

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 413, 482, and 489**

[CMS-1063-F]

RIN 0938-AM34**Medicare Program; Clarifying Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals With Emergency Medical Conditions****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: This final rule clarifies policies relating to the responsibilities of Medicare-participating hospitals in treating individuals with emergency medical conditions who present to a hospital under the provisions of the Emergency Medical Treatment and Labor Act (EMTALA).

The final rule responds to public comments received on a May 9, 2002 proposed rule (67 FR 31404) that both reiterated the agency's interpretations under EMTALA and proposed clarifying changes relating to the implementation of the EMTALA provisions. These reiterations and clarifying changes related to, among other areas, seeking prior authorization from insurers for services, emergency patients presenting at off-campus outpatient clinics that do not routinely provide emergency services, the applicability of the EMTALA provisions to hospital inpatients and outpatients, the circumstances under which physicians must serve on hospital medical staff "on-call" lists, and the responsibilities of hospital-owned ambulances.

These reiterations and clarifying changes are needed to ensure uniform and consistent application of policy and to avoid any misunderstanding of EMTALA requirements by individuals, physicians, or hospital employees.

DATES: The provisions of this final rule are effective on November 10, 2003.

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I. Background

Sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867 of the Social Security Act (the Act) impose specific obligations on Medicare-participating hospitals and critical access hospitals (CAHs) that offer emergency services. (Throughout this final rule, when we reference the obligation of a “hospital” under these sections of the Act and in our regulations, we mean to include CAHs as well.) These obligations concern individuals who come to a hospital emergency department and request examination or treatment for medical conditions, and apply to all of these individuals, regardless of whether or not they are beneficiaries of any program under the Act. Section 1867 of the Act sets forth requirements for medical screening examinations for medical conditions, as well as necessary stabilizing treatment or appropriate transfer. In addition, section 1867(h) of the Act specifically prohibits a delay in providing required screening or stabilization services in order to inquire about the individual’s payment method or insurance status. Section 1867(d) of the Act provides for the imposition of civil monetary penalties on hospitals and physicians responsible for the following: (a) Negligently failing to

appropriately screen an individual seeking medical care; (b) negligently failing to provide stabilizing treatment to an individual with an emergency medical condition; or (c) negligently transferring an individual 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 individual 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 1985 (COBRA). 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 individuals with emergency conditions if the individuals 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 [or her] behalf) to determine whether an emergency medical condition exists or if the patient is in active labor.” (H.R. Rept. No. 99-241, Part I, 99th Cong., 1st Sess. (1985), p.27.)

In addition, section 1867(d)(2) of the Act provides for a private right of enforcement for any individual who is harmed as a “direct result” of a violation of the Act. In enacting this section of the law, Congress did not intend for the statute to be used as a Federal malpractice statute. Indeed, many courts are in agreement that

EMTALA is not a Federal malpractice statute (for example, *Bryan v. Rectors and Visitors of University of Virginia*, 95 F.3d 349, 351 (4th Cir. 1996); *Lopez-Soto v. Hawayek*, 175 F.3d 170, 177 (1st Cir. 1999); and *Baker v. Adventist Health, Inc.*, 260 F.3d 987, 994 (3rd Cir. 2001)).

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

- 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 (a))

- Defines certain terms, including “comes to the emergency department,” “emergency medical condition,” “stabilized,” and “to stabilize.” (Paragraph (b))

- Addresses procedures a hospital must follow when it determines, with respect to a patient, 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 individual. If the hospital does not have the capabilities to stabilize the individual, an appropriate transfer to another facility is permitted. (Paragraph (c)) A transfer is appropriate when the medical benefits of the transfer outweigh the medical risks of the transfer and other requirements, specified in the regulations, are met. (Paragraph (d)) In addition, the hospital may transfer an unstable patient who makes an informed written request. A hospital may not delay an appropriate medical screening examination, or further examination or treatment, to inquire about the patient’s payment method or insurance status. (Paragraph (c))

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 Quality Improvement Organizations (QIOs). (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 whom it has reason to believe may have been transferred inappropriately; to post signs in the emergency department describing an individual'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 changing 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 (both under the statute and under the common law) 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 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. Therefore, in a proposed rule published in the **Federal Register** on May 9, 2002 as part of the annual proposed rules for the acute care hospital inpatient prospective payment system (67 FR 31469), we solicited comments from hospitals, physicians, patients, and beneficiary groups on certain proposed changes to the EMTALA policies as discussed in sections III. through XIV. of this preamble.

II. Special Advisory Bulletin on EMTALA Obligations

On November 10, 1999, CMS (then HCFA) and the Office of the Inspector General (OIG) published jointly in the **Federal Register** a Special Advisory Bulletin addressing the requirements of the EMTALA statute and the obligations of hospitals to medically screen all individuals seeking emergency services and to provide stabilizing medical treatment as necessary to all individuals, 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 did not amend the Code of Federal Regulations, the Special Advisory Bulletin informs individuals of HHS policy regarding application of the EMTALA 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. of this preamble, in the May 9, 2002 proposed rule, we proposed 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.

III. Summary of the Provisions of the May 9, 2002 Proposed Rule Relating to EMTALA and Hospital Responsibility for Communication With Medicare+Choice Organizations Concerning Post-Stabilization Care Services

A. Summary of the Proposed Provisions Relating to EMTALA

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 where individuals have been admitted as inpatients without being stabilized, or patients who had been stabilized later experience a deterioration in their medical condition. Some hospitals are uncertain about whether various conditions of participation (CoPs) 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 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-participating hospitals in

emergency cases, in the May 9, 2002 proposed rule (67 FR 31469), we proposed changes to § 489.24 to clarify its application in 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 proposed to change the requirements relating to individuals who present with what may be emergency medical conditions at off-campus outpatient clinics and facilities that do not routinely provide emergency medical services. We believe these changes will enhance the quality and promptness of emergency care by permitting individuals to be referred to appropriately equipped emergency facilities close to such clinics, rather than being transported to the main campus emergency department, which may be located at a greater distance from the clinic.

- We proposed to clarify the extent to which EMTALA applies to inpatients and outpatients. We believe these clarifications will enhance understanding for hospitals as to what their obligations are under EMTALA, so that they more clearly understand to whom they are obligated under this provision of the statute, and whose care will be governed by the Medicare hospital CoPs.

- We proposed to clarify the circumstances in which physicians, particularly specialty physicians, must serve on hospital medical staff "on-call" lists. We expect these clarifications will 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. We proposed clarification of the on-call list requirements to permit hospitals to continue to attract physicians to serve on their medical staffs and thereby continue to provide services to emergency room patients.

- We proposed 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.

In the May 9, 2002 proposed rule, we specifically solicited comments on all of these proposed changes. In response to the proposed rule, we received approximately 600 pieces of correspondence, most of which contained multiple comments. A large number of these comments were received on the last day of the comment period for the proposed rule (July 8, 2002). Because of the number and nature of the public comments we received on our proposed clarifications and our limited timeframe for developing the final acute care hospital inpatient prospective payment system regulations for publication by the statutory deadline of August 1, we decided, with one exception (application of the EMTALA provisions to provider-based entities), to address the public comments and finalize the proposed clarifications relating to implementation of EMTALA in a separate document. This final rule is that separate document.

In the next several sections of the preamble of this final rule, we summarize the public comments received on the proposed EMTALA clarifications and present our responses to those comments, including any further revisions that we are making in this final rule to the proposed regulation changes as a result of these comments.

B. Summary of the Proposed Provisions Relating to Communication with Medicare+Choice Organizations Concerning Post-Stabilization Care Services

In the May 9, 2002 proposed rule (67 FR 31471), we proposed 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 (proposed § 489.24(d)(6)). We received a number of public comments on this proposed provision. However, we are not addressing public comments received on this provision in this final rule but plan to address them in future policy guidance.

IV. General Comments on the Proposed Rule

Comment: Some commenters expressed overall support for our proposed clarifying changes to establish more flexible standards on EMTALA, but did not offer specific recommendations for modifying them. However, one commenter, the administrator of a small rural hospital in the Midwest, expressed concern that our

proposals appear to represent a shift from national requirements to community-based standards, under which the level of emergency care available in a community would be determined by the medical staffs of individual hospitals. This commenter stated that, in many cases, it is possible to continue to maintain emergency department services in the local community only because of the pressure exerted on physicians by EMTALA to continue to see patients in the emergency department. Therefore, the commenter recommended that any changes in EMTALA regulatory requirements be directed to making those requirements more stringent and specific and stated that relaxing EMTALA requirements as proposed will only undermine the efforts of small rural hospitals to maintain viable emergency services for their patients.

Response: We appreciate the commenters' support, and have kept their views in mind in considering the comments of those respondents who recommended revisions. In regard to the commenter's recommendations that we make the EMTALA requirements more stringent (rather than relaxing them) for the benefit of small rural hospitals, we note that we received many comments expressing concern that the current requirements may be too burdensome, and therefore, the commenters recommended more flexible EMTALA rules. We considered all of the comments received when finalizing our policy.

V. Prior Authorization (§ 489.24(d)(4))

A. Provisions of the Proposed Rule

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 existing regulations 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 a hospital's actions in seeking prior authorization from an insurer could result in a delay in the provision of services required by EMTALA. Our existing policy prohibits 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 individual and has initiated any further medical examination and treatment that may be required to stabilize the patient's emergency medical condition.

In the May 9, 2002 proposed rule, we solicited public comments as to whether the regulations should be 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 (67 FR 31471).

In addition, we proposed to clarify that an emergency physician is not precluded from contacting the patient's physician at any time to seek advice or information 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 services or stabilizing treatment.

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

B. Summary of Public Comments and Departmental Responses

1. General Comments

Comment: Several commenters expressed general approval of our proposals without recommending more specific changes.

Response: We appreciate the commenters' support of the proposals and have taken their views into account in considering the comments of those respondents who recommended revisions.

2. Concurrent Authorization and Furnishing of Stabilizing Services

Comment: Two commenters recommended that we delete any reference to seeking authorization for post-stabilization services concurrently with the provision of stabilizing treatment. The commenters believed clinical staff cannot easily distinguish between screening services and stabilizing treatment, and thus may be uncertain as to when stabilizing treatment has begun in order to seek authorization for the services. Another

commenter believed that allowing such concurrent authorization serves no useful purpose and leaves the hospital open to charges that the steps taken to obtain concurrent authorization actually delay stabilization services. This commenter also recommended that the regulations not allow the concurrent authorization of stabilizing treatment and the furnishing of actual stabilizing treatment.

Response: We recognize that the distinction between screening services and stabilizing treatment may be difficult to define outside the context of a specific case. However, we believe clinicians will be able, when dealing with a particular patient or case, to identify clearly when the assessment of an individual has concluded and they have begun stabilizing the patient with an emergency medical condition. We expect that these clinical judgments will be the basis for determining when contact will be appropriate, and that surveyors will use their own clinical training and experience in evaluating clinicians' actions.

Regarding the comment that authorization serves no useful purpose, we note that the regulation merely permits, but does not require, hospitals to seek concurrent authorization with the furnishing of stabilizing treatment. We do not believe it is appropriate to prohibit the practice in all cases and, therefore, are not making any revision to the proposed language, which we are adopting in this final rule, based on this comment.

We would like to clarify again that hospitals that choose to seek concurrent authorization while administering stabilizing treatment must not delay such treatment in order to obtain authorization. Even if the approving insurer or physician denies authorization for the stabilizing treatment, the hospital is *obligated* under EMTALA to provide the necessary stabilizing treatment (if the hospital has such capabilities).

Comment: Some commenters stated that restrictions on contact with a patient's insurer are not appropriate because a hospital's administrative staff might not be fully aware of the status of an individual's treatment (that is, whether a screening has occurred and stabilizing treatment has been initiated) and that a hospital might, therefore, violate this requirement inadvertently by requesting authorization prematurely, even though no delay in the screening or stabilization actually occurs.

Response: We recognize the possibility pointed out by the commenter, but believe that hospitals

will be able to develop procedures to alert administrative staff as to when contact may be initiated.

3. Authorization Requests by Nonphysician Practitioners

Comment: Five commenters recommended that we state more specifically that CMS' policies on prior authorization apply to authorization for both hospital and physician (and nonphysician practitioner) services. In addition, the commenters recommended that the regulations be revised to clarify whether EMTALA policies also apply to emergency medical or stabilizing services furnished by nonphysician practitioners.

A number of commenters recommended that the regulations be revised to state that nurse practitioners and all other medical or hospital personnel involved in the individual's treatment, and not just emergency physicians, are permitted to contact the patient's physician for information and advice relevant to the patient's medical history and needs, as long as screening services or stabilizing treatment are not inappropriately delayed.

Another commenter recommended a change in the wording of proposed § 489.24(d)(4)(iii) regarding contacts between emergency physicians and individuals' personal physicians. The commenter believed that the regulations should also allow such contacts with the individual's physician to be initiated by a qualified medical person other than a physician, such as a physician assistant or nurse practitioner.

Response: We agree with the commenters that the prior authorization policies apply equally to hospital services, physician services, and nonphysician practitioner services, and are revising § 489.24(d)(4)(ii) to clarify this point. We also agree that qualified medical personnel other than physicians, such as nonphysician practitioners (physician assistants and nurse practitioners), should be permitted to initiate such contacts, and are revising § 489.24(d)(4)(iii) in this final rule accordingly.

Comment: A number of commenters recommended that the final rule be revised to state that concurrent contact with an individual's insurer (that is, contact undertaken by administrative staff not involved in patient screening or treatment that occurs while clinical staff continue to screen the individual) is not a violation of EMTALA as long as it does not delay screening or stabilization.

Response: We recognize that section 1867(h) of the Act states only that a

hospital may not delay an EMTALA screening or stabilization in order to inquire about the individual's method of payment or insurance status, and does not specifically address the issue of when it is appropriate for contact with the individual's insurer to be made. Hospitals have in the past expressed a need for further guidance on the agency's policy in this area and the Special Advisory Bulletin cited earlier was developed to provide guidance on this and other issues. We do not wish to be overly prescriptive on this issue, but do believe that hospitals should have a clear statement of the agency's policy and that the policy should strike a reasonable balance between the need to avoid creating circumstances in which screening or stabilization will be likely to be delayed and the equally important need to protect the individual from avoidable liability for the costs of emergency health care services. We believe the policy in the Special Advisory Bulletin and reiterated in proposed rule strikes that balance. Therefore, we are not adopting the commenters' suggestion.

Further, we note that many insurers now provide a "window" of at least 24 hours following emergency department treatment during which authorization can be obtained. In addition, many States have enacted revisions to their insurance statutes over the past several years that explicitly contemplate the existence of the Federal EMTALA statute. As a practical matter, we believe this feature of private insurance contracts, as well as State laws governing health insurance contracts, will allow screening and stabilization to go forward without compromising the individual's rights to have care covered under his or her health plan.

4. Medical Staff Communications

Comment: Two commenters objected to the proposed language under which contact by an emergency physician with the individual's physician is not prohibited as long as the consultation does not inappropriately delay EMTALA-mandated screening or stabilization. One commenter stated that it is never appropriate for regulations to restrict physicians' communications with one another. The other commenter stated that section 1867(h) of the Act governs only contacts for the purpose of insurance information and does not relate in any way to contact with the individual's physician. The commenter believed the proposed language at § 489.24(d)(4)(iii) should be deleted because, in the commenter's view, it implies that some contacts with individuals' physicians might be

prohibited by EMTALA, and that making such contacts therefore could expose the hospital or the emergency physician to sanctions.

Response: We agree that physician communication regarding patient medical status and information is essential. We expect the regulations will dispel any possible concerns about the appropriateness of this communication. Therefore, we do not believe it is necessary to make any change in the regulations in this final rule based on this comment.

Comment: Two commenters stated that the proposed language regarding contact with the patient's physician not being prohibited as long as the consultation does not inappropriately delay EMTALA-mandated screening or stabilization is unclear, and recommended that it be revised to state that such contact is not inappropriate as long as it does not otherwise delay the start of the medical screening examination.

Response: We do not believe the language as proposed is less clear than the commenters' recommended alternative. The commenters' alternative could suggest instead that delays in stabilizing treatment would be acceptable. Therefore, we are not adopting the recommendation of the commenters.

Comment: One commenter suggested that CMS clarify the proposed regulatory language by citing lists of appropriate referral physicians or participating providers as examples of the types of information that may appropriately be obtained as long as prior authorization is not sought.

Response: We agree that it would not be inappropriate to discuss the types of information the commenter cited with the patient's attending physician. However, we do not believe these types of information are representative samples of the types of information that such contacts should elicit. Therefore, we are not making any change in the final rule based on this comment.

5. Out-of Network Coverage

Comment: Some commenters stated that they understood the need to avoid delaying EMTALA screening or stabilization to obtain prior authorization, but suggested that, if such authorization is not obtained, patients might be left with substantial financial responsibility. The commenters noted that individuals may request information about the costs of services while awaiting a screening examination. They stated that, while it is important to avoid even the appearance of coercion of an individual to leave the

emergency department, it is also important to recognize the patient's right to be informed of potential financial liability for services (including increased liability for out-of-network services) before, rather than after, the services are furnished. These commenters recommended that the regulations be revised to state that a hospital may request financial or coverage information as long as doing so does not delay screening or stabilization. The commenters also recommended that we state that there may be discussion of the limits of an individual's health insurance coverage if the individual asks about the charges for the emergency department visit.

Response: As noted in the Special Advisory Bulletin cited earlier (64 FR 61355), current Interpretive Guidelines indicate that hospitals may continue to follow reasonable registration processes for individuals presenting with an emergency medical condition. Reasonable registration processes may include asking whether an individual is insured and, if so, what that insurance is, as long as that inquiry does not delay screening or treatment. Reasonable registration processes should not unduly discourage individuals from remaining for further evaluation. As requested by the commenter, in this final rule, we are revising proposed § 489.24(d)(4) by adding a new paragraph (iv) to clarify this policy. To avoid any misunderstanding of the requirement, we have revised the language of the interpretive guidelines to state that reasonable registration processes must not unduly discourage individuals from remaining for further evaluation.

Regarding a hospital's response to an individual's inquiry about financial liability for emergency services, the Special Advisory Bulletin states that any such inquiry should be answered by a staff member who is well-trained and knowledgeable and that the staff member should explain to the individual that, regardless of the individual's ability to pay, the hospital stands ready and willing to provide any necessary screening or stabilization services or both. Staff should encourage the individual to defer further discussion of financial responsibility issues, if possible, until after any necessary screening has been performed. We do not believe that this explanation needs to be included in the regulations.

Comment: One commenter suggested that, in the interest of avoiding any appearance that an individual's screening or stabilization may have been influenced by the individual's perceived

ability or inability to pay, financial information collected by registration or billing staff should not be included in the patient chart that goes back to the clinical staff who are caring for the individual.

Response: We agree that such a procedure could help avoid the perception of improper financially based influences on screening or treatment decisions. We do not believe it is necessary to revise the final rule to require that such information be excluded from the patient's chart.

C. Provisions of the Final Rule on Prior Authorizations

In summary, we are adopting the proposed changes relating to prior authorization for necessary stabilizing treatment for emergency medical conditions under § 489.24(d)(4) as final, with the following modification:

We are revising paragraph (d)(4)(ii) to indicate that prior authorization policies apply to services furnished by a hospital, a physician, or a nonphysician practitioner.

We are revising paragraph (d)(4)(iii) to specify that an emergency physician as well as any nonphysician practitioner involved in the emergency treatment is not precluded from contacting the individual's physician at any time to seek advice regarding the individual's medical history as long as the consultation does not delay screening and stabilizing services.

We are adding a new paragraph (d)(4)(iv) to specify that hospitals may follow reasonable registration processes for individuals for whom examination or treatment is required under EMTALA, as long as the procedures do not result in a delay in screening or treatment.

VI. Clarification of "Comes to the Emergency Department" (§ 489.24(a) and (b))

A. Background

Section 1867(a) of the Act and our existing 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. Section 1867(b) of the Act and our existing regulations at § 489.24(c) provide, in part, that 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 an individual comes to a hospital, but does not present to the hospital's emergency department.

B. Provisions of the Proposed Rule

In the May 9, 2002 proposed rule (67 FR 31472), we proposed to consolidate the EMTALA requirements for screening (currently in § 489.24(a)) and for stabilization or appropriate transfer (currently in § 489.24(c)) into a single revised paragraph (a). This consolidation was not intended to change the substance of the requirements, but only to set forth more concisely, in a single opening paragraph, the essential requirements of EMTALA. In proposed paragraph (b), we proposed to clarify the criteria for determining under what conditions a hospital is obligated by EMTALA to screen and, if necessary, stabilize or transfer an individual who comes to a hospital, presenting either at its dedicated emergency department, as we proposed to define, or elsewhere on hospital property, and requests examination or treatment, or has such a request made on his or her behalf.

In developing the proposed criteria, we recognized that 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. In recognition of this possibility, and for other reasons explained in the preamble to the proposed rule (including the need to assure that an individual is not denied services simply because he or she failed to actually enter the hospital's designated emergency department), we proposed to clarify under proposed § 489.24(b) that 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 we proposed to define that term) 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 they believe to 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 proposed to define "dedicated emergency department." We proposed that "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 proposed 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 the 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, if these departments provide emergency psychiatric 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.)

In the May 9, 2002 proposed rule, we solicited public comments on whether this proposed definition should more explicitly define what is a "dedicated emergency department" (67 FR 31472). Specifically, we sought comments on whether a "significant portion of time" should be defined more objectively; for example, in terms of some minimum number or minimum percent 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 proposed considering a qualifying criterion that is based on determining whether the facility is used "regularly" for the evaluation or treatment of emergency medical conditions, and how we could define "regularly." We further sought

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.

C. Summary of Public Comments and Departmental Responses

1. General Support

Comment: Many commenters supported our proposed revised definition of "dedicated emergency department." The commenters believed the proposed revised definition is clear and did not need to be further revised.

Response: We appreciate the support of the commenters and have taken their views into account in considering the comments of those respondents who recommended revisions.

2. Objective Test of "Significant Portion of the Time"

Comment: Some commenters believed that an objective test (such as a percentage of emergency patients seen or treated for emergency medical conditions) to determine dedicated emergency department status would reduce confusion in the provider industry. Several other commenters stated that while a finite, objective test, such as a standard of 20, 30, 40 percent or more of all patients seen, would be desirable because of the certainty and consistency it would provide in determining a "significant portion of the time" for purposes of "dedicated emergency department" determination, the commenters believed the percentages cited by us are too low.

One commenter asked us to clarify what is meant by patients who "seek emergency care" in our discussion of whether "significant portion of the time" should be defined more objectively. For instance, the commenter stated the view that while many patients present for immediate care of nonemergency problems (and these patients must be screened for an emergency under EMTALA regulations), they should not be counted in determining whether a department is considered a dedicated emergency department.

Response: After consideration of these comments and the following related comments in this section VII.C. of this preamble, we believe that providing an objective criterion as part of the definition of "dedicated emergency department" for purposes of EMTALA will provide predictability and consistency to the health care industry, as the commenters suggest. Therefore, as

one part of the definition of "dedicated emergency department," as described in more detail below, we are specifying in this final rule that a department or facility that does not otherwise qualify as a "dedicated emergency department" based on State licensure or the way it is held out to the public will nevertheless be considered to be a dedicated emergency department if, during the calendar year immediately preceding the calendar year in which a determination is being made, based on a representative sample of patient visits that occurred during that calendar year, the department or facility provided at least one-third of all its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment. We adopted this definition because we believe it adds the element of objectivity requested by many commenters and thus enables hospitals to know in advance whether they will be subject to EMTALA. We included a reference to a "representative sample" of visits for two reasons. First, we believe any determination under this definition must be based on information that accurately represents the type and mix of services delivered by the department or facility over a period of time, not merely during certain parts of the year. However, we also recognize that the large number of visits provided by some departments or facilities will make it a practical necessity to sampling techniques to obtain information on the type of care furnished instead of attempting to review all records of all visits by all patients during a year. Therefore, we intend to issue instructions, through interpretative guidelines, to our surveyors on how to determine such a representative sample. In addition, we may develop a series of questions and answers for posting on our website that will provide further clarification and guidance to providers.

In response to the comment regarding visits for the care of nonemergency problems, we agree that such visits should not normally be counted as being for the treatment of emergency medical conditions. However, as discussed in section VIII. of this preamble, individuals who suffer an unexpected emergency medical condition after they arrive at the hospital for an outpatient visit but before they begin an outpatient encounter and individuals whose appearance or behavior would cause a prudent layperson observer to believe they need examination or treatment for an emergency medical condition would

be counted toward the "one-third" standard.

Comment: One commenter recommended that we use the term "regularly" instead of "a significant portion of the time" in the definition of dedicated emergency department. The commenter opposed the use of additional qualifying criteria (percentages) to determine whether a facility is used "regularly" for the evaluation and treatment of emergency medical conditions and believed that hospitals should have maximum flexibility to determine which part of their facility is appropriate for the delivery of emergency care.

Response: As explained in the response to the previous comment, we believe that an objective criterion relating to the percentage of visits for the treatment of emergency medical conditions, such as the one we are including in this final rule for purposes of EMTALA, provides needed predictability for those who are determining dedicated emergency department status. In addition, we believe this objective criterion in the definition of dedicated emergency department, along with the other two criteria in the definition in this final rule, provides the most flexibility for determining dedicated emergency department status, as the commenter suggested.

Comment: One commenter suggested that we not include an objective standard of "significant portion of the time" for the determination of a hospital's "dedicated emergency department." The commenter believed that an objective standard for "significant" may have the unintended effect of creating a benchmark that some providers might use to avoid their EMTALA obligations. For example, the commenter stated, if the standard for "significant portion of the time" is set at 30 percent, a hospital's labor and delivery department may determine that its staff spend only 15 percent of their time evaluating and treating outpatients who meet the regulatory definition of emergency medical condition. The commenter stated that if the majority of the staff's time is spent caring for inpatients in active labor, such a hospital may then decide that its labor and delivery department no longer has to provide an emergency medical screening examination to all women who present with contractions, since the department does not meet the objective criteria of being used a significant portion of the time for the initial evaluation and treatment for emergency medical conditions.

Another commenter did not support the percentage-based definition of dedicated emergency department proposed because the commenter believed "it potentially could result in a patient having or not having EMTALA protections based on a fraction of a percentage point and dependent on the accounting method chosen to determine volume." Also, the commenter believed that volumes fluctuate by days, weeks, and months, among other things. The commenter stated that fluctuating volume could potentially cause an area or department to move in and out of EMTALA coverage as the volume fluctuates.

Response: We agree with the commenters that using objective criteria in the determination of a hospital's dedicated emergency department may lead to some cases in which the standard is exceeded or not met by a narrow margin. However, this result is an unavoidable consequence of any objective standard. By assessing a facility's performance over a calendar year, we believe that the effects of seasonal or other variations in utilization will be mitigated.

In response to the comment concerning labor and delivery departments, we would like to clarify that CMS believes that EMTALA requires that a hospital's dedicated emergency department would not only encompass 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, to individuals who may present as unscheduled ambulatory patients but are routinely admitted to be evaluated and treated. Because labor is a condition defined by statute as one in which EMTALA protections are afforded, any area of the hospital that offers such medical services to treat individuals in labor to at least one-third of the ambulatory individuals who present to the area for care, even if the hospital's practice is to admit such individuals as inpatients rather than treating them on an outpatient basis, *would* be considered a dedicated emergency department under our revised definition in this final rule. In such cases, whether the department of the hospital chooses to directly admit the emergency patient upon presentation is irrelevant to the determination of whether the department is a dedicated emergency department.

3. Nature of Care

Comment: Some commenters believed that the amount of time a facility is used for emergency screening and treatment is not relevant, and that it is the “nature of the care provided” that distinguishes it as a dedicated emergency department.

Response: We appreciate the comment concerning the “nature of the care provided” as determinative of meeting the definition of “dedicated emergency department” rather than the amount of time a facility is used for emergency screening and treatment. However, if we used the suggested language of “nature of the care provided” as the standard for determining “dedicated emergency department” status, we believe that treatment for one emergency case by one hospital clinic would meet the suggested standard. We believe that the suggested standard is too general in its reach and would encompass too many departments of hospitals. Therefore, we are not adopting the commenters’ proposed language.

4. State Law Criterion

Comment: Several commenters suggested that “dedicated emergency department” status should be determined by State law in the State in which the hospital is located. Another commenter suggested that we define “dedicated emergency department” as any facility licensed by the State in which it is situated as an emergency department. The commenter stated that this would avoid the confusion as to whether urgent care or walk-in clinics do or do not devote a “significant portion of time” to the provision of emergency services.

Response: As explained under section VII.D. of this preamble, based on consideration of all of the comments received, in this final rule we are revising the proposed definition of “dedicated emergency department” to state that a facility licensed by the State as an emergency department will be recognized as such under Federal EMTALA rules. However, because of the variations in State licensure laws, we do not agree that *only* facilities that are licensed as emergency departments by the State should be considered dedicated emergency departments for purposes of EMTALA, and have therefore included other criteria for dedicated emergency department status, as specified in this final rule.

5. Held Out to the Public Standard

Comment: Many commenters agreed with statements in the preamble of the proposed rule to the effect that a “held

out to the public standard” is appropriate for determining “dedicated emergency department” status. One commenter specifically suggested that a “dedicated emergency department” should be defined as “the department of a hospital that is held out to the public as the appropriate place to go for the examination and treatment of emergency medical conditions as defined in this section.”

Similarly, another commenter stated that a “24/7” rule with routine emergency care may be more appropriate to designating a “dedicated emergency department” rather than our proposal of tracking patients and developing some minimum percentage of emergency patients. The commenter stated that if the area is not open and staffed on a continuous basis, and it is not held out to the public as such, then it should *not* be considered a dedicated emergency department.

Response: As explained in section VI.D. of this preamble, we are revising the proposed definition of “dedicated emergency department” in several areas. In the revised definition of dedicated emergency department that we are adopting in this final rule, we state that a department or facility that is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment will be considered to be a dedicated emergency department. Consistent with what we have stated above, we believe that most provider-based urgent care centers that are held out to the public as such will meet the revised definition of dedicated emergency department for purposes of EMTALA.

6. Labor and Delivery Departments and Psychiatric Units

Comment: Several commenters addressed our clarification in the preamble of the proposed rule at 67 FR 31472 that other types of hospital departments, such as labor and delivery and psychiatric units, could qualify as a dedicated emergency department for purposes of EMTALA under our proposed definition.

One commenter stated that if a hospital has a department held out to the public as the place to go for a labor or psychiatric emergency medical condition, that department should fall under the definition of “dedicated emergency department” for purposes of EMTALA.

Two commenters stated that it was unclear which of the EMTALA requirements (such as the EMTALA log

would apply to the labor and delivery unit and the psychiatric unit that meet the definition of “dedicated emergency department.” In addition, these commenters asked whether EMTALA would apply to all patients who present to these locations or only to obstetrical and psychiatric patients who present under orders of their physicians at the locations.

Response: As explained further below, under the revised definition in this final rule, departments of the hospital will be considered to be “dedicated emergency departments” if they are held out to the public as places that provide care for emergency medical conditions on an urgent, nonappointment basis. These departments will be subject to EMTALA requirements applicable to dedicated emergency departments, including requirements related to maintenance of an emergency department log and on-call requirements. Individuals who present at these locations and request examination or treatment for a medical condition or have such a request made on their behalf must be screened under EMTALA and, if an emergency medical condition is determined to exist, provided necessary stabilizing treatment, because these locations are dedicated emergency departments.

We note that the dedicated emergency department to which an individual presents does not necessarily have to be the one to do EMTALA screening and stabilization. For example, if a man with cold symptoms or another medical condition were to seek treatment in the obstetrics and gynecology department rather than the general emergency department, this presentation would create an EMTALA obligation for the hospital, but the hospital would not be prohibited from transporting the individual to its general emergency department for screening and stabilization if that action were medically indicated.

7. Use of Arizona State Bill Language Defining Freestanding Urgent Care Center

Comment: One commenter cited language of a State bill (Arizona SB1098 (1999)) that, if enacted, would amend the Arizona State statutes to create standards in Arizona for “freestanding urgent care centers.” The commenter suggested that we adopt the legislative language for a “freestanding urgent care center” as the Medicare definition of “dedicated emergency department.” Specifically, the commenter suggested that the definition state:

An “emergency department” means a medical facility that, regardless of its

posted or advertised name, meets the following requirements:

- (a) Is a department of a hospital and is intended to routinely provide unscheduled medical services; or
- (b) Meets any one of the following requirements:

(1) Is open 24 hours a day to provide unscheduled medical care, excluding, at its option, weekends or certain holidays;

(2) By its posted or advertised name, give the impression to the public that it provides medical care for urgent, immediate or emergency conditions; or

(3) Routinely provides ongoing unscheduled medical services for more than 8 consecutive hours for an individual patient.

Response: We have considered this suggested Arizona bill language defining urgent care centers for the State and believe it has merits for further revision of the CMS definition of "dedicated emergency department," with some modification.

Under subparagraph (2) of the revised definition in this final rule, we are adopting as one of three options that a "dedicated emergency department" may be any department or facility of a hospital, regardless of whether it is located on or off the main hospital campus, that is held out to the public as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment. We have not limited the definition to a hospital "department" because we do not believe it would be appropriate to exclude facilities that otherwise function as dedicated emergency departments from that definition solely because they may not fully meet the requirements for departments of providers in 42 CFR 413.65.

Second, under subparagraph (3) of the revised definition in this final rule, we are adopting the criterion that during the calendar year immediately preceding the calendar year in which a determination is being made, based on a representative sample of patient visits that occurred during that calendar year, the department or facility provided at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment. We are not using the Arizona bill 24-hour or 8-hour requirements because we believe an objective measure based on outpatient visits for the treatment of emergency medical conditions will be easier to understand and implement and better reflects the operating patterns of some emergency departments, including those at small or rural hospitals, or both, that

may not offer treatment for emergency medical conditions continuously on a 24-hour, 7 days a week basis. (The hospital CoPs governing emergency services of hospitals (§ 482.55) and CAHs (§ 485.618) do not require that emergency departments be operated continuously. Under some circumstances, such as local shortages of emergency care personnel or limited demand for emergency services, hospitals and CAHs may choose to open and staff their emergency departments on less than a 24-hour, 7 days a week basis.)

8. Urgent Care Centers

Comment: Many commenters were concerned that hospital "urgent care centers" or "acute care centers" would be included, inappropriately, as "dedicated emergency departments" for purposes of EMTALA. The commenters stated that urgent care centers "are capable of responding to an urgent need, but not an emergency medical condition."

Several commenters suggested that only those urgent care centers that are functioning and holding themselves out to the public as an emergency department should be considered a dedicated emergency department for purposes of EMTALA.

Response: We believe it would be very difficult for any individual in need of emergency care to distinguish between a hospital department that provides care for an "urgent need" and one that provides care for an "emergency medical condition" need. Indeed, to CMS, both terms seem to demonstrate a similar, if not exact, functionality. Therefore, we are not adopting the commenters' suggestion to except urgent care centers from dedicated emergency department status. As we have discussed above, if the department or facility is held out to the public as a place that provides care for emergency medical conditions, it would meet the definition of dedicated emergency department. An urgent care center of this kind would fall under this criterion for dedicated emergency department status.

Although not specifically stated in a comment, an underlying issue is that urgent care centers, participating in Medicare through a hospital, and which operate as satellite facilities off the main hospital campus, would meet the current definition of a dedicated emergency department, but would generally not have the capacity on site to treat patients who had been screened and determined to have serious emergency conditions. In this situation, some might argue that it would be

inappropriate for such a facility to refer a patient in an unstable condition to the main hospital campus (which could be 30 miles or more away and involve a lengthy ambulance ride) rather than to a nearby hospital that would be able to treat a patient.

Both under past and current rules, a transfer from an urgent care center to a nonaffiliated hospital is allowed under EMTALA where the facility at which the individual presented cannot stabilize the individual and the benefits of transfer exceed the risks of transfer and certain other regulatory requirements are met. Thus, our rules permit a satellite facility covered under the definition of dedicated emergency department, in this example, to screen and determine whether the case is too complex to be treated on site, that a lengthy ambulance ride to an affiliated hospital would present an unacceptable risk to the individual, and then conclude that the benefit of transfer exceeds the risk of transfer. In this case, the satellite facility could then transfer the individual to an appropriate nearby medical facility.

9. Evaluation and Treatment Issue

Comment: One commenter was concerned about the "evaluation and treatment" aspect of our proposed "dedicated emergency department" definition, and suggested that the reference to evaluation would make the definition overly inclusive, since an ambulatory clinic might have no patients *treated* as emergencies, but many *evaluated* (and ruled out) for emergencies. The commenter believed that part of *any* prudent ambulatory practice is to consider first the possibility of an emergency with *all* patients who are seen. The commenter suggested dropping the "evaluation and" portion of the definition to rely exclusively on an area's treatment of actual emergencies as the criterion.

Response: We agree that reference to evaluation may make the definition of "dedicated emergency department" overly inclusive, in that it would count any individuals coming to emergency rooms who are evaluated but not treated for such conditions to rule out emergency medical conditions. Therefore, we are limiting the objective criterion in the third part of the "dedicated emergency department" definition in this final rule to a department or facility that provides at least one-third of all its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

10. Prudent Layperson Observer Standard

Comment: Two commenters expressed opposing opinions regarding our language at 67 FR 31477 of the preamble portion of the proposed rule that stated that the definition of “dedicated emergency department” 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. One commenter believed that while the prudent layperson standard makes sense as it relates to the assessment of an individual’s *medical condition*, it is less appropriate with respect to an individual’s assessment of an appropriate *site of service*. The commenter stated that such assessments would likely vary, depending on factors such as perceived seriousness of the individual’s condition, and urged CMS to adopt an objective test to avoid the uncertainty inherent in a “prudent layperson standard” for determinations of dedicated emergency department status.

Another commenter supported our proposed adoption of the “prudent layperson standard” in determining whether a facility is a dedicated emergency department and stated that the prudent layperson standard is preferable to the “significant portion of the time” or “regularly” definitions or standards.

Response: We believe that our revised definition of “dedicated emergency department” specified under section VII.D. of this final rule establishes an objective standard of determination. For instance, we believe it is an objective standard of dedicated emergency department status whether or not an emergency department is licensed by the State. We also believe that it is an objective standard if a hospital department holds itself out to the public as providing emergency care.

We understand the comment concerning an individual’s assessment of an appropriate site of service. However, in view of the revised “dedicated emergency department” definition we are adopting in this final rule, we believe the prudent layperson standard is unnecessary for assessment of an area of the hospital as a dedicated emergency department. We believe our revised criteria for such status will permit the status of departments or facilities to be objectively determined.

11. Specially Equipped and Staffed Area

Comment: Several commenters addressed the “specially equipped and

staffed area of the hospital” part of the proposed definition of “dedicated emergency department.” One commenter, a hospital, stated that it has a main campus and several off-site locations, all of which are considered departments of the hospital and that none of these off-site departments are dedicated to the provision of emergency care. They also indicated that none of the staff at these off-campus departments are qualified to provide such care. One commenter believed our definition of “dedicated emergency department” should incorporate a provision that staff be specially trained in providing emergency medical care.

Another commenter requested that we clarify the terms “specialized staff” and “specialized equipment” in the proposed “dedicated emergency department” definition. The commenter suggested that “true” emergency departments have coding equipment and coding staff who know how to assign appropriate billing codes.

Several commenters believed that we should clarify that CMS will apply EMTALA only if a site is functioning as a dedicated emergency department. Another commenter stated that the obligations of EMTALA should apply to those hospital departments or other off-site locations that provide “traditional” emergency department services.

Response: As we explained earlier, based on our review of comments on the proposed definition of “dedicated emergency department,” we are adopting an alternative definition of that term that does not include a reference to special equipment or staffing. Therefore, we have not attempted to further define “specialized staff” or “specialized equipment” in this final rule.

We agree with the latter comments, but the range of comments received on the definition of a dedicated emergency department included in our proposed rule illustrates that there are varying differences in opinion as to what “functioning as a dedicated emergency department” and “traditional emergency department services” mean. Therefore, we do not believe these phrases alone are sufficient to define a dedicated emergency department. EMTALA applies not only to dedicated emergency departments but also to presentations for emergency care anywhere on hospital property.

Comment: One commenter brought to our attention a contradiction in the preamble to the proposed rule when we discuss the definition of “dedicated emergency department” at 67 FR 31472. On the one hand, the commenter recognized that we proposed to define

“dedicated emergency department” as an area that is “specially staffed and equipped” for emergency care and that “is used a significant portion of the time” for evaluation of patients for emergency medical conditions. However, the commenter pointed out that, in the same paragraph, CMS proposed that EMTALA applicability also be extended to hospital departments “that are held out to the public as an appropriate place to come for medical services on an urgent, nonappointment basis.” Because the “held out to the public” test was not included in the proposed regulation text, the commenter requested clarification on this point.

One commenter believed that only an area of the hospital with an “Emergency” sign or a “well-accepted synonym in its title” should be impacted by the EMTALA regulations.

Response: As noted earlier, and as explained more fully in section VII.D. of this preamble, we are adopting a revised definition of “dedicated emergency department” that does not reference special equipment or staffing, but does recognize departments or facilities that are held out to the public as places that provide care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment. We believe this revised definition will resolve any uncertainty about the “held out to the public” test.

We agree that use of the term “emergency” or a well-recognized synonym in a facility’s signage would help to identify how the facility is held out to the public and will keep this comment in mind as we develop interpretative guidelines for EMTALA surveys. However, we are not including the suggested language in the final rule because we are concerned that it could be overly prescriptive.

12. Unscheduled Appointments Criterion

Comment: Several commenters addressed the issue of defining dedicated emergency department as one that accepts unscheduled appointments. One commenter suggested that the definition of “dedicated emergency department” should focus on why the patient is present at the hospital’s emergency department. The commenter suggested that the definition should include any location that the hospital holds out as open to evaluate patients seeking unscheduled evaluation or treatment for a medical condition.

Similarly, another commenter recommended that we revise the definition of dedicated emergency department to state that it is a specially

equipped and staffed area of the hospital that is primarily dedicated to “unscheduled” evaluation and treatment of outpatients for emergency medical conditions.

One commenter suggested that our proposed definition of dedicated emergency department be revised to specify that departments of the hospital that accept walk-in or unscheduled patients for assessment are deemed to be dedicated emergency departments for the purposes of EMTALA. The commenter stated that this definition would exempt routine clinics or hospital-based physician offices that function on an appointment-only basis, administrative areas, inpatient units, and laboratory areas that provide testing but do not provide assessment or diagnosis services for patients.

Another commenter asked us to include places that are “held out to the public as an appropriate place to come for medical services on an urgent, nonappointment basis” under the definition of dedicated emergency department. This suggestion would include the labor and delivery department of a hospital, but would exclude outpatient clinics that permit “walk-in patients”, according to the commenter.

The commenter suggested that “dedicated emergency department” be defined as any area of the hospital that provides more than 10 percent of its nonscheduled patients treatment for outright emergencies.

Response: We agree that the practice of accepting patients without requiring appointments is an important indicator of emergency department status. After consideration of all of the comments on this issue, we are adopting in this final rule a criterion in the definition of “dedicated emergency department” that permits a department or facility to be considered a dedicated emergency department if it is held out to the public as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

13. Related Definition of “Hospital With an Emergency Department”

Comment: One commenter requested that we amend the proposed regulatory text at § 489.24(a), consistent with our proposed definition of “dedicated emergency department,” to state that EMTALA requirements apply to a hospital that has a *dedicated* emergency department. Other commenters suggested that our proposed definition of “hospital with an emergency department” at § 489.24(b) should either be deleted or revised so that it is defined

as a “hospital with a dedicated emergency department,” to make it consistent with our definition of “dedicated emergency department.”

Response: We considered the suggestion that we amend the “Application” paragraph of § 489.24(a) to limit EMTALA applicability to hospitals with dedicated emergency departments. However, “hospital with an emergency department” is a term of art from section 1867 of the Act that we have separately included in the definitions under § 489.24(b) to mean generally “a hospital that offers services for emergency medical conditions.” Thus, we believe it would be preferable to keep the statutory language “hospital with an emergency department” in the Application section in the regulation text. To clarify our policy in this area, we are revising the definition of “Hospital with an emergency department” under § 489.24(b) to state that it means a hospital with a dedicated emergency department as defined in § 489.24(b).

14. Other Related Suggested Revisions

Comment: One commenter recommended that the last sentence in proposed paragraph (1) of the definition of “Comes to the emergency department” in § 489.24(b) be revised to read:

“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 an *emergency medical condition*.” [New language is underlined.]

(As proposed, this definition would require only that the prudent layperson observer believe that the individual needs examination or treatment for a *medical condition*.)

Response: Section 1867 of the Act requires a hospital to provide examination and necessary stabilizing treatment to any individual who “comes to the hospital” for emergency care. We are interpreting this statutory requirement to mean that individuals who present to areas of the hospital other than departments that are labeled “Emergency” must receive care from the hospital. We believe we have clarified this requirement in prior rulemakings and in the proposed rule. However, we are including this clarification in this final rule, as well, as part of the revised final definition of dedicated emergency department.

Comment: One commenter stated that if the proposed rules are adopted as

final, on-call physicians and hospitals will refuse to accept transfers if the transfers will be received through the hospital dedicated emergency department. The commenter believed that if we apply EMTALA to patients admitted via the dedicated emergency department, it will create “perverse incentives” for hospitals and physicians to avoid admitting patients through the dedicated emergency department. The commenter stated: “On-call physicians will be reluctant to agree to accept patients for admission through the ED because then their stabilizing care of the patient in the hospital will subject them to civil monetary penalties and civil liability under EMTALA.”

Response: It is a statutory requirement under section 1867(g) of the Act that receiving hospitals with special capabilities *must* accept the transfer of an individual with an unstable emergency medical condition. The receiving hospitals must accept the patients whether or not they are received through that hospital’s dedicated emergency department—the EMTALA obligation for the receiving hospital transfers with the individual until the condition has been stabilized. Therefore, we do not believe on-call physicians and hospitals would refuse to accept transfers if the transfers are being received through the hospital dedicated emergency department, as the commenter believed. In particular, we hold this view because the EMTALA obligation is incurred at the time of arrival of the individual in accordance with an appropriate transfer, regardless of which door the individual enters or whether he or she is admitted immediately to the receiving hospital.

D. Provisions of the Final Rule Regarding Clarification of “Come to the Emergency Department”

For the reasons discussed throughout section VII. of this preamble, and after full consideration of the public comments received—

We are adopting as final the proposed organizational changes to § 489.24(a) on the application of EMTALA to include both the screening and stabilization or transfer requirements. (We note that later in this preamble under section X., we make an additional change to paragraph (a) to clarify that if the hospital admits the individual as an inpatient for further treatment after screening, the hospital’s obligation under EMTALA ends.)

We are adopting paragraphs (1) and (2) under the proposed definition of “come to the emergency department” as final without changes.

We are revising the proposed definition of “dedicated emergency department” at § 489.24(b), to read as follows:

“Dedicated emergency department” means any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:

(1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department;

(2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or

(3) During the calendar year immediately preceding the calendar year in which a determination under § 489.24 is being made, based on a representative sample of patient visits that occurred during that calendar year, it provided at least one-third of all its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

We believe this revised definition of “dedicated emergency department” sufficiently addresses many of the suggested proposals submitted by the commenters on determining what is an emergency department for purposes of EMTALA.

We are revising the proposed definition of “hospital with an emergency department” to make it consistent with our revised definition of “dedicated emergency department.”

VII. Applicability of EMTALA: Individuals Come to the Dedicated Emergency Department for Nonemergency Services (§ 489.24(c))

A. Background

We sometimes receive questions 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 VII. of this preamble, which addresses the definition of a hospital’s dedicated emergency department, 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 medical condition.

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 medical 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.

B. Provisions of the Proposed Rule

To clarify our policy in this area, in the May 9, 2002 proposed rule (67 FR 31473), we proposed to redesignate paragraphs (c) through (h) of § 489.24 as paragraphs (d) through (i) (we proposed to remove existing paragraph (i)) 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 the regulations. (In the May 9, 2002, proposed rule, we included an Example 1 as illustrative of application of this policy (67 FR 31473).)

C. Summary of Public Comments and Departmental Responses

Comment: Many commenters addressed our proposed clarification of presentments of individuals to

dedicated emergency departments for nonemergency services at 67 FR 31473. One commenter stated that only those individuals requesting a “medical examination” be required to receive a medical screening examination by a physician or other qualified medical personnel. Another commenter recommended that EMTALA not apply to requests for nonemergency care inside the dedicated emergency department. One commenter believed that EMTALA should not apply to individuals coming to the dedicated emergency department to obtain previously scheduled or followup care.

Response: At 67 FR 31473, *et seq.*, of the preamble to the May 9, 2002 proposed rule, and also above, we explicitly clarified the issue concerning when 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. To address this scenario, we stated that hospitals are not obligated to provide screening services beyond those needed to determine whether an emergency medical condition exists. In addition, we proposed regulatory language to address the issue (proposed § 489.24(c)) to specify 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. Therefore, while EMTALA *does* apply to any individual who presents to a hospital’s dedicated emergency department with a medical condition, it does so only to the extent that the individual must be screened for emergency medical conditions and supplied necessary stabilizing treatment.

Section 1867(a) of the Act clearly states that a hospital with an emergency department is required to provide an appropriate medical screening examination to every individual who presents at the hospital’s emergency department with a medical condition. However, this screening is only necessary to the extent it takes the hospital to determine whether the individual has an emergency medical condition. Once the individual is screened and it is determined the individual has only presented to the dedicated emergency department for a

nonemergency purpose, such as followup care, the hospital's EMTALA obligation ends for that individual at the completion of the medical screening examination.

Comment: One commenter noted that, in many cases, individuals come to the dedicated emergency department of the hospital at which their regular physician practices and ask to be seen for nonemergency medical conditions that could appropriately be treated in the physician's office. The commenter asked whether, in these circumstances, a registered nurse or other qualified medical person on duty at the dedicated emergency department could perform a screening to rule out the presence of an emergency medical condition and, if it is determined that the patient does not have an emergency medical condition, refer the patient to the physician's office for treatment.

Another commenter stated that we should provide more guidance to allow busy emergency departments to refer patients without an "emergency medical condition" to primary care or specialty care clinics, or both.

Response: As stated in proposed § 489.24(c), if an individual comes to a dedicated emergency department and a request is made for examination or treatment of a medical condition, but the nature of the request makes it clear that the condition is not of an emergency nature, the hospital is required to perform only 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. Under the circumstances described by these commenters, the regulations would not require that such screening be done by a physician. On the contrary, we believe the individual could be screened by the appropriate nonphysician emergency department staff and, if no emergency medical condition is found to exist, referred to his or her physician's office for further treatment. Because we believe that proposed paragraph (c) clearly would permit such a referral, we do not believe a further regulations change is needed in this final rule to clarify this point. We note that while EMTALA does not require that all screenings be performed by an M.D. or D.O., any nonphysician (such as an emergency room registered nurse) who performs such screening should be an individual whom the hospital has designated as a "qualified medical person" for purposes of appropriate transfer certification under § 489.24(d)(1)(ii)(C) (redesignated in this final rule as § 489.24(e)(1)(ii)(C)).

Comment: Many commenters believed that the final rule should make clear that EMTALA does not apply to nonemergency services delivered in a dedicated emergency department and does not apply to a site other than a dedicated emergency department unless emergency services are requested.

Similarly, several commenters requested that we clarify that a hospital has no obligation under EMTALA to an individual who presents at a dedicated emergency department but does not request examination or treatment for a medical condition. Specifically, one commenter believed that we should clarify that hospitals are not required under EMTALA to provide medical screening examinations to individuals who request a medical service that is not examination or treatment for a medical condition, such as preventive care services, pharmaceutical services, or medical clearances for law enforcement purposes (such as blood alcohol tests required by police).

Response: We agree that a hospital has no obligation under EMTALA to an individual who comes to a dedicated emergency department if there is no request made by or on behalf of the individual for examination or treatment for a medical condition, and the individual's appearance or behavior would not cause a prudent layperson observer to believe that examination or treatment for a medical condition is needed and that the individual would request that examination or treatment if he or she were able to do so. We do not agree that a hospital has no obligation under EMTALA to an individual who presents at a dedicated emergency department for "nonemergency purposes" because such a purpose can be a medical one and the statute requires that a hospital perform a medical screening examination to any individual who presents to the emergency department with a medical condition. We agree with another commenter that if an individual presents to a dedicated emergency department and requests services that are not examination or treatment for a medical condition, such as preventive care services, the hospital is not obligated to provide a medical screening examination under EMTALA to this individual.

We note that pharmaceutical services in a dedicated emergency department may be for medical conditions and are, therefore, subject to EMTALA. We also wish to emphasize that the applicable principle is that presentations to a dedicated emergency department that meet other applicable criteria for EMTALA applicability will be

considered to be subject to EMTALA if there is a request by or on behalf of the individual for examination or treatment for a medical condition, or the appearance or behavior of the individual would cause a prudent layperson observer to believe that the individual needed such examination or treatment and that the individual would request that examination or treatment if he or she were able to do so. Under this general principle, we will evaluate specific presentations, including requests by law enforcement authorities for medical clearance of persons who are about to be incarcerated or for blood alcohol or other tests to be used as evidence in criminal proceedings, on a case-by-case basis.

For example, an individual being maintained on psychotropic medication may come to an emergency department and complain of experiencing suicidal or homicidal urges because he or she has exhausted his or her supply of medication. If examination of the individual verifies the existence of an emergency medical condition and a supply of the patient's normal medication is required to stabilize that condition, then EMTALA would require that the hospital provide that medication. Of course, this does not mean that hospitals are required by EMTALA to provide medication to patients who do not have an emergency medical condition, simply because the patient is unable to pay or does not wish to purchase the medication from a retail pharmacy. We will address these types of issues in our interpretative guidelines.

Comment: One commenter noted that the issue of nonemergency patient care that takes place in the dedicated emergency department and overcrowding is a significant concern. The commenter stated that education aimed at the public by CMS to help them understand appropriate alternatives could contribute to reducing abuse.

Response: We agree that it is worthwhile to encourage patients to seek more appropriate sources of nonemergency care, and will take this into account as we develop EMTALA-related patient information and education material.

Comment: One commenter described a situation where hospitals use their emergency departments as an access point for registration purposes for the entire hospital after the normal registration area is closed. The commenter asked whether every individual would be covered under EMTALA and would require a medical screening even though not everyone is

coming to the emergency department seeking emergency medical treatment.

Similarly, another commenter stated that some hospitals, particularly rural ones, have found that it is most cost-effective for the hospital if it was configured to have one hospital entrance for patients who present for emergency care and for patients who do not present for emergency care. The commenter requested clarification on whether an EMTALA screening would be required for both types of patients who walk through that one entrance.

One commenter described a situation where a hospital operates ambulatory care centers and other facilities (such as primary care clinics) in tandem with the hospital's dedicated emergency department. The commenter believed the nondedicated emergency department of the hospital should be explicitly excepted from the definition of "dedicated emergency department" to address this "tandem" scenario.

Response: Regarding the first two comments, we agree that EMTALA does not apply to individuals who may pass through a hospital's emergency department but do not request examination or treatment for a medical condition, have such a request made on their behalf, or indicate through their appearance or behavior that examination or treatment for a medical condition would, in the judgment of a prudent layperson, be needed. We have not revised the final rule on this point, but intend to take it into account in developing interpretative guidelines and training materials for EMTALA surveyors. The third comment does not raise an issue of EMTALA policy, but merely shows that it will be necessary in some cases to determine exactly which physical locations constitute a hospital's dedicated emergency department. Such decisions will be made a case-by-case basis by CMS, based on information provided by the State survey agency.

Comment: One commenter suggested that we define whether there has been a request for examination or treatment under EMTALA by the resources that it would take to fulfill the request. The commenter gave an example of a request for unscheduled medical services that would require the service of a "qualified medical provider." The commenter stated that a request to take out stitches does not require a doctor or consultation with a doctor unless there is an additional complaint expressed.

Response: While this is an interesting suggestion, we believe that it is one that would be difficult to implement as an objective standard, because estimates of resources needed will necessarily be

subjective. Therefore, we are not revising the final rule based on this comment.

Comment: One commenter believed that the standard stated at proposed § 489.24(c), "the nature of the request makes it clear the medical condition is not of an emergency nature", is too subjective. The commenter believed it would almost certainly invite State surveyors to second guess the determination of the qualified medical person.

Response: The purpose of conducting an EMTALA investigation is to ascertain whether or not the hospital has violated the requirements of § 489.24 or the related requirements of § 489.20. The survey is conducted in accordance with applicable CMS survey procedures and policies. The surveyor's recommendation of a violation determination is based on facts uncovered by the onsite investigation. The CMS regional office will make the final compliance determination with information obtained after the onsite investigation by the State survey agency.

Comment: Several commenters believed that triage of the individual presenting to the dedicated emergency department should be adequate for purposes of fulfilling EMTALA screening obligations. Specifically, one commenter did not believe that EMTALA should apply to individuals who present to the dedicated emergency department with no "significant distress or risk" as determined by triage of vital signs, and "who are comfortable and active" in a waiting area whereby they are well provided for while they are waiting for care or treatment.

Another commenter asked us to clarify whether vital signs must be obtained in every medical screening examination upon presentation to a hospital's dedicated emergency department.

Response: Section 1867(a) of the Act requires that individuals coming to the emergency department be provided a medical screening examination. The statute states:

"In the case of a hospital that has a hospital emergency department, if any individual (whether or not eligible for benefits under this title) comes to the emergency department and a request is made on the individual's behalf for examination or treatment for a medical condition, the hospital must provide for 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 (within

the meaning of subsection (e)(1)) exists."

Triaging is not equivalent to a medical screening examination. Triaging merely determines the "order" in which patients will be seen, not the presence or absence of an emergency medical condition. If the medical screening examination is appropriate and does not reveal an emergency medical condition, the hospital has no further obligation under § 489.24.

The decision to take vital signs may be required by the qualified medical professional or the hospital's emergency department's policies and procedures, or both. Vital signs are indicators of a patient's level of wellness and are valuable parameters to assist health professionals in making medical decisions concerning a patient's health needs. The patient's medical condition and the discretion of the practitioner will determine the need for monitoring of vital signs.

We do not believe the taking of a patient's vital signs is required for every presentation to a hospital's dedicated emergency department. As we have stated above, we expect that, in most cases in which a request is made for medical care that clearly is unlikely to involve an emergency medical 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 medical condition and the hospital's EMTALA obligation would thereby be satisfied.

Comment: One commenter requested that we modify proposed § 489.24(c) to provide that EMTALA imposes no minimum requirements for conducting medical screening examinations for cases falling within this paragraph. The commenter stated that the extent of the necessary examination is within the sole discretion of the qualified medical personnel performing the examination.

Response: As required by statute, 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 for examination or treatment for a medical condition. While we will refrain from dictating what type of medical screening examination is required for each individual who presents to the dedicated emergency department, we believe that such screenings should be provided to each individual commensurate with the condition that is presented. As we have stated previously, this does not mean that all EMTALA screenings must be equally extensive. Hospitals are not obligated to

provide screening services beyond those needed to determine that there is no emergency medical condition.

We agree with the commenter that the extent of the necessary examination is generally within the judgment and discretion of the qualified medical personnel performing the examination. However, we note that the extent and quality of the screening by the qualified medical personnel are subject to review (by QIOs and State surveyors, for example), in the case of a complaint filed in accordance with section 1867 of the Act.

Comment: One commenter expressed concern about enforcement of the standard stated in proposed § 489.24(c). The commenter was concerned with the scenario in which it is later determined that an individual who had presented to the dedicated emergency department for such medical treatment as suture removal (as used in the example at 67 FR 31473) was, in fact, suffering from an emergency medical condition, and this emergency medical condition was not detected during this less extensive examination.

Response: As we stated in the proposed rule, hospitals are not obligated to provide screening services in the dedicated emergency department beyond those needed to determine that there is no emergency medical condition. We assume that qualified medical personnel or physicians will be performing the medical screening examination (however modified for the condition presented) to determine whether the individual is suffering an emergency medical condition. If it is later found that the individual *had* been suffering an emergency medical condition upon presentation to the dedicated emergency department but only asks for examination or treatment for the suture removal, or some lesser medical condition, and a complaint is filed for an alleged dumping in accordance with section 1867 of the Act, as stated above, the extent and quality of the screening by the qualified medical personnel would be subject to review by State surveyors to permit a determination to be made as to whether there was an EMTALA violation. We note that if, upon investigation of the alleged dumping, it is found that an adequate medical screening had been performed, the hospital would not be found liable under EMTALA.

Comment: One commenter asked why CMS needed to add a new § 489.24(c) to reinforce the requirement that all visits to the emergency department triggers EMTALA obligations, whether the individual is requesting emergency services or coming for nonemergency

services. The commenter indicated that "any individual" who comes to the emergency department requesting care is already covered by EMTALA.

Another commenter stated that the real issue is when a hospital is required to perform a medical screening examination and when it is *not* required to perform one. The commenter indicated that staff of hospital emergency departments should be able to ask patients why they have come to the emergency department.

Response: In proposed § 489.24(c), and accompanying language in the preamble at 67 FR 31473, we attempted to provide some guidance to hospitals and physicians 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 for emergency medical evaluation or treatment. While we have repeatedly stated that we are refraining from dictating to hospitals standards for medical screening examinations, we hoped to address some concerns in the provider community that all EMTALA screenings must be equally extensive to each individual who presents to the dedicated emergency department. Rather, once an individual states that he or she is not at a hospital's dedicated emergency seeking emergency care as the commenter suggested, some brief questioning by qualified medical personnel of why the individual is there would be adequate to fulfill the requirements of the medical screening examination for purposes of EMTALA.

Comment: One commenter asked for clarification on whether EMTALA applies to individuals who seek outpatient services from the hospital on an unscheduled basis; for example, when an individual's physician directs the individual to go to the hospital to obtain laboratory and x-rays so that the physician may determine whether the individual has pneumonia or another condition.

Response: As explained elsewhere in this preamble, whether EMTALA applies to a specific individual will depend on whether the individual presents to the hospital's dedicated emergency department or to another area of the hospital, and on what type of request for examination or treatment is made. For example, an individual being sent to a hospital for specific diagnostic tests ordered by a physician outside the hospital would normally be directed by that physician to go to the hospital's laboratory and radiology department, not to the dedicated emergency department. In either setting, a simple request for a diagnostic test or

image generally would not be considered a request for examination or treatment for what may be an emergency medical condition, so the hospital would have no EMTALA obligation to that individual. However, if the individual were to tell the hospital staff at the laboratory or radiology department that he or she needed emergency care, EMTALA would apply. EMTALA also would apply if, in the absence of a verbal request, the individual's appearance or behavior were such that a prudent layperson observer would believe the individual needed examination or treatment for an emergency medical condition and that the individual would request that examination or treatment if he or she were able to do so. Of course, in any actual complaint investigation, the State survey agency and, where appropriate, the QIO would review all actual relevant facts and circumstances to ensure that the regulations are applied appropriately in that case.

Comment: One commenter was concerned with the example at 67 FR 31473 of the proposed rule of a woman presenting to a hospital's emergency department with a request for suture removal. The commenter asked for information on the location of the outpatient clinic to which the qualified medical nurse refers the woman for the suture removal after the nurse screens the woman for any emergency medical conditions and also the timing of the clinic's evaluation. The commenter also stated that it would be helpful to clarify that "same-day on-campus referral" to another medical facility outside the dedicated emergency department is not mandatory for EMTALA purposes.

Response: By the commenter's request for information about the location of the outpatient clinic to which the patient is referred, we assume the commenter is interested in whether the outpatient clinic in the example is a department of the hospital (that is, provider-based). We do not see this as a particularly relevant fact, nor do we see the issue of timing of that outpatient clinic's evaluation to the issue of the applicability of EMTALA to that patient on the part of the hospital.

However, we do believe that it would not be an *EMTALA* obligation for the qualified medical nurse in the example to make the referral to the outpatient clinic upon finding that the woman does not have an emergency medical condition. Nevertheless, it would appear to us that good standards of practice would dictate that any qualified medical personnel screening the patient would refer the patient elsewhere for treatment of her obvious medical

condition, rather than simply sending her out of the emergency department upon finding that she did not have an emergency medical condition.

D. Provisions of the Final Rule

We are adopting, as final, the proposed provisions under § 489.24(c).

VIII. Applicability of EMTALA: Individual Presents at an Area of the Hospital's Main Campus Other Than the Dedicated Emergency Department (§ 489.24(b))

A. Background

Routinely, individuals come to hospitals as outpatients for many nonemergency medical purposes. 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 IX.B. of this preamble). However, questions have arisen as to whether a hospital would incur an EMTALA obligation with respect to an individual presenting at that area (that is, an on-campus area of the hospital other than a dedicated emergency department) who requests examination or treatment for what is believed to be an emergency medical condition, or had such a request made on his or her behalf.

B. Provisions of the Proposed Rule

In the May 9, 2002 proposed rule (67 FR 31473 and 31506), we proposed to specify in the regulations (§ 489.24(b), definition of “come to the emergency department”) that, for an individual who presents on hospital property other than the dedicated emergency department and requests examination or treatment for what may be an emergency medical condition, 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. We further explained that if there is no actual request, for example, if 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 treatment for an emergency medical condition. We stated that the proposed policy was appropriate because section 1867 protections should not be denied to

those individuals whose need for emergency services arises upon arrival on hospital property at the hospital’s main campus, but before they have presented to the dedicated emergency department.

Under the proposed policies, a request for examination or treatment by an individual presenting for what is believed to 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. In some cases, the request may 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.

Our proposal, and the considerations on which it is based, are further discussed in the preamble to the May 9, 2000 proposed rule (67 FR 31473). We also specifically solicited comments from hospitals and physicians on examples of ways in which hospitals presently react to situations in which individuals request emergency care in areas of the hospital other than the hospital’s emergency department.

In the May 9, 2002 proposed rule, we also proposed that EMTALA would not apply to an individual who experiences what may be an emergency medical condition if the individual is an outpatient (as that term is defined in 42 CFR 410.2). We explained that we would consider such an individual to be an outpatient if he or she has begun an encounter (as that term is defined in 42 CFR 410.2) with a health professional at the outpatient department. Because such individuals are patients of the hospital already, 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 our 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 CoPs (as discussed in section XIV. of the preamble). Hospitals that fail to provide treatment to these patients could face termination of their Medicare provider agreements for a violation of the CoPs.

In addition, as patients of a health care provider, these individuals are accorded protections under State statutes or common law (for example, State malpractice law and patient abandonment torts) as well as under general rules of ethics governing the medical profession. Our proposal, and the considerations on which it is based, are further discussed in the preamble to the May 9, 2002 proposed rule (67 FR 31473 through 31474).

In the proposed rule, we also proposed to retitle the definition of “property” at § 489.24(b) to “hospital property” and relocate it as a separate definition. In addition, we proposed to clarify which areas and facilities are not considered hospital property.

C. Summary of Public Comments and Departmental Responses

1. Presentation Outside the Dedicated Emergency Department

Comment: Regarding our proposed clarifications on the applicability of EMTALA for presentations on hospital property outside the dedicated emergency department, one commenter believed that, while the clarifications were necessary, “it is perhaps a sad indictment of our healthcare system that we actually have to mandate medical providers that someone unconscious must receive immediate medical care. * * * Anyone doing this sort of denial of care deserves more than an EMTALA citation.” Many other commenters expressed concern about the absence from the proposed regulatory text of qualifying language that is set forth in the preamble of the proposed rule. Specifically, one commenter cited the proposed preamble language at 67 FR 31473 that states:

“* * * 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.” (Emphasis added.) The commenter further cited the preamble at 67 FR 31474:

“We are proposing that EMTALA would not apply to * * * an individual who * * * 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." (Emphasis added.)

The commenter then compared this language in the preamble to the proposed regulatory text at § 489.24(b) that would hold a hospital accountable under EMTALA when an individual has presented on hospital property other than a 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. * * *." The commenter was concerned that neither of the preamble's purported tests for EMTALA's applicability outside of the dedicated emergency department that are quoted above is referenced in the proposed regulatory text: neither the test of whether the individual came to the hospital in an attempt to gain access to the hospital for emergency care, nor the objective test of whether the patient has begun an encounter with a health professional at the outpatient department. This commenter believed that the regulatory text should be revised to clearly state that EMTALA is not applicable to outpatients who have initiated an encounter with a health professional in a hospital outpatient department other than a dedicated emergency department.

Another commenter suggested that we substitute the term "member of the public" for "outpatients" in the definition of dedicated emergency department ("a 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"). The commenter believed that the clear implication of the definition is that an outpatient may be covered under EMTALA, a conclusion that is inconsistent with other provisions in the proposed rule.

Other commenters requested that we clarify that EMTALA would not apply when individuals arrive on the orders of their physicians, such as when a pregnant woman or a psychiatric patient arrives upon a physician's order either for testing or because he or she is in need of immediate medical care. In addition, some commenters believed that CMS should clearly state that only the Medicare hospital CoPs and not EMTALA would apply to individuals with scheduled outpatient appointments or procedures.

Another commenter disagreed with the CMS statement in the preamble to the proposed rule that EMTALA does not apply to "established patients" who

need emergency care while on hospital property. The commenter stated that it may be impossible to distinguish such a patient from anyone else experiencing a similar emergency also on hospital property, and was concerned that the concept of excluding an established patient from EMTALA will raise many definitional and logistical issues.

One commenter believed that we intended for EMTALA not to apply in situations where the individual has arrived for an appointment, even if they had not yet been assisted. The commenter urged clarification on this issue.

One commenter stated that there may be occasions where individuals present to the hospital for outpatient services where *no* orders are necessary to provide services to the individual, such as annual mammograms or health fairs. The commenter requested that EMTALA should not apply to individuals in these circumstances.

Response: As we describe above, in the preamble to the May 9, 2002 proposed rule, we proposed that EMTALA would *not* apply to an individual who 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 a hospital outpatient department for the purpose of keeping a previously scheduled appointment. In response to the comments requesting further clarification of the text of the regulations, and in consideration of the role of the Medicare hospital CoPs in protecting the health and safety of hospital outpatients, we are revising the final rule to state that EMTALA does not apply to any individual who, *before* the individual presents to the hospital for examination or treatment for an emergency medical condition, has begun to receive outpatient services as part of an encounter, as defined in 42 CFR 410.2, other than an encounter that the hospital is obligated by EMTALA to provide. We believe this revised language sufficiently encompasses any individuals who come to a hospital to receive nonemergency services and have begun to receive those services. Such individuals would be included under this policy, regardless of whether or not they began the nonemergency encounter in order to keep a previously scheduled appointment or under orders of a physician or other medical practitioner. We also assume that specific mention of outpatient registration is unnecessary in the revised language because we believe all individuals who have begun an encounter under § 410.2 are registered outpatients in the hospital's records. This change is reflected in the revision

of the proposed definition of "patient" under § 489.24(b) in this final rule. As we stated in the preamble to the proposed rule, we believe it is inappropriate to consider such individuals, who are hospital outpatients who have protections under the CoPs, to have "come to the hospital" for purposes of EMTALA as well, even if they subsequently experience an emergency medical condition.

We note that individuals who are already patients of a hospital and who experience emergency medical conditions are protected by existing Medicare hospital CoPs. We discuss these CoPs in greater detail in section XIII. of this final rule. Hospitals that fail to provide treatment to these patients could face termination of their Medicare provider agreements for a violation of the CoPs. In the January 24, 2003

Federal Register (68 FR 3435 through 3436), we describe the process by which we enforce compliance with these CoPs. For example, we explained that if our surveyors discover noncompliance with the hospital CoPs, "the hospital will be scheduled for termination from the Medicare and Medicaid programs." Thus, for violations of the CoPs, as well as for violations of EMTALA (compliance with which is a Medicare participation requirement) hospitals face the extreme sanction of termination from the Medicare program. 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.

In response to the comment concerning the individual who comes to the hospital for purposes of an annual mammogram or health fair, with or without an order or referral by a physician, that individual is not presenting to the hospital with a particular emergency medical condition. Therefore, EMTALA would not apply. We believe this is consistent with our policy stated elsewhere in this preamble.

Of course, where EMTALA applies to a particular individual who has presented to the hospital for examination or treatment for an emergency medical condition, EMTALA's application does not end just because the individual has begun an outpatient encounter; *only* screening and, where necessary, stabilization, admission for inpatient services, or appropriate transfer end the hospital's EMTALA obligation to the individual (see section VIII. of this preamble for further discussion of the issue of when an EMTALA obligation ends). The fact

that protections under the CoPs may later be afforded to an outpatient who is already protected by EMTALA does not end the individual's EMTALA protection.

In response to the commenter's concern that we incorporate the language regarding coming to the hospital in order "to gain access to the hospital for emergency care" into the regulation text, while in most emergency cases individuals will come to a hospital in order to gain access to emergency care at the hospital, not all emergency patients start out that way. Some individuals may come to the on-campus hospital property for reasons other than to seek medical services for themselves (examples would include a hospital employee, or a visitor of the hospital). Such individuals would not be protected by the hospital CoPs if they happen to experience what may be an emergency medical condition while on hospital property, since they are not hospital patients. Therefore, we are clarifying here that we consider such individuals to have "come to the emergency department." Under section 1867(a) of the Act, such individuals are protected by EMTALA and hospitals must provide them with screening and necessary stabilizing treatment.

To address the comment concerning the substitution of the term "outpatients" in the proposed definition of "dedicated emergency department", we mention the comment in this section of the preamble of this final rule because, as the commenter pointed out, it would appear to be inconsistent with our policy in our proposed regulations text at § 489.24 that EMTALA would not apply to any *patient*, as defined in proposed § 489.24(b), who would include "outpatients" as defined at § 410.2, and yet we would use the term "outpatients" in our application of EMTALA for individuals that present at dedicated emergency departments. In addition, we also proposed in the preamble to the proposed rule that EMTALA would not apply to outpatients with emergency medical conditions that arise during an encounter. We are clarifying in this final rule that EMTALA *will* apply to any individual who presents to the hospital for examination or treatment for an emergency medical condition, but EMTALA *will not* apply to individuals who have begun to receive outpatient services as part of an encounter, as defined in § 410.2, other than an encounter that the hospital is obligated by EMTALA to provide.

In this final rule, in response to comments, we are revising our definition of "dedicated emergency

department" at § 489.24(b) to specify that such a department is a unit in the hospital that meets at least one of three criteria, one of which is that it is any department or facility of the hospital that provides for the examination or treatment of emergency medical conditions for at least one-third of all of its outpatient visits, based on a representative sample of patient visits for the calendar year immediately preceding the calendar year in which a determination is being made. This revised language avoids using the term "individuals" or "member of the public" and would sufficiently encompass any person, including hospital staff who may become ill, who comes to a hospital's emergency department for medical care.

In addition, we are revising the proposed definition of "patient" under § 489.24(b) to indicate that EMTALA does not apply to an individual who has begun to receive outpatient services as part of an encounter, as defined in § 410.2, other than an encounter that the hospital is obligated by EMTALA to provide.

Comment: One commenter asked us to clarify whether EMTALA is triggered for an individual who comes to the hospital as an outpatient for a scheduled appointment and who, after treatment has commenced, experiences an emergency medical condition, and is then moved to the dedicated emergency department for treatment. Similarly, the commenter asked whether an individual transported by the hospital to the dedicated emergency department from an off-campus department that is not a dedicated emergency department is an EMTALA patient upon arrival. The commenter asked whether individuals in these two settings should be handled differently.

Response: As we have described above, in this final rule, we are providing that individuals who have begun to receive outpatient services during an encounter are not protected under EMTALA if they are later found to have an emergency medical condition (even if they are then transported to the hospital's dedicated emergency department). These individuals are considered patients of the hospital and are protected by the Medicare hospital CoPs and relevant State law. In addition, as we describe below, individuals who present to a provider-based, off-campus department that is not a dedicated emergency department with emergency conditions are not protected by EMTALA, but rather by the hospital CoPs as well as relevant State law.

Comment: A number of commenters expressed concern about EMTALA applicability to individuals who present at a hospital for emergency care outside the dedicated emergency department. One commenter stated that establishing a "different set of expectations" for departments that are not dedicated emergency departments when an individual presents for care is likely to cause confusion and is asking potentially nonclinical persons to make clinical judgments they have no training to make. Another commenter stated that medical personnel cannot be at all hospital locations to conduct screening and stabilization services, and believed that we should revise how medical staff are required to respond to medical emergencies in nonemergency department locations.

Response: As we have expressed above, whether an individual presents for care at a hospital's dedicated emergency department, or elsewhere on hospital property, if EMTALA is triggered, the hospital has the same obligations to that individual. It is up to the hospital to determine how best to provide the screening and necessary stabilizing treatment to the individual who presented. In either case, the hospital is responsible for treating the individual within the capabilities of the hospital as a whole, not necessarily in terms of the particular department at which the individual presented. Whether the hospital sets up procedures to immediately transport the individual to the hospital's dedicated emergency department, or whether the hospital sets up procedures to send a "trauma crew" or "crash team" of physicians and nurses out to the individual on site, we do not believe it is appropriate for us to dictate to hospitals how best to treat individuals who present for emergency care in hospital departments other than dedicated emergency department locations.

In addition, we do not believe treatment of an emergency patient would involve having nonclinical hospital staff making determinations about an individual's medical condition; rather, we envision that, as stated above, hospitals would set up procedures to provide for emergency care to individuals who present in hospital departments other than dedicated emergency department locations on the hospital campus.

2. Prudent Layperson Standard

Comment: A number of commenters expressed concern about our proposed "prudent layperson" standard. We stated in the proposed rule that, for both presentations inside the dedicated

emergency department and also elsewhere on hospital property, a request for examination or treatment 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 an emergency medical condition (or examination or treatment for a medical condition for presentments inside the dedicated emergency department).

Many other commenters supported our proposed prudent layperson standard; they believed that the standard would ensure that the obvious emergency situation would be addressed, even if the individual were unable to verbalize the request.

Several other commenters requested that we substitute the term "obvious implied request" or "implied request," instead of relying on the perceptions of a prudent layperson for individuals who are unable to articulate their needs.

Many commenters believed that hospitals must be on notice of an individual's presentment in order for EMTALA to be triggered to that individual. One commenter stated: "Because an EMTALA obligation is triggered by a patient-generated request, hospital personnel must be made aware of the individual's presence and observe the appearance or behavior or both of that person in order to respond appropriately. Additionally, all hospitals need policies that describe steps to be taken to assure that a person in clear need, for example, a visitor who collapses in the cafeteria, receives medical attention."

Several commenters requested that the final rule make clear that EMTALA does not apply to an individual presenting on on-campus hospital property other than a dedicated emergency department unless emergency services are requested.

Response: First, we agree with the commenters that hospital personnel must be aware of the individual's presence and observe the appearance or behavior, or both, of that person in order for EMTALA to be triggered. Obviously, the hospital must be on notice of the individual's existence and condition for any violation of the statute to take place. This also applies to presentments for off-campus dedicated emergency departments; only if the hospital's staff are aware of an individual's presence in the department for examination or treatment for a medical condition is EMTALA triggered.

We also agree with the commenters that EMTALA does not apply elsewhere on on-campus hospital property other

than a dedicated emergency department unless *emergency services* are requested. As we clarified in section V.J.8 of the preamble of the May 9, 2002 proposed rule (67 FR 31473 through 31474), and also as we discuss in section IX. of the preamble, a request for treatment 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 physically incapable of making the request, the request from the individual will be considered to exist if a prudent layperson observer would believe, based upon the individual's appearance or behavior, that the individual needs examination or treatment for an emergency medical condition.

However, to address the commenters who requested an "obvious implied request standard" instead of the "prudent layperson standard", we believe the prudent layperson standard is necessary for both presentments inside the dedicated emergency department and elsewhere on hospital property. We are concerned about the circumstance where hospital staff observe the appearance or behavior of an individual who clearly has an emergency medical condition, but do nothing to provide treatment for that individual.

In addition, the term "prudent layperson" is consistent with the Medicare and Medicaid programs, in general. We believe it is appropriate and realistic to utilize this objective standard in the EMTALA context as well, because it reflects a standard for judging whether the hospital should have acted—it does not shift control of events to any particular individual layperson.

Comment: One commenter who supported the prudent layperson standard suggested that the proposed regulatory language at paragraphs (1) and (2) under the definition of "comes to the emergency department" under § 489.24(b) is too broad and could encompass situations for which CMS did not intend EMTALA to apply. The commenter recommended that CMS modify the language in those paragraphs to state: "a request on behalf of the individual will be considered to exist if the individual is unable to make the request and a prudent layperson observer would believe. * * *" The commenter stated that an individual need not rely on the prudent layperson observer if he or she is able to request examination or treatment for himself or herself.

Another commenter requested that CMS limit application of the prudent layperson language to circumstances where the need for emergency services is clear and the individual cannot make the request and there is no one to make the request on behalf of the individual.

Response: We agree with the commenters that the prudent layperson standard is to be relied upon only in circumstances where the individual is unable to make the request for examination or treatment of himself or herself. However, we do not agree that a change in the regulatory language is needed. We believe that our proposed regulatory language in that section, which states: "*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 * * *," (emphasis added), encompasses any situation in which an individual has come to the hospital and a prudent layperson observer would believe the individual may have an emergency medical condition and that the individual would request examination or treatment if he or she were able to do so, whether or not the individual is unaccompanied.

Comment: One commenter stated that hospital staff do not want to be in the position of interpreting the "prudent layperson" terminology. Another commenter was concerned that some members of a hospital's staff may not be "prudent laypeople" who are in the position of determining whether someone needs emergency care. For example, a hospital may employ a disabled worker to provide basic yard services. A third commenter stated that many hospitals use volunteers to staff courtesy desks to assist patient families and provide directions in and around the hospital. The commenter was concerned that requesting volunteer hospital staff to provide emergency care for individuals presenting at the hospital outside of the dedicated emergency department is "excessive." The commenter stated that if volunteers are assigned this responsibility, they may no longer provide volunteer services and the hospital would need to add paid staff, which would increase the cost of care. The commenter added that these volunteers or other staff would need training to comply with this new definition and responsibility.

Response: Our rationale for the prudent layperson standard is to determine whether an EMTALA obligation has been triggered toward a particular individual. It is a legal standard that would be used to determine whether EMTALA was

triggered—it is not meant for hospital staff, including volunteers, to be “interpreting” the prudent layperson standard. Rather, we foresee that in cases in which hospital staff or other individuals at the hospital have witnessed the behavior of the individual upon his or her presentation to the hospital, the prudent layperson standard will be applied to the facts (the appearance and behavior of the presenting individual) to determine if EMTALA had been triggered.

Comment: One commenter stated that EMTALA should apply only in situations where the prudent layperson believes the individual needs emergency examination or treatment, and not simply examination or treatment at some later date or time.

Response: We proposed the prudent layperson standard to apply to presentations both inside and outside the dedicated emergency department. Therefore, for presentations inside the dedicated emergency department, the proposed standard is that the prudent layperson observer would believe, based on the individual’s appearance or behavior, that the individual needs examination or treatment for a *medical condition*. For presentations on hospital property outside the dedicated emergency department, the prudent layperson would believe the individual needs examination or treatment for an *emergency medical condition*. However, we do agree with the commenter that the standard is that the prudent layperson would believe that the individual needs the examination or treatment at the time of the presentation (when the hospital is on notice of the individual’s existence on hospital property), and not at a later date or time.

Comment: One commenter describes a scenario where an individual with a bad cough and wheezing visits a family member in the dedicated emergency department. The commenter believed that, even though the individual may need examination or treatment, the hospital should have no duty to offer or provide care unless that individual actually asks for care. The commenter indicated that in such a case it should not matter whether a prudent layperson observer would believe that the individual *needs* care.

Response: We agree with the commenter that the prudent layperson standard should not be applied so broadly as to mandate EMTALA screenings for individuals who are fully capable of making a verbal request for examination or for a medical condition, but elect not to do so. Inherent in such a standard is not only the notion that the individual’s appearance or behavior

would lead a prudent layperson observer to believe that the individual needs examination or treatment for a medical condition, but a belief by the prudent layperson that there has been no verbal request only because the individual’s medical condition, or some other factor beyond the individual’s control, such as a language barrier, makes a verbal request impossible. We are not revising the final rule based on this commenter’s concern because we believe it is not feasible to attempt to codify all of the various conditions and circumstances under which a verbal request would not be possible. However, we will keep this concern in mind as we develop interpretative guidelines or other instructional material for State surveyors.

3. Determination of “What May Be an Emergency Medical Condition”

Comment: Several commenters did not agree with the language used in the regulatory standard for EMTALA applicability outside the dedicated emergency department that the presenting individual requests examination or treatment for *what may be* an emergency medical condition. One commenter stated that the universe of conditions that may be emergency medical conditions is extraordinarily broad and recommended that this standard be clarified to avoid unnecessary and excessive EMTALA obligations to individuals presenting outside of dedicated emergency departments. The commenter recommended that EMTALA is triggered outside of the dedicated emergency department only when the individual “requests examination or treatment for what more likely than not is an emergency medical condition.”

Response: When we proposed the “what may be an emergency medical condition” language in the definition of “come to the emergency department” at § 489.24(b), we did so to clarify that an emergency medical condition would not actually have to *exist* upon examination of such an individual presenting outside the dedicated emergency department. Instead, the individual presenting (or the prudent layperson observer) must believe he or she needs emergency care. We do not believe it is necessary to adopt the commenter’s suggested clarifying language. We believe we have provided sufficient explanation about “what may be an emergency medical condition” both in our response above and in the preamble to the proposed rule (67 FR 31473).

Comment: One commenter requested that CMS clarify that the proposed standard language “such a request

would be considered to exist if the individual requests examination or treatment *for what the individual believes* to be an emergency condition” (67 FR 31473) (emphasis added), is an objective standard. The commenter was concerned about our enforcement of this standard; specifically, the concern was that the determination as to whether an EMTALA obligation has been triggered would hinge on a subjective belief that an emergency medical condition exists.

Response: EMTALA is triggered when there has been a *request* for medical care inside the dedicated emergency department or for emergency care on hospital property outside the dedicated emergency department. The request can only be made by or on behalf of the individual or the request from the individual would be considered to exist if a prudent layperson would believe the individual needs emergency care. We believe this standard for when EMTALA is triggered is based on objective criteria; that is, the act of the individual or someone acting on his or her behalf requesting medical care for what the individual believes or what the person accompanying the individual believes to be an emergency medical condition. It is also objective when the prudent layperson standard is considered in determining whether, based on the appearance, signs, and symptoms of the individual presenting to the hospital, a prudent layperson would believe that the individual has a medical condition (in the dedicated emergency department) or an emergency medical condition (in a nondedicated emergency department).

4. Other Issues

Comment: One commenter requested that we clarify that, although it may be appropriate for staff of the dedicated emergency department to leave the department in order to provide emergency medical treatment to an individual who has presented on hospital property outside the dedicated emergency department, it is not required that an emergency department “physician” leave to respond and provide treatment to an individual.

Response: Under these circumstances, EMTALA requires that the hospital must provide treatment to the individual within its capabilities; if the hospital lacks, for instance, sufficient specific staff, the hospital should must provide alternative means of treating such an individual, within its capabilities, or provide an appropriate transfer. Or if the hospital decides to send other medical staff rather than physician staff to an emergency patient who has presented on hospital property

outside the dedicated emergency department, that action is within the hospital's discretion. CMS would look to see what type of capabilities the hospital has in responding to such emergency cases and whether the hospital responded appropriately.

Comment: One commenter believed that having different EMTALA policies based on which door of the hospital the individual enters is fundamentally flawed and exacerbates the confusion about when the EMTALA duty has been met. The commenter requested that we simplify the issue by delineating that EMTALA applies in any case of any individual who comes to the dedicated emergency department and for whom a request for emergency care is made, until that individual is stabilized or admitted.

Another commenter found it confusing to have a separate definition of dedicated emergency department. The commenter stated that it is already well-established and accepted that any individual who arrives anywhere on hospital property, whether it is the emergency department or a sidewalk within 250 yards of the main building and requests care for a emergency medical condition triggers EMTALA obligations for the hospital. Therefore, the commenter added, it is immaterial whether or not an individual presents to a "dedicated emergency department," since arrival anywhere on a hospital campus automatically triggers EMTALA.

Response: As we explain in the discussion above regarding clarification of the definition of "dedicated emergency department," and also in the proposed rule, there has been much confusion on the applicability of EMTALA to individuals who present for emergency care, but do not make it to a hospital's emergency department. We have stated previously that an individual may not be denied emergency services simply because a person failed to actually enter a hospital's emergency department. That is, under certain conditions, an individual does not need to present at a hospital's emergency department in order to be protected by EMTALA.

Thus, in clarifying our policy, it is necessary to address *where* and under what conditions the individual is presenting in order to determine whether EMTALA is triggered. EMTALA is not triggered by a request for physical therapy (that is, for a *medical condition*) at the hospital's on-campus physical therapy department. However, EMTALA would be triggered by that same request inside a hospital's dedicated emergency department, since

the statute clearly states that requests for examination or treatment of "medical conditions" at emergency departments trigger EMTALA. By the same token, request for treatment of a gunshot wound at the on-campus radiology department would also trigger EMTALA, since a gunshot wound is clearly an "emergency medical condition."

We believe that, in making our clarification of "dedicated emergency department," we are assisting in clarifying a hospital's responsibilities under EMTALA to screen and provide necessary stabilizing treatment to an individual who comes to a hospital, presenting either at its dedicated emergency department or elsewhere on hospital property; that is, we are clarifying at what point EMTALA is triggered. The "which door" concept is integral to this analysis. An individual can "come to the emergency department" under the statute 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 and request examination or treatment for a *medical condition*; or the individual can present elsewhere on hospital property (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 an *emergency medical condition*.

D. Provisions of the Final Rule

In summary, in consideration of the comments discussed under this section, in this final rule, we are—

- Adopting as final the proposed definition of hospital property under § 489.24(b) with one clarifying editorial change concerning the language in the proposed definition about excluding other areas or structures that are located within 250 yards of the hospital's main building." We are removing the proposed phrase "located within 250 yards of the hospital's main building" because the phrase is duplicative of the language in the definition of "us" at § 413.65(b). "Campus" includes the 250 yards concept in its definition; therefore, by referencing § 413.65(b) in the definition of "hospital property" under EMTALA, we are already including the concept of 250 yards.

- Adopting as final the proposed definition of patient under § 489.24(b), with a modification to reflect the nonapplicability of EMTALA to an individual who has begun to receive outpatient services at an encounter at the hospital other than an encounter that the hospital is obligated by EMTALA to provide.

IX. Scope of EMTALA Applicability to Hospital Inpatients (§ 489.24(d)(2))

A. Background and Provisions of the Proposed Rule

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*, 525 U.S. 249 (1999)) 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, in the May 9, 2002 proposed rule (67 FR 31475), we proposed that EMTALA would apply to admitted emergency patients until they have been stabilized.

As we noted in the proposed rule, 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 these cases, we stated that the hospital continues to be obligated under section 1867 of the Act, irrespective of the inpatient admission, and that 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. We believed that such a policy would provide protections under the statute to those patient populations that are most vulnerable—individuals who are experiencing emergency medical conditions (including women in labor who are admitted to the hospital).

In addition, we proposed to clarify in the proposed rule that an individual 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 an individual does not relieve the hospital

of its EMTALA obligation (67 FR 31475). We proposed that such an individual would continue to be covered by EMTALA until the individual's overall medical stability with respect to all conditions is achieved.

Based on an analysis of the statute (sections 1867(b)(1)(A), (c)(2), and (e)(1) of the Act) and the legislative history (131 Cong. Rec. 28.587 and 28.588 (1985) and H.R. Rept. No. 241 (I)(1985), reprinted in 1986 U.S.C.C.A.N. 579, 605.), we explained why we believed that EMTALA continued to apply to admitted emergency patients until they have been stabilized or appropriately transferred.

For a detailed discussion of the proposed policy on the applicability of EMTALA to admitted patients with unstabilized emergency medical conditions, see the preamble to the May 9, 2002 proposed rule at 67 FR 31475.

In addition, except for the limited circumstances described above, we proposed to clarify that EMTALA does not apply to nonemergency hospital inpatients. Most hospital admissions do not consist of emergency cases. In most cases, an individual who comes to the hospital and requests admission does so to obtain elective (nonemergency) diagnosis or treatment for a medical condition. We noted 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.

We proposed to redesignate paragraph (c) of § 489.24 as paragraph (d), and include stabilization requirements under a new proposed § 489.2(d)(2). (Proposed redesignated paragraph (d) was proposed to be revised further as explained in section V.K.9.b. of the preamble of the May 9, 2002 proposed rule (67 FR 31456).) In addition, we proposed to include the requirements for nonapplicability of EMTALA to nonemergency hospital inpatients under proposed redesignated § 489.24(d)(2).

B. Summary of Public Comments and Departmental Responses

1. Applicability of EMTALA to Inpatients

Comment: Many commenters expressed concern about our clarification in the proposed rule on the applicability of EMTALA to hospital inpatients. Some commenters agreed with the entirety of the CMS proposed policy that a hospital's EMTALA stabilization and transfer obligations should continue to apply to an admitted emergency patient. One commenter

stated that "this clarification will allow hospitals to find an endpoint to their EMTALA obligations, specifically when the patient's emergency [medical] condition is stabilized."

However, many commenters expressed the view that EMTALA should not apply to any inpatient, even one who was admitted through the dedicated emergency department and for whom the hospital had incurred an EMTALA obligation to stabilize. Several commenters noted that hospitals have extensive CoPs responsibilities with respect to inpatients or State tort law obligations, and argued that the hospital's assumption of responsibility for the individual's care on an inpatient basis should be deemed to meet the hospital's obligation under EMTALA. Many commenters recommended that the regulations be revised to state that a hospital's EMTALA obligation may be met by admitting an individual as an inpatient.

Two commenters stated that CMS has "no evidence there is a current problem" for the dumping of inpatients with emergency medical conditions. Therefore, the commenters believed EMTALA applicability should end upon inpatient admission.

One commenter (a group of neurosurgeons and neurologists) believed that EMTALA was not intended to apply to an inpatient admitted through the dedicated emergency department. Several commenters cited the recent ruling by the Court of Appeals for the Ninth Circuit in *Bryant v. Adventist Health System* (289 F.3d 1162 (9th Cir. 2002)) that EMTALA generally ceases to apply once an individual is admitted for inpatient care; these commenters believed we should adopt the opinion for the national policy.

Response: In attempting to resolve the issue about EMTALA applicability to admitted emergency patients, we were assisted by referring to cases in which the courts have had to address the same issue. In several instances, the courts concluded that a hospital's obligations under EMTALA end at the time that a hospital admits an individual to the facility as an inpatient. See *Bryan v. Rectors and Visitors of the University of Virginia*, 95 F.3d 349 (4th Cir. 1996); *Bryant v. Adventist Health Systems/West*, 289 F.3d 1162 (9th Cir. 2002); and *Harry v. Marchant*, 291 F.3d 767 (11th Cir. 2002). In reaching this result, the courts focused on the definition of "to stabilize" set out in the statute at section 1867(e)(3)(A) of the Act. In this definition, the Congress defined this concept by specifically linking the hospital's obligation to provide

stabilizing treatment to individuals presenting with emergency medical conditions to the context in which the services are provided.

In particular, the courts found that the statute requires that stabilizing care must be provided in a way that avoids material deterioration of an individual's medical condition if the individual is being transferred from the facility. The courts gave great weight to the fact that hospitals have a discrete obligation to stabilize the condition of an individual when moving that individual out of the hospital to either another facility or to his or her home as part of the discharge process. Thus, should a hospital determine that it would be better to admit the individual as an inpatient, such a decision would not result in either a transfer or a discharge, and, consequently, the hospital would not have an obligation to stabilize under EMTALA. The courts have generally acknowledged that this limitation on the scope of the stabilization requirement does not protect hospitals from challenges to the decisions they make about patient care; only that redress may lie outside EMTALA. For example, a hospital may face liability for negligent behavior that results in harm to persons it treat after they are admitted as inpatients, but such potential liability would flow from medical malpractice principles, not from the hospital's obligations under EMTALA.

As many courts have ruled, EMTALA does not purport to establish a medical malpractice cause of action nor establish a national standard of care. In our view, apart from the possible malpractice implications redressable outside the statute, hospitals that fail to meet their obligations to provide quality care to inpatients may also face consequences affecting their Medicare certification under the applicable CoPs at 42 CFR Part 482. We discuss these CoPs and the process by which we enforce compliance with these CoPs in greater detail in section XIII. of this preamble. In a January 24, 2003 final rule (68 FR 3435), we explained that if our surveyors discover noncompliance with the hospital CoPs, "the hospital will be scheduled for termination from the Medicare and Medicaid programs." Thus, for hospital CoPs violations, as well as for EMTALA violations (compliance with which is a Medicare participation requirement), hospitals face the extreme sanction of termination from the Medicare program.

As a result of these court cases, and because we believe that existing hospital CoPs provide adequate, and in some cases, superior protection to patients, we are interpreting hospital

obligations under EMTALA as ending once the individuals are admitted to the hospital inpatient care. As an example of a case in which the hospital CoPs provide protection superior to that mandated by EMTALA, the discharge planning CoP in 42 CFR 482.43 includes specific procedural requirements that must be satisfied to show that there has been adequate consideration given to a patient's needs for post-discharge care. EMTALA does not include such specific requirements.

We believe that, as the agency charged with enforcement of EMTALA, it is appropriate to pay deference to the numerous Federal courts of appeal that have decided upon this issue. Although the decisions of the courts in these EMTALA private right of action cases are not necessarily binding for our enforcement purposes, we do believe that consistent judicial interpretation of this matter, when combined with the many comments received on this matter, dictate the policy that we articulate in this final rule.

Moreover, given the numerous hospital CoPs that protect inpatients, as well as patients' rights under State law, we believe that patients are sufficiently protected under our policy as we have articulated it in this final rule. However, a hospital cannot escape liability under EMTALA by ostensibly "admitting" a patient, with no intention of treating the patient, and then inappropriately transferring or discharging the patient without having met the stabilization requirement. If it is discovered upon investigation of a specific situation that a hospital did not admit an individual in good faith with the intention of providing treatment (that is, the hospital used the inpatient admission as a means to avoid EMTALA requirements), then liability under EMTALA may attach.

2. Definition of Stability

Comment: One commenter took issue with our proposed regulatory language on when EMTALA ends for hospital inpatients at § 489.24(d)(2)(ii), which states:

"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 * * *."

The commenter believed the proposed standard, "stable for a transfer of the type usually undertaken with respect to patients having the same medical conditions," could undermine both patient safety and the EMTALA statute if hospitals only document that a patient is as stable as similarly situated patients for an appropriate transfer. The commenter requested that the final rule specify that the hospital may satisfy its EMTALA obligations to an admitted patient only by documenting that it has provided stabilizing treatment to the point that the emergency medical condition has been resolved.

Response: As stated earlier in this section of the preamble, in this final rule we have decided not to interpret EMTALA as requiring hospitals to continue to provide stabilizing treatment (as that term is understood under EMTALA) to individuals once the individuals are admitted in good faith to the hospital for inpatient care. Therefore, the above comment on documenting stability for inpatients is no longer an issue that we need to address in the inpatient setting. However, as we have also stated above, a hospital that admits patients but do not so do in good faith may face consequences under both EMTALA and the applicable Medicare CoPs.

Comment: Many commenters asked for clarification of when, how, and if EMTALA applies to transfers from the inpatient care setting (when the individual has not yet been stabilized) to another acute care hospital. In addition, many commenters asked for clarification of the issue of "stability" in the inpatient setting. On the one hand, the commenters stated, we have stated that if the admitted emergency patient could have been transferred as "stable" under the statute, 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 (67 FR 31476). However, some commenters pointed out that the statute appears to support a "stable for discharge" standard to end the EMTALA obligation.

Another commenter recommended that we clarify that a hospital inpatient may be stable for transfer or stable for discharge for purposes of EMTALA.

One commenter stated that because of possible confusion on the part of the emergency department staff of what constitutes "stable" under the EMTALA regulations in the inpatient setting, many patients may be identified as

stable who are technically medically unstable. The commenter recommended that CMS clarify who the reasonable parties are, to determine whether a patient is stable and can be transported to provide the best outcome for that patient.

Another commenter requested that CMS clarify that once an inpatient has been stabilized for discharge, EMTALA no longer applies, even if the patient requires followup care. The commenter requested guidance on whether, for example, the fact that a patient who is being discharged will eventually need to receive a cast or risk further injury influences the point of stabilization for EMTALA purposes.

One commenter recommended that CMS clarify the EMTALA followup care requirements, for "stable for discharge," until the individual's emergency medical condition is resolved. The commenter suggested that the hospital merely be required to present the individual with a plan for followup care, listing, for example, names of physicians who are qualified to provide the individual's care or who are on the individual's health care plan.

Response: As noted earlier, we are clarifying in this final rule that EMTALA does not apply to individuals who have been admitted in good faith to inpatient sections of the hospital, regardless of whether the individuals are experiencing emergency medical conditions. Therefore, transfer and stability issues for that individual, once he or she is admitted, would be governed by the Medicare hospital CoPs, State law, and professional considerations, not EMTALA requirements. Regarding the situation of an outpatient who is being released from the hospital but is expected to need followup care at a later time, we note that the EMTALA definition of "to stabilize" requires only that such medical treatment of the condition be provided as may be necessary to assure, within reasonable medical probability, that no material deterioration of the individual's condition is likely to result from the transfer (including discharge) of the individual from the facility. Thus, a hospital clearly may stabilize an individual, thereby satisfying its EMTALA obligation to that individual, even though followup care may be needed.

Comment: One commenter asked us to clarify the preamble language at 67 FR 31475 that discusses the provision that a hospital inpatient admitted with an unstabilized emergency medical condition who goes in and out of apparent stability with sufficient rapidity or frequency would not be

considered "stabilized" within the meaning of § 489.24. The commenter requested clarification of the term "medically stable"; that is, whether "stable" in this context refers to the medical definition of "stable."

Response: Again, because we are clarifying in this final rule that, except in limited circumstances, EMTALA does not apply to hospital inpatients, the comment above on stability as an inpatient is not relevant for purposes of EMTALA.

Comment: Several commenters asked us to clarify that EMTALA would not apply to inpatients who are stable but who are scheduled for inpatient surgery for an emergency medical condition, such as patients who need an angiogram or bypass surgery, after seeing their physician for chest pain. One commenter requested clarification on the issue of individuals directly admitted to the hospital for an emergency medical condition, for example, appendicitis, although the individual is not seeking emergency services from the hospital.

Response: As we have clarified above, once an individual has been admitted as an inpatient (including individuals who have been directly admitted as inpatients upon presentation to the hospital), EMTALA no longer applies, except in the limited circumstances discussed above concerning admissions not made in good faith.

3. Logs on EMTALA Patients

Comment: One commenter who supported our proposed policy on the applicability of EMTALA to admitted emergency patients asked whether the hospital inpatient departments would be required to post signs specifying the EMTALA rights of patients and keep a log of patients who are still covered by EMTALA. The commenter also asked whether the inpatient departments would be required to have EMTALA policy and procedure manuals.

Response: Because we have decided in this final rule that EMTALA does not apply to individuals who are admitted as inpatients in good faith, the comment above concerning the posting of signs, maintenance of logs on inpatients covered by EMTALA, and policies and procedures for EMTALA purposes as described by the commenter will not be required.

4. Other Issues

Comment: One commenter believed that the CMS proposed approach of EMTALA nonapplicability to admitted elective inpatients is inappropriate. The commenter gave several reasons for this belief: Every court in the United States

that has considered the issue of hospital obligation has concluded that EMTALA application commenced when the hospital or its agents "became aware" that the individual had an emergency medical condition or was unstable as provided by the law; the U.S. Supreme Court case in *Roberts v. Galen of Virginia*, 525 U.S. 249 (1999) specifically stated that the obligations to stabilize, provide additional care or provide an appropriate transfer, or both, are completely unrelated to whether or not the patient came to the emergency department under section 1867(a) of the Act; and *Lopez-Soto v. Hawayek*, 175 F.3d 170 (1st Cir. 1999), interpreted the *Roberts* case and addressed and rejected the arguments made by CMS in support of the CMS interpretation of the law and held that once the patient was in the hospital, EMTALA attached when the hospital or doctor knew of the unstable condition.

Response: We disagree with the commenter. After reviewing the EMTALA statute and its legislative history, we find no indication that Congress intended EMTALA to apply to hospital inpatients. To the contrary, the legislative history makes several references to individuals who were denied emergency medical care at hospital emergency rooms, but we find no references to similar problems faced by hospital inpatients. (See H.R. Rept. No. 99-241 (I), at 27 (1985), reprinted in 1986 U.S.C.C.A.N. 579, 605.) Therefore, we believe that Congress intended for EMTALA to address the issue of inadequate emergency care for individuals who presented with emergency medical conditions seeking such care from hospital emergency departments. Moreover, while we are not bound by judicial precedent in cases in which we were not a party, we are familiar with the *Roberts v. Galen*, 525 U.S. 249 (1999), and *Lopez-Soto v. Hawayek*, 175 F.3d 170 (1st Cir. 1999) cases and believe that they do not pose any barrier to the position we are taking in this rule.

In *Roberts*, the Court addressed the issue of whether an individual must prove that a hospital acted with an improper motive in failing to stabilize that individual and concluded that the stabilization provision found in the Social Security Act at section 1867(b)(1) contained no such requirement. The Court did not address the issue of when a hospital's EMTALA obligation to stabilize an individual ends. However, the *Lopez-Soto* case did address the stabilization issue, and in that case the court concluded that a hospital has an obligation to stabilize an individual with an emergency medical condition

before arranging a transfer of that person to another facility, regardless of whether the individual presented to the emergency department with the emergency medical condition or elsewhere at the hospital.

Because the court in *Lopez-Soto* was not clear about the inpatient status of the individual, a baby, it is not clear to us whether this decision is necessarily inconsistent with the view of the statute we are taking in this final rule. For example, if the baby in *Lopez-Soto* was not an inpatient at the time it presented with an emergency medical condition, then we would agree that the hospital, under this final rule, would be obligated to respond to the baby's condition as if it had been initially presented to the hospital's emergency department. On the other hand, if the baby were, in fact, an inpatient at the time the emergency first presented itself to hospital staff, the court's holding would be inconsistent with the views adopted in this final rule, and, to this extent, we would disagree with the court's conclusion. As we have explained elsewhere in this preamble, we believe such a conclusion oversteps the requirement of the statute that limits its scope to individuals who have presented themselves to a hospital *prior* to the time they become an inpatient of that facility. However, this is not to say that hospitals are without patient obligations in these cases. Hospitals clearly owe a duty to inpatients, but those obligations derive from the Medicare hospital CoPs at section 1861(e) of the Act and the implementing regulations at 42 CFR Part 482, not from EMTALA. In addition, as we have stated, if it is discovered upon investigation of a specific situation that a hospital did not admit an individual in good faith with the intention of providing treatment, but instead used the inpatient admission merely as a means to avoid EMTALA requirements, then liability under EMTALA may attach.

Comment: One commenter who did not support our proposed policy on the nonapplicability of EMTALA to admitted elective patients requested that we clarify the EMTALA obligations to such individuals who experience an emergency after being admitted to the hospital. Specifically, the commenter was concerned about the transfer of such an unstable individual to a hospital that has special capabilities to treat the individual.

Response: Since EMTALA is not triggered for admitted elective patients who experience an emergency during the inpatient admission, (except in limited circumstances), the EMTALA transfer requirements would not apply

to the transfer of such an individual to another hospital.

Comment: One commenter stated that our language in the preamble that discusses the applicability of EMTALA to “admitted emergency patients” (67 FR 31476) appears to apply only to patients admitted via the emergency department, whereas the language in the proposed regulatory text at § 489.24(d)(2)(ii) states that EMTALA applies to inpatient care “if a hospital admits an individual with unstable emergency medical condition for stabilizing treatment.” The commenter requested us to clarify whether EMTALA applies in the inpatient setting but only to an individual admitted via the dedicated emergency department or whether it applies to any individual who has an emergency medical condition.

Response: As stated earlier, our decision in this final rule is that EMTALA no longer applies to any individual who is admitted as an inpatient (except in limited circumstances of circumvention.)

Comment: One commenter recommended that the definition of “inpatient” for purposes of EMTALA would specifically include patients who have been admitted to the hospital but, due to bed availability, are being “boarded” and physically located in the dedicated emergency department.

Another commenter asked us to clarify whether EMTALA would apply to the stabilization of individuals with emergency medical conditions while awaiting admission in the dedicated emergency department or to an unstable patient who is being “held” or “boarded” in the operating room or angiography suite prior to movement to an inpatient bed.

Response: As we have stated, EMTALA applies to an individual who presents to the hospital with an emergency medical condition. If such a condition is found when the individual is screened, the hospital must provide stabilizing treatment, even if the individual is awaiting admission in the dedicated emergency department. Once the individual has been stabilized, the EMTALA obligations end.

In response to the issue about the definition of “inpatient” for purposes of EMTALA, we are revising our proposed definition of “patient” under § 489.24(b) that specified that an inpatient is one who is “receiving inpatient hospital services as defined in § 409.10(b).” Upon further consideration, we believe it would be more helpful to adopt the definition of “inpatient” from Section 210 of the Medicare Hospital Manual (CMS Publication Number 10 (1989)),

which is a well-utilized definition in the Medicare program for purposes of Medicare payment. Under that section, an “inpatient is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. Generally a person is considered an inpatient if formally admitted as an inpatient with the expectation that he [or she] will remain at least overnight and occupy a bed even though it later develops that he [or she] can be discharged or transferred to another hospital and does not actually use a hospital bed overnight.” We believe adopting such a definition for EMTALA purposes would provide further guidance in determining who is an inpatient.

To respond specifically to the commenter, individuals who are “boarded” and admitted in the dedicated emergency department would be determined to be inpatients for purposes of EMTALA if, generally, they have been admitted by the hospital with the expectation that they will remain at least overnight and occupy beds in the hospital. We believe such an expectation would be documented based on the information in the individual’s medical record.

Comment: One commenter compared the proposed regulatory language regarding the application of EMTALA to inpatients in proposed § 489.24(d)(2)(i) to the language in proposed § 489.24(d)(2)(ii). The commenter stated that although paragraph (d)(2)(i) requires the hospital to have *found* the emergency medical condition and have *actual knowledge* that the condition exists, before it can incur a duty to stabilize under EMTALA, paragraph (d)(2)(ii) does not require that the hospital be aware that the individual had an emergency medical condition at the time of admission.

Response: Proposed § 489.24(d)(2) was based on the proposed policy that EMTALA applied to an individual who was admitted as an inpatient. In this final rule, we are revising our policy to state that EMTALA obligations end toward an individual upon inpatient admission, regardless of the stability of the individual (except in limited circumstances of circumvention). Because we are revising the regulation text to reflect this revised policy, the above comment on proposed § 489.24(d)(2) is no longer relevant.

Comment: One commenter suggested that the final rule should clarify the application of the psychiatric specific definitions of “stable for transfer” and “stable for discharge” in the State Operations Manual.

Response: In the 1998 State Operations Manual at Tag A407 on page V-9, we state: “for purposes of transferring a patient from one facility to a second facility for *psychiatric conditions*, the patient is considered to be stable when he/she is protected and prevented from injuring himself/herself or others. For purposes of discharging a patient (other than for the purpose of transfer from one facility to a second facility), for psychiatric conditions, the patient is considered to be stable when he/she is no longer considered to be a threat to him/herself or to others.” However, we note that, generally, psychiatric patients with emergency medical conditions are treated no differently for purposes of EMTALA than any other individual who presents to the hospital with an emergency medical condition. We intend to address the issue of treatment of individuals with psychiatric conditions for purposes of EMTALA in future operating instructions for our State surveyors.

Comment: The commenter also suggested that the final rule clarify that any retrospective review of a physician’s determination that an individual is stable will only be based upon the information and clinical data readily available at the time of such determination.

Response: We will keep in mind the commenter’s suggestion about retrospective review when we develop future operating instructions for our State surveyors. In addition, the commenter has stated our current position as specified in the 1998 State Operations Manual, page V-9: “the purpose of the professional medical review (physician review) is to provide peer review using information available to the hospital at the time the alleged violation took place.”

Comment: One commenter asked for clarification on the point of whether EMTALA should apply when an ambulance delivers an individual through the dedicated emergency department as a direct admit.

Response: As we have clarified above, whenever there is a direct admission of a particular individual as an inpatient, EMTALA no longer applies.

C. Provisions of the Final Rule

In this final rule, we are adopting as final the proposed definition of “patient” under § 489.24(b) with modifications. We are further clarifying what “outpatients” are not subject to the EMTALA obligations.

We also are providing that a hospital’s obligations under EMTALA end once an individual is admitted for inpatient care. As explained above, we believe

that this is the appropriate policy because existing hospital CoPs provide adequate, and in some cases, superior protection to inpatients. (See section XIII. of this preamble for a detailed discussion of regarding the hospital CoPs). In addition, numerous courts have held that EMTALA obligations end upon inpatient admission. At least two courts ruled on the identical issue after we published our May 9, 2002 proposed rule.

We also are adding language to adopt our established definition of "inpatient" in section 210 of the Medicare Hospital Manual (CMS Publication No. 10) who are also not subject to the EMTALA obligations. In addition, we are adopting as final the proposed § 489.24(d)(2) with modifications. We are clarifying that a hospital is required to provide care to its inpatients in accordance with the Medicare hospital CoPs.

X. Applicability of EMTALA to Provider-Based Entities (§§ 413.65(g)(1), 482.12(f), 489.24(b), and 489.24(i))

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 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' EMTALA obligations with respect to off-campus departments.

A. Applicability of EMTALA to Off-Campus Hospital Departments (§§ 489.24(b) and (i) and § 413.65(g)(1))

1. Background

In the April 7, 2000 final rule (65 FR 18504), we 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.

2. Provisions of the Proposed Rule

After further consideration, in the May 9, 2002 proposed rule (67 FR 31476), we proposed 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 proposed 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).

As proposed, this 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 an individual as appropriate places to go for emergency care. Therefore, we proposed to revise the definition of "Hospital with an emergency department" at § 489.24(b) to account for these off-campus dedicated emergency departments and also to amend the definition of "Comes to the emergency department" at § 489.24(b) to include this same language. We believe these proposed changes 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 the preamble of the May 9, 2002 proposed rule ("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 also proposed to delete all of existing § 489.24(i), which, as noted above, was established in the April 7, 2000 final rule. We proposed 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 the Medicare hospital CoP 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, in the May 9, 2002 proposed rule, we proposed 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. The change to § 482.12(f) in this final rule will be taken into account in finalizing the December 16, 1997 proposal.) However, the hospital would not incur an EMTALA obligation with respect to the individual.

In summary, we proposed 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 solicited 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 proposed to delete all of existing § 489.24(i) and to make conforming revisions to § 413.65(g)(1).

3. Summary of Public Comments and Departmental Responses

Comment: Numerous commenters expressed strong support for the proposal to limit the applicability of EMTALA, in cases of off-campus departments, to only those departments that qualify as dedicated emergency departments. Some commenters stated that EMTALA should not apply to an off-campus department that does not hold itself out as an emergency department. Other commenters believed this would be appropriate because a prudent layperson would not regard the department as an appropriate place at which to seek emergency care. These commenters stated that an individual with a broken arm might regard the hospital’s orthopedic department as an appropriate source of care, but that this should not mean that the orthopedic department should be treated as a dedicated emergency department.

Other commenters stated that EMTALA should not apply to any off-campus department unless CMS provides a narrower definition of “dedicated emergency department” and clarifies whether or under what circumstances EMTALA will apply to urgent care facilities. However, the commenters did not provide any indication of why the definition is believed to be too broad or how they would recommend changing it.

Several commenters stated that EMTALA should not apply to an off-campus urgent care center unless the center is functioning and holding itself out to the public as an emergency department.

Response: We agree that EMTALA should apply to off-campus departments only if they qualify as dedicated emergency departments, and have addressed the commenters’ suggestion as part of the revision of the definition of a dedicated emergency department. In addition, we are adopting in this final rule the proposed standard under § 482.12(f)(3) that hospitals have appropriate protocols in place for dealing with individuals who come to off-campus nonemergency facilities to seek emergency care.

Regarding the suggestion that a hospital’s orthopedic department might be determined to be a dedicated emergency department because an individual person would look to it for emergency orthopedic care, as we have noted above, the definition of “dedicated emergency department” in section VIII. of this preamble does not include “prudent layperson” standard. Rather, with this final rule, “dedicated emergency department” means any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that (1) is licensed by the State in which it is located under applicable State law as an emergency room or emergency department; (2) is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or (3) during the calendar year immediately preceding the calendar year in which a determination under § 489.24 is being made, based on a representative sample of patient visits that occurred during that calendar year, provides at least one-third of all of its outpatient visits for the examination or treatment of emergency medical conditions. If the orthopedic department does not meet any of these three criteria for dedicated emergency department status, it is not a dedicated emergency department for EMTALA purposes, regardless of what the individual may believe as to the status of the department.

4. Provisions of the Final Rule

We are adopting, as final with modifications as discussed in earlier sections of this preamble, the proposed revisions of the definition of “come to the emergency department,” “hospital with an emergency department,” and “dedicated emergency department” at § 489.24(b), which encompass off-campus hospital departments that would be perceived by individuals as appropriate places to go for emergency care. We also are adopting as final the related proposed deletion of the provisions under § 489.24(i) and the conforming change to § 413.65(g)(1). In addition, we are adopting, as final, the proposed new § 482.12(f)(3) which provides that the governing body of a hospital must assure that the medical staff has written policies and procedures in effect with respect to off-campus departments for appraisal of emergencies and referrals, when appropriate.

B. On-Campus Provider-Based Applicability

1. Background

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.

2. Provisions of the Proposed Rule

To avoid confusion on this point and to prevent any inadvertent extension of EMTALA requirements outside the hospital setting, in the May 9, 2002 proposed rule (67 FR 31477), we proposed 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 proposed 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 specifically sought comments on this proposed revised definition. Generally, the 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 Web site: <http://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.

We stated that if this proposed change limiting EMTALA applicability to only those on-campus departments of the hospital became final, 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 furnish 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.

In the May 9, 2002 proposed rule, we solicited 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 requires immediate medical attention.

We proposed 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).

In the August 1, 2002 final rule issued following the May 9, 2002 proposed rule (67 FR 50090), we only adopted as final the deletion of the second sentence of the existing § 413.65(g)(1) that address the nonapplicability of EMTALA to provider-based entities. We did not adopt other proposed clarifications concerning application of EMTALA to provider-based departments, on or off the campus, or any other proposals concerning EMTALA.

3. Summary of Public Comments and Departmental Responses

Comment: Several commenters expressed general approval of the proposed clarifications of the definition of "hospital property" for purposes of the EMTALA regulations and stated that the proposals will lead to more precise interpretation of the regulations.

Response: We agree, and are adopting the proposed clarifications as part of this final rule.

Comment: One commenter expressed strong opposition to the proposed clarification under which on-campus provider-based entities would not be subject to EMTALA. The commenter noted that individuals seeking emergency treatment may be severely confused or agitated, so that they would be unable to determine whether a particular area or facility is a dedicated emergency department, and that in

some cases such individuals may also be physically unable to proceed to the dedicated emergency department. The commenter also stated that provider-based departments frequently are located close to the main hospital campus, typically receive higher reimbursement from Medicare by virtue of their provider-based status, and may be indistinguishable, especially to an individual in a crisis situation, from areas at which emergency care is provided. The commenter suggested that, in view of this, it is not unreasonable to expect the provider-based entity to assume responsibility for ensuring that individuals who present with emergency care needs receive screening and stabilization. Therefore, the commenter recommended that we require that provider-based entities either ensure that transfer to a dedicated emergency department occurs safely, or provide screening and stabilization at the entity if it is able safely to do so.

Response: We understand and share the commenter's concern for individuals seeking emergency services who come to provider-based entities for assistance, but note that the legislative provision under which EMTALA responsibilities apply (section 1867 of the Act) is specific to hospitals, and does not extend to nonhospital entities (such as rural health clinics or physician offices), even where those entities may be located adjacent to hospital facilities and owned or operated by hospitals, or both. Therefore, we are not making a revision in this final rule based on this comment.

4. Provisions of the Final Rule

We are adopting, as final with minor editorial changes as explained earlier in this preamble, the proposed revision of "come to the emergency department" and "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 of the hospital's main building that 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." This will clarify that on-campus provider-based entities would not be subject to EMTALA.

We are also adopting as final without modification the proposed clarifying change to § 413.65(g)(1).

XI. EMTALA and On-Call Requirements (§ 489.24(j))

A. Background

We have frequently received inquiries concerning the statutory requirement that hospitals maintain an "on-call" list of physicians to provide services to patients who seek care in hospital emergency departments. We believe there are a number of misconceptions in the provider industry concerning these on-call requirements. Therefore, as in the May 9, 2002 proposed rule (67 FR 31478), we are including a section that clarifies what kinds of obligations physicians and hospitals 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 maintain 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; that is a determination to be made between the hospital and the physicians on its on-call roster. 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 (for example, 20 or more years) or age (for example, 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 a 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 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 in that specialty. 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.

B. Provisions of the Proposed Rule

To clarify our policies on EMTALA requirements regarding the availability of on-call physicians, in the May 9, 2002 proposed rule, we proposed 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 proposed paragraph further specified

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.

C. Summary of Public Comments and Departmental Responses

1. General Comments

Comment: Numerous commenters expressed strong support for the proposal to clarify in regulations that physicians are not required to be on call at all times and that a hospital is responsible for maintaining an on-call list in a manner that best meets the needs of its patients.

Response: We appreciate these commenters' support and have kept their views in mind in evaluating the other comments recommending specific changes in the proposed rule for this final rule.

2. Minimal Interpretation of On-Call Responsibility

Comment: One commenter recommended that the requirement for an explicit list of on-call physicians be eliminated because, in the opinion of the commenter, physicians may be less willing to agree to be on call if they are required to commit in advance to be available at specific times. Numerous commenters did not request elimination of the requirement but stated that the requirement should be interpreted narrowly, as meaning only that the list of physicians willing to be on call is to be maintained and available in the emergency department, and that on-call services of those physicians must be available to each patient regardless of ability to pay. The commenters asked that the regulations be revised to specify that the on-call requirement does not require hospitals to maintain any particular level of on-call coverage, since hospitals are not legally authorized or practically empowered to control physician availability for on-call coverage.

Response: We cannot eliminate the requirement for an on-call list from the regulations, as that requirement is mandated by section 1866(a)(1)(I)(iii) of the Act. While we understand the rationale for interpreting section 1866 of the Act as imposing only a minimal on-call requirement, we also note that on-call physician services, like other services for the examination and treatment of emergency medical conditions, must be made available

within the capability of the hospital, under sections 1867(a) and (b) of the Act. Therefore, we are not adopting these commenters' recommendations.

Comment: Some commenters expressed concern that the proposed changes allowing hospitals and physicians more flexibility to set on-call policies might actually increase overcrowding in hospital emergency departments. The commenters stated that patients who require specialty physician care often must wait in the emergency department for extended periods, since the physician's presence is needed to authorize either admission or an appropriate transfer.

One commenter suggested that adoption of the more flexible regulations on on-call responsibility would only exacerbate this problem. To prevent that, the commenter recommended that a hospital that is unable to maintain full-time specialty coverage in one or more areas be required to have a transfer agreement with a hospital that has that level of coverage and will accept all patients in that specialty or subspecialty area. The commenter also recommended that we prescribe a maximum time for which patients could be required to wait in the emergency department for specialty care and that provision be made for patients who must be held beyond that time to be admitted either to an inpatient bed or to an outpatient holding area outside the emergency department, to await the arrival of a specialist. The commenter noted that this placement would not end the hospital's EMTALA obligation, but would free emergency department resources to permit more emergency patients to be treated.

Response: We agree that it is appropriate for hospitals to have referral agreements with other hospitals to facilitate appropriate transfers of patients who require specialty physician care that is not available within a reasonable period of time at the hospital to which the patient is first presented. Hospitals that cannot maintain full-time on-call coverage in specific medical specialties should also keep local EMS staff advised of the times during which certain specialties will not be available, thereby minimizing the number of cases in which individuals must be transferred due to lack of complete on-call coverage. However, we are not mandating the maintenance of such agreements in this final rule. Even though such agreements may be desirable, we recognize that hospitals may be unable, despite their best efforts, to secure such advance agreements from specialty hospitals. (We note that, even in the absence of an advance agreement,

a participating hospital with specialized capabilities or facilities that has the capacity to treat an individual but refuses to accept an appropriate transfer would thereby violate the EMTALA requirement on nondiscrimination (section 1867(g) of the Act) and could be liable for termination of its provider agreement or civil money penalties, or both.)

We also agree that it would be appropriate for hospitals to limit individuals' waiting time in the emergency department, and to either admit the individual as an inpatient or move him or her to another appropriate outpatient area for treatment in cases where the arrival of a specialist is unavoidably delayed. However, given the heavy demand on emergency department resources and the variations in numbers of patients needing emergency care, we do not believe it is feasible to mandate uniform national limits on how long patients may be held in emergency departments.

3. Recommended Definition of "Best Meets the Needs of the Hospital's Patients"

Comment: Some commenters recommended that the requirement to maintain an on-call list that best meets the needs of the hospital's patients be revised to specifically recognize potential limits on on-call physician availability, by stating that the list must best meet the needs of patients in accordance with the resources available to the hospital, including the availability of on-call physicians. Another commenter recommended that the regulation be revised to mandate maintenance of an on-call list that meets patient needs to the extent permitted by the physician resources available to the hospital through its organized medical staff. Still another commenter recommended that the list be one that best meets the needs of the hospital's patients in accordance with the resources available to the hospital. Another commenter stated that the language as proposed does not clarify whether the on-call coverage must be determined by the needs of the hospital's inpatients or its outpatients, and suggested that the regulation be clarified to state that the on-call list be maintained in a manner that best meets the needs of the hospital's patients who are receiving services required under EMTALA.

Response: After consideration of these comments, we agree that the regulations should be further revised to explicitly acknowledge the limits on availability of on-call staff in many specialties and geographic areas. Therefore, we are

revising proposed § 489.24(j) in this final rule to state that the list must be maintained in a manner that best meets the needs of the hospital's patients who are receiving services required under EMTALA in accordance with the capability of the hospital, including the availability of on-call physicians.

Comment: One commenter recommended that the regulations be revised to state that hospitals are not required to provide on-call physician coverage in specialties not available to the hospital's inpatients. Some commenters also stated that, at a minimum, CMS should require that if a hospital offers a service to the public, the service must be available through on-call coverage at the emergency department. For example, one commenter stated that some hospitals have departments of neurology and may have as many as 10 to 20 board-certified neurologists on its medical staff, but do not offer on-call services of neurologists to emergency patients. This commenter believed further specificity as to on-call obligations would avoid this problem.

Response: We agree that a hospital would not be required to maintain on-call physician coverage for types of services it does not routinely offer, but there are many reasons why a hospital would not have physician specialty care available on an on-call basis, even if such specialty care is above the range of specialty care available to inpatients. Therefore, we are not adopting this comment in this final rule.

Regarding the recommendation that a hospital be required to provide on-call coverage in any specialty offered to the hospital's patients, we agree that this would be a reasonable expectation and note that interpretative guidelines for EMTALA in the Medicare State Operations Manual (CMS Publication No. 7), page V-15, state that if a hospital offers a service to the public, the service should be available through on-call coverage of the emergency department. However, we are concerned that if this expectation were adopted as a requirement for all hospitals with emergency departments as part of this final rule, it might establish an unrealistically high standard that not all hospitals could meet. Therefore, we are not adopting this comment in this final rule.

Comment: One commenter recommended that the regulations be revised to clarify how CMS will deal with situations in which two hospitals with similar numbers of physicians on staff provide widely varying levels of on-call coverage. For example, one hospital with 3 neurosurgeons on staff might be able to provide "24/7"

coverage, while another hospital with 3 neurosurgeons on staff might provide coverage only 10 days per month.

Response: We agree that a situation of the type described by the commenter could raise questions regarding the second hospital's commitment to obtaining on-call coverage, but note that many factors, including the overall supply of specialty physicians in an area, the extent to which hospitals offer specialty care through the use of "itinerant" physicians from other areas, and the availability of specialty care at other nearby hospitals, might all influence the hospital's decisions regarding the level of on-call coverage it can reasonably expect to provide. Because we are concerned that establishing overly prescriptive standards might impose an unrealistically high burden for some hospitals, we are not adopting any further regulatory requirements for handling situations in which hospitals' levels of on-call coverage vary significantly. We will continue to investigate such situations in response to complaints and will take appropriate action if the level of on-call coverage is unacceptably low.

4. Physicians' Responsibility for On-Call Coverage

Comment: Some commenters suggested that the proposal to allow hospitals greater flexibility to maintain on-call coverage that best meets the needs of their patients may be more restrictive than necessary to prevent discrimination or may have the unintended effect of reducing access to on-call services. These commenters argued for a more precise description of how patient needs can best be met, or for elimination of the "best meets the needs" clause. Some commenters stated that by allowing a hospital flexibility and declining to adopt any specific standards as to when a hospital may or may not be required to provide on-call coverage, CMS may be placing the EMTALA on-call burden on hospitals with no corresponding responsibility on the part of physicians, whose participation is necessary for the hospital to meet its obligation.

Some commenters recommended that the regulations be further revised to more specifically address the responsibilities of physicians to make themselves available when on call, the accountability of physicians for EMTALA compliance, and the acceptability of transferring patients when specialty physicians are not available. Other commenters recommended that more specific rules

be adopted regarding the times at which physicians are expected to be on call.

Another commenter cited a study by the University of California at Los Angeles titled "A Day in the Life of a California Emergency Department: Waiting Times and Resources, Trends in Use and Capacity, and Perceptions of Emergency Professionals." The commenter stated that the study finding indicated that, during the study period (December 2000 through May 2001), a significant number of on-call physicians either did not respond to call at all or responded only after a delay of at least 20 minutes, and that many took longer than 35 minutes to arrive. The commenter stated that the study documents the refusal of many on-call physicians to fulfill their on-call responsibilities and argued that hospitals should not be held responsible in such cases.

Another commenter also believed the proposed rules unfairly burden hospitals with the responsibility for maintaining on-call coverage but do not provide any guidance on a medical staff member's obligation to participate in on-call panels. The commenter expressed concern that the proposed language would, if adopted, allow physicians to either refuse to be on call, shift their practices to facilities not requiring on-call service, or demand exorbitant payment for on-call service. To avoid these effects, the commenter recommended that CMS either furnish additional detailed guidance on how hospitals can obtain on-call coverage when physicians refuse to provide it, or mandate that participation on on-call panels at hospitals subject to EMTALA is required as a condition of being a Medicare-participating physician.

Response: We understand the commenters' concern, but do not believe it would be practical or equitable to attempt to adopt more prescriptive rules on such matters as the number of hours per week physicians must be on call or the numbers of physicians needed to fulfill on-call responsibilities at particular hospitals. We believe these are local decisions that can be made reasonably only at the individual hospital level through coordination between the hospitals and their staffs of physicians.

Regarding situations in which physicians may irresponsibly refuse to fulfill the on-call responsibilities they have agreed to accept, we note that current law (section 1867(d)(1)(B) of the Act) provides penalties for physicians who negligently violate a requirement of section 1867 of the Act, including on-call physicians who refuse to appear when called. We further note that

physicians who practice in hospitals do so under privileges extended to them by those hospitals, and that hospitals facing a refusal by physicians to assume on-call responsibilities or to carry out the responsibilities they have assumed could suspend, curtail, or revoke the offending physician's practice privileges. Moreover, when an EMTALA violation involving on-call coverage is found to have occurred, surveyors and CMS regional office staff will review all facts of the situation carefully to ensure that hospitals that have acted in good faith to ensure on-call coverage are not unfairly penalized for failure by individual physicians to fulfill their obligations.

Therefore, we are not making any change in the final rule based on these comments.

5. Hospital Responsibility for On-Call Coverage

Comment: One commenter stated that when the initial EMTALA legislation was enacted in 1986, emergency physicians were finding it virtually impossible to find specialists willing to come to the emergency department to treat emergency patients, and that the 1988 amendments to the EMTALA statute making it explicit that physicians are covered by on-call requirements have significantly improved the availability of on-call services in hospital emergency departments. Because of this improvement, the commenter stated that CMS should not give credence to allegations that EMTALA is making on-call coverage more difficult to obtain. The commenter further stated that even though the proposed regulatory language is virtually identical to the position CMS has taken in the past regarding on-call responsibilities, in the current climate the language is very likely to be viewed as offering assurances that physicians have no obligation to provide on-call coverage. To avoid this result, which the commenter believed would compromise the quality of patient care and lead to patient deaths, the commenter recommended that CMS clearly state that the proposed regulatory language does not represent a change in policy and that hospitals and physicians that fail to meet their on-call obligations as determined by EMTALA will be cited for noncompliance. The commenter also recommended that a safe harbor be created for EMTALA compliance, but does not describe the specific terms under which the safe harbor should be made available.

Other commenters also expressed concern about diminished access to on-

call services as a result of perceptions of the proposals. These commenters stated that, because public hospitals typically are the only hospitals in a community committed to maintaining full-time on-call coverage in many specialties, other hospitals may view flexible requirements in this area as an opportunity to reduce their on-call coverage, thus further unfairly shifting the on-call burden to public hospitals and the physicians who practice in them. The commenters believed CMS should issue guidance stating more specifically how hospitals that maintain less than full-time on-call coverage will be evaluated under EMTALA.

Response: We understand the concerns expressed by the commenters about possible reductions in access to on-call services and wish to emphasize that the proposals are not intended to signal any change in CMS' position regarding hospitals' responsibility to comply with EMTALA. We also understand the desire by some for more specific guidance regarding the level of on-call coverage to be provided and the types of services for which on-call coverage must be available. However, under section 1867(a) of the Act, the EMTALA screening must be provided "within the capability of the hospital's emergency department" and that under section 1867(b) of the Act, further medical screening and stabilizing treatment must be made available only "within the staff and facilities available at the hospital." Given the wide variation in the size, staffing, and capabilities of the institutions that participate in Medicare as hospitals, we do not believe it is feasible for us to mandate any particular minimum level of on-call coverage that must be maintained by all hospitals subject to EMTALA, or to specify that on-call coverage is required for all services offered at the hospital. Therefore, we are not making any changes to our proposal in this final rule based on this comment.

Comment: Several commenters expressed support for the clarification that EMTALA does not require 24/7 on-call coverage at all hospitals, but some of the commenters suggested that the regulations be further strengthened to prohibit hospitals from maintaining such coverage when their capacity does not support it. Another commenter stated that we should not only clarify that EMTALA does not require "24/7" on-call coverage at all hospitals, but should prohibit hospitals from requiring physicians to be on call 24 hours a day, 7 days a week. Another commenter stated that CMS should prohibit hospitals from requiring physicians to be on call at times when they are

already committed to being on call at another hospital. One commenter stated that CMS should at least establish a grievance procedure that would allow physicians to challenge on-call requirements that the physicians believe are unreasonable.

Response: We appreciate the commenters' expression of support for the proposed clarification of our policy in this area, and agree with commenters that EMTALA does not require any physician to be on call at all times. However, we do not believe it would be appropriate for CMS to prescribe levels of on-call coverage; on the contrary, these matters should be worked out between individual hospitals and their medical staff. Therefore, we have not included any provision on the level of on-call coverage hospital may require. Also, we have no statutory authority to mandate the kind of appeals procedure for on-call requirements that was recommended. Therefore, we are not making any change in this final rule based on grievance procedures.

Comment: One commenter suggested that hospitals may be reducing physician staffing in some specialties (below the levels needed to treat all patients, including insured and uninsured patients) and relying on on-call coverage to meet the need to care for indigent patients. The commenter suggested that the regulations be revised to prohibit this practice.

Response: We understand the commenter's concern, but do not believe we can establish realistic objective standards for levels of physician staffing. However, we will keep the comment in mind as we prepare interpretive guidelines and conduct surveyor training, and will review any actual case situations involving understaffing of emergency departments carefully, to determine whether services mandated by EMTALA are, in fact, being provided within the capability of the hospital.

6. Simultaneous Call and Performance of Other Physician Services While on Call

Comment: A number of commenters stated that, because of shortages of physicians in certain specialties (for example, orthopedics or neurosurgery) in some areas, the proposed regulations regarding on-call coverage should be revised to state explicitly that it is not a violation of EMTALA for a physician to be on call simultaneously at two or more hospitals, as long as each hospital has a back-up plan for ensuring that needed care is received from another physician or through an appropriate transfer when the on-call physician is

not in fact available. The commenters also recommended that the regulations be revised to clarify that it is not a violation of EMTALA for a physician to schedule and perform elective surgery while he or she is on call, if such a back-up plan is in place at each hospital for which the physician is on call.

Some commenters suggested that the physician's performance of elective surgery that a physician has freely undertaken should be used as an example of a circumstance that is beyond the physician's control. One of these commenters recommended that physicians who have agreed to be on call, but subsequently engage in activities that make it impossible to fulfill their commitment, should be allowed to make alternative arrangements for responding to calls. Another commenter recommended that the regulations be revised to provide specific examples of situations beyond a physician's control.

Still another commenter recommended that proposed paragraph (j) be revised to state that physicians may provide simultaneous call at more than one hospital, provided the number and geographic proximity of the hospitals are such that a single physician can reasonably provide on-call services at each facility. The commenter recommended that further language be added to state that physicians who are on call may schedule office visits or elective surgery without incurring penalties under EMTALA. The commenter believed the policies and procedures of the hospital for responding to situations in which the particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician's control should be developed in consultation with the hospital's medical staff and that the examples of situations beyond a physician's control should include situations when the physician is already treating another patient. Some commenters stated that a Program Memorandum issued by CMS on June 13, 2002, stated that when a physician is performing surgery while being on call, having another physician available to respond to calls is an acceptable way to fulfill the physician's on-call responsibility but that having the capability to arrange appropriate transfers is also an acceptable form of compliance. The commenters recommended that CMS revise proposed § 489.24(j) to reflect this policy.

Another commenter stated that the regulation should state more specifically what types of back-up plans would be acceptable when a physician has

scheduled elective surgery while on call.

Response: We agree that it is important that policy regarding simultaneous call and scheduling of elective surgery while on call be clearly communicated to, and understood by, affected hospitals and physicians. Therefore, on June 13, 2002, we issued Survey and Certification Letter No. S&C-02-35, to clarify that we believe hospitals should continue to have the flexibility to meet their EMTALA obligations by managing on-call physician coverage in a manner that maximizes patient stabilizing treatment as efficiently and effectively as possible. The letter further states that when the on-call physician is simultaneously on-call at more than one hospital in the geographic area, all hospitals involved must be aware of the on-call schedule, as each hospital independently has an EMTALA obligation.

In addition, the letter clarifies that hospitals must have policies and procedures to follow when an on-call physician is simultaneously on call at another hospital and is not available to respond. Hospital policies may include, but are not limited to, procedures for back-up on-call physicians, or the implementation of an appropriate EMTALA transfer according to § 489.24(d). The letter reaffirms CMS' view that hospitals have flexibility in adopting specific policies and procedures to meet their EMTALA obligations, so long as they meet the needs of the individuals who present for emergency care.

To avoid any misunderstanding of our policies in this area, we are revising proposed § 489.24(j) in this final rule to state the conditions under which simultaneous calls and elective surgery while on call are permitted.

7. Limiting On-Call Responsibility by Subspecialty

Comment: Some commenters stated that physicians' hospital privileges are typically more expansive than their actual scope of practice, in that a physician privileged in a broad specialty might in fact function only within a much narrower subspecialty. For example, a physician privileged by the hospital to treat all orthopedic cases might in fact limit his or her practice to pediatric cases. The commenters expressed concern that such a subspecialty physician might be disadvantaged by agreeing to be on call, since he or she could then be expected to treat types of patients that the physician would not normally see. To prevent this outcome, the commenters recommended that the EMTALA

regulations be revised to authorize such a physician to decline to come in when called if he or she believes that another physician can more competently care for the patient and should be called in.

Another commenter suggested that while subspecialists may be better qualified in their general specialties than emergency physicians, generalists may not necessarily be equally competent for all patients. For example, an ophthalmologist specializing in corneal or retinal surgery may have greater expertise in general ophthalmology than an emergency physician, but a fully competent general surgeon may nevertheless not have the specialized training and experience needed to perform emergency surgery on an infant. The commenter recommended that the regulations be revised to make it clear that, in such cases, the on-call physician is permitted to fulfill his or her on-call obligation by calling in another physician who has the necessary skills to care for the patient. The commenter also recommended formation of a private-public work group, similar to that described in proposed legislation (H.R. 3191, the "Medicare Appeals, Regulatory, and Contracting Improvement Act of 2001") to assist in resolving on-call issues. Another commenter recommended that the regulations be revised to state that physicians are not required to respond to calls for types of care for which they do not hold privileges.

Response: We agree with the commenter who stated the general principle is that patients should receive the best emergency care available. However, as pointed out by another commenter, a physician who is in a narrow subspecialty may, in fact, be medically competent in his or her general specialty, and in particular may be able to promptly contribute to the individual's care by bringing to bear skills and expertise that are not available to the emergency physician or other qualified medical personnel at the hospital. While the emergency physician and the on-call specialist may need to discuss the best way to meet the individual's medical needs, we also believe any disagreement between the two regarding the need for an on-call physician to come to the hospital and examine the individual must be resolved by deferring to the medical judgment of the emergency physician or other practitioner who has personally examined the individual and is currently treating the individual. We understand the concern of the commenter who believed the final rule should state that physicians are not

required to respond to calls for types of care for which they do not have privileges. However, we do not agree that a revision to the regulation is needed. On the contrary, we believe that it is the responsibility of the hospital that is maintaining the on-call list to ensure that physicians on the list are granted whatever privileges they would need to furnish care in the facility. Therefore, we are not revising the final rule as recommended by this commenter.

Comment: Some commenters recommended that the EMTALA regulations be revised to state explicitly that there may be situations in which a transfer to another medical facility, which may be either a hospital or a physician office, would be appropriate because the skills and experience of the local on-call physician may not be ideal for a particular individual. One commenter explained that such a clarification would help avoid inconveniencing on-call physicians, who might otherwise be required to come to a hospital to attend to relatively minor needs.

Response: While we agree that there may be some cases in which it is more beneficial to an individual to be transferred to another facility because of the greater availability of specialty physician services, we do not believe any change to the regulations is needed to acknowledge this possibility. On the contrary, existing regulations at § 489.24(c)(1) (now § 489.24(d)(1) in this final rule) make it quite clear that an appropriate transfer is one in which the expected benefits of appropriate medical treatment at another facility outweigh the risks associated with transfer. We also do not believe that individuals being seen in emergency departments would regard their emergency medical conditions as minor needs. Therefore, we are not making any changes in the regulations in this final rule based on these comments.

Comment: One commenter recommended that proposed § 489.24(j) be further revised to state that specialty hospitals, particularly those without dedicated emergency departments, are not required to maintain on-call lists under EMTALA.

Response: Existing regulations at § 489.20(r)(2), which implement the requirement for an on-call list, make it clear that this requirement does not apply to any hospital other than one with a dedicated emergency department. Therefore, we do not believe a change in the regulations is needed to clarify this point.

8. Other On-Call Issues

Comment: Some commenters stated that some physicians may choose to come to a hospital to see private patients at times when they are not shown as being on call under the listing the hospital maintains for EMTALA purposes. The commenters believed such physicians should not be considered to be on call under EMTALA simply because they come to the hospital under these circumstances, and expressed the belief that such a policy would be consistent with EMTALA interpretive guidelines stating that physicians are not expected to be on call whenever they are visiting their own patients in a hospital.

Response: We understand that physicians may sometimes come to a hospital to see their own patients, either as part of regular rounds or in response to requests from the patient or the patient's family, and agree that visits of this type should not necessarily be interpreted as meaning that the physician is on call. On the other hand, some physicians have in the past expressed a desire to refuse to be included on a hospital's on-call list but nevertheless take calls selectively. These physicians might, for example, respond to calls for patients with whom they or a colleague at the hospital have established a doctor-patient relationship, while declining calls from other patients, including those whose ability to pay may be in question. Such a practice would clearly be a violation of EMTALA. Because it may be difficult to distinguish the two practices from one another outside the context of a careful review of patient records, we are not making any revision to this final rule based on this comment. However, we will keep it in mind as we develop the interpretative guidelines and training materials for implementing EMTALA.

Comment: One commenter expressed approval of the preamble statement (67 FR 31478 of the May 9, 2002 proposed rule) that exempting senior medical staff from on-call responsibilities does not necessarily violate EMTALA. However, this commenter believed that statement should also be reflected in the text of the final regulations.

Response: We continue to believe such exemptions are not necessarily inconsistent with EMTALA, but they were mentioned in the preamble to illustrate rather than define the types of flexibility a hospital may exercise in maintaining its on-call list in a way that best meets patient needs. Thus, we do not believe this one example of

flexibility should be singled out for inclusion in the regulations.

Comment: One commenter stated that Federally Qualified Health Centers (FQHCs) are required under policies of the Public Health Service to maintain referral arrangements with hospitals for acceptance of health center patients, and that it is recommended that FQHCs maintain admitting privileges at those hospitals for their patients. However, the commenter was concerned that any monetary penalties for noncompliance with EMTALA on-call responsibilities will have to be paid by the health centers, and that physicians who learn that they will incur an on-call responsibility at a hospital as a cost of being privileged there may choose to stop practicing at the health centers, thereby depriving the health centers' patients of the physicians' services. Therefore, the commenter recommended that CMS provide some safe harbors, such as unspecified personal services or a high volume of patients needing care, that would protect physicians from EMTALA liability if they fail to be on call or are on call but fail to come to the hospital emergency department when called.

Response: As we noted above, this final rule makes explicit provision for two of the occurrences that physicians and other commenters have indicated to us are responsible for physicians' inability to respond to calls even though they have agreed to do so. In addition, we plan to direct State surveyors, in enforcing the EMTALA provisions, to be aware of situations in which circumstances beyond a physician's control may prevent him or her from responding promptly to calls. We believe these actions on our part will ensure sufficient flexibility and, therefore, we are not at this time further defining a set of specific "safe harbors." However, we will continue to monitor the commenter's concerns and will undertake further rulemaking if warranted in the future.

Comment: One commenter stated that some physicians, such as orthopedists, frequently use physician assistants in their practices. The commenter provided a number of examples of how a physician assistant could respond appropriately to a call from an emergency department, participate in the screening of an individual, and either provide the necessary stabilization or post-stabilization services, or arrange for the performance of those services by the physician. The commenter asked us to clarify that, in some instances, physician assistants may appropriately provide on-call coverage, by revising the EMTALA

regulations to state that physicians included on a hospital's on-call list may delegate their on-call responsibilities to the physician assistants they supervise, as long as all services provided by the physician assistants are furnished in accordance with State scope of practice laws and with hospital and medical bylaws.

Response: We agree that there may be circumstances in which a physician assistant may be the appropriate practitioner to respond to a call from an emergency department or other hospital department that is providing screening or stabilization mandated by EMTALA. However, any decision as to whether to respond in person or direct the physician assistant to respond should be made by the responsible on-call physician, based on the individual's medical needs and the capabilities of the hospital, and would, of course, be appropriate only if it is consistent with applicable State scope of practice laws and hospital bylaws, rules, and regulations.

D. Provisions of the Final Rule

In this final rule, we are adopting the proposed § 489.24(j) as final with the following modifications: We are specifying that the on-call list must be maintained in a manner that best meets the needs of the hospital's patients who are receiving services required under EMTALA, in accordance with the capability of the hospital, including the availability of on-call physicians. We also are revising paragraph (j) to state the conditions under which simultaneous call and elective surgery while on call are permitted. For editorial reasons, we are revising the language of § 489.24 to state under paragraph (j)(3)(ii) that hospitals must "provide" rather than "insure" that emergency services are available. No change in policy is being made by this editorial change.

XII. EMTALA Applicability to Hospital-Owned Ambulances (§ 489.24(b))

A. Background

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 closest hospital to the individual geographically, whether or not that hospital owns the ambulance.

B. Provisions of the Proposed Rule

To avoid imposing requirements that are inconsistent with local EMS requirements, in the May 9, 2002 proposed rule, we proposed to clarify, at proposed revised § 489.24(b), in paragraph (3) of the definition of "Comes to the emergency department", an exception to our existing rule requiring EMTALA applicability to hospitals that own and operate ambulances. We proposed to 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.

C. Summary of Public Comments and Departmental Responses

Comment: A number of commenters expressed strong support for the proposal to clarify that EMTALA does not apply to a hospital-owned ambulance when the ambulance is operating under communitywide protocols that require it to transport an individual to a hospital other than the hospital that owns the ambulance. One commenter asked whether a hospital would have any EMTALA obligation with respect to a patient who refuses transport from the planned pickup site (for example, the site of an automobile accident), and whether EMTALA would apply if the physician in the emergency department provides "medical command."

Another commenter recommended that the regulations be further revised to state that individuals presenting to

hospital-owned ambulances are subject to EMTALA and must be transported to the hospital that owns the ambulance, unless the hospital EMS personnel on board the ambulance determine that doing so would put the patient's life or safety at risk. The commenter further recommended that if the on-board hospital EMS personnel believe that transporting the individual to the owner hospital would risk the life or health of the individual, the personnel should be authorized to redirect the ambulance to the closest appropriate hospital without violating EMTALA.

Response: We appreciate the support of those commenters who expressed approval of the proposal and have kept their views in mind in responding to other comments on this issue. In regard to the comment about an individual who refuses transport from a planned pickup site, we believe such cases should be treated as refusals to consent to treatment and should be handled in accordance with the requirements for documenting such refusals in existing § 489.24(c)(2) (redesignated in this final rule as § 489.24(d)(3)).

We understand that the term "hospital-owned ambulances operating under medical command" describes a situation in which the destination of an ambulance is not determined by the ambulance personnel but by a physician in radio contact with ambulances in the community. We believe individuals on board such ambulances would not be considered to have "come to the hospital" for EMTALA purposes if the physician providing the medical command is not employed or otherwise affiliated with the hospital that owns the ambulance. If the physician's direction of the ambulance (medical command) is provided subject to communitywide protocols that require the individual to be transported to a hospital other than the hospital that owns the ambulance, such as the closest appropriate hospital, the hospital would be considered to be operating under communitywide protocols. With respect to situations in which hospital EMS personnel on board the ambulance determine that transporting the individual to the owner hospital would put the patient's life or safety at risk, we recognize that there may be some situations in which redirection of the ambulance is necessary to protect the life or safety of the individual and that under these circumstances it would not be an EMTALA violation to transport the individual to the closest hospital capable of treating his or her condition. However, we believe such cases can best be identified and resolved on a case-by-case basis and, therefore, are not

revising the final regulations based on this comment.

Comment: One commenter recommended that the proposed clarification of the nonapplicability of EMTALA to hospital-owned ambulances when the ambulance is operating under communitywide protocols be extended to air ambulances as well as ground ambulances.

Response: We agree and in this final rule are revising § 489.24(b), the definition of "come to the emergency department," accordingly.

Comment: One commenter recommended that guidance provided in the State Operations Manual, to the effect that hospitals have no EMTALA obligation with respect to individuals who are in ambulances that are neither hospital-owned and operated nor on hospital property, be incorporated into the regulatory language.

Response: We agree that this statement of policy is accurate, but believe the proposed regulatory language makes this clear. Therefore, we are not making revision in the final rule based on this comment.

Comment: One commenter referenced the recently issued CMS guidance, in the form of letters to Regional Administrators and State Survey Agencies, regarding EMTALA responsibilities in the event of a bioterrorist attack. The commenter believed this guidance might be viewed as being inconsistent with a hospital's statutory responsibility to provide screening services under EMTALA, and suggested that the regulatory language be revised to reflect the guidance, so that hospitals that follow it are not at risk for a citation of noncompliance with EMTALA.

Response: We agree that hospitals should be informed of their EMTALA responsibilities in the event of a bioterrorist attack or other national emergency. We also believe the commenter's suggestion is consistent with the intent of section 143 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188, enacted June 12, 2002). That legislation amended section 1135 of the Act to authorize the Secretary to temporarily waive or modify the application of certain Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) requirements, including requirements for the imposition of sanctions for the otherwise inappropriate transfer of an unstabilized individual, if the transfer arises out of the circumstances of the emergency.

To help inform hospitals of their responsibilities in such situations, we

have added a new paragraph (a)(2) to § 489.24(a). The new paragraph specifies that sanctions under EMTALA for an inappropriate transfer during a national emergency do not apply to a hospital with a dedicated emergency department located in an emergency area, as specified in section 1135(g)(1) of the Act. In the event of such a national emergency, CMS would issue appropriate guidance to hospitals.

Comment: One commenter stated that, in some areas of the country, ambulance protocols requiring emergency patients to be taken to the closest appropriate hospital are not determined on a community-by-community basis. Instead, the protocols apparently are established by individual ambulance service medical directors in conformity with State law and are filed with the State EMS board. The commenter expressed concern that the proposed regulatory language on communitywide EMS protocols would not protect hospitals in such States from inappropriate EMTALA liability, and cited several examples of situations in which a hospital-owned and operated ambulance might be required to bypass appropriate hospitals to reach the owner hospital. To avoid this result, the commenter recommended that the regulations be revised either to state that hospital-owned and operated ambulances are not included in the definition of "hospital property" or to provide an exemption for hospital-owned ambulances operated in accordance with protocols on file with and approved by the State ambulance licensing authority.

Response: We agree that protocols mandated by State law should be given the same deference as those established on a communitywide basis. However, we believe the reference in § 489.24(b)(3)(i) to communitywide EMS protocols which direct that the individual be transported to a hospital other than the hospital that owns the ambulance is broad enough to encompass those communitywide protocols that have been adopted in conformity with State law. Therefore, we are not revising the provision in the final rule based on this comment.

Comment: One commenter stated that most ambulance protocols direct that individuals be taken to the "closest appropriate facility" rather than the "nearest hospital" and suggested that this change in wording of the regulation text would be appropriate because, in some cases, individuals may need to be taken to a freestanding emergency facility or some other location that is not a hospital. The commenter also recommended that hospital-owned and

operated ambulances be given an exemption from the requirements for situations in which the individual or family asks that the individual be transported to another facility other than the hospital that owns the ambulance.

Response: We agree that it would be more appropriate to refer to requirements that the individuals be taken to the “closest appropriate facility” rather than the “nearest hospital”, and are including this change in paragraph (3) of the definition of “come to the emergency department” under § 489.24(b) of this final rule.

Regarding the redirection of an ambulance at the request of the individual’s family, we believe existing regulations at § 489.24(c)(2) (now § 489.24(d)(3) of this final rule) regarding informed refusals of treatment would permit the ambulance to transport the individual to another facility. A medical record for the individual must be established and the refusal clearly documented in that record, in accordance with these regulatory requirements.

D. Provisions of the Final Rule

We are adopting, as final, the proposed revision to paragraph (3) under the definition of “come to the emergency department” under § 489.24(b) as it related to the applicability to EMTALA to hospital-owned ambulances, with the following modifications:

We are specifying the nonapplicability of EMTALA to hospital-owned “air” ambulances (in addition to ground ambulances), when the ambulance is operating under communitywide protocols.

We are specifying that an individual in an ambulance owned and operated by the hospital is not considered to have “come to the emergency department” if the ambulance is operated under communitywide EMS protocols or EMS protocols “mandated by State law” that direct it to transport the individual to a hospital other than the hospital that owns the ambulance. We also are specifying that an individual in an ambulance owned and operated by the hospital is not considered to have “come to the emergency department” if the ambulance is operated at the direction of a physician who is not employed or otherwise affiliated with the hospital that owns the ambulance or if the physician’s direction of the destination of the ambulance is subject to communitywide protocols that require the individual to be transported to a hospital other than the hospital that owns the ambulance.

We are changing the term “closest hospital” to “closest appropriate facility”.

In addition, we are adding a new § 489.24(a)(2) to specify EMTALA responsibilities in the event of a bioterrorist attack.

XIII. Conditions of Participation for Hospitals

We are reminding hospitals and others that while these final regulations make it clear that, while stabilizing an individual with an emergency medical condition (or admitting the individual to the hospital as an inpatient) relieves the hospital of its EMTALA obligations, it does not relieve the hospital of all further responsibility for the patient who is admitted. Stabilization or inpatient admission also does not indicate that the hospital is thus free to improperly discharge or transfer the individual to another facility. Inpatients who experience acute medical conditions receive protections under the Medicare hospital CoPs, which are found at 42 CFR part 482. In addition, as noted earlier in this preamble and in the May 9, 2002 proposed rule 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 hospital CoPs. There are six hospital CoPs that provide these protections: emergency services, governing body, discharge planning, quality assessment and performance improvement, medical staff, and outpatient services. In the May 9, 2002 proposed rule, we proposed to make only one change in these CoPs: one relating to the governing body having written policies and procedures in effect for off-campus departments that do not offer emergency services for appraisal of emergencies and referral when appropriate (§ 482.12(f)(3)).

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 CoP (§ 482.12(f)(2), which applies to all Medicare-participating hospitals) would apply. This CoP 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 CoP (§ 482.43, which applies to all Medicare-participating hospitals) requires hospitals to have a discharge planning process that applies to all patients. This CoP 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 CoP in carrying out such a transfer.

The hospital CoP 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 CoP, as well, and may result in a citation of noncompliance at the medical staff condition level for the hospital.

Finally, the quality assessment and performance improvement CoP (§ 482.21, which applies to all Medicare-participating hospitals) requires the governing body to ensure that there is an effective, hospital-wide quality assessment and performance improvement program to evaluate the provision of patient care. In order to comply with this CoP, 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 assessment and performance improvement CoP.

A hospital’s failure to meet the CoPs 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. As we explained in the preamble to the January 24, 2003 final rule (69 FR 3435), the CoPs are the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. The

CoPs are intended to protect patient health and safety and to ensure that high quality care is provided to all patients. The State survey agencies (SAs), in accordance with section 1864 of the Social Security Act (the Act), survey hospitals to assess compliance with the CoPs. The SAs conduct surveys using the instructions in the State Operations Manual (SOM), (Health Care Financing Administration (HCFA) Publication No. 7). The SOM contains the regulatory language of the CoPs as well as interpretive guidelines and survey procedures and probes that elaborate on regulatory intent and give guidance on how to assess provider compliance. Under § 489.10(d), the SAs determine whether hospitals have met the CoPs and report their recommendations to us. The standards, procedures, and SA personnel involved in developing recommendations regarding EMTALA compliance are the same as those for recommendations regarding CoP compliance, since alleged violations of EMTALA are treated as allegations that a hospital has not complied with a requirement for Medicare participation.

Under the authority of section 1865 of the Act and the regulations at § 488.5, hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA) are deemed to meet the requirements in the CoPs, and therefore, are not routinely surveyed for CoP compliance by the SAs. However, all Medicare and Medicaid participating hospitals are required to be in compliance with our CoPs regardless of their accreditation status.

Comment: Some commenters expressed general approval of the proposed revision to § 482.12(f), which is applicable to hospitals that provide emergency services but have departments off campuses that do not provide emergency services.

Response: We appreciate these commenters' support and have kept their views in mind in evaluating the other comments recommending specific changes in this final rule.

Comment: Some commenters stated that the proposed revision to § 482.12(f) seems to imply that hospitals must have staff trained in appraisal of emergencies on duty on a 24-hour per day, 7-day a week basis to comply with the requirement. The commenters believed that this would be an unreasonable requirement.

Response: We agree that such a requirement for off-campus departments would be unreasonably stringent. Therefore, we plan to clarify in the

interpretive guidelines or training materials used to implement this requirement that the policies and procedures in place for appraisal of emergencies and referral when appropriate must be implemented only within the hours of operation and normal staffing capability of the facility.

Comment: Some commenters opposed adding a specific CoP provision for off-campus departments of hospitals that have dedicated emergency departments but do not offer emergency services at their off-campus locations. The commenters believed this is an unnecessary burden on hospital governing bodies and medical staffs.

Response: We do not agree that adding this condition will impose an unnecessary burden on hospitals. First, the amount of burden will be minimal, because the regulation does not require that the facilities provide emergency care or add to their existing medical capabilities, but only that appropriate policies and procedures be in place. While developing and implementing these policies and procedures will require some effort from facilities that do not have them in place, the effort involved should be considerably less than that required to comply with current regulations at § 489.24(i) regarding EMTALA compliance by hospitals with off-campus nonemergency departments, which are being replaced by the condition. We also do not agree that any remaining burden associated with the revised requirement is unnecessary. On the contrary, the ability of such an off-campus facility to respond promptly and appropriately to an unexpected request for emergency care can be crucial to the health and safety of the individual with the emergency condition.

Because we believe that the burden of having a plan in place to deal with an occasional emergency is minimal and the potential benefit to the individual of having such a plan is considerable, we are not making changes to the proposed CoP in this final rule in response to this comment.

XIV. Other Issues

A. Editorial/Clarifying Changes

In addition to the changes to § 489.24 discussed in sections V. through XIII. of this preamble, we are revising § 489.24(d)(3) (Refusal to consent to treatment) to refer to an individual or a person acting on the individual's behalf who "does not consent to the examination or treatment," rather than referring to an individual or a person acting on the individual's behalf who

"refuses to consent to examination and treatment." We are making a parallel change in § 489.24(d)(5) (Refusal to consent to transfer). We are making these changes only for editorial reasons and in the interest of clarity; these revisions do not represent any change in policy.

B. Out-of-Scope Comments

We received a number of public comments on issues that were not addressed as part of the May 9, 2002 proposed rule. Because the issues addressed in the comments were not part of the proposed rule, we are not providing responses to them in this final rule. We will consider them in the future if we consider changes in related policy areas.

XV. Information Collection Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

§ 482.12 Conditions of Participation: Governing Body

New § 482.12(f)(3) specifies 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 have written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.

While this information collection requirement is subject to the PRA, the fact that this requirement is a usual, customary, and prudent business and

medical practice exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2). It is standard for medical facilities to have written policies and procedures pertaining to medical emergencies. Having written policies and procedures saves time deciding what to do and thus benefits the patient; it also gives the provider liability protection.

In the May 9, 2002 proposed rule (67 FR 31496), we solicited, public comment on this information collection requirement. However, we did not receive any public comments on this information collection requirement.

§ 489.24 Special responsibilities of Medicare hospitals in emergency cases.

Paragraph (d) of this section requires that, if the hospital offers an 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) does not consent to the examination or treatment: (1) 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; (2) 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); and (3) the written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

Paragraph (d) of this section also requires that, 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) does not consent to the transfer: (1) 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); (2) 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; and (3) the medical record must contain a description of the proposed transfer that was refused by or on behalf of the individual.

The burden associated with these requirements is the time it will take a hospital to secure a written refusal, create a written document containing

the information the patient has been given, and describing in the patient's record what was refused. These information collection requirements are currently approved under 0938-0667.

Paragraph (j) of this section requires that 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 who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians. It also requires that the hospital 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 and to provide that emergency services are available to meet the needs of patients with emergency medical conditions if it elects to permit on-call physicians to schedule elective surgery during the time that they are on call or to permit on-call physicians to have simultaneous on-call duties.

The burden associated with these requirements is the time it will take to create the list and write down the policies and procedures. We believe that these actions reflect usual, customary, and prudent medical and business practices; the burden is exempt from the PRA under 5 CFR 1320.3(b)(2). We believe that the providers have the necessary written information available to the staff in times of emergencies to reduce the time it takes to contact a doctor or to decide what to do if the doctor is unavailable. These actions benefit the patient and give the provider liability protection.

We note that these requirements in paragraph (j) are revisions of provisions that were included in the May 9, 2002 proposed rule.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: Julie Brown, CMS-1063-F Room C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244-1850; and Office of Information and Regulatory Affairs, Office of Management and

Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

Comments submitted to OMB may also be e-mailed to the following address: e-mail: baguilar@omb.eop.gov; or faxed to OMB at (202) 395-6974.

XVI. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

B. Executive Order 12866

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year).

We have determined that this final rule is not a major rule as defined in 5 U.S.C. 804(2). As explained below, we do not have sufficient information to estimate the precise economic impact of this final rule. However, in general, this final rule diminishes rather than increases the EMTALA compliance burden on hospitals and physicians as this burden exists under current regulations. In both the previous EMTALA rules, the proposed EMTALA rule published on June 16, 1988 (53 FR 22513) and the preamble to the interim final rule published on June 22, 1994 (59 FR 32120), we explained, and the Secretary certified, that those regulations would not have a significant impact on a substantial number of small entities and would not have a significant impact on the operations of a substantial number of small rural hospitals. As explained above, this final rule further reduces compliance burden and cost. Therefore, we estimate that the total impact of these changes will be less than the threshold for a major rule (\$100 million or more in any 1 year).

C. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity.

In the preamble of the May 9, 2002 proposed rule, we stated that we believed it would be difficult to quantify the impact of the proposed changes and solicited comments on how such an impact estimate could be developed. We did not receive any comments on this point. Neither the proposed EMTALA rule published on June 16, 1988 (53 FR 22513) nor the interim final rule published on June 22, 1994 (50 FR 32086) included a quantitative analysis of the economic impact of the rule. However, in the preamble to each rule, we explained that because the great majority of hospitals do not refuse to treat individuals or transfer patients inappropriately based on their perceived inability to pay, the economic impact of those rules was minimal. Since this rule is only a modification of the previous EMTALA rules, we believe that the impact of this final rule is also minimal. For the reasons explained above, we are confident that the overall effect of this final rule will be to reduce rather than increase the EMTALA compliance burden for hospitals and physicians. For example, the compliance burden for hospitals will be reduced because off-campus provider-based departments that are not dedicated emergency departments will no longer have any EMTALA responsibilities. The burden for physicians should be reduced by the changes that allow them to be on call simultaneously at multiple locations, and to schedule other procedures while they are on call. Because we do not have enough information to precisely predict the dollar amount of the reduced burden, we have not attempted to produce a quantified estimate of the impact of this final rule. However, based on the reduction in burden relative to current regulations, we have determined that this final rule will not have a significant impact on a substantial number of small entities.

D. Effects on Rural Hospitals

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a

significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 100 beds that is located outside of a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA). Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98-21) designated hospitals in certain New England counties as belonging to the adjacent NECMA. Thus, for purposes of payments to hospitals, we classify these hospitals as urban hospitals. As explained above, the compliance burden and cost associated with this final rule is expected to be significantly less than the burden associated with existing regulations. Based on the reduction in burden relative to current regulations, we have determined that this final rule will not have a significant impact on the operations of small rural hospitals.

E. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) also requires that agencies assess anticipated costs and benefits before issuing a final rule that has been preceded by a proposed rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This final rule will not mandate any requirements that may result in an expenditure, in any 1 year for State, local, or tribal governments or for the private sector of \$110 million.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule in light of Executive Order 13132 and have determined that it will not have any significant impact on the rights, roles, and responsibilities of State, local, or tribal governments.

G. Executive Order 12866

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant program-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

- For the reasons set forth in this preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

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

- A. Part 413 is amended as follows:
- 1. The authority citation for part 413 continues 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 adding introductory text under paragraph (g) and revising paragraph (g)(1) to read as follows:

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

* * * * *

(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.

* * * * *

PART 482—CONDITIONS FOR PARTICIPATION FOR HOSPITALS

- B. 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 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

- C. 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”, “Inpatient”, 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 new paragraphs (c) and (j).
- I. Revising newly redesignated paragraph (d).
- J. 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)(ii)” 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) *Applicability of provisions of this section.* (1) 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—

(i) 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) who is determined qualified by hospital bylaws or rules and regulations and who meets the requirements of § 482.55 of this chapter concerning emergency services personnel and direction; and

(ii) 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. If the hospital admits the individual as an inpatient for further treatment, the hospital’s obligation under this section ends, as specified in paragraph (d)(2) of this section.

(2) *Nonapplicability of provisions of this section.* Sanctions under this section for inappropriate transfer during a national emergency do not apply to a hospital with a dedicated emergency department located in an emergency area, as specified in section 1135(g)(1) of the Act.

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

* * * * *

Comes to the emergency department means, with respect to an individual who is not a patient (as defined in this section), 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. 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 a ground or air ambulance owned and operated by the hospital for purposes of examination and treatment for a medical condition at a hospital’s

dedicated emergency department, even if the ambulance is not on hospital grounds. However, an individual in an ambulance owned and operated by the hospital is not considered to have “come to the hospital’s emergency department” if—

(i) The ambulance is operated under communitywide emergency medical service (EMS) protocols that direct it to transport the individual to a hospital other than the hospital that owns the ambulance; for example, to the closest appropriate facility. 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;

(ii) The ambulance is operated at the direction of a physician who is not employed or otherwise affiliated with the hospital that owns the ambulance; or

(4) Is in a ground or air nonhospital-owned ambulance on hospital property for presentation for examination and treatment for a medical condition at a hospital’s dedicated emergency department. However, 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. The hospital may direct the ambulance to another facility 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 diversion instructions and transports the individual onto hospital property, the individual is considered to have come to the emergency department.

Dedicated emergency department means any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:

(1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department;

(2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or

(3) During the calendar year immediately preceding the calendar year in which a determination under

this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

* * * * *

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 of the hospital’s main building that 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 with a dedicated emergency department as defined in this paragraph (b).

Inpatient means an individual who is admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services as described in § 409.10(a) of this chapter with the expectation that he or she will remain at least overnight and occupy a bed even though the situation later develops that the individual can be discharged or transferred to another hospital and does not actually use a hospital bed overnight.

* * * * *

Patient means—

(1) An individual who has begun to receive outpatient services as part of an encounter, as defined in § 410.2 of this chapter, other than an encounter that the hospital is obligated by this section to provide;

(2) An individual who has been admitted as an inpatient, as defined in this section.

* * * * *

(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.* Subject to the provisions of paragraph (d)(2) of this section, 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.

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

(2) *Exception: Application to inpatients.* (i) If a hospital has screened an individual under paragraph (a) of this section and found the individual to have an emergency medical condition, and admits that individual as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its special responsibilities under this section with respect to that individual.

(ii) This section is not applicable to an inpatient who was admitted for elective (nonemergency) diagnosis or treatment.

(iii) A hospital is required by the conditions of participation for hospitals under Part 482 of this chapter to provide care to its inpatients in accordance with those conditions of participation.

(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) does not consent to the examination or 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 paragraph (d)(1) 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 an individual to seek, authorization from the individual's insurance company for screening or stabilization services to be furnished by a hospital, physician, or nonphysician practitioner 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 paragraph (d)(1) of this section.

(iii) An emergency physician or nonphysician practitioner is not precluded from contacting the individual's physician at any time to seek advice regarding the individual'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.

(iv) Hospitals may follow reasonable registration processes for individuals for whom examination or treatment is required by this section, including asking whether an individual is insured and, if so, what that insurance is, as

long as that inquiry does not delay screening or treatment. Reasonable registration processes may not unduly discourage individuals from remaining for further evaluation.

(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) does not 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.

* * * * *

(j) *Availability of on-call physicians.*

(1) 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 who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians.

(2) The hospital must have written policies and procedures in place—

(i) 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; and

(ii) To provide that emergency services are available to meet the needs of patients with emergency medical conditions if it elects to permit on-call physicians to schedule elective surgery during the time that they are on call or to permit on-call physicians to have simultaneous on-call duties.

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

Dated: April 3, 2003.

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

Dated: June 27, 2003.

Tommy G. Thompson,
Secretary.

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