hospital emergency rooms were refusing to accept or treat patients with emergency conditions if the patients did not have insurance:

"* * * The Committee is most concerned that medically unstable patients are not being treated appropriately. There have been reports of situations where treatment was simply not provided. In numerous other situations, patients in an unstable condition have been transferred improperly, sometimes without the consent of the receiving hospital.

"There is some belief that this situation has worsened since the prospective payment system for hospitals became effective. The Committee wants to provide a strong assurance that pressures for greater hospital efficiency are not to be construed as license to ignore traditional community responsibilities and loosen historic standards.

"[Under the statute] [a]ll participating hospitals with emergency departments would be required to provide an appropriate medical screening examination for any individual who requests it (or has a request made on his behalf) to determine whether an emergency medical condition exists or if the patient is in active labor." (H.R. Rept. No. 99-241, Part 1, 99th Cong., 1st Sess. (1985), p. 27.)

The regulations implementing section 1867 of the Act are found at 42 CFR 489.24, Special responsibilities of Medicare hospitals in emergency cases. Section 489.24 provides for the following:

- Paragraph (a) requires that when an individual presents to a hospital's emergency department and a request is made on the individual's behalf for examination or treatment of a medical condition, the hospital must provide for an appropriate medical screening examination to determine whether or not an emergency medical condition exists.

- Paragraph (b) provides the definitions of terms, including "comes to the emergency department," "emergency medical condition," "stabilized," and "to stabilize."

- Paragraph (c) addresses procedures a hospital must follow when it determines that an emergency medical condition exists. If the hospital determines that an emergency medical condition exists, the hospital must provide for further medical examination and treatment as required to stabilize the patient. If the hospital does not have the capabilities to stabilize the patient, an appropriate transfer to another facility is permitted. A transfer is appropriate when the medical benefits of the transfer outweigh the medical risks of the transfer and other requirements, specified in the regulation at paragraph (d), are met. Also, the hospital may transfer an unstable patient who makes an informed written request. Paragraph (c) further states that a hospital may not delay an appropriate medical screening examination, or further examination or treatment, to inquire about the individual's payment method or insurance status.

In addition, § 489.24 addresses: (a) Restriction of a transfer until the individual is stabilized; (b) the responsibilities of the receiving hospital; (c) termination of the provider agreement for failure to comply with EMTALA requirements; and (d) matters concerning consultation with Peer Review Organizations (paragraphs (d) through (h), respectively).

Some EMTALA-related requirements are implemented under regulations at §§ 489.20(l), (m), (q), and (r)(1), (r)(2), and (r)(3). Those regulations deal with a hospital's obligations to report the receipt of patients that it has reason to believe may have been transferred inappropriately; to post signs in the emergency department describing a patient's rights to emergency treatment under section 1867 of the Act; and to maintain patient records, physician on-call lists, and emergency room logs. We

are including this brief description for informational purposes but, because we are not proposing to change the regulations in § 489.20, they will not be discussed further in this document.

In promulgating these cited regulatory sections and in enforcing the provisions of EMTALA, we are aware of the necessary balance between the hospital's and a physician's legal duty to provide examination and treatment under the statute and the practical realities of the manner in which hospitals and medical staffs are organized and operated on a day-to-day basis, as well as proper mobilization of resources within hospitals in order to comply with these legal duties. Reports of overcrowding in hospital emergency departments are common in many parts of the country. Within the requirements of EMTALA, individuals should be treated at the appropriate site of care.

Hospitals and physicians have now had over 15 years of experience in organizing themselves to comply with the provisions of EMTALA. Throughout this section of this proposed rule relating to EMTALA, we solicit comments from hospitals, physicians, patients, and beneficiary groups on the proposed changes to the EMTALA policies.

2. Special Advisory Bulletin on EMTALA Obligations

On November 10, 1999, CMS (previously, HCFA) and the Office of the Inspector General (OIG) published jointly in the **Federal Register** a Special Advisory Bulletin addressing the requirements of the patient antidumping statute and the obligations of hospitals to medically screen all patients seeking emergency services and provide stabilizing medical treatment as necessary to all patients, including enrollees of managed care plans, whose conditions warrant it (64 FR 61353). The Special Advisory Bulletin addressed issues of dual staffing of hospital emergency rooms by managed care and nonmanaged care physicians, prior authorization requirements of some managed care plans, use of advance beneficiary notices (ABNs) or other financial responsibility forms, handling of individuals' inquiries about financial liability for emergency services, and voluntary withdrawal of a treatment request. Although it does not amend the Code of Federal Regulations, the Special Advisory Bulletin informs individuals of HHS policy regarding application of the patient antidumping statute and offers advice on the best practices to follow to avoid violation of the requirements imposed under that statute.

As discussed further in section V.J.4. of this preamble, we are now proposing to codify certain policies on prior authorization that are currently stated only in the Special Advisory Bulletin. We believe these changes in the regulations are needed to ensure uniform and consistent application of policy and to avoid any misunderstanding of EMTALA requirements by patients, physicians, or hospital employees.

3. EMTALA Provisions in This Proposed Rule

Recently, a number of questions have been raised about the applicability of § 489.24 to specific situations. These questions arise in the context of managed care plans' requirements for prior authorization, case experiences involving elective procedures, and situations when patients have been admitted as inpatients but are not stabilized, or later experience a deterioration in their medical condition. Some hospitals are uncertain whether various conditions of participation found in 42 CFR part 482 apply to these situations or whether the EMTALA requirements included in the provider agreement regulations at § 489.24 apply, or both. Some representatives of the provider community have asked us to reexamine CMS policy on the applicability of EMTALA to provider-based departments. Finally, there have also been questions concerning the applicability of EMTALA to physicians who are "on call" and to hospitals that own ambulances when those ambulances operate under communitywide emergency medical services (EMS) protocols. To help promote consistent application of the regulations concerning the special responsibilities of Medicare hospitals in emergency cases, we are proposing changes to § 489.24 to clarify its application to these situations and at the same time address concerns about EMTALA raised by the Secretary's Advisory Committee on Regulatory Reform. These changes are discussed more fully below and include the following:

- We are proposing to change the requirements relating to emergency patients presenting at those off-campus outpatient clinics that do not routinely provide emergency services. We believe these changes would enhance the quality and promptness of emergency care by permitting individuals to be referred to appropriately equipped emergency facilities close to such clinics.
- We are proposing to clarify when EMTALA applies to both inpatients and

outpatients. We believe these clarifications would enhance overall patient access to emergency services by helping to relieve administrative burdens on frequently overcrowded emergency departments.

- We are proposing to clarify the circumstances in which physicians, particularly specialty physicians, must serve on hospital medical staff "on-call" lists. We expect these clarifications would help improve access to physician services for all hospital patients by permitting hospitals local flexibility to determine how best to maximize their available physician resources. We are currently aware of reports of physicians, particularly specialty physicians, severing their relationships with hospitals, especially when those physicians belong to more than one hospital medical staff. Physician attrition from these medical staffs could result in hospitals having no specialty physician service coverage for their patients. Our proposed clarification of the on-call list requirement would permit hospitals to continue to attract physicians to serve on their medical staffs and thereby continue to provide services to emergency room patients.

- We are proposing to clarify the responsibilities of hospital-owned ambulances so that these ambulances can be more fully integrated with citywide and local community EMS procedures for responding to medical emergencies and thus use these resources more efficiently for the benefit of these communities.

We solicit comments on all of these proposed changes.

4. Prior Authorization

Some managed care plans may seek to pay hospitals for services only if the hospitals obtain approval from the plan for the services before providing the services. Requirements for this approval are frequently referred to as "prior authorization" requirements. However, EMTALA (specifically, section 1867(h) of the Act and our regulation at § 489.24(c)(3)) explicitly prohibit hospitals from delaying screening or stabilization services in order to inquire about the individual's method of payment or insurance status. Thus, prior authorization requirements are a matter of concern because hospitals could, in seeking prior authorization from an insurer, present a barrier to or delay in the provision of services required by EMTALA.

After review of these considerations, we believe that our existing policy will best implement the intent of the statute by prohibiting a participating hospital from seeking authorization from the

individual's insurance company for screening services or services required to stabilize an emergency medical condition until after the hospital has provided the appropriate medical screening examination required by EMTALA to the patient and has initiated any further medical examination and treatment that may be required to stabilize the patient's emergency medical condition.

We are soliciting comments as to whether the regulations should be further revised to state that the hospital may seek other information (apart from information about payment) from the insurer about the individual, and may seek authorization for all services concurrently with providing any stabilizing treatment, as long as doing so does not delay required screening and stabilization services.

In addition, we are proposing to specify that an emergency physician is not precluded from contacting the patient's physician at any time to seek advice regarding the patient's medical history and needs that may be relevant to the medical screening and treatment of the patient, as long as this consultation does not inappropriately delay required screening or stabilization services.

As explained earlier, this policy was stated in a Special Advisory Bulletin published jointly by CMS (then HCFA) and the OIG. However, we are now proposing to clarify existing language at § 489.24(c)(3) (proposed to be redesignated as paragraph (d)(4)) in this proposed rule to include this policy in the regulations.

5. Hospital Responsibility for Communication With Medicare+Choice Organizations Concerning Post-Stabilization Care Services

Section 422.113 of our existing regulations establishes rules concerning the responsibility of Medicare+Choice organizations for emergency and post-stabilization care services provided to Medicare+Choice enrollees (65 FR 40170, June 29, 2000). Under § 422.113(c)(2), a Medicare+Choice organization is financially responsible for post-stabilization care under certain circumstances, including situations in which the organization cannot be contacted or does not respond timely to a hospital's request for preapproval of this care.

It has come to our attention that, in some instances, hospitals may have failed to contact Medicare+Choice organizations on a timely basis to seek authorization for post-stabilization services. In such a case, the Medicare+Choice organization does not

have the opportunity provided for under the regulations to decide whether to approve the provision of post-stabilization services at the hospital where the emergency services were provided, or to require that the enrollee instead be transferred to another hospital for such services. Therefore, we are proposing to add a new paragraph (d)(6) under § 489.24 to specify that a hospital must promptly contact the Medicare+Choice organization after a Medicare+Choice enrollee who is treated for an emergency medical condition is stabilized.

6. Clarification of "Comes to the Emergency Department"

Section 1867(a) of the Act and our regulations at § 489.24(a) provide, in part, that if any individual comes to the emergency department of a hospital and a request is made on that individual's behalf for examination or treatment of a medical condition, the hospital must provide an appropriate medical screening examination within the capability of the hospital's emergency department. If the hospital determines that such an individual has an emergency medical condition, the hospital is further obligated to provide either necessary stabilizing treatment or an appropriate transfer. Occasionally, questions have arisen as to whether these EMTALA requirements apply to situations in which a patient comes to a hospital, but does not present to the hospital's emergency department. We are proposing to clarify under what circumstances a hospital is obligated under EMTALA to screen, stabilize, or transfer an individual who comes to a hospital, presenting either at its dedicated emergency department, as proposed to be defined below, or elsewhere on hospital property, seeking examination or treatment.

Sometimes individuals come to hospitals seeking examination or treatment for medical conditions that could be emergency medical conditions, but present for examination or treatment at areas of the hospital other than the emergency department. For example, a woman in labor may go directly to the labor and delivery department of a hospital or a psychiatric outpatient experiencing a psychiatric crisis may present at the psychiatry department. In the June 22, 1994 final rule (59 FR 32098), we defined "comes to the emergency department" at § 489.24(b) to clarify that a hospital's EMTALA obligations are triggered whenever an individual presents on hospital property in this manner in an attempt to gain access to the hospital for emergency care and requests examination or

treatment for an emergency medical condition. At the time we adopted this interpretation of "comes to the emergency department," we explained:

"We believe that section 1867 of the Act also applies to all individuals who attempt to gain access to the hospital for emergency care. An individual may not be denied services simply because the person failed to actually enter the facility's designated emergency department." (59 FR 32098)

We repeated this standard for situations in which a hospital becomes bound to meet EMTALA's screening and stabilization or transfer requirements with respect to individuals who present on hospital property in an attempt to gain access to the hospital for emergency care, but outside of a hospital's emergency department, in interpretative guidelines published in the State Operations Manual:

"If an individual arrives at a hospital and is not technically in the emergency department, but is on the premises (including the parking lot, sidewalk and driveway) of the hospital and requests emergency care, he or she is entitled to a medical screening examination." (State Operations Manual Appendix V—Responsibilities of Medicare Participating Hospitals in Emergency Cases, V-16)

Thus, an individual can "come to the emergency department," creating an EMTALA obligation on the part of the hospital, in one of two ways: The individual can present at a hospital's dedicated emergency department (as proposed to be defined below) and request examination or treatment for a medical condition; or the individual can present elsewhere on hospital property in an attempt to gain access to the hospital for emergency care (that is, at a location that is on hospital property but is not part of a dedicated emergency department), and request examination or treatment for what may be an emergency medical condition.

Because of the need to clarify the applicability of EMTALA to a particular individual depending on where he or she presents on hospital property in order to obtain emergency care, we are proposing to define "dedicated emergency department." "Dedicated emergency department" would mean a specially equipped and staffed area of the hospital that is used a significant portion of the time for the initial evaluation and treatment of outpatients for emergency medical conditions, as defined in § 489.24(b), and is either located: (1) On the main hospital campus; or (2) off the main hospital campus and is treated by Medicare under § 413.65(b) as a department of the

hospital. The EMTALA statute was intended to apply to individuals presenting to a hospital for emergency care services. Accordingly, we believe it is irrelevant whether the dedicated emergency department is located on or off the hospital main campus, as long as the individual is presenting to "a hospital" for those services. Therefore, we are proposing in our definition of "dedicated emergency department" that such a department may be located on the main hospital campus, or it may be a department of the hospital located off the main campus. (We note that this proposed definition would encompass not only what is generally thought of as a hospital's "emergency room," but would also include other departments of hospitals, such as labor and delivery departments and psychiatric units of hospitals, that provide emergency or labor and delivery services, or both, or other departments that are held out to the public as an appropriate place to come for medical services on an urgent, nonappointment basis.)

We are soliciting public comment on whether this proposed definition should more explicitly define what is a "dedicated emergency department." Specifically, we are seeking comment on whether a "significant portion of the time" should be defined more objectively; for example, in terms of some minimum number or minimum percentage of patients (20, 30, 40 percent or more of all patients seen) presenting for emergency care at a particular area of the hospital in order for it to qualify as a "dedicated emergency department." As an alternative, we could also consider a qualifying criteria that is based on determining whether the facility is used "regularly" for the evaluation or treatment of emergency medical conditions. Similarly, we are seeking comments on how we could define "regularly" more objectively in our consideration of this alternative. We further seek comments from hospitals, physicians, and others on how hospitals currently organize themselves to react to situations in which individuals come to a hospital requesting a screening examination or medical treatment, or both.

This proposed rule would clarify for hospitals that they must provide at least a medical screening examination to all individuals who present to an area of a hospital meeting the definition of dedicated emergency department and request examination or treatment for a medical condition, or have such a request made on their behalf. As we explain in section V.J.7. of this preamble, individuals who present to an

area of a hospital other than a dedicated emergency department on hospital property must receive a medical screening examination under EMTALA, only when the individual requests examination or treatment for what may be an emergency medical condition, or has such a request made on his or her behalf, as provided in the proposed changes to § 489.24(b) in this proposed rule.

7. Applicability of EMTALA: Individual Comes to the Dedicated Emergency Department for Nonemergency Services

We sometimes receive questions as to whether EMTALA's requirements apply to situations in which an individual comes to a hospital's dedicated emergency department, but no request is made on the individual's behalf for emergency medical evaluation or treatment. In view of the specific language of section 1867 of the Act and the discussion in section V.J.6. of this proposed rule, which proposes to define a hospital's dedicated emergency department as a specially equipped and staffed area of the hospital that is used a significant portion of the time for the initial evaluation and treatment of outpatients for emergency medical conditions located on the main hospital campus or at an off-campus department of the hospital, we believe that a hospital must be seen as having an EMTALA obligation with respect to any individual who comes to the dedicated emergency department, if a request is made on the individual's behalf for examination or treatment for a medical condition, whether or not the treatment requested is explicitly for an emergency condition. A request on behalf of the individual would be considered to exist if a prudent layperson observer would believe, based on the individual's appearance or behavior, that the individual needs examination or treatment for a medical condition. This does not mean, of course, that all EMTALA screenings must be equally extensive. The statute plainly states that the objective of the appropriate medical screening examination is to determine whether or not an emergency medical condition exists. Therefore, hospitals are not obligated to provide screening services beyond those needed to determine that there is no emergency.

In general, a medical screening examination is the process required to reach, with reasonable clinical confidence, a determination about whether a medical emergency does or does not exist. We expect that in most cases in which a request is made for medical care that clearly is unlikely to involve an emergency condition, an

individual's statement that he or she is not seeking emergency care, together with brief questioning by qualified medical personnel, would be sufficient to establish that there is no emergency condition and that the hospital's EMTALA obligation would thereby be satisfied.

To clarify our policy in this area, we are proposing to redesignate paragraphs (c) through (h) of § 489.24 as paragraphs (d) through (i) (we are proposing to remove existing paragraph (i), as explained in section V.J.10. of this preamble) and to add a new paragraph (c) to state that if an individual comes to a hospital's dedicated emergency department and a request is made on his or her behalf for examination or treatment for a medical condition, but the nature of the request makes it clear that the medical condition is not of an emergency nature, the hospital is required only to perform such screening as would be appropriate for any individual presenting in that manner, to determine that the individual does not have an "emergency medical condition" as defined in paragraph (b). (See example 1 below.)

Example 1: A woman walks up to the front desk of a hospital's emergency room, a dedicated emergency department, and tells the hospital employee attending the front desk that she had a wound sutured several days earlier and was directed by her doctor to have the sutures removed that day. The front desk attendant registers the woman according to the hospital's normal registration procedure and directs the woman to the waiting area. An emergency nurse, who has been designated by the hospital as a "qualified medical person" (as provided for in existing § 489.24(a)), calls the woman into the examination area of the emergency room. The nurse asks the woman if she has experienced any discomfort or noticed any problems in the area sutured. The woman explains that she is feeling fine, and the wound is not causing her any discomfort, but that her doctor had directed her a week ago to have the sutures removed that day. The nurse physically inspects the sutures and determines that the wound is healing appropriately. The nurse explains to the woman that she does not have an emergency medical condition and may direct the woman to an outpatient clinic where nonemergency personnel will provide the services the woman has requested.

Application: In this case, the woman presented at the hospital's dedicated emergency department and requested examination or treatment for a medical condition—specifically, she asked that her sutures be removed. Therefore, the hospital is bound under section 1867(a) of the Act to provide her a medical screening examination in order to determine whether or not she has an emergency medical condition. The

actions of the nurse, "a qualified medical person," constitute an appropriate medical screening examination under EMTALA because the nurse has determined, with reasonable clinical confidence, that the woman has no emergency medical condition. This appropriate medical screening examination fully satisfies the hospital's EMTALA obligations as to that woman; because the screening examination revealed no emergency medical condition, the hospital properly referred the woman to an outpatient clinic for nonemergency care.

8. Applicability of EMTALA: Individual Presents at an Area of the Hospital on the Hospital's Main Campus Other Than the Dedicated Emergency Department

Routinely, individuals come to hospitals as outpatients for many nonemergency medical purposes, and if such an individual initially presents at an on-campus area of the hospital other than a dedicated emergency department, we would expect that the individual typically would not be seeking emergency care. Under most of these circumstances, EMTALA would therefore not apply (this concept is further discussed in section V.J.8. of this preamble). A hospital would, however, incur an EMTALA obligation with respect to an individual presenting at that area who requests examination or treatment for what may be an emergency medical condition, or had such a request made on his or her behalf. This policy would not require that an emergency medical condition be found, upon subsequent medical examination, to exist. Rather, EMTALA is triggered in on-campus areas of the hospital other than a dedicated emergency department where, in an attempt to gain access to the hospital for emergency care, an individual comes to a hospital and requests an examination or treatment for a medical condition that may be an emergency.

We are proposing to specify in the regulations that such a request would be considered to exist if the individual requests examination or treatment for what the individual believes to be an emergency medical condition. Where there is no actual request because, for example, the individual is unaccompanied and is physically incapable of making a request, the request from the individual would be considered to exist if a prudent layperson observer would believe, based upon the individual's appearance or behavior, that the individual needs emergency examination or treatment. We believe this proposed policy is appropriate because it would not be

consistent with the intent of section 1867 of the Act to deny its protections to those individuals whose need for emergency services arises upon arrival on hospital on-campus property at the hospital's main campus but have not been presented to the dedicated emergency department.

Under the proposed policies discussed above, a request for examination or treatment by an individual presenting for what may be an emergency medical condition at an on-campus area of the hospital other than the dedicated emergency department would not have to be expressed verbally in all cases, but in some cases should be inferred from what a prudent layperson observer would conclude from an individual's appearance or behavior. While there may be a request (either through the individual or a prudent layperson), thereby triggering an EMTALA obligation on the part of the hospital, this policy does not mean that the hospital must maintain emergency medical screening or treatment capabilities in each department or at each door of the hospital, nor anywhere else on hospital property other than the dedicated emergency department. If an individual presents at an on-campus area of the hospital other than the dedicated emergency department in an attempt to gain access to the hospital for emergency care, EMTALA would mandate that the hospital (as a whole) would provide for screening and stabilizing the individual. For example, upon presentation of an individual requesting emergency care, if the department to which the individual presents cannot readily provide screening and, if needed, stabilization services, the department may arrange for appropriate staff to provide these services. Care required to be provided under EMTALA should be provided in the most appropriate setting, as determined by the hospital.

Example 2: An individual bleeding profusely from a severe scalp laceration enters a hospital through the main entry for hospital visitors, and says to one of the receptionists: "I need help." The receptionist sees that the individual's head is bleeding and, noting his request, arranges to have the individual taken to the dedicated emergency department. Minutes later, the staff from the emergency department arrive and transport the individual to the hospital's emergency department to complete the screening and to give any necessary stabilizing treatment.

Application: The individual presented at an on-campus area of the hospital other than the dedicated emergency department (in this case, the main entry for hospital visitors), with his head bleeding profusely, asking for

help. The receptionist, a prudent layperson observing the individual, believed that the individual was seeking emergency examination or treatment, thereby triggering an EMTALA obligation on the part of the hospital. (We note that EMTALA would have been triggered even if no verbal request had been made, since the individual's appearance indicated the clear possibility of an emergency medical condition.) Since the main entry for hospital visitors did not have emergency examination or treatment capabilities, the receptionist appropriately called the hospital's emergency department to summon emergency department staff to provide emergency care for that individual. Once the emergency department staff arrived and transported the individual to the hospital's emergency department, and provided him with the emergency care needed and stabilized the individual, the hospital had satisfied its EMTALA obligation to that individual.

Again, we solicit comments from hospitals and physicians that give examples of ways in which hospitals presently react to situations such as for the example noted above.

Most individuals who come to hospitals as outpatients come for many nonemergency purposes; under most circumstances, EMTALA would not apply. We are proposing that EMTALA would not apply to such an individual who then experiences what may be an emergency medical condition if the individual is an outpatient (as that term is defined at 42 CFR § 410.2) who has come to the hospital outpatient department for the purpose of keeping a previously scheduled appointment. We would consider such an individual to be an outpatient if he or she has begun an encounter (as that term is defined at § 410.2) with a health professional at the outpatient department. Because such individuals are patients of the hospital already, that is, they have a previously established relationship with the hospital, and have come to the hospital for previously scheduled medical appointments, we believe it is inappropriate that they be considered to have "come to the hospital" for purposes of EMTALA. However, we note that such an outpatient under this proposal who experiences what may be an emergency medical condition after the start of an encounter with a health professional would have all protections afforded to patients of a hospital under the Medicare hospital conditions of participation (as discussed in section V.J.13. of this proposed rule). Hospitals that fail to provide treatment to these

patients could face termination of their Medicare provider agreements for a violation of the conditions of participation. In addition, as patients of a health care provider, these individuals are accorded protections under State statutes or common law as well as under general rules of ethics governing the medical professions.

Example 3: A patient who had been discharged from inpatient status following knee replacement surgery comes to the hospital outpatient department for a physical therapy session which had been scheduled 2 weeks earlier. While undergoing therapy, the patient complains of chest pains and lightheadedness. Acting under protocols established by the hospital, staff of the outpatient department contact the hospital's dedicated emergency department, which dispatches appropriate personnel to the department. The patient is taken to the hospital's dedicated emergency department for examination. Upon arrival in the dedicated emergency department, she is given a medical screening examination, which reveals that she has an emergency medical condition related to coronary artery disease. She is stabilized in the dedicated emergency department and is released to the care of her daughter.

Application: In this case, the individual is an outpatient. While she is in a physical therapy session in an outpatient department of the hospital, she experiences what may be an emergency medical condition—chest pains and lightheadedness. This outpatient is under the care of the hospital; she is in a previously scheduled physical therapy appointment and clearly has a previously established relationship with the hospital. In addition, the encounter with hospital staff has begun since her condition arose while she was undergoing therapy. Therefore, although the individual may be experiencing what may be an emergency medical condition, the hospital is not obligated under EMTALA. However, the hospital appropriately provided treatment for this patient, as required under the Medicare conditions of participation (specifically, 42 CFR § 482.55, which requires the hospital to fulfill its condition of participation responsibility for emergency care by contacting the hospital's dedicated emergency department and providing care to the individual through staff of that department). We solicit comments from hospitals and physicians as to what current practices are when an outpatient with a previously scheduled appointment experiences an emergency medical condition.

We are proposing to retitle the definition of "property" at § 489.24(b) to "hospital property" and relocate it as a

separate definition. In addition, we are proposing to clarify which areas and facilities are not considered hospital property.

9. Scope of EMTALA Applicability to Hospital Inpatients

While most issues regarding EMTALA arise in connection with ambulatory patients, questions have occasionally been raised about whether EMTALA applies to inpatients. In late 1998, the United States Supreme Court considered a case (*Roberts v. Galen of Virginia*) that involved, in part, the question of whether EMTALA applies to inpatients in a hospital. In the context of that case, the United States Solicitor General advised the Supreme Court that the Department of Health and Human Services (DHHS) would develop a regulation clarifying its position on that issue. After reviewing the issue in the light of the EMTALA statute, we are proposing that EMTALA would apply to inpatients only under limited circumstances, as described in the following paragraphs.

As noted earlier, once a hospital has incurred an EMTALA obligation with respect to an individual, that obligation continues while the individual remains at the hospital, so that any transfer to another medical facility or discharge of the individual must be in compliance with the rules restricting transfer until the individual is stabilized under existing § 489.24(d). In many cases, medical judgment will dictate that a patient be admitted to the hospital for further treatment on an inpatient basis because the patient's emergency medical condition has not yet been stabilized.

In these cases, the hospital continues to be obligated under section 1867, irrespective of the inpatient admission. Admitting an individual whose emergency medical condition has not been stabilized does not relieve the hospital of further responsibility to the individual under this section. An individual's emergency medical condition will be considered to have been stabilized only when the criteria in § 489.24(b) are met; that is, the individual's condition must be such that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during a transfer of the individual from the facility or, if the patient is a pregnant woman who is having contractions, that the woman has delivered the child and the placenta.

Consistent with the above policy, we emphasize that an admission to inpatient status cannot be used to evade EMTALA responsibilities. Indeed,

permitting inpatient admission to end EMTALA obligations would provide an obvious means of circumventing these requirements that would seemingly contradict the point of the statute to protect emergency patient health and safety. This point should be particularly evident in the case of a woman in labor, a central focus of the statute. Such women are frequently admitted, and the statute clearly contemplated protecting them until completion of the delivery (that is, stabilization). In addition, if an inpatient who had been admitted from the dedicated emergency department with an unstabilized emergency medical condition was never stabilized as an inpatient and is transferred, we would still apply EMTALA in reviewing the transfer. In this context, stability for transfer reflects a complex medical judgment that can be made only based on review of all relevant information in each particular case, including all conditions that could cause the patient to be medically unstable. A patient who goes in and out of apparent stability with sufficient rapidity or frequency would not be considered "stabilized" within the meaning of § 489.24; transient stability of such a patient does not relieve the hospital of its EMTALA obligation. Such a patient would continue to be covered by EMTALA until the patient's overall medical stability with respect to all conditions is achieved.

Except for the limited circumstances described above, we are proposing to clarify that EMTALA does not apply to hospital inpatients. We believe EMTALA does not apply to hospital inpatients because we interpret section 1867 of the Act by reading the statutory language as a whole, with the requirements of paragraphs (b), "Necessary Stabilizing Treatment for Emergency Medical Conditions and Labor," and (c), "Restricting Transfer Until Individual is Stabilized," applying only to those individuals who satisfy the threshold requirement of coming to the hospital and requesting emergency care (as interpreted in this proposed regulation). This interpretation is based upon the statutory language and the legislative history. First, the Congress defined "emergency medical condition" at section 1867(e)(1) of the Act by referring solely to "acute symptoms," which are self-identified, and did not mention other potentially relevant indications, in particular, signs or objective data. "Signs" are observable findings that are identified or confirmed by a clinician based on examination and use of objective data (for example, physiologic measurements, x-ray

results). When a patient's condition deteriorates in the inpatient setting, awareness of a situation potentially requiring emergency care is based on any symptoms, signs, and objective data, reflecting a situation that is not captured by the targeted definition at section 1867(e)(1) of the Act. If the Congress had intended EMTALA to apply to transfers at any time during an inpatient stay, it would not have used a definition of emergency medical condition that focuses exclusively on symptoms and that uniquely defines the individual's status at the time of his or her initial presentation to the hospital, not his or her status as an inpatient. Furthermore, the definition of "appropriate transfer" in paragraph (c)(2) of section 1867 of the Act includes a variety of terms (observation, signs, symptoms, preliminary diagnosis) associated with patient information that is gathered at the initial stage of clinical intervention, when the course of treatment is just beginning. Thus, it would appear to be clear that the authors of this legislation understood the precise meanings of these clinical terms and utilized them accordingly. Further indication that Congress intended this result is the language in section 1867(b)(1)(A) of the Act (stabilization), which requires that the hospital provide "for such further medical examination" as necessary to stabilize. Congress' use of the word "further" acknowledges that there was some initial treatment that occurred in the emergency department.

In addition, the legislative history of EMTALA is replete with references to the problem of individuals denied emergency medical care at hospital emergency rooms, whereas there is no explicit reference to similar problems faced by hospital inpatients. (See, for example, 131 Cong. Rec. 28,587 and 28,588 (1985)). When the Congress considered the need for EMTALA legislation, it noted that Medicare-participating hospitals were bound to meet hospital conditions of participation, but that no specific requirements then existed for appropriate treatment of emergency patients. (See H.R. Rept. No. 241 (I)(1985), reprinted in 1986 U.S.C.C.A.N. 579, 605.) Arguably, the Congress also considered other protections available to hospital inpatients (for example, private causes of action).

This interpretation that EMTALA was not intended to apply to transfers at any time during an inpatient's stay is further supported by the language of the appropriate transfer provisions of section 1867(c) of the Act. While that paragraph does refer to individuals at a

“hospital,” rather than individuals at an “emergency department,” the same paragraph also makes reference to actions to be taken by “a physician * * * physically present in the emergency department.” This explicit mention of a hospital emergency department, even in a paragraph that generally cites an individual at a “hospital,” supports the view that EMTALA was not intended to apply to admitted inpatients who may become unstable subsequent to admission, but only to patients who initially come to the hospital’s emergency department with an emergency medical condition, and only until the condition has been stabilized. Finally, we note that once a hospital admits an individual as a patient, that hospital has a variety of other legal, licensing, and professional obligations with respect to the continued proper care and treatment of such patients.

a. Admitted Emergency Patients. A related issue concerns whether a hospital may satisfy its EMTALA obligations to an admitted emergency inpatient only by effectuating an actual stable discharge or appropriate transfer. We are proposing to clarify that even when an admitted emergency patient is not actually transferred, a determination may be made as to whether or not the patient has been stabilized such that he or she could be transferred at a certain point without likely material deterioration of the patient’s condition, as defined in section 1867(e)(3)(B) of the Act. Under our proposed policy, if the admitted emergency patient could have been transferred as “stable” under the statute and the period of stability is documented by relevant clinical data in the patient’s medical record, the hospital has satisfied its EMTALA obligation by meeting the statutory requirement of providing stabilizing treatment to the point of stability for transfer, and the hospital’s obligation under EMTALA ends, even though the patient may remain in inpatient status at the hospital. If, after stabilization, the individual who was admitted as an inpatient again has an apparent decline of his or her medical condition, either as a result of the injury or illness that created the emergency for which he or she initially came to the dedicated emergency department or as a result of another injury or illness, the hospital must comply with the conditions of participation under 42 CFR Part 482, but has no further responsibility under EMTALA with respect to the individual.

We also note that, just because a hospital may stabilize a patient for purposes of ending its EMTALA obligation to that patient, this does not

relieve the hospital of any further health and safety obligations as to that patient under the Medicare program. While they remain patients in that hospital, these patients are still protected by a number of Medicare health and safety standards (conditions of participation), as explained further below. In addition, as explained above, nothing under EMTALA in any way changes a hospital’s other legal, licensing, and professional obligations with respect to the continued proper care and treatment of its patients.

Example 4: A patient comes to Hospital C’s emergency department and requests treatment for an emergency medical condition. The patient knows he has severe heart disease and his chest pains have become more frequent. The patient receives an appropriate medical screening examination and is found to have an emergency medical condition, as indicated by a pain pattern and EKG abnormalities consistent with unstable angina. Stabilizing treatment in the emergency department on an outpatient basis, consisting of oxygen, nitrates and heparin, is initiated.

After several hours of outpatient care, the emergency physician determines that the patient is still not stable for purposes of discharge to his home. The emergency physician concludes that the patient can be treated most effectively by being admitted to Hospital C where he is currently being treated as an outpatient. The patient is admitted as an inpatient for further treatment. The attending physician knows that patients with indications for coronary angioplasty are usually transferred to Hospital D in another city because Hospital D has specialized capabilities that are unavailable at admitting Hospital C. A trip to Hospital D typically requires 2 hours travel by ground ambulance. The physician determines that the patient is stable for purposes of this type of transfer; that is, such a transfer is not likely to result in a material deterioration of the patient’s condition, and documents relevant clinical data in the patient’s medical record. Even though patients with this degree of coronary arterial disease and acute infarction risk are usually transferred, the patient opposes transfer and wants to remain in the local community. In accordance with the wishes of the patient and his family, the attending physician agrees to treat the patient in Hospital C while informing the patient of the risks involved.

Application: In this situation, the admitted patient is not stable for purposes of discharge to his home but the attending physician determined that the patient is stable for the type of transfer usually undertaken by Hospital C for patients with unstable angina considered for angioplasty. This stabilization, which is documented by relevant clinical data in the patient’s medical record, ends Hospital C’s EMTALA obligation to the patient, and that obligation would not be reinstated

by any subsequent deterioration in the patient’s condition.

We are proposing to redesignate paragraph (c) of § 489.24 as paragraph (d), and include these stabilization requirements under a new proposed § 489.2(d)(2). (Proposed redesignated paragraph (d) would be revised further as explained in section V.K.9.b. of this preamble.)

b. Admitted Elective (Nonemergency) Patients. Most hospital admissions do not consist of emergency cases. In most cases, a patient who comes to the hospital and requests admission does so to obtain elective (nonemergency) diagnosis or treatment for a medical condition. Questions have arisen, however, as to whether a hospital would be bound under EMTALA in the situation in which an admitted nonemergency inpatient experiences a deterioration of his or her medical condition.

Under our interpretation of section 1867 of the Act as described above, we believe EMTALA was intended to provide protection to patients coming to a hospital to seek care for an emergency condition. Therefore, we believe that the EMTALA requirements do not extend to admitted nonemergency inpatients. These patients are protected by a number of the Medicare hospital conditions of participation, as explained further under section V.K.13. of this preamble. These patients are further protected by a hospital’s other legal, licensing, and professional obligations with respect to the continued proper care and treatment of its patients.

We are proposing to also include these requirements under the proposed redesignated § 489.24(d)(2).

10. Applicability of EMTALA to Provider-Based Entities

On April 7, 2000, we published a final rule specifying the criteria that must be met for a determination regarding provider-based status (65 FR 18504). The regulations in that the April 2000 final rule were subsequently revised to incorporate changes mandated by section 404 of Public Law 106–554 (66 FR 59856, November 30, 2001). However, those revisions did not substantively affect hospitals’ obligations with respect to off-campus departments.

a. Applicability of EMTALA to Off-Campus Hospital Departments. In the April 7, 2000 final rule (65 FR 18504), we also clarified the applicability of EMTALA to hospital departments not located on the main provider campus. At that time, we revised § 489.24 to include a new paragraph (i) to specify the antidumping obligations of hospitals

with respect to individuals who come to off-campus hospital departments for the examination or treatment of a potential emergency medical condition. As explained in the preamble to the April 7, 2000 final rule, we made this change because we believed it was consistent with the intent of section 1867 of the Act to protect individuals who present on hospital property (including off-campus hospital property) for emergency medical treatment. Since publication of the April 7, 2000 final rule, it has become clear that many hospitals and physicians continue to have significant concerns with our policy on the applicability of EMTALA to these off-campus locations. After further consideration, we are proposing to clarify the scope of EMTALA's applicability in this scenario to those off-campus departments that are treated by Medicare under § 413.65(b) to be departments of the hospital, and that are equipped and staffed areas that are used a significant portion of the time for the initial evaluation and treatment of outpatients for emergency medical conditions. That is, we are proposing to narrow the applicability of EMTALA to only those off-campus departments that are "dedicated emergency departments" as defined in proposed revised § 489.24(b).

This proposed definition would include such departments whether or not the words "emergency room" or "emergency department" were used by the hospital to identify the departments. The definition would also be interpreted to encompass those off-campus hospital departments that would be perceived by a prudent layperson as appropriate places to go for emergency care. Therefore, we are proposing to revise the definition of "Hospital with an emergency department" at § 489.24(b) to account for these off-campus dedicated emergency departments and to also amend the definition of "Comes to the emergency department" at § 489.24(b) to include this same language. We believe this proposed change would enhance the quality of emergency care by facilitating the prompt delivery of emergency care in those cases, thus permitting individuals to be referred to nearby facilities with the capacity to offer appropriate emergency care.

In general, we expect that off-campus departments that meet the proposed definitions stated above would in practice be functioning as "off-campus emergency departments." Therefore, we believe it is reasonable to expect the hospital to assume, with respect to these off-campus departments, all EMTALA obligations that the hospital must assume with respect to the main

hospital campus emergency department. For instance, the screening and stabilization or transfer requirements described in section V.K.1. of this preamble ("Background") would extend to the off-campus emergency departments, as well as to any such departments on the main hospital campus.

In conjunction with this proposed change in the extent of EMTALA applicability with respect to off-campus facilities, we are also proposing to delete all of existing § 489.24(i), which, as noted above, was established in the April 7, 2000 final rule. We are proposing to delete this paragraph in its entirety because its primary purpose is to describe a hospital's EMTALA obligations with respect to patients presenting to off-campus departments that do not routinely provide emergency care. Under the proposals outlined above, however, a hospital would have no EMTALA obligation with respect to individuals presenting to such departments. Therefore, it would no longer be necessary to impose the requirements in existing § 489.24(i). Even though off-campus provider-based departments that do not routinely offer services for emergency medical conditions would not be subject to EMTALA, some individuals may occasionally come to them to seek emergency care. Under such circumstances, we believe it would be appropriate for the department to call an emergency medical service (EMS) if it is incapable of treating the patient, and to furnish whatever assistance it can to the individual while awaiting the arrival of EMS personnel. Consistent with the hospital's obligation to the community and similar to our requirements under § 482.12(f)(2) that apply to hospitals that do not provide emergency services, we would expect the hospital to have appropriate protocols in place for dealing with individuals who come to off-campus nonemergency facilities to seek emergency care. To clarify a hospital's responsibility in this regard, we are proposing to revise § 482.12(f) by adding a new paragraph (3) to state that if emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff of the hospital has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate. (We note that, in a separate document (62 FR 66758, December 16, 1997), we proposed to relocate the existing § 482.12(f)

requirement to a new section of Part 482. Any change to the existing § 482.12(f) that is adopted as a result of the proposal described above will be taken into account in finalizing the December 19, 1997 proposal.) However, the hospital would not incur an EMTALA obligation with respect to the individual.

In summary, we are proposing in existing § 489.24(b) to revise the definitions of "comes to the emergency department" and "hospital with an emergency department", and to include these off-campus departments in our new definition of "dedicated emergency department." We welcome comments on whether this new term is needed or if the term "emergency department" could be defined more broadly to encompass other departments that provide urgent or emergent care services. We are proposing to delete all of existing § 489.24(i) and to make conforming revisions to § 413.65(g)(1).

b. On-Campus Provider-Based Applicability. At existing § 413.65(g)(1), we state, in part, that if any individual comes to any hospital-based entity (including an RHC) located on the main hospital campus, and a request is made on the individual's behalf for examination or treatment of a medical condition, the entity must comply with the antidumping rules at § 489.24. Since provider-based entities, as defined in § 413.65(b), are not under the certification and provider number of the main provider hospital, this language, read literally, would appear to impose EMTALA obligations on providers other than hospitals, a result that would not be consistent with section 1867, which restricts EMTALA applicability to hospitals. To avoid confusion on this point and to prevent any inadvertent extension of EMTALA requirements outside the hospital setting, we are proposing to clarify that EMTALA applies in this scenario to only those *departments* on the hospital's main campus that are provider-based; EMTALA would not apply to provider-based *entities* (such as RHCs) that are on the hospital campus.

In addition, we are proposing in § 489.24(b) to revise the definition of "Comes to the emergency department" to include an individual who presents on hospital property, in which "hospital property" is in part defined as "the entire main hospital campus as defined at § 413.65(b) of this chapter, including the parking lot, sidewalk, and driveway, but excluding other areas or structures that may be located within 250 yards of the hospital's main building but are not part of the hospital, such as physician offices, RHCs, SNFs, or other entities

that participate separately in Medicare, or restaurants, shops, or other nonmedical facilities." We are specifically seeking comments on this proposed revised definition. Generally, this proposed language would clarify that EMTALA does not apply to provider-based entities, whether or not they are located on a hospital campus. This language is also consistent with our policy as stated in questions and answers published on the CMS website: www.cms.gov (CMS EMTALA guidance, 7/20/01, Q/A # 1) that clarifies that EMTALA does not apply to other areas or structures located on the hospital campus that are not part of the hospital, such as fast food restaurants or independent medical practices.

If this proposed change limiting EMTALA applicability to only those on-campus departments of the hospital becomes finalized, we believe that if an individual comes to an on-campus provider-based entity or other area or structure on the campus not applicable under the new policy and presents for emergency care, it would be appropriate for the entity to call the emergency medical service if it is incapable of treating the patient, and to render whatever assistance it can to the individual while awaiting the arrival of emergency medical service personnel. However, the hospital on whose campus the entity is located would not incur an EMTALA obligation with respect to the individual.

We welcome comments from providers and other interested parties on the proper or best way to organize hospital resources to react to situations on campus where an individual patient or prospective patient requires immediate medical attention.

We are proposing in § 489.24(b) to revise the definition of "Comes to emergency department" (specifically, under proposed new paragraph (1)) and make conforming changes at § 413.65(g)(1).

11. EMTALA and On-Call Requirements

We have frequently received inquiries concerning the applicability of EMTALA for physicians on call. We believe there are a number of misconceptions in the provider industry concerning the extent to which EMTALA requires physicians to provide on-call coverage. Therefore, we are including a section in this preamble that clarifies what kinds of obligations physicians have to provide on-call coverage under EMTALA.

Section 1866(a)(1)(I)(iii) of the Act states, as a requirement for participation in the Medicare program, that hospitals must keep a list of physicians who are

on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition. If a physician on the list is called by a hospital to provide emergency screening or treatment and either fails or refuses to appear within a reasonable period of time, the hospital and that physician may be in violation of EMTALA as provided for under section 1867(d)(1)(C) of the Act.

The CMS State Operations Manual (SOM) further clarifies a hospital's responsibility for the on-call physician. The SOM (Appendix V, page V-15, Tag A404) states:

- Each hospital has the discretion to maintain the on-call list in a manner to best meet the needs of its patients.
- Physicians, including specialists and subspecialists (for example, neurologists), are not required to be on call at all times. The hospital must have policies and procedures to be followed when a particular specialty is not available or the on-call physician cannot respond because of situations beyond his or her control.

Thus, hospitals are required to maintain a list of physicians on call at any one time and physicians or hospitals, or both, may be responsible under the EMTALA statute to provide emergency care if a physician who is on the on-call list fails to or refuses to appear within a reasonable period of time. However, Medicare does not set requirements on how frequently a hospital's staff of on-call physicians are expected to be available to provide on-call coverage. We are aware that practice demands in treating other patients, conferences, vacations, days off, and other similar factors must be considered in determining the availability of staff. We also are aware that some hospitals, particularly those in rural areas, have stated that they incur relatively high costs of compensating physician groups for providing on-call coverage to their emergency departments, and that doing so can strain their already limited financial resources. CMS allows hospitals flexibility to comply with EMTALA obligations by maintaining a level of on-call coverage that is within their capability.

We understand that some hospitals exempt senior medical staff physicians from being on call. This exemption is typically written into the hospital's medical staff bylaws or the hospital's rules and regulations, and recognizes a physician's active years of service (20 or more years) or age (that is, 60 years of age or older), or a combination of both. We wish to clarify that providing such exemptions to members of hospitals'

medical staff does not necessarily violate EMTALA. On the contrary, we believe that the hospital is responsible for maintaining an on-call list in a manner that best meets the needs of its patients as long as the exemption does not affect patient care adversely. Thus, CMS allows hospitals flexibility in the utilization of their emergency personnel.

We also note that there is no predetermined "ratio" that CMS uses to identify how many days that a hospital must provide medical staff on-call coverage based on the number of physicians on staff for that particular specialty. In particular, CMS has no rule stating that whenever there are at least three physicians in a specialty, the hospital must provide 24 hour/7 day coverage. Generally, in determining EMTALA compliance, CMS will consider all relevant factors, including the number of physicians on staff, other demands on these physicians, the frequency with which the hospital's patients typically require services of on-call physicians, and the provisions the hospital has made for situations in which a physician in the specialty is not available or the on-call physician is unable to respond.

Example 5: Hospital D has 75 beds and is located in a rural area. The hospital provides on-call coverage of orthopedic services on all weekdays and the first 3 weekends of each month. On the fourth weekend of one month, an individual presents at Hospital D's dedicated emergency department and requests examination for a medical condition. The emergency physician on duty screens the individual and finds that she has an orthopedic emergency medical condition requiring the services of an orthopedist. Hospital D does not have on-call orthopedic physician coverage on this date and, therefore, transfers the individual to an urban hospital 20 miles away for necessary treatment. The transfer is arranged in accordance with procedures that Hospital D has for meeting patient needs when a particular specialty is not available or the physician cannot respond for reasons beyond his or her control.

Analysis: Hospital D incurred an EMTALA obligation when the individual presented at Hospital D's dedicated emergency department and requested examination for a medical condition. At that time, Hospital D did not have on-call coverage to provide necessary stabilizing treatment for what was an orthopedic emergency medical condition, even though an orthopedic physician was on-call at other times. The emergency physician at Hospital D weighed the risks involved to transfer the individual to an urban hospital with capabilities to treat the individual and found that it would be more beneficial to the individual to transfer him or her

to the urban hospital 20 miles away, than to provide screening and stabilizing treatment within Hospital D's capabilities (which, at that time, did not include orthopedic services). Hospital D has satisfied its EMTALA obligation by providing screening services within its capability, followed by an appropriate transfer, under procedures developed in advance. To clarify our policies on EMTALA requirements regarding the availability of on-call physicians, we are proposing to add to § 489.24 a new paragraph (j) to specify that each hospital has the discretion to maintain the on-call list in a manner to best meet the needs of its patients. This paragraph would further specify that physicians, including specialists and subspecialists (for example, neurologists), are not required to be on call at all times, and that the hospital must have policies and procedures to be followed when a particular specialty is not available or the on-call physician cannot respond because of situations beyond his or her control.

12. EMTALA Applicability to Hospital-Owned Ambulances

We stated in the June 22, 1994 final rule (59 FR 32098) that if an individual is in an ambulance owned and operated by a hospital, the individual is considered to have come to the hospital's emergency department, even if the ambulance is not on hospital property. This policy, currently set forth at § 489.24(b), was necessary because we were concerned that some hospitals that owned and operated ambulances at that time were transporting individuals who had called for an ambulance to other hospitals, thereby evading their EMTALA responsibilities to the individuals.

Concerns have since been raised by the provider industry about applications of this policy to ambulances that are owned by hospitals but are operating under communitywide EMS protocols that may require the hospital-owned and other ambulances to transport individuals to locations other than the hospitals that own the ambulances. For instance, we understand that some community protocols require ambulances to transport individuals to the nearest hospital to the patient geographically, whether or not that hospital owns the ambulance.

To avoid imposing requirements that are inconsistent with local EMS requirements, we are proposing to clarify, at proposed revised § 489.24(b) in the definition of "Comes to the emergency department", an exception to our existing rule requiring EMTALA applicability to hospitals that own and

operate ambulances. Our proposal would account for hospital-owned ambulances operating under communitywide EMS protocols. Under our proposal, the rule on hospital-owned ambulances and EMTALA does not apply if the ambulance is operating under a communitywide EMS protocol that requires it to transport the individual to a hospital other than the hospital that owns the ambulance. In this case, the individual is considered to have come to the emergency department of the hospital to which the individual is transported, at the time the individual is brought onto hospital property.

13. Conditions of Participation for Hospitals

We are reminding hospitals and others that while this proposed regulation would make it clear that stabilizing an emergency inpatient relieves the hospital of its EMTALA obligations, it does not relieve the hospital of all further responsibility for the patient who is admitted or indicate that the hospital is thus free to improperly discharge or transfer him or her to another facility. Inpatients who experience acute medical conditions receive protections under the hospital conditions of participation, which are found at 42 CFR part 482. In addition, as noted earlier in this preamble, we believe that outpatients who experience what may be an emergency medical condition after the start of an encounter with a health professional would have all protections afforded to patients of a hospital under the Medicare conditions of participation. There are six conditions of participation that provide these protections: emergency services, governing body, discharge planning, quality assurance, medical staff, and outpatient services. We are not proposing in this proposed rule to make changes to any of the conditions of participation.

If a hospital inpatient develops an acute medical condition and the hospital is one that provides emergency services, the hospital is required to ensure that it meets the emergency needs of the patient in accordance with accepted standards of practice. Similarly, regardless of whether the hospital provides emergency services, if an inpatient develops an acute medical condition, the governing body condition of participation (§ 482.12(f)(2), which applies to all Medicare-participating hospitals) would apply. This condition of participation requires that the hospital governing body must ensure that the medical staff has written policies and procedures for appraisal of

emergencies, initial treatment, and referral when appropriate.

The discharge planning condition of participation (§ 482.43, which applies to all Medicare-participating hospitals) requires hospitals to have a discharge planning process that applies to all patients. This condition of participation ensures that patient needs are identified and that transfers and referrals reflecting adequate discharge planning are made by the hospital. If an inpatient develops an acute medical condition and the hospital either does not offer emergency services or does not have the capability to provide necessary treatment, a transfer to another hospital with the capabilities to treat the emergency medical condition could be warranted. Hospitals are required to meet the discharge planning condition of participation in carrying out such a transfer.

The hospital condition of participation governing medical staff (§ 482.22) requires that the hospital have an organized medical staff that operates under bylaws approved by the governing body and is responsible to the governing body for the quality of medical care provided to patients by the hospital. Should the medical staff not be held accountable to the governing body for problems regarding a lack of provision of care to an inpatient who develops an emergency medical condition, this lack of accountability may be reviewed under the medical staff condition of participation, as well, and may result in a citation of noncompliance at the medical staff condition level for the hospital.

Finally, the quality assurance condition of participation (§ 482.21, which applies to all Medicare-participating hospitals) requires the governing body to ensure that there is an effective, hospital-wide quality assurance program to evaluate the provision of patient care. In order to comply with this condition of participation, the hospital must evaluate the care it provides hospital-wide. Complaints regarding a lack of provision of care to an inpatient who develops an emergency medical condition must be addressed under the hospital's quality assurance program and may be reviewed under the quality assurance condition of participation.

A hospital's failure to meet the conditions of participation requirements cited above may result in a finding of noncompliance at the condition level for the hospital and lead to termination of the hospital's Medicare provider agreement.

K. Provider-Based Entities

1. Background

a. The April 7, 2000 Final Rule

Since the beginning of the Medicare program, some providers, which we refer to as “main providers,” have functioned as a single entity while owning and operating multiple provider-based departments, locations, and facilities that were treated as part of the main provider for Medicare purposes. Having clear criteria for provider-based status is important because this designation can result in additional Medicare payments for services furnished at the provider-based facility, and may also increase the coinsurance liability of Medicare beneficiaries for those services.

In the April 7, 2000 **Federal Register** (65 FR 18504), we published a final rule specifying the criteria that must be met for a determination regarding provider-based status. The regulations at § 413.65(a)(2) define provider-based status as “the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or satellite facility, that complies with the provisions of this section.” The regulations at existing § 413.65(b)(2) state that before a main provider may bill for services of a facility as if the facility is provider-based, or before it includes costs of those services on its cost report, the facility must meet the criteria listed in the regulations at § 413.65(d). Among these criteria are the requirements that the main provider and the facility must have common licensure (when appropriate), the facility must operate under the ownership and control of the main provider, and the facility must be located in the immediate vicinity of the main provider.

The effective date of these regulations was originally October 10, 2000, but was subsequently delayed and is now in effect for new facilities or organizations for cost reporting periods beginning on or after January 10, 2001, as explained further below. Program instructions on provider-based status issued before that date, found in Section 2446 of the Provider Reimbursement Manual, Part 1 (PRM-1), Section 2004 of the Medicare State Operations Manual (SOM), and CMS Program Memorandum (PM) A-99-24, will apply to any facility for periods before the new regulations become applicable to it. (Some of these instructions will not be applied because they have been superseded by specific legislation on provider-based status, as

described in section V.K.3. of this preamble).

b. Frequently Asked Questions Regarding Provider-Based Issues

Following publication of the April 7, 2000 final rule, we received many requests for clarification of policies on specific issues related to provider-based status. In response, we published a list of “Frequently Asked Questions” and the answers to them on the CMS website at www.hcfa.gov/medlearn/provqa.htm. (This document can also be obtained by contacting any of the CMS (formerly, HCFA) Regional Offices.) These questions and answers did not revise the regulatory criteria, but do provide subregulatory guidance for their implementation.

c. Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Public Law 106-554)

On December 21, 2000, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 (Public Law 106-554) was enacted. Section 404 of BIPA contains provisions that significantly affect the provider-based regulations at § 413.65. Section 404 includes a grandfathering provision for facilities treated as provider-based on October 1, 2000; alternative criteria for meeting the geographic location requirement; and criteria for temporary treatment as provider-based.

(1) Two-Year “Grandfathering”

Under section 404(a) of BIPA, any facilities or organizations that were “treated” as provider-based in relation to any hospital or CAH on October 1, 2000, will continue to be treated as such until October 1, 2002. For the purpose of this provision, we interpret “treated as provider-based” to include those facilities with formal CMS determinations, as well as those facilities without formal CMS determinations that were being paid as provider-based as of October 1, 2000. As a result, existing provider-based facilities and organizations may retain that status without meeting the criteria in the existing regulations under §§ 413.65(d), (e), (f), and (h) until October 1, 2002. These provisions concern provider-based status requirements, joint ventures, management contracts, and services under arrangement. Thus, the provider-based facilities and organizations affected under section 404(a) of BIPA are not required to submit an application for or obtain a provider-based status determination in order to

continue receiving reimbursement as provider-based during this period.

These provider-based facilities and organizations are not exempt from the EMTALA responsibilities of provider-based facilities and organizations set forth at § 489.24, which we are proposing to revise as discussed above, or from the obligations of hospital outpatient departments and hospital-based entities in existing § 413.65(g), such as the responsibility of off-campus facilities to provide written notices to Medicare beneficiaries of coinsurance liability. These rules are not preempted by the grandfathering provisions of section 404 of BIPA because they do not set forth criteria that must be met for provider-based status as a department of a hospital, but instead identify responsibilities that flow from that status. These responsibilities become effective for hospitals on the first day of the hospital’s cost reporting period beginning on or after January 10, 2001.

(2) Geographic Location Criteria

Section 404(b) of BIPA provides that those facilities or organizations that are not included in the grandfathering provision at section 404(a) are deemed to comply with the “immediate vicinity” requirements of the existing regulations under § 413.65(d)(7) if they are located not more than 35 miles from the main campus of the hospital or CAH. Therefore, those facilities located within 35 miles of the main provider satisfy the immediate vicinity requirement as an alternative to meeting the “75/75 test” under existing § 413.65(d)(7).

In addition, BIPA provides that certain facilities or organizations are deemed to comply with the requirements for geographic proximity (either the “75/75 test” or the “35-mile test”) if they are owned and operated by a main provider that is a hospital with a disproportionate share adjustment percentage greater than 11.75 percent and is (1) owned or operated by a unit of State or local government, (2) a public or private nonprofit corporation that is formally granted governmental powers by a unit of State or local government, or (3) a private hospital that has a contract with a State or local government that includes the operation of clinics of the hospital to ensure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare or Medicaid.

These geographic location criteria will continue indefinitely. While those facilities or organizations treated as provider-based on October 1, 2000 are covered by the 2-year grandfathering

provision noted above, the geographic location criteria at section 404(b) of BIPA and the existing regulations at § 413.65(d)(7) will apply to facilities or organizations not treated as provider-based as of that date, effective with the hospital's cost reporting period beginning on or after January 10, 2001. On October 1, 2002, the statutory moratorium on application of these criteria to the grandfathered facilities will expire. In this proposed rule, we are proposing a further delay, as discussed below.

(3) Criteria for Temporary Treatment as Provider-Based

Section 404(c) of BIPA also provides that a facility or organization that seeks a determination of provider-based status on or after October 1, 2000, and before October 1, 2002, shall be treated as having provider-based status for any period before a determination is made. Thus, recovery for overpayments will not be made retroactively once a request for a determination during that time period has been made. For hospitals that do not qualify for grandfathering under section 404(a) of BIPA, a request for provider-based status should be submitted to the appropriate CMS Regional Office. Until a uniform application is available, at a minimum, the request should include the identity of the main provider and the facility or organization for which provider-based status is being sought and supporting documentation for purposes of applying the provider-based status criteria in effect at the time the application is submitted. Once such a request has been submitted on or after October 1, 2000, and before October 1, 2002, CMS will treat the facility or organization as being provider-based from the date it began operating as provider-based until the effective date of a CMS determination that the facility or organization is not provider-based.

Facilities requesting a provider-based status determination on or after October 1, 2002, will not be covered by the provision concerning temporary treatment as provider-based in section 404(c) of BIPA. Thus, as stated in § 413.65(n), the CMS Regional Offices will make provider-based status effective as of the earliest date on which a request for determination has been made and all requirements for provider-based status in effect as of the date of the request are shown to have been met, not on the date of the formal CMS determination. Under existing regulations at § 413.65(j), if a facility or organization does not qualify for provider-based status and CMS learns that the provider has treated the facility

or organization as provider-based without having obtained a provider-based determination under applicable regulations, CMS will review all payments and may seek recovery for overpayments, including overpayments made for the period of time between submission of the request or application for provider-based status and the issuance of a formal CMS determination. (As explained in the previous paragraph, such retroactive recovery of payments would not be made for any period to the extent it is prohibited by section 404(c) of BIPA.)

d. The August 24, 2001 and November 30, 2001 Published Regulations

In August 24, 2001 **Federal Register** (66 FR 44672), we proposed to revise the provider-based regulations to reflect the changes mandated by section 404 of BIPA and to make other technical and clarifying changes in those regulations. In the November 30, 2001 **Federal Register** (66 FR 59856), following consideration of public comments received on the August 24, 2001 proposal, we published a final rule that revised the provider-based regulations. However, the only substantive changes in the provider-based regulations were those required by the BIPA legislation.

2. Proposed Changes

In the preamble to the proposed rule published on August 24, 2001 (66 FR 44709), we stated our intent to reexamine the EMTALA regulations and, in particular, to reconsider the appropriateness of applying EMTALA to off-campus locations. We announced that we planned to review these regulations with a view toward ensuring that these locations are treated in ways that are appropriate to the responsibility for EMTALA compliance of the hospital as a whole. We also pointed out that, at the same time, we want to ensure that those departments that Medicare pays as hospital-based departments are appropriately integrated with the hospital as a whole.

In addition, since the statutory grandfathering provision in the BIPA legislation remains in effect only until October 1, 2002, many hospital representatives have contacted CMS to request more guidance because they are concerned that their facilities are not in compliance with existing regulations and would not be able to continue billing as provider-based once the grandfathering provision expires. These hospital representatives are also concerned that the organizational and contractual changes needed to meet current provider-based requirements could take several months to complete.

Moreover, resolution of some of the issues surrounding the provider-based regulations is needed in order to allow development of a uniform application form to enable the CMS Regional Offices to efficiently process the multitudes of requests for provider-based determinations that we expected as the grandfathering period expires.

To address the provider-based issues raised by the hospital industry and to allow for an orderly and uniform implementation strategy once grandfathering ends, we are proposing the following regulatory changes:

a. Scope of Provider-Based Requirements (§ 413.65(a))

Since publication of the April 2000 final rule, we have received many questions about which specific facilities or organizations are subject to the provider-based requirements. In the "Frequently Asked Questions" posted on the CMS website, we identified a number of facility types for which provider-based determinations would not be made, since such determinations would not affect either Medicare payment or Medicare beneficiary liability or scope of benefits. The regulations at § 413.65(a) were further revised to incorporate the exclusion of these facility types from review under the provider-based criteria. We now are proposing to further revise § 413.65(a)(1)(ii) to state that provider-based determinations will not be made with respect to independent diagnostic testing facilities that furnish only services paid under a fee schedule, such as facilities that furnish only screening mammography services, as defined in section 1861(jj) of the Act, facilities that furnish only clinical diagnostic laboratory tests, or facilities that furnish only some combination of these services. A provider-based determination would not be appropriate for a facility that furnishes only screening mammography because of a change made by section 104 of BIPA. That legislation, which amended section 1848(j)(3) of the Act, mandates that all payment for screening mammography services furnished on or after January 1, 2000, be made under the Medicare Physician Fee Schedule (MPFS). Under the MPFS methodology, Medicare payment for the service, regardless of the setting in which it is furnished, is set at the lesser of the fee schedule amount or the actual charge; and no Part B deductible applies. Regardless of the setting, Part B coinsurance is assessed at 20 percent of the lesser of the fee schedule amount or the actual charge. Because the status of a facility as provider-based or freestanding would

not affect the amount of Medicare or Medicaid payment, the beneficiary's scope of benefits, or the beneficiary's liability for coinsurance or deductible amounts, it is not necessary to make a provider-based determination regarding facilities that furnish only screening mammography. We are also proposing to revise § 413.65(a)(1)(ii) by adding a new paragraph (j) to state that we will not make provider-based determinations with respect to departments of providers (for example, laundry or medical records departments) that do not furnish types of health care services for which separate payment could be claimed under Medicare or Medicaid. (Such services frequently are referred to as "billable" services.) As explained more fully below, we would not make determinations with respect to these departments because their status (that is, whether they are provider-based or not) would have no impact on Medicare or Medicaid payment or on the scope of benefits or beneficiary liability under either program.

Despite the previous clarifications described above, providers, associations, and their representatives have continued to state that they are confused as to which facilities or organizations will be the subject of provider-based determinations.

In this document, we are proposing to further clarify the types of facilities that are subject to the provider-based rules, by making several changes to the definitions of key terms in § 413.65(a)(2). First, we are proposing to revise the definition of "department of a provider" to remove the reference to a physician office as being a department of a provider. While a hospital outpatient department, in fact, may furnish services that are clinically indistinguishable from those of physician offices, physician offices and provider departments are paid through separate methods under Medicare and beneficiaries may be liable for different coinsurance amounts. Thus, it is essential to distinguish between these facility types, and we believe avoiding confusion on this issue requires us to remove the reference to a hospital department as a physician office.

We also are proposing to revise § 413.65(a)(2) to state that a "department of a provider", "provider-based entity", or "remote location of a hospital" comprises both the specific physical facility that serves as the site of services of a type for which separate payment could be claimed under the Medicare or Medicaid programs, and the personnel and equipment needed to deliver the services at that facility. We believe this change would help to clarify that we

would make determinations with respect to entities considered in their role as sources of health care services and not simply as physical locations. We also wish to clarify that we do not intend to make provider-based determinations with respect to various organizational components or units of providers that may be designated as "departments" or "organizations" but do not themselves furnish types of services for which separate payment could be claimed under Medicare or Medicaid. Examples of components for which we would not make provider-based determinations include the medical records, housekeeping, and security departments of a hospital. Such departments do perform functions that are essential to the provision of inpatient and outpatient hospital services, but the departments do not provide health care services for which Medicare or Medicaid benefits are provided under title XVIII or title XIX of the Act, and for which separate payment therefore could be claimed, assuming certification and other applicable requirements were met, to one or both programs. Therefore, neither Medicare or Medicaid program liability nor beneficiary liability or scope of benefits would be affected by the ability or inability of these departments to qualify as "provider-based." (We also would not make a provider-based determination with respect to any facility or organization that furnishes only types of health care services for which separate payment could be claimed under either Medicare or Medicaid, even if the facility or organization met all requirements for provider-based status. For example, if a hospital that is not eligible for DSH payments under Medicare or Medicaid or for IME payments under Medicare were to establish a dedicated facility providing only types of cosmetic surgery or experimental therapies that could not be covered under either Medicare or Medicaid, no determination would be made with respect to that facility.)

By contrast, Medicare or Medicaid payment (or both) to hospital departments that provide diagnostic or therapeutic radiology services to outpatients, or primary care, ophthalmology, or other specialty services to outpatients are affected by provider-based status, as would beneficiary liability for Medicare coinsurance amounts. Therefore, we would make provider-based determinations for these departments.

Similarly, if two acute care hospitals that have approved graduate medical education (GME) programs were to

merge to form a single, multicampus hospital consisting of the main hospital campus and a remote location, it would be appropriate to make a determination as to whether the remote location is provider-based with respect to the main hospital campus. Such a determination would be needed because each hospital with an approved residency training program has its own hospital-specific cap on the number of residents (or FTE cap), its own PRA, and its own Medicare utilization used for purposes of receiving Medicare GME payments. A merger of the two hospitals would aggregate the two hospitals' individual FTE caps into a merged FTE cap under the main hospital's provider number, and would require recalculation of the hospital's PRA and a merging of these entities' respective Medicare utilization, resulting in a level of Medicare GME payment to the merged hospital that exceeds the sum of the payments that would be made to each hospital as separate entities. Thus, a provider-based determination would be appropriate and necessary in such a case, even though payment for services by both facilities would be made under the Medicare acute care hospital inpatient prospective payment system.

In deciding whether to make a provider-based determination with respect to a particular facility, it would not be significant that the facility might have a low rate of Medicare utilization, might be utilized by only Medicare or only Medicaid patients, or might not have admitted any Medicare or Medicaid patients in a particular period. The fact that the facility furnishes types of services that are billable under Medicare or Medicaid, or both, would be sufficient to make a determination appropriate.

We are proposing to retain the rules that a department of a provider or a remote location of a hospital (such as, for example, one campus of a multicampus hospital) may not by itself be qualified to participate in Medicare as a provider under the regulations on provider agreements in § 489.2, and the Medicare conditions of participation do not apply to a department as an independent entity. However, we are proposing to delete the requirement at § 413.65(a)(2) that such a department may not be licensed to provide services in its own right. Some States require separate licensing of facilities that Medicare would treat as a department of a hospital or other provider. In these States, we would not require a common license. We would retain the provision that, for purposes of Part 413, the term "department of a provider" does not

include an RHC or, except as specified in § 413.65(m), an FQHC.

Questions have arisen regarding whether the provider-based criteria in § 413.65 are applicable in determining payment for ambulance services. Medicare is converting payment for ambulance services to a fee schedule, as described in a final rule published on February 27, 2002 (67 FR 9100). The ambulance fee schedule is effective April 1, 2001, and involves a transition period. During this transition period, the status of an ambulance supplier as provider-based could influence the amount of Medicare payment. However, the specific provider-based criteria in § 413.65 were not developed for ambulance suppliers, and we believe that many of these criteria could not reasonably be applied to them. Therefore, we are not proposing to apply the criteria at § 413.65 to ambulance services.

b. Further Delay in Effective Date of Provider-Based Rules

As noted earlier, § 413.65(b) was recently revised to reflect the "grandfathering" provision in section 404(a)(1) of BIPA. Under that provision, if a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until October 1, 2002.

It now appears likely that any new provider-based rules that may be adopted as the result of this rulemaking effort will not be published in final before mid-summer of 2002. To allow hospitals and other facilities the time they need to make contractual and organizational changes to comply with the new rules, and to ensure that CMS Regional Offices and contractors are able to provide for an orderly transition to the new provider-based rules, we believe an additional delay in the effective date of the provider-based criteria is needed. Therefore, we are proposing to revise § 413.65(b)(2) to state that if a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. We are proposing to further provide that the requirements, limitations, and exclusions specified in § 413.65(d) through (j) (as proposed to be redesignated) will not apply to that hospital or CAH for that facility until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. For purposes of paragraph

(b)(2), a facility would be considered as having been provider-based on October 1, 2000, if on that date it either had a written determination from CMS that it was provider-based, or was billing and being paid as a provider-based department or entity of the hospital. We are proposing to make the new requirements effective on October 1, 2002, with respect to provider-based status for facilities not qualifying for the grandfathering provision.

c. Revision of Application Requirement

Existing regulations at § 413.65(b)(2) establish an explicit application requirement for all facilities seeking provider-based status, except for grandfathered facilities and those treated as provider-based pending a determination on an application filed on or after October 1, 2000, and before October 1, 2002. Under existing § 413.65(b)(3), a main provider or a facility must contact CMS, and the facility must be determined by CMS to be provider-based, before the main provider bills for services of the facility as if the facility were provider-based, or before it includes costs of those services on its cost report. Many providers and provider representatives have expressed concern that the requirement to file an application will increase paperwork burden for hospitals unnecessarily. In response to these concerns, we are proposing to revise the application requirements as follows:

First, we would delete the existing application requirement under § 413.65(b)(3). We are proposing to revise this section to state that except where payment is required to be made under BIPA, as specified in proposed revised § 413.65(b)(2) and (b)(5), if a potential main provider seeks an advance determination of provider-based status for a facility that is located on the main campus of the potential main provider, the provider would be required to submit an attestation stating that its facility meets the criteria in § 413.65(d) and, if it is a hospital, also attest that its facility will fulfill the obligations of hospital outpatient departments and hospital-based entities, as described in proposed § 413.65(g). The provider also would be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS upon request. We note that, under our proposal, there would no longer be an explicit requirement that a provider-based approval be obtained before a facility is treated as provider-based for billing or cost reporting purposes. However, under the proposed revisions to existing § 413.65(k) (Correction of

errors) as described below, CMS would provide a delay in the effective date for any facility that is found not to meet the provider-based criteria following a previous advance determination, if the reason the provider-based criteria are not met is a material change in the provider-facility relationship that was properly reported to CMS. The removal of provider-based status would be effective as of the first cost reporting period following notification of the redetermination, but not less than 6 months after the date of notification.

We are further proposing that if the facility is not located on the main campus of the potential main provider, the provider that wishes to obtain an advance determination of provider-based status would be required to submit an attestation stating that its facility meets the criteria in proposed revised §§ 413.65(d) and (e) and, if the facility is operated as a joint venture or under a management contract, the requirements in proposed §§ 413.65(f) and (h), as applicable. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in proposed revised § 413.65(g). The provider seeking such an advance determination would be required to supply documentation of the basis for its attestations to CMS at the time it submits its attestations. We believe the use of a self-attestation process would strike an appropriate balance between the legitimate interests of hospitals in reducing paperwork and reporting, and the equally legitimate need of CMS to ensure proper accountability for compliance with the qualification requirements for a status that typically leads to a higher level of Medicare or Medicaid payment.

We note that, under these proposed revisions to the application procedures at § 413.65(b), a hospital would not be explicitly required to submit an application and receive a provider-based determination for a facility before the time at which the hospital may bill for services at that facility as provider-based. However, we are considering, alternatively, retaining the existing regulations at § 413.65(b)(2) which state that, except where payment is required to be made under BIPA as specified in proposed revised §§ 413.65(b)(2) and (b)(5), hospitals are explicitly required to submit provider-based applications, and to withhold billing as provider-based until CMS determines that a facility meets the provider-based rules. We are soliciting comments on the

appropriateness of this or other alternative application procedures.

d. Requirements Applicable to All Facilities or Organizations

Under existing § 413.65, all facilities seeking provider-based status with respect to a hospital or other main provider must meet a common set of requirements. These include requirements relating to common licensure (paragraph (d)(1)), operation under the ownership and control of the main provider (paragraph (d)(2)), administration and supervision (paragraph (d)(3)), integration of clinical services (d)(4), financial integration (paragraph (d)(5)), public awareness (paragraph (d)(6)), and location in the immediate vicinity of the main provider (paragraph (d)(7)). (In addition, as described more fully below, specific rules applicable to all facilities rule out provider-based status for facilities operated as joint ventures by two or more providers (paragraph (e)) and limit the types of management contracts that facilities seeking provider-based status may operate under (paragraph (f)).)

Since publication in final of the existing provider-based rules in April 2000, hospitals and other providers have expressed concern that the requirements outlined above are overly restrictive and do not allow them enough flexibility to enter into appropriate business arrangements with other facilities. We understand these concerns, and agree that Medicare rules should not restrict legitimate business arrangements that do not lead to abusive practices or disadvantage Medicare beneficiaries. At the same time, we believe our existing rules provide a high level of assurance that a facility complying with them is, in fact, an integral and subordinate part of the facility with which it is based, and do not accord provider-based status to facilities that are not integral and subordinate to a main provider, but in fact have only a nominal relationship with that provider.

After considering all comments received on these issues, we believe that further changes in the provider-based rules would be appropriate. In particular, we agree with those who argue that a facility's or organization's location relative to the main campus of the provider is relevant to the integration that is likely to exist between the facility or organization and the main provider. For example, if a facility or organization is located on the main campus of a provider, is operated under the main provider's State license, is medically and financially integrated with that provider, and is held out to

the public and other payers as a part of that provider, we believe the necessary degree of integration of the facility or organization into the main provider can be assumed to exist. We also are concerned that further prescribing the types of management contracts or other business arrangements that may exist between the main provider and the facility or organization would unnecessarily restrict its flexibility to establish cost-effective agreements without significantly enhancing the integration of the facility or organization into the main provider. Therefore, we are proposing to simplify the requirements applicable to facilities or organizations located on the campus of the main provider (as campus is defined in existing regulations at § 413.65(a)(2)). Under our proposal, all facilities seeking provider-based status, including both on-campus and off-campus facilities, would be required to comply with the existing requirements regarding licensure, clinical services integration, financial integration, and public awareness. (These requirements are currently codified at §§ 413.65(d)(1), (d)(4), (d)(5), and (d)(6) and, under this proposed rule, would be redesignated as paragraphs (d)(1) through (d)(4), respectively, of § 413.65.)

With respect to financial integration, existing regulations at § 413.65(d)(5) require that the financial operations of the facility or organization be fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization. The regulations also require that costs of a provider-based facility or organization be reported in a cost center of the provider, and that the financial status of any provider-based facility or organization be incorporated and readily identified in the main provider's trial balance.

Some hospital representatives have questioned the appropriateness of requiring that the costs of a remote location of a hospital be reported in a single cost center, noting that such costs ordinarily would appear in multiple cost centers of the main provider, with (for example) employee health and welfare costs of the remote location being included in the corresponding cost center of the main provider. In recognition of this concern, we are proposing to revise the requirement to state that the costs of a facility or organization that is a hospital department must be reported in a cost center of the provider, and that costs of a provider-based facility or organization other than a hospital department must be reported in the appropriate cost

center or cost centers of the main provider.

Paragraph (d) of § 413.65 would be retitled "Requirements applicable to all facilities or organizations" and, as indicated by its revised title, would set forth those core requirements that any facility or organization would have to meet to qualify for provider-based status.

We are proposing to delete from this paragraph (d) the requirements in existing paragraphs (d)(2) and (d)(3) relating to operation under the ownership and control of the main provider and administration and supervision because we are proposing to no longer apply these requirements to on-campus facilities or organizations. These requirements would be moved to paragraph (e) as described below to reflect the proposed limitation of their applicability to off-campus departments. The core requirements for all facilities or organizations, including facilities located on the main campus, also would not include the requirement regarding location in the immediate vicinity of the main provider (existing § 413.65(d)(7)). Because any facilities or organizations located on the campus of the main provider automatically meet the requirement regarding location in the immediate vicinity (existing § 413.65(d)(7)), the requirement is only of relevance to off-campus facilities or organizations. For clarity, we are proposing to relocate the requirement to paragraph (e) as described below.

We also are proposing to require, in paragraph (d)(5) of § 413.65, all hospital outpatient departments and hospital-based entities, including those located on campus and those located off the campus of the main provider hospital, to fulfill the obligations currently codified and proposed to be retained at § 413.65(g) in order to qualify for provider-based status. (Fulfillment of these obligations is currently required under § 413.65(g).) As explained further below, we also are proposing other changes to paragraph (g).

e. Additional Requirements Applicable to Off-Campus Facilities or Organizations

We recognize that facilities or organizations located off the main provider campus may also be sufficiently integrated with the main provider to justify provider-based designation. However, the off-campus location of the facilities or organizations may make such integration harder to achieve, and such integration should not simply be presumed to exist. Therefore, to ensure that off-campus facilities or organizations seeking

provider-based status are appropriately integrated, we are proposing to retain for these facilities or organizations certain requirements that we are proposing to remove for on-campus facilities or organizations. These requirements are set forth in proposed new § 413.65(e). The requirements set forth in proposed paragraphs (e)(1), (e)(2), and (e)(3) include the requirements on operation under the ownership and control of the main provider (existing § 413.65(d)(2)), administration and supervision (existing § 413.65(d)(3)), and location (existing § 413.65(d)(7)). We also are proposing to include language in proposed new § 413.65(e) to state more clearly that a facility or organization seeking provider-based status must be located in the same State or, when consistent with the laws of both States, in adjacent States.

f. Joint Ventures

Consistent with our views as expressed earlier in this preamble regarding the assumption that a higher degree of integration can be presumed for on-campus facilities or organizations and in recognition of the need to promote reasonable cooperation among providers and avoid costly duplication of specialty services, we are proposing to revise the regulations on joint ventures (currently set forth under § 413.65(e)) to limit their scope to facilities or organizations not located on the campus of any potential main provider. Specifically, we would redesignate § 413.65(e) as § 413.65(f) and revise it to state that a facility or organization that is not located on the campus of the potential main provider cannot be considered provider-based if the facility or organization is owned by two or more providers engaged in a joint venture. We also are proposing to make minor changes to the second sentence of the redesignated paragraph (f) to clarify its meaning.

g. Clarification of Obligations of Hospital Outpatient Departments and Hospital-Based Entities

Existing regulations impose specific obligations for hospital outpatient departments and hospital-based entities, but do not specify the sanction that applies if the facility or organization does not fulfill its obligations. To clarify policy on this issue and emphasize the importance of compliance with the requirements in this area, we are proposing to revise existing § 413.65(g) to state that to qualify for provider-based status in relation to a hospital, a facility or organization must comply with these requirements. In regard to

these obligations, we are proposing to make three changes in existing 413.65(g). First, for reasons explained in section V.J. of this preamble, we are proposing to revise paragraph (g)(1) by deleting the second sentence of that paragraph. In paragraph (g)(2), we are proposing to delete the reference to site-of-service reductions and instead refer to more accurately determined physician payment amounts, in order to more accurately describe how payment under the physician fee schedule is determined. In addition, we are proposing to revise the first sentence of paragraph (g)(7) to clarify that the notice requirements in it do not apply where a beneficiary is examined or treated for a medical condition in compliance with the antidumping rules in § 489.24. This clarification is needed because we believe it would be a violation of the antidumping requirements if examination or treatment required under § 489.24 was delayed in order to permit notification of the beneficiary or the beneficiary's authorized representative. We would further revise § 413.65(g)(7) to state that notice is required once the beneficiary has been appropriately screened and the existence of an emergency has been ruled out or the emergency condition has been stabilized.

h. Management Contracts

Under existing regulations, facilities or organizations operated under management contracts may be considered provider-based only if they meet specific requirements in § 413.65(f) (proposed to be redesignated as § 413.65(h)). In particular, staff of the facility or organization, other than management staff, may not be employed by the management company but must be employed either by the provider or by another organization, other than the main provider, which also employs the staff of the main provider. Under existing regulations, these requirements apply equally to on-campus and off-campus facilities or organizations.

Consistent with our intent to simplify provider-based requirements for on-campus facilities or organizations, we are proposing to restrict the applicability of proposed redesignated paragraph (h) to off-campus facilities or organizations. In addition, we are proposing two additional changes that we believe are needed to respond to questions that are raised frequently about the regulation. First, we would specify that a facility or organization operated under a management contract may be considered provider-based only if the main provider (or an organization that also employs the staff of the main

provider and that is not the management company) employs the staff of the facility or organization who are directly involved in the delivery of patient care, except for management staff and staff who furnish patient care services of a type that would be paid for by Medicare under a fee schedule established by regulations at 42 CFR Part 414. We would not specify who may employ other support staff, such as maintenance or security personnel, and who are not directly involved in providing patient care, nor would we require licensed professional caregivers such as physicians, physician assistants, or certified registered nurse anesthetists to become provider employees. We also are proposing to revise the regulations to clarify at § 413.65(h)(2) that so-called "leased" employees (that is personnel who are actually employed by the management company but provide services for the provider under a staff leasing arrangement) are not considered to be employees of the provider for purposes of this provision.

i. Inappropriate Treatment of a Facility or Organization as Provider-Based

Below we describe the steps that we would take if we discover that a facility is billing as provider-based without having requested a determination, or if the facility received a provider-based determination but the main provider did not inform CMS of a subsequent material change that affected the provider-based status of its facility.

(1) Inappropriate Billing

The existing regulations at § 413.65(i) state that if we discover that a provider is billing inappropriately, we will recover the difference between the amount of payments that actually were made and the amount of payments that CMS estimates should have been made in the absence of a determination of provider-based status. Existing § 413.65(j)(2) states that we would 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 are met. In addition, existing § 413.65(j)(5) describes a procedure under which CMS would continue payments to a provider for services of a facility or organization that had been found not to be provider-based, at an adjusted rate calculated as described in existing paragraph (j)(2), for up to 6 months in order to permit the facility or organization adequate time to meet applicable enrollment and other billing requirements. While CMS is not legally obligated to continue payments in this matter, we believe it would be

appropriate to do so, on a time-limited basis, to allow for an orderly transition to either provider-based or freestanding status for the facility and to avoid disruption in the delivery of services to patients, particularly Medicare patients, who may be relying on the facility for their medical care.

We are proposing to adopt a policy concerning recoupment and continuation of payment that closely parallels the policy stated in existing regulations at § 413.65(j). Under proposed § 413.65(j)(1), if CMS learns that a provider has treated a facility or organization as provider-based and the provider did not request an advance determination of provider-based status from CMS under proposed § 413.65(b)(3), and CMS determines that the facility or organization did not meet the requirements for provider-based status under proposed § 413.65(d) through (i), as applicable (or, in any period before the effective date of these regulations, the provider-based requirements in effect under Medicare program regulations or instructions), CMS would take several actions. First, we are proposing to issue notice to the provider, in accordance with proposed paragraph (j)(3), that payments for past cost reporting periods may be reviewed and recovered as described in proposed paragraph (j)(2)(ii), that future payments for services in or at the facility or organization will be adjusted as described in proposed paragraph (j)(4), and that continued payments to the provider for services of the facility or organization will be made only in accordance with proposed paragraph (j)(5). In addition, as detailed in proposed § 413.65(j)(1)(ii), CMS would, except for providers protected under section 404(a) or (c) of BIPA (implemented at § 413.65(b)(2) and (b)(5)) or the exception for good faith effort at existing § 413.65(i)(2) and (i)(3)), recover the difference between the amount of payments that actually was made to that provider for services at the facility or organization and an estimate of the payments that CMS would have made to that provider for services at the facility or organization in the absence of compliance with the requirements for provider-based status. We are proposing to make recovery for all cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889. Also, we are proposing to adjust future payments to approximate the amounts that would be paid for the same services furnished by a freestanding facility.

Recovery of past payments would be limited in certain circumstances. If a provider did not request a provider-

based determination for a facility by October 1, 2002, but is included in the grandfathering period under § 413.65(b)(2), we are proposing to recoup all payments subject to the reopening rules at §§ 405.1885 and 405.1889, but not for any period before the provider's cost reporting period beginning on or after July 1, 2003.

(2) Good Faith Effort

We are proposing to retain the existing exception for good faith effort (proposed redesignated § 413.65(j)(2)). Under this exception, we would not recover any payments for any period before the beginning of the hospital's first cost reporting period beginning on or after January 10, 2001 (the effective date of the existing provider-based regulations for providers not grandfathered under § 413.65(b)(2)) if during all of that period—

- The requirements regarding licensure and public awareness at § 413.65(d)(1) and proposed redesignated (d)(4) were met;
- All facility services were billed as if they had been furnished by a department of a provider, a remote location of a hospital, a satellite facility, or a provider-based entity of the main provider; and
- All professional services of physicians and other practitioners were billed with the correct site-of-service indicator, as described at proposed redesignated and revised § 413.65(h)(2).

Under proposed § 413.65(j)(5), CMS would continue payment to a provider for services of a facility or organization for a limited period of time, in order to allow the facility or organization or its practitioners to meet necessary enrollment and other requirements for billing on a freestanding basis. Specifically, the notice of denial of provider-based status sent to the provider would ask the provider to notify CMS in writing, within 30 days of the date the notice is issued, as to whether the provider intends to seek an advance determination of provider-based status for the facility or organization, or whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services as a freestanding facility. If the provider indicates that it will not be seeking an advance determination or that the facility or organization or its practitioners will not be seeking to enroll, or if CMS does not receive a response within 30 days of the date the notice was issued, all payments under proposed paragraph (j)(5) would end as of the 30th day after the date of notice.

If the provider indicates that it will be seeking an advance determination, or that the facility or organization or its practitioners will be seeking to meet enrollment and other requirements for billing for services in a freestanding facility, payment for services of the facility or organization would continue, at the adjusted amount described in proposed paragraph (j)(4) for as long as is required for all billing requirements to be met (but not longer than 6 months). Continued payment would be allowed only if the provider or the facility or organization or its practitioners submits, as applicable, a complete request for an advance provider-based determination or 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 furnishes all other information needed by CMS to process the request for provider-based status or, as applicable, the enrollment application and verify that other billing requirements are met. If the necessary applications or information are not provided, CMS would terminate all payment to the provider, facility, or organization as of the date CMS issues notice that necessary applications or information have not been submitted.

j. Temporary Treatment as Provider-Based and Correction of Errors

Under proposed revised § 413.65(k), we would specify the procedures for payment for the period between the time a request is submitted until a provider-based determination is made, and the steps we would take if we discover that a facility for which a provider previously received a provider-based determination no longer meets the requirements for provider-based status.

First, we are proposing that, if a provider submits a complete request for a provider-based determination for a facility that has not previously been found by CMS to have been inappropriately treated as provider-based under proposed revised § 413.65(j), the provider may bill and be paid for services at the facility as provider-based from the date of the application until the date that we determine that the facility or organization does not meet the provider-based rules under § 413.65. If CMS determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that actually was made since the date the complete request for a provider-based determination was submitted and the amount of payments that CMS estimates

should have been made in the absence of compliance with the provider-based requirements. We would consider a request “complete” only if it included all information we need to make an advance determination of provider-based status under § 413.65(b)(3).

Second, similar to what we specify in existing § 413.65(k), if we determine that a facility or organization that previously received a provider-based determination no longer qualifies for provider-based status, and the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider reported to CMS as is required under § 413.65(c), treatment of the facility or organization as provider-based ceases with the date that CMS determines that the facility or organization no longer qualifies for provider-based status.

Third, if we determine that a facility or organization that had previously received a provider-based determination no longer qualifies for provider-based status, and if the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did not report to CMS, as required under § 413.65(c), we are proposing to take the actions with respect to notice to the provider, adjustment of payments, and continuation of payment described in proposed paragraphs (j)(3), (j)(4), and (j)(5). In short, we would treat such cases in the same way as if the provider had never obtained an advance determination. However, with respect to recovery of past payments for providers included in the grandfathering provision at proposed revised § 413.65(b)(2), we would not recover payments for any period before the provider’s first cost reporting period beginning on or after July 1, 2003.

Also, we are proposing that the exception for good faith effort concerning recovery of overpayments under proposed revised §§ 413.65(j)(2) described above would apply to any period before the beginning of the hospital’s first cost reporting period beginning on or after January 10, 2001.

k. Technical Amendments

We are proposing to correct a typographical error in the heading of paragraph (m) of § 413.65 so that it reads “FQHCs and ‘look alike’”.

In paragraph (n) of § 413.65, we are proposing to add a cross-reference to the requirements for provider-based status described in paragraph (b), for purposes

of specifying the effective date of provider-based status.

L. CMS Authority Over Reopening of Intermediary Determinations and Intermediary Hearing Decisions on Provider Reimbursement

Our existing regulations provide various means for the reopening and revision of an intermediary determination or an intermediary hearing decision on provider reimbursement by the fiscal intermediary or the intermediary hearing officer(s) responsible for the determination or the hearing decision, respectively. (In this discussion, we will use the term “intermediary” to refer to, as applicable, the intermediary responsible for an intermediary determination (see §§ 405.1801(a) and 405.1803) or the intermediary hearing officer or panel of intermediary hearing officers responsible for an intermediary hearing decision (see §§ 405.1817 and 405.1831.)) Section 405.1885(a) provides that an intermediary “may” reopen an intermediary determination or an intermediary hearing decision, on its own initiative or at the request of a provider, within 3 years of the date of the notice of the intermediary determination or intermediary hearing decision. However, while § 405.1885(a) provides the intermediary with some discretion about whether to reopen an intermediary determination or an intermediary hearing decision, we have always considered the intermediary’s discretion to be limited by any directives that may be issued by CMS. Thus, although § 405.1885(a) provides that the intermediary “may” reopen, that provision neither states nor implies that the Secretary lacks authority to direct the intermediary to reopen or not reopen a specific matter. Furthermore, CMS has prescribed, in Medicare Provider Reimbursement Manual, Part I (“PRM”), section 2931.2, criteria that guide the intermediary’s reopening actions under “405.1885(a) in the absence of a particular directive from CMS. Also, given that the intermediaries are CMS’ contractors, we have always believed that, under basic principles of agency law, we have inherent authority to direct the actions of our own agents with respect to reopening matters under “405.1885(a), just as for any other aspect of program administration. See also 42 U.S.C. 1395h and 1395kk(a); and 42 CFR 421.1(c), 421.5(b), 421.100(f), 421.124(a), and 421.126(b).

Under § 405.1885(b), an intermediary determination or an intermediary hearing decision “shall be reopened and revised by the intermediary if, within the aforementioned 3-year period, the

Centers for Medicare & Medicaid Services notifies the intermediary that such determination or decision is inconsistent with the applicable law, regulations, or general instructions issued by the Centers for Medicare & Medicaid Services.” We have always considered the CMS notice, which is a precondition of mandatory intermediary reopening under § 405.1885(b), to be one in which we explicitly direct the intermediary to reopen. We have never considered a notice or other document from CMS that only states or implies that an intermediary determination or an intermediary hearing decision is inconsistent with law, regulations, CMS ruling, or CMS general instructions, sufficient to require intermediary reopening under § 405.1885(b). Moreover, our understanding has always been that the phrase “law, regulations, or general instructions” in § 405.1885(b) refers to the legal provisions in effect, as we understand such legal provisions, at the time the intermediary rendered the determination or hearing decision. Conversely, we have never considered changes in, or judicial explications of, “law, regulations, or general instructions,” that occur after the intermediary rendered the determination or hearing decision, sufficient to require intermediary reopening under § 405.1885(b). Also, § 405.1885(b) refers to the Secretary’s agreement with an intermediary; we believe such agreement requires the intermediary to apply the law, regulations, CMS rulings, and CMS general instructions in effect, as we understand such legal provisions, when the intermediary determination or hearing decision was rendered. Accordingly, we have not instructed intermediaries to reopen and recover reimbursement, or to reopen and award additional reimbursement, due to a subsequent change in law or policy, whether the subsequent change is made in response to judicial precedent or otherwise.

Section 405.1885(c) provides: “Jurisdiction for reopening a determination or decision rests exclusively with that administrative body that rendered the last determination or decision.” We have always interpreted § 405.1885(c) to provide that authority to reopen an intermediary determination or an intermediary hearing decision is vested exclusively with the responsible intermediary, as distinct from the Provider Reimbursement Review Board (PRRB) and the Administrator of CMS (in the context of reviewing PRRB

determine the Federal rate each year under paragraph (c) of this section.

15. Section 412.312 is amended by adding a new paragraph (e) to read as follows:

§ 412.312 Payment based on the Federal rate.

(e) Payment for extraordinary circumstances. Payment for extraordinary circumstances is made as provided for in § 412.348(f) for cost reporting periods beginning on or after October 1, 2001.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

C. Part 413 is amended as follows: 1. The authority citation for part 413 is revised to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395hh, 1395rr, 1395tt, and 1395ww).

- 2. Section 413.65 is amended by— A. Revising paragraph (a)(1)(ii)(G) and adding a new paragraph (a)(1)(ii)(J). B. Revising the definition of “Department of a provider”, “Provider-based entity”, and “Remote location of a hospital” under paragraph (a)(2). C. Revising paragraphs (b)(2), (b)(3), and (d). D. Removing paragraph (j). E. Redesignating paragraphs (h) and (i) as paragraphs (i) and (j), respectively. F. Redesignating paragraph (f) as paragraph (h). G. Redesignating paragraph (e) as paragraph (f). H. Adding a new paragraph (e). I. Revising redesignated paragraph (f). J. Revising the introductory text of paragraph (g), and paragraphs (g)(1), (g)(2), and (g)(7). K. Revising redesignated paragraphs (h), (i), and (j). L. Revising paragraph (k). M. Revising the heading of paragraph (m). N. Revising paragraph (n).

§ 413.65 Requirements for a determination that a facility or an organization had provider-based status.

- (a) Scope and definitions. (1) Scope. (ii) This section does not apply to the following facilities:

(G) Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services (as defined in section 1861(jj) of the Act), facilities that furnish only clinical diagnostic laboratory tests, or facilities that furnish only some combination of these services.

(J) Departments of providers that perform functions necessary for the successful operation of the providers but do not furnish services of a type for which separate payment could be claimed under Medicare or Medicaid (for example, laundry or medical records departments).

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

Provider-based entity means a provider of health care services, or an RHC as defined in § 405.2401(b) of this chapter, that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the name, ownership, and administrative and financial control of the main provider, in accordance with the provisions of this section. A provider-based entity comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A provider-

based entity may, by itself, be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity.

Remote location of a hospital means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term “remote location of a hospital” does not include a satellite facility as defined in § 412.22(h)(1) and § 412.25(e)(1) of this chapter.

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

(3)(i) Except as specified in paragraphs (b)(2) and (b)(5) of this section, if a potential main provider seeks an advance determination of provider-based status for a facility that is located on the main campus of the potential main provider, the provider would be required to submit an attestation stating that the facility meets the criteria in paragraph (d) of this section and if it is a hospital, also attest that it will fulfill the obligations of hospital outpatient departments and

hospital-based entities described in paragraph (g) of this section. The provider seeking such an advance determination would also be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS upon request.

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

* * * * *

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

(1) *Licensure.* The department of the provider, the remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except in areas where the State requires a separate license for the department of the provider, the remote location of a hospital, or the satellite facility, or in States where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility under a single license. If a State health facilities' cost review commission or other agency that has authority to regulate the rates charged by hospitals or other providers in a State finds that a particular facility or organization is not part of a provider, CMS will determine that the facility or organization does not have provider-based status.

(2) *Clinical services.* The clinical services of the facility or organization seeking provider-based status and the main provider are integrated as evidenced by the following:

(i) Professional staff of the facility or organization have clinical privileges at the main provider.

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

(iii) The medical director of the facility or organization seeking provider-based status maintains a reporting relationship with the chief medical officer or other similar official of the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the main provider and the chief medical officer or other similar official of the main provider, and is under the same type of supervision and accountability as any other director, medical or otherwise, of the main provider.

(iv) Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility or organization, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility or organization seeking provider-based status and the main provider.

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

(vi) Inpatient and outpatient services of the facility or organization and the main provider are integrated, and patients treated at the facility or organization who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.

(3) *Financial integration.* The financial operations of the facility or organization are fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization. The costs of a facility or organization that is a hospital department are reported in a cost center of the provider, costs of a provider-based facility or organization other than a hospital department are reported in the appropriate cost center or cost centers of the main provider, and the financial status of any provider-based facility or organization is incorporated and readily identified in the main provider's trial balance.

(4) *Public awareness.* The facility or organization seeking status as a department of a provider, a remote location of a hospital, or a satellite facility is held out to the public and

other payers as part of the main provider. When patients enter the provider-based facility or organization, they are aware that they are entering the main provider and are billed accordingly.

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

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

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

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

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

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

(iv) The main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies (such as fringe benefits or code of conduct), and final approval for medical staff appointments in the facility or organization.

(2) *Administration and supervision.* The reporting relationship between the facility or organization seeking provider-based status and the main provider must have the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its existing departments, as evidenced by

compliance with all of the following requirements:

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

(ii) The facility or organization is operated under the same monitoring and oversight by the provider as any other department of the provider, and is operated just as any other department of the provider with regard to supervision and accountability. The facility or organization director or individual responsible for daily operations at the entity—

(A) Maintains a reporting relationship with a manager at the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and its existing departments; and

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

(iii) The following administrative functions of the facility or organization are integrated with those of the provider where the facility or organization is based: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services. Either the same employees or group of employees handle these administrative functions for the facility or organization and the main provider, or the administrative functions for both the facility or organization and the entity are—

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

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

(3) *Location.* The facility or organization is located within a 35-mile radius of the main campus of the hospital or CAH that is the potential main provider, except when the requirements in paragraph (e)(3)(i), (e)(3)(ii), or (e)(3)(iii) of this section are met:

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

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

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

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

(ii) The facility or organization demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria and demonstrates that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12-month period—

(A) At least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider;

(B) At least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (for example, at least 75 percent of the patients of an RHC seeking provider-based status received inpatient hospital services from the hospital that is the main provider); or

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

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

(v) An RHC that is otherwise qualified as a provider-based entity of a hospital that is located in a rural area, as defined in § 412.62(f)(1)(iii) of this chapter, and has fewer than 50 beds, as determined under § 412.105(b) of this chapter, is not subject to the criteria in paragraphs (e)(3)(i) through (e)(3)(iii) of this section.

(f) *Provider-based status for joint ventures.* A facility or organization that is not located on the campus of the potential main provider cannot be

considered provider-based if the facility or organization is owned by two or more providers engaged in a joint venture. For example, where a hospital has jointly purchased or jointly created a facility under joint venture arrangements with one or more other providers, and the facility is not located on the campus of the hospital or the campus of any other provider engaged in the joint venture arrangement, no party to the joint venture arrangement can claim the facility as provider-based.

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

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

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

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

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

* * * * *

(7) When a Medicare beneficiary is treated in a hospital outpatient department of hospital-based entity (other than an RHC) that is not located on the main provider's campus, and the treatment is not required to be provided by the antidumping rules in § 489.24 of this chapter, the hospital must provide written notice to the beneficiary, before the delivery of services, of the amount of the beneficiary's potential financial liability (that is, that the beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the physician service, and of the amount of that liability).

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

(ii) If the exact type and extent of care needed is not known, the hospital may furnish a written notice to the patient that explains that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based.

(iii) The hospital may furnish an estimate based on typical or average charges for visits to the facility, while stating that the patient's actual liability will depend upon the actual services furnished by the hospital.

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

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

* * * * *

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

(1) The main provider (or an organization that also employs the staff of the main provider and that is not the management company) employs the staff of the facility or organization who are directly involved in the delivery of patient care, except for management staff and staff who furnish patient care services of a type that would be paid for by Medicare under a fee schedule established by regulations at Part 414 of this chapter. "Leased" employees (that is, personnel who are actually employed by the management company but provide services for the provider under a staff leasing or similar agreement) are not considered to be employees of the provider for purposes of this paragraph.

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

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

(4) The management contract is held by the main provider itself, not by a parent organization that has control over both the main provider and the facility or organization.

(i) *Furnishing all services under arrangement.* A facility or organization

may not qualify for provider-based status if all patient care services furnished at the facility or organization are furnished under arrangements.

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

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

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

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

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

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

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

(3) *Notice to provider.* CMS will issue written notice to the provider that

payments for past cost reporting periods may be reviewed and recovered as described in paragraph (j)(1)(ii) of this section, and that future payments for services in or of the facility or organization will be adjusted as described in paragraph (j)(4) of this section.

(4) *Adjustment of payments.* CMS will adjust future payments to the provider or the facility or organization, or both, to approximate as closely as possible the amounts that would be paid for the same services furnished by a freestanding facility.

(5) *Continuation of payment.* (i) The notice of denial of provider-based status sent to the provider will ask the provider to notify CMS in writing, within 30 days of the date the notice is issued, of whether the provider intends to seek an advance determination of provider-based status for the facility or organization under paragraph (b)(3) of this section or whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services in a freestanding facility.

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

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

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

(B) Furnishes all other information needed by CMS to process the request for provider-based status or the enrollment application, as applicable,

and verifies that other billing requirements are met.

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

(k) *Temporary treatment as provider-based and correction of errors.* (1) If a provider submits a complete request for a provider-based determination for a facility or organization that has not previously been found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section, the provider may bill and be paid for services of the facility or organization as provider-based from the date of the application until the date that CMS determines that the facility or organization does not meet the provider-based rules. If CMS subsequently determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that actually was made since the date the complete request for a provider-based determination was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements. For purposes of this paragraph (k), a complete request is one that includes all information needed to permit CMS to make an advance determination under paragraph (b)(3) of this section.

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

(3) If CMS determines that a facility or organization that had previously been determined to be provider-based under paragraph (b) of this section no longer qualifies for provider-based status, and if the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did not report to CMS, as required under paragraph (c) of this section, CMS will take the actions with respect to notice to the provider,

adjustment of payments, and continuation of payment described in paragraphs (j)(3), (j)(4), and (j)(5) of this section, and will recover past payments to the provider to the extent described in paragraph (j)(1)(ii) of this section.

* * * * *

(m) *FQHCs and "look alikes".* * * *

(n) *Effective date of provider-based status.* Provider-based status for a facility or organization is effective on the earliest date on which a request for provider-based status, as described in paragraph (b) of this section, has been made and all of the requirements of this part have been met.

3. Section 413.70 is amended by revising paragraph (b)(3)(i) to read as follows:

§ 413.70 Payment for services of a CAH.

* * * * *

(b) *Payment for outpatient services furnished by CAH.*

* * * * *

(3) *Election to be paid reasonable costs for facility services plus fee schedule for professional services.* (i) A CAH may elect to be paid for outpatient services in any cost reporting period under the method described in paragraphs (b)(3)(ii) and (b)(3)(iii) of this section. This election must be made in writing, made on an annual basis, and delivered to the intermediary servicing the CAH by a date determined by that intermediary, which may be no less than 14 days and no more than 60 days before the start of each affected cost reporting period. An election of this payment method, once made for a cost reporting period, remains in effect for all of that period and applies to all services furnished to outpatients during that period.

* * * * *

4. Section 413.86 is amended by—

A. Adding a definition of "Affiliation agreement" in alphabetical order under paragraph (b).

B. Revising the last sentence of the introductory text of paragraph (e)(5)(i).

C. Revising paragraph (e)(5)(i)(B).

D. Adding a new paragraph (e)(5)(i)(C).

E. Redesignating paragraphs (g)(5)(iv), (g)(5)(v), and (g)(5)(vi) as paragraphs (g)(5)(v), (g)(5)(vi), and (g)(5)(vii), respectively.

F. Republishing the introductory text of paragraph (g)(5) and adding a new paragraph (g)(5)(iv).

G. Redesignating paragraphs (g)(7) through (g)(12) as paragraphs (g)(8) through (g)(13), respectively.

H. Adding a new paragraph (g)(7).

I. Making the following cross-reference changes:

i. In redesignated paragraph (g)(5)(vii), "paragraph (g)(8)" is removed and "paragraph (g)(9)" is added in its place.

ii. In paragraph (g)(6), "paragraph (g)(12)" is removed and "paragraph (g)(13)" is added in its place.

iii. In redesignated paragraphs (g)(8)(iv) and (g)(8)(v), "paragraph (g)(7)" is removed and "paragraph (g)(8)" is added in its place.

iv. In redesignated paragraph (g)(9)(i), "paragraph (g)(8)" is removed and "paragraph (g)(9)" is added in its place.

v. In the introductory text of redesignated paragraph (g)(9)(iii), "paragraph (g)(8)(iii)(B)" is removed and "paragraph (g)(9)(iii)(B)" is added in its place; and "paragraph (g)(8)(iii)(A)" is removed and "paragraph (g)(9)(iii)(A)" is added in its place.

vi. In redesignated paragraph (g)(9)(iii)(A)(2), "paragraph (g)(8)(iii)(B)(2)" is removed and "paragraph (g)(9)(iii)(B)(2)" is added in its place.

vii. In the introductory text of redesignated paragraph (g)(12), "paragraph (g)(11)(i) through (g)(11)(vi)" is removed and "paragraph (g)(12)(i) through (g)(12)(vi)" is added in its place.

The additions and revisions read as follows:

§ 413.86 Direct graduate medical education payments.

* * * * *

(b) *Definitions.* * * *

Affiliation agreement means a written, signed, and dated agreement by responsible representatives of each respective hospital in an affiliated group, as defined in this section, that specifies—

(1) The term of the agreement (which, at a minimum is one year), beginning on July 1 of a year;

(2) Each participating hospital's direct and indirect FTE caps existing at the time of affiliation;

(3) The adjustment to each hospital's FTE caps in each year that the affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to one hospital's direct and indirect FTE caps that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect FTE caps of at least the same amount; and

(4) The names of the participating hospitals and their Medicare provider numbers.

* * * * *

(e) *Determining per resident amounts for the base period.* * * *

(5) *Exceptions—(i) Base period for certain hospitals.* * * * The per

resident amount is based on the lower of the amount specified in paragraph (e)(5)(i)(A) or in paragraph (e)(5)(i)(B) of this section, subject to the provisions of paragraph (e)(5)(i)(C) of this section.

* * * * *

(B) Except as specified in paragraph (e)(5)(i)(C) of this section—

(1) For base periods that begin before October 1, 2002, the updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area, as that term is used in the prospective payment system under part 412 of this chapter.

(2) For base periods beginning on or after October 1, 2002, the weighted mean value of per resident amounts of all hospitals located in the same geographic wage area is calculated using all per resident amounts (including primary care and obstetrics and gynecology and nonprimary care) and FTE resident counts from the most recently settled cost reports of those teaching hospitals.

(C) If, under paragraph (e)(5)(i)(B)(1) or (e)(5)(i)(B)(2) of this section, there are fewer than three existing teaching hospitals with per resident amounts that can be used to calculate the weighted mean value per resident amount, for base periods beginning on or after October 1, 1997, the per resident amount equals the updated weighted mean value of per resident amounts of all hospitals located in the same census region as that term is used in § 412.62(f)(1)(i) of this chapter.

* * * * *

(g) *Determining the weighted number of FTE residents.* * * *

(5) For purposes of determining direct graduate medical education payment—

* * * * *

(iv) Hospitals that are part of the same affiliated group (as described under paragraph (b) of this section) may elect to apply the limit on an aggregate basis as described under paragraph (g)(7) of this section.

* * * * *

(7) A hospital may receive a temporary adjustment to its FTE cap, which is subject to the averaging rules under paragraph (g)(5)(iii) of this section, to reflect residents added or subtracted because the hospital is participating in an affiliated group (as defined under paragraph (b) of this section). Under this provision—

(i) Each hospital in the affiliated group must submit the affiliation agreement, as defined under paragraph (b) of this section, to the CMS fiscal intermediary servicing the hospital and send a copy to CMS's Central Office no later than July 1 of the residency

program year during which the affiliation agreement will be in effect.

(ii) There must be a rotation of a resident(s) among the hospitals participating in the affiliated group during the term of the affiliation agreement such that more than one of the hospitals count the proportionate amount of the time spent by the resident(s) in their FTE resident counts. No resident may be counted in the aggregate as more than one FTE.

(iii) The net effect of the adjustments (positive or negative) on the affiliated hospitals' aggregate FTE cap for each affiliation agreement must not exceed zero.

(iv) If the affiliation agreement terminates for any reason, the FTE cap of each hospital in the affiliated group will revert to the individual hospital's pre-affiliation FTE cap that is determined under the provisions of paragraph (g)(4) of this section.

* * * * *

PART 482—CONDITIONS FOR PARTICIPATION FOR HOSPITALS

D. Part 482 is amended as follows:

1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1320 and 1395hh).

2. Section 482.12 is amended by adding a new paragraph (f)(3), to read as follows:

§ 482.12 Condition of participation: Governing body.

* * * * *

(f) *Standard: Emergency services.*

* * *

(3) If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

E. Part 485 is amended as follows:

1. The authority citation for Part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Act (42 U.S.C. 1302 and 1396hh).

2. In § 485.645, the introductory text of paragraph (d) is republished and paragraph (d)(6) is revised, to read as follows.

§ 485.645 Special requirements for CAH providers of long-term care services (“swing-beds”).

* * * * *

(d) *SNF services.* The CAH is substantially in compliance with following SNF requirements contained in subpart B of part 483 of this chapter.

* * * * *

(6) Comprehensive assessment, comprehensive care plan, and discharge planning (§ 483.20(b), (k), and (l) of this chapter, except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under § 483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in § 413.343(b) of this chapter).

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

F. Part 489 is amended as follows:

1. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Act (42 U.S.C. 1302 and 1395hh).

2. Section 489.24 is amended by—

A. Revising paragraph (a).

B. Republishing the introductory text of paragraph (b) and revising the definitions of “Comes to the emergency department” and “Hospital with an emergency department”.

C. Adding definitions of “Dedicated emergency department”, “Hospital property”, and “Patient” in alphabetical order under paragraph (b).

D. Under the definition of “Emergency medical condition” under paragraph (b), redesignating paragraphs (i), (i)(A), (i)(B), (i)(C), (ii), (ii)(A), and (ii)(B) as paragraphs (1), (1)(i), (1)(ii), (1)(iii), (2), (2)(i), and (2)(ii), respectively.

E. Under the definition of “Participating hospital” under paragraph (b), redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively.

F. Under the definitions of “Stabilized” and “To stabilize” under paragraph (b), “paragraph (i)” is removed and “paragraph (1)” is added in its place; and “paragraph (ii)” is removed and “paragraph (2)” is added in its place.

G. Removing paragraph (i); and redesignating paragraph (c) through (h) as paragraphs (d) through (i), respectively.

H. Adding a new paragraph (c).

I. Revising newly redesignated paragraph (d).

J. Adding a new paragraph (j).

K. Making the following cross-reference changes:

- i. In redesignated paragraph (e)(1)(i), “paragraph (d)(2)” is removed and “paragraph (e)(2)” is added in its place.
- ii. In redesignated paragraph (e)(1)(ii)(C), “paragraph (d)(1)(ii)(B)” is removed and “paragraph (e)(1)(ii)(B)” is added in its place.
- iii. In redesignated paragraph (e)(2)(iii), “paragraph (d)(1)(i)” is removed and “paragraph (e)(1)(ii)” is added in its place.
- iv. In redesignated paragraph (e)(2)(iii), “paragraph (f)” is removed and “paragraph (g)” is added in its place.
- v. In redesignated paragraph (e)(3), “paragraph (d)(1)(ii)(C)” is removed and “paragraph (e)(1)(ii)(C)” is added in its place.
- vi. In redesignated paragraph (g), “paragraph (a) through (e)” is removed and “paragraphs (a) through (f)” is added in its place.
- vii. In redesignated paragraph (h)(1), “paragraph (g)(3)” is removed and “paragraph (h)(3)” is added in its place; and “paragraph (g)(2)(iv) and (v)” is removed and “paragraphs (h)(2)(iv) and (v)” is added in its place.
- viii. In redesignated paragraph (h)(2) introductory text, “paragraph (g)(1)” is removed and “paragraph (h)(1)” is added in its place.
- ix. In redesignated paragraph (h)(2)(iii)(B), “paragraph (g)(2)(iii)(A)” is removed and “paragraph (h)(2)(iii)(A)” is added in its place.
- x. In redesignated paragraph (h)(2)(vi), “paragraph (g)(2)(v)” is removed and “paragraph (h)(2)(v)” is added in its place.
- xi. In redesignated paragraph (h)(4), “paragraph (g)” is removed and “paragraph (h)” is added in its place; and “paragraph (g)(2)(v)” is removed and “paragraph (h)(2)(v)” is added in its place.

The additions and revisions read as follows:

§ 489.24 Special responsibilities of Medicare hospitals in emergency cases.

(a) *Application.* In the case of a hospital that has an emergency department, if an individual (whether or not eligible for Medicare benefits and regardless of ability to pay) “comes to the emergency department”, as defined in paragraph (b) of this section, the hospital must—

(1) Provide an appropriate medical screening examination within the capability of the hospital’s emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition

exists. The examination must be conducted by an individual(s) determined qualified by hospital bylaws or rules and regulations and who meet the requirements of § 482.55 of this chapter concerning emergency services personnel and direction; and

(2) If an emergency medical condition is determined to exist, provide any necessary stabilizing treatment, as defined in paragraph (d) of this section, or an appropriate transfer as defined in paragraph (e) of this section.

(b) *Definitions.* As used in this subpart—

* * * * *

Comes to the emergency department means, with respect to an individual who is not a patient, the individual—

(1) Has presented at a hospital’s dedicated emergency department, as defined in this section, and requests examination or treatment for a medical condition, or has such a request made on his or her behalf. In the absence of such a request by or on behalf of the individual, a request on behalf of the individual will be considered to exist if a prudent layperson observer would believe, based on the individual’s appearance or behavior, that the individual needs examination or treatment for a medical condition;

(2) Has presented on hospital property, as defined in this section, other than the dedicated emergency department, and requests examination or treatment for what may be an emergency medical condition, or has such a request made on his or her behalf (except for certain outpatients as specified in paragraph (d)(3) of this section). In the absence of such a request by or on behalf of the individual, a request on behalf of the individual will be considered to exist if a prudent layperson observer would believe, based on the individual’s appearance or behavior, that the individual needs emergency examination or treatment;

(3) Is in an ambulance owned and operated by the hospital for presentation for examination and treatment for a medical condition at a hospital’s dedicated emergency department, even if the ambulance is not on hospital grounds. This provision does not apply if the ambulance is operating under communitywide EMS protocols that direct it to transport the individual to a hospital other than the hospital that owns the ambulance; for example, to the nearest hospital. In this latter case, the individual is considered to have come to the emergency department of the hospital to which the individual is transported, at the time the individual is brought onto hospital property; or

(4) Is in a nonhospital-owned ambulance on hospital property for presentation for examination and treatment for a medical condition at a hospital’s dedicated emergency department. An individual in a nonhospital-owned ambulance off hospital property is not considered to have come to the hospital’s emergency department, even if a member of the ambulance staff contacts the hospital by telephone or telemetry communications and informs the hospital that they want to transport the individual to the hospital for examination and treatment. In the latter circumstance, the hospital may deny access if it is in “diversionary status,” that is, it does not have the staff or facilities to accept any additional emergency patients. If, however, the ambulance staff disregards the hospital’s instructions and transports the individual onto hospital property, the individual is considered to have come to the emergency department.

Dedicated emergency department means a specially equipped and staffed area of the hospital that is used a significant portion of the time for the initial evaluation and treatment of outpatients for emergency medical conditions, as defined in this section, and that is located—

- (1) On the main hospital campus; or
- (2) Off the main hospital campus and is treated by Medicare under § 413.65(b) of this chapter as a department of the hospital.

* * * * *

Hospital property means the entire main hospital campus as defined in § 413.65(b) of this chapter, including the parking lot, sidewalk, and driveway, but excluding other areas or structures that are located within 250 yards of the hospital’s main building but are not part of the hospital, such as physician offices, rural health centers, skilled nursing facilities, or other entities that participate separately under Medicare, or restaurants, shops, or other nonmedical facilities.

Hospital with an emergency department means a hospital that offers services for emergency medical conditions (as defined in this paragraph (b)) within its capability to do so, including a hospital that offers these services at locations other than its main hospital campus.

* * * * *

Patient, for purposes of this section, means an individual who is either an outpatient as defined in § 410.2 of this chapter, or is receiving inpatient hospital services as defined in § 409.10(b) of this chapter.

* * * * *

(c) *Use of dedicated emergency department for nonemergency services.* If an individual comes to a hospital's dedicated emergency department and a request is made on his or her behalf for examination or treatment for a medical condition, but the nature of the request makes it clear that the medical condition is not of an emergency nature, the hospital is required only to perform such screening as would be appropriate for any individual presenting in that manner, to determine that the individual does not have an emergency medical condition.

(d) *Necessary stabilizing treatment for emergency medical conditions.*—(1) *General.* If any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either—

(i) Within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition; or

(ii) For transfer of the individual to another medical facility in accordance with paragraph (e) of this section.

(2) *Application to inpatients—admitted emergency patients.*

(i) When an individual has been screened under paragraph (a) of this section and found to have an emergency medical condition, and the individual has not been stabilized as defined in paragraph (b) of this section, the provisions of this section would apply, even if the hospital admits the patient as an inpatient. Admitting an individual whose emergency medical condition has not been stabilized does not relieve the hospital of further responsibility to the individual under this section.

(ii) If a hospital admits an individual with an unstable emergency medical condition for stabilizing treatment, as an inpatient, stabilizes that individual's emergency medical condition, and this period of stability is documented by relevant clinical data in the individual's medical record, the hospital has satisfied its special responsibilities under this section with respect to that individual. If the patient is stable for a transfer of the type usually undertaken with respect to patients having the same medical conditions, the hospital's special responsibilities under this section are satisfied, even if no transfer occurs and the individual remains at the hospital as an inpatient for followup care. If, after stabilization, the individual who was admitted as an inpatient again has an apparent decline of his or her medical condition, either as a result of the injury or illness that

created the emergency for which he or she initially came to the dedicated emergency department or as a result of another injury or illness, the hospital must comply with the conditions of participation for hospitals under part 482 of this chapter but has no further responsibility under this section with respect to the individual.

(iii) A hospital has no responsibility under this section with respect to an inpatient who was admitted for elective (nonemergency) diagnosis or treatment. If such an inpatient has an abrupt deterioration of his or her medical condition after admission, the hospital must comply with the conditions of participation for hospitals under part 482 of this chapter and is not required to comply with the special responsibilities of this section.

(3) *Refusal to consent to treatment.* A hospital meets the requirements of paragraph (d)(1)(i) of this section with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) refuses to consent to the examination and treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of the person acting on his or her behalf). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

(4) *Delay in examination or treatment.* (i) A participating hospital may not delay providing an appropriate medical screening examination required under paragraph (a) of this section or further medical examination and treatment required under paragraphs (d)(1) and (d)(2) of this section in order to inquire about the individual's method of payment or insurance status.

(ii) A participating hospital may not seek, or direct a patient to seek, authorization from the individual's insurance company for screening or stabilization services to an individual until after the hospital has provided the appropriate medical screening examination required under paragraph (a) of this section, and initiated any further medical examination and treatment that may be required to stabilize the emergency medical

condition under paragraphs (d)(1) and (d)(2) of this section.

(iii) An emergency physician is not precluded from contacting the patient's physician at any time to seek advice regarding the patient's medical history and needs that may be relevant to the medical treatment and screening of the patient, as long as this consultation does not inappropriately delay services required under paragraph (a) or paragraphs (d)(1) and (d)(2) of this section.

(5) *Refusal to consent to transfer.* A hospital meets the requirements of paragraph (d)(1)(ii) of this section with respect to an individual if the hospital offers to transfer the individual to another medical facility in accordance with paragraph (e) of this section and informs the individual (or a person acting on his or her behalf) of the risks and benefits to the individual of the transfer, but the individual (or a person acting on the individual's behalf) refuses to consent to the transfer. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of a person acting on his or her behalf). The written document must indicate the person has been informed of the risks and benefits of the transfer and state the reasons for the individual's refusal. The medical record must contain a description of the proposed transfer that was refused by or on behalf of the individual.

(6) *Hospital responsibility for communication with Medicare+Choice organizations after stabilization of an emergency medical condition.* When an enrollee of a Medicare+Choice organization who is treated for an emergency medical condition is stabilized and needs further hospital care, the hospital must promptly contact the Medicare+Choice organization to obtain preapproval of the further hospital care, consistent with the provisions of § 422.113 of this chapter.

* * * * *

(j) *Availability of on-call physicians.* Each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients. Physicians, including specialists and subspecialists, are not required to be on call at all times. The hospital must have written policies and procedures in place to respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician's control.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: April 24, 2002.

Thomas A. Scully,
Administrator, Centers for Medicare &
Medicaid Services.

Dated: April 26, 2002.

Tommy G. Thompson,
Secretary.

[Editorial Note: The following Addendum and appendixes will not appear in the Code of Federal Regulations.]

Addendum—Proposed Schedule of Standardized Amounts Effective with Discharges Occurring On or After October 1, 2002 and Update Factors and Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning On or After October 1, 2002

I. Summary and Background

In this Addendum, we are setting forth the proposed amounts and factors for determining prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs. We are also setting forth proposed rate-of-increase percentages for updating the target amounts for hospitals and hospital units excluded from the acute care hospital inpatient prospective payment system.

For discharges occurring on or after October 1, 2002, except for SCHs, MDHs, and hospitals located in Puerto Rico, each hospital's payment per discharge under the acute care hospital inpatient prospective payment system will be based on 100 percent of the Federal national rate.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; or 75 percent of the updated hospital-specific rate based on FY 1996 costs per discharge, plus the greater of 25 percent of the updated FY 1982 or FY 1987 hospital-specific rate or 50 percent of the Federal DRG payment rate. Section 213 of Public Law 106-554 amended section 1886(b)(3) of the Act to allow all SCHs to rebase their hospital-specific rate based on their FY 1996 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever is higher.

For hospitals in Puerto Rico, the payment per discharge is based on the sum of 50 percent of a Puerto Rico rate and 50 percent of a Federal national rate. (See section II.D.3. of this Addendum for a complete description.)

As discussed below in section II. of this Addendum, we are proposing to make changes in the determination of the prospective payment rates for Medicare inpatient operating costs for FY 2003. The changes, to be applied prospectively effective

with discharges occurring on or after October 1, 2002, would affect the calculation of the Federal rates. In section III. of this Addendum, we discuss our proposed changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2003. Section IV. of this Addendum sets forth our proposed changes for determining the rate-of-increase limits for hospitals excluded from the prospective payment system for FY 2003. The tables to which we refer in the preamble to this final rule are presented at the end of this Addendum in section V.

II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for FY 2003

The basic methodology for determining prospective payment rates for hospital inpatient operating costs is set forth at § 412.63. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico is set forth at §§ 412.210 and 412.212. Below, we discuss the factors used for determining the prospective payment rates.

In summary, the proposed standardized amounts set forth in Tables 1A and 1C of section V. of this Addendum reflect—

- Updates of 2.75 percent for all areas (that is, the market basket percentage increase of 3.3 percent minus 0.55 percentage points);
- An adjustment to ensure the proposed DRG recalibration and wage index update and changes are budget neutral, as provided for under sections 1886(d)(4)(C)(iii) and (d)(3)(E) of the Act, by applying new budget neutrality adjustment factors to the large urban and other standardized amounts;
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for in section 1886(d)(8)(D) of the Act, by removing the FY 2002 budget neutrality factor and applying a revised factor;
- An adjustment to apply the new outlier offset by removing the FY 2002 outlier offsets and applying a new offset; and
- An adjustment in the Puerto Rico standardized amounts to reflect the application of a Puerto Rico-specific wage index.

A. Calculation of Adjusted Standardized Amounts

1. Standardization of Base-Year Costs or Target Amounts

Section 1886(d)(2)(A) of the Act required the establishment of base-year cost data containing allowable operating costs per discharge of inpatient hospital services for each hospital. The preamble to the September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data were established in the initial development of standardized amounts for the acute care hospital inpatient prospective payment system.

Section 1886(d)(9)(B)(i) of the Act required us to determine the Medicare target amounts for each hospital located in Puerto Rico for its cost reporting period beginning in FY 1987. The September 1, 1987 final rule (52 FR 33043, 33066) contains a detailed

explanation of how the target amounts were determined and how they are used in computing the Puerto Rico rates.

The standardized amounts are based on per discharge averages of adjusted hospital costs from a base period or, for Puerto Rico, adjusted target amounts from a base period, updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. Sections 1886(d)(2)(B) and (d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, indirect medical education costs, and costs to hospitals serving a disproportionate share of low-income patients.

Under sections 1886(d)(2)(H) and (d)(3)(E) of the Act, in making payments under the acute care hospital inpatient prospective payment system, the Secretary estimates from time to time the proportion of costs that are wages and wage-related costs. Since October 1, 1997, when the market basket was last revised, we have considered 71.1 percent of costs to be labor-related for purposes of the acute care hospital inpatient prospective payment system. As discussed in section IV. of the preamble to this proposed rule, we are proposing to revise the labor share of the standardized amount (the proportion adjusted by the wage index) to be 72.5 percent. The average labor share in Puerto Rico is 71.3 percent. We are proposing to revise the discharge-weighted national standardized amount for Puerto Rico to reflect the proportion of discharges in large urban and other areas from the FY 2001 MedPAR file.

2. Computing Large Urban and Other Area Averages

Sections 1886(d)(2)(D) and (d)(3) of the Act require the Secretary to compute two average standardized amounts for discharges occurring in a fiscal year: one for hospitals located in large urban areas and one for hospitals located in other areas. In addition, under sections 1886(d)(9)(B)(iii) and (d)(9)(C)(i) of the Act, the average standardized amount per discharge must be determined for hospitals located in large urban and other areas in Puerto Rico. Hospitals in Puerto Rico are paid a blend of 50 percent of the applicable Puerto Rico standardized amount and 50 percent of a national standardized payment amount.

Section 1886(d)(2)(D) of the Act defines "urban area" as those areas within a Metropolitan Statistical Area (MSA). A "large urban area" is defined as an urban area with a population of more than 1 million. In addition, section 4009(i) of Public Law 100-203 provides that a New England County Metropolitan Area (NECMA) with a population of more than 970,000 is classified as a large urban area. As required by section 1886(d)(2)(D) of the Act, population size is determined by the Secretary based on the latest population data published by the Bureau of the Census. Urban areas that do not meet the definition of a "large urban area" are referred to as "other urban areas." Areas