

# EMTALA and Emergency-Related Federal Regulations

Source: Title 42, Code of Federal Regulations, Sections 413.65, 482.12, 485.618(d), 489.20 and 489.24  
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NOTE: Ellipses (...) indicate omitted text.

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

(a) *Scope and definitions.*

...

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

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

...

(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 Sections 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 Section 489.24(b) of this chapter.

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## Part 482—Conditions of Participation for Hospitals

### § 482.12 Conditions of participation: Governing body.

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(f) *Standard: Emergency Services.*

...

(2) If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

(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.

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### **Part 485—Conditions of Participation for Community Access Hospitals**

#### **§ 485.618 Conditions of participation: Emergency services.**

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(d) *Standard: Personnel.*

(1) Except as specified in paragraph (d)(3) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact, and available on site within the following timeframes:

(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or

(ii) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets the criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) The State has determined, under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse with training and experience in emergency care can be utilized to conduct specific medical screening examinations only if—

(i) The registered nurse is on site and immediately available at the CAH when a patient requests medical care; and

(ii) The nature of the patient's request for medical care is within the scope of practice of a registered nurse and consistent with applicable state laws and the CAH's bylaws or rules and regulations.

(3) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if—

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;

(iii) The State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural healthcare plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience

in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section;

(iv) Once a Governor submits a letter, as specified in paragraph (d)(3)(iii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

(4) The request, as specified in paragraph (d)(3)(iii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

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### **Subpart B—Essentials of Medicare Provider Agreements**

#### **§ 489.20 Basic commitments.**

The provider agrees to the following:

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(l) In the case of a hospital as defined in Section 489.24(b) to comply with Section 489.24.

(m) In the case of a hospital as defined in Section 489.24(b), to report to CMS or the State survey agency any time it has reason to believe it may have received an individual who has been transferred in an unstable emergency medical condition from another hospital in violation of the requirements of Section 489.24(e).

...

(q) In the case of a hospital as defined in Section 489.24(b)—

(1) To post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area), a sign (in a form specified by the Secretary) specifying rights of individuals under Section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and

(2) To post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital participates in the Medicaid program under a State plan approved under title XIX.

(r) In the case of a hospital as defined in Section 489.24(b) (including both the transferring and receiving hospitals), to maintain —

(1) Medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of the transfer;

(2) An on-call list of physicians who are on the hospital's medical staff or who have privileges at the hospital, or who are on the staff or have privileges at another hospital participating in a formal community call plan, in accordance with Section 489.24(j)(2)(iii),

available to provide treatment necessary after the initial examination to stabilize individuals with emergency medical conditions who are receiving services required under Section 489.24 in accordance with the resources available to the hospital; and

(3) A central log on each individual who comes to the emergency department, as defined in Section 489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.

...

(w) In the case of a hospital as defined in Section 489.24(b), to furnish written notice to all patients at the beginning of their hospital stay or outpatient visit if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week, in order to assist the patients in making informed decisions regarding their care, in accordance with Section 482.13(b)(2) of this subchapter. The notice must indicate how the hospital will meet the medical needs of any patient who develops an emergency medical condition, as defined in Section 489.24(b), at a time when there is no physician present in the hospital. For purposes of this paragraph, the hospital stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or outpatient service.

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#### **§ 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 Section 482.55 of this chapter concerning emergency services personnel and direction;<sup>1</sup> 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)(i) When a waiver has been issued in accordance with Section 1135 of the Act that includes a waiver under Section 1135(b)(3) of the Act, sanctions under this section for an inappropriate transfer or for the direction or relocation of an individual to receive medical screening at an alternate location do not apply to a hospital with a dedicated emergency department if the following conditions are met:

(A) The transfer is necessitated by the circumstances of the declared emergency in the emergency area during the emergency period.

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<sup>1</sup> Section 482.55 is the Medicare Condition of Participation for emergency services.

(B) The direction or relocation of an individual to receive medical screening at an alternate location is pursuant to an appropriate State emergency preparedness plan or, in the case of a public health emergency that involves a pandemic infectious disease, pursuant to a State pandemic preparedness plan.

(C) The hospital does not discriminate on the basis of an individual's source of payment or ability to pay.

(D) The hospital is located in an emergency area during an emergency period, as those terms are defined in Section 1135(g)(1) of the Act.

(E) There has been a determination that a waiver of sanctions is necessary.

(ii) A waiver of these sanctions is limited to a 72-hour period beginning upon the implementation of a hospital disaster protocol, except that, if a public health emergency involves a pandemic infectious disease (such as pandemic influenza), the waiver will continue in effect until the termination of the applicable declaration of a public health emergency, as provided under Section 1135(e)(1)(B) of the Act.

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

*Capacity* means the ability of the hospital to accommodate the individual requesting examination or treatment of the transferred individual. Capacity encompasses such things as numbers and availability of qualified staff, beds and equipment and the hospital's past practices of accommodating additional patients in excess of its occupancy limits.

*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 the 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.

*Emergency medical condition* means—

(1) A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances and/or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in—

(i) Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

(ii) Serious impairment to bodily functions; or

(iii) Serious dysfunction of any bodily organ or part; or

(2) With respect to a pregnant woman who is having contractions—

(i) That there is inadequate time to effect a safe transfer to another hospital before delivery; or

(ii) That transfer may pose a threat to the health or safety of the woman or the unborn child.

*Hospital* includes a critical access hospital as defined in Section 1861(mm)(1) of the Act.

*Hospital property* means the entire main hospital campus as defined in Section 413.65(b) of this chapter,<sup>2</sup> 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 Section 409.10(a) of this chapter<sup>3</sup> 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.

*Labor* means the process of childbirth beginning with the latent or early phase of labor and continuing through the delivery of the placenta. A woman experiencing contractions is in true labor unless a physician, certified nurse-midwife, or other qualified medical person acting within his or her scope of practice as defined in hospital medical staff bylaws and State law, certifies that, after a reasonable time of observation, the woman is in false labor.

*Participating hospital* means (1) a hospital or (2) a critical access hospital as defined in Section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under Section 1866 of the Act.

*Patient* means —

(1) An individual who has begun to receive outpatient services as part of an encounter, as defined in Section 410.2 of this chapter,<sup>4</sup> 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.

*Stabilized* means, with respect to an “emergency medical condition” as defined in this section under paragraph (1) of that definition, that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility or, with respect to an “emergency medical condition” as defined in this section under paragraph (2) of that definition, that the woman has delivered the child and the placenta.

*To stabilize* means, with respect to an “emergency medical condition” as defined in this section under paragraph (1) of that definition, to provide such medical treatment of the condition necessary to assure, within reasonable medical probability, that no material

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<sup>2</sup> The definition of “campus” in Section 413.65 is set forth on page B.1.

<sup>3</sup> Section 409.10(a) defines “inpatient hospital or inpatient CAH services” as including bed and board; nursing and related services; use of hospital and CAH facilities; medical social services; drugs, biologicals, supplies, appliances and equipment; certain other diagnostic and therapeutic services; medical and surgical services provided by interns and residents; and transportation services.

<sup>4</sup> Section 410.2 defines “encounter” as a “direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient.”

deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility or that, with respect to an “emergency medical condition” as defined in this section under paragraph (2) of that definition, the woman has delivered the child and the placenta.

*Transfer* means the movement (including the discharge) of an individual outside a hospital’s facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who (i) has been declared dead, or (ii) leaves the facility without the permission of any such person.

(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.<sup>5</sup> 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.

(e) *Restricting transfer until the individual is stabilized—(1) General.* If an individual at a hospital has an emergency medical condition that has not been stabilized (as defined in paragraph (b) of this section), the hospital may not transfer the individual unless—

(i) The transfer is an appropriate transfer (within the meaning of paragraph (e)(2) of this section); and

(ii)(A) The individual (or a legally responsible person acting on the individual's behalf) requests the transfer, after being informed of the hospital's obligations under this section and of the risk of transfer. The request must be in writing and indicate the reasons for the request as well as indicate that he or she is aware of the risks and benefits of the transfer;

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<sup>5</sup> However, California law is stricter. See "State Requirements," page 4.3.

(B) A physician (within the meaning of section 1861(r)(1) of the Act) has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the woman or the unborn child, from being transferred. The certification must contain a summary of the risks and benefits upon which it is based; or

(C) If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as determined by the hospital in its bylaws or rules and regulations) has signed a certification described in paragraph (e)(1)(ii)(B) of this section after a physician (as defined in section 1861(r)(1) of the Act) in consultation with the qualified medical person, agrees with the certification and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based.

(2) A transfer to another medical facility will be appropriate only in those cases in which—

(i) The transferring hospital provides medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;

(ii) The receiving facility—

(A) Has available space and qualified personnel for the treatment of the individual; and

(B) Has agreed to accept transfer of the individual and to provide appropriate medical treatment;

(iii) The transferring hospital sends to the receiving facility all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of the transfer, including available history, records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) required under paragraph (e)(1)(ii) of this section, and the name and address of any on-call physician (described in paragraph (g) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment. Other records (e.g., test results not yet available or historical records not readily available from the hospital's files) must be sent as soon as practicable after transfer; and

(iv) The transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer.

(3) A participating hospital may not penalize or take adverse action against a physician or a qualified medical person described in paragraph (e)(1)(ii)(C) of this section because the physician or qualified medical person refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized, or against any hospital employee because the employee reports a violation of a requirement of this section.

(f) *Recipient hospital responsibilities.* A participating hospital that has specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or, with respect to rural areas, regional referral centers (which, for purposes of this subpart, mean hospitals meeting the requirements of referral centers found at Section 412.96 of this chapter)) may not refuse to accept from a

referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual.

(1) The provisions of this paragraph (f) apply to any participating hospital with specialized capabilities, regardless of whether the hospital has a dedicated emergency department.

(2) The provisions of this paragraph (f) do not apply to an individual who has been admitted to a referring hospital under the provisions of paragraph (d)(2)(i) of this section.

(g) *Termination of provider agreement.* If a hospital fails to meet the requirements of paragraphs (a) through (f) of this section, CMS may terminate the provider agreement in accordance with Section 489.53.

(h) Consultation with Quality Improvement Organizations (QIOs) —

(1) *General.* Except as provided in paragraph (h)(3) of this section, in cases where a medical opinion is necessary to determine a physician's or hospital's liability under Section 1867(d)(1) of the Act, CMS requests the appropriate QIO (with a contract under Part B of title XI of the Act) to review the alleged section 1867(d) violation and provide a report on its findings in accordance with paragraphs (h)(2)(iv) and (v) of this section. CMS provides to the QIO all information relevant to the case and within its possession or control. CMS, in consultation with the OIG, also provides to the QIO a list of relevant questions to which the QIO must respond in its report.

(2) *Notice of review and opportunity for discussion and additional information.* The QIO shall provide the physician and hospital reasonable notice of its review, a reasonable opportunity for discussion, and an opportunity for the physician and hospital to submit additional information before issuing its report. When a QIO receives a request for consultation under paragraph (h)(1) of this section, the following provisions apply—

(i) The QIO reviews the case before the 15th calendar day and makes its tentative findings.

(ii) Within 15 calendar days of receiving the case, the QIO gives written notice, sent by certified mail, return receipt requested, to the physician or the hospital (or both if applicable).

(iii)(A) The written notice must contain the following information:

(1) The name of each individual who may have been the subject of the alleged violation.

(2) The date on which each alleged violation occurred.

(3) An invitation to meet, either by telephone or in person, to discuss the case with the QIO, and to submit additional information to the QIO within 30 calendar days of receipt of the notice, and a statement that these rights will be waived if the invitation is not accepted. The QIO must receive the information and hold the meeting within the 30-day period.

(4) A copy of the regulations at 42 C.F.R. 489.24.

(B) For purposes of paragraph (h)(2)(iii)(A) of this section, the date of receipt is presumed to be 5 days after the certified mail date on the notice, unless there is a reasonable showing to the contrary.

(iv) The physician or hospital (or both where applicable) may request a meeting with the QIO. This meeting is not designed to be a formal adversarial hearing or a mechanism for discovery by the physician or hospital. The meeting is intended to afford the physician

and/or the hospital a full and fair opportunity to present the views of the physician and/or hospital regarding the case. The following provisions apply to that meeting:

(A) The physician and/or hospital has the right to have legal counsel present during that meeting. However, the QIO may control the scope, extent, and manner of any questioning or any other presentation by the attorney. The QIO may also have legal counsel present.

(B) The QIO makes arrangements so that, if requested by CMS or the OIG, a verbatim transcript of the meeting may be generated. If CMS or OIG requests a transcript, the affected physician and/or the affected hospital may request that CMS provide a copy of the transcript.

(C) The QIO affords the physician and/or the hospital an opportunity to present, with the assistance of counsel, expert testimony in either oral or written form on the medical issues presented. However, the QIO may reasonably limit the number of witnesses and length of such testimony if such testimony is irrelevant or repetitive. The physician and/or hospital, directly or through counsel, may disclose patient records to potential expert witnesses without violating any non-disclosure requirements set forth in part 476 of this chapter.

(D) The QIO is not obligated to consider any additional information provided by the physician and/or the hospital after the meeting, unless, before the end of the meeting, the QIO requests that the physician and/or hospital submit additional information to support the claims. The QIO then allows the physician and/or the hospital an additional period of time, not to exceed 5 calendar days from the meeting, to submit the relevant information to the QIO.

(v) Within 60 calendar days of receiving the case, the QIO must submit to CMS a report on the QIO's findings. CMS provides copies to the OIG and to the affected physician and/or the affected hospital. The report must contain the name of the physician and/or the hospital, the name of the individual, and the dates and times the individual arrived at and was transferred (or discharged) from the hospital. The report provides expert medical opinion regarding whether the individual involved had an emergency medical condition, whether the individual's emergency medical condition was stabilized, whether the individual was transferred appropriately, and whether there were any medical utilization or quality of care issues involved in the case.

(vi) The report required under paragraph (h)(2)(v) of this section should not state an opinion or conclusion as to whether section 1867 of the Act or Section 489.24 has been violated.

(3) If a delay would jeopardize the health or safety of individuals or when there was no screening examination, the QIO review described in this section is not required before the OIG may impose civil monetary penalties or an exclusion in accordance with section 1867(d)(1) of the Act and 42 C.F.R. part 1003 of this title.

(4) If the QIO determines after a preliminary review that there was an appropriate medical screening examination and the individual did not have an emergency medical condition, as defined by paragraph (b) of this section, then the QIO may, at its discretion, return the case to CMS and not meet the requirements of paragraph (h) except for those in paragraph (h)(2)(v).

(i) *Release of QIO assessments.* Upon request, CMS may release a QIO assessment to the physician and/or hospital, or the affected individual, or his or her representative. The QIO physician's identity is confidential unless he or she consents to its release. (See Section 476.132 and 476.133 of this chapter.)

(j) *Availability of on-call physicians.* In accordance with the on-call list requirements specified in Section 489.20(r)(2), a hospital must have written policies and procedures in place —

(1) 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

(2) To provide that emergency services are available to meet the needs of individuals with emergency medical conditions if a hospital elects to —

(i) Permit on-call physicians to schedule elective surgery during the time that they are on-call;

(ii) Permit on-call physicians to have simultaneous on-call duties; and

(iii) Participate in a formal community call plan. Notwithstanding participation in a community call plan, hospitals are still required to perform medical screening examinations on individuals who present seeking treatment and to conduct appropriate transfers. The formal community plan must include the following elements:

(A) A clear delineation of on-call coverage responsibilities; that is, when each hospital participating in the plan is responsible for on-call coverage.

(B) A description of the specific geographic area to which the plan applies.

(C) A signature by an appropriate representative of each hospital participating in the plan.

(D) Assurances that any local and regional EMS system protocol formally includes information on community on-call arrangements.

(E) A statement specifying that even if an individual arrives at a hospital that is not designated as the on-call hospital, that hospital still has an obligation under Section 489.24 to provide a medical screening examination and stabilizing treatment within its capability, and that hospitals participating in the community call plan must abide by the regulations under Section 489.24 governing appropriate transfers.

(F) An annual assessment of the community call plan by the participating hospitals.