Summary of 09 Sept 2003 EMTALA Revisions

- The provisions of this final rule were effective on November 10, 2003 -

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This most recent ruling 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), also known as the "patient anti-dumping statute".

Background:

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 (the 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 are 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.

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.

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.

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.

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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.

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.

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. In addition, the hospital may transfer an unstable patient who makes an informed written request.

Some EMTALA-related 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.

<u>This brings us to today…</u>

The Centers for Medicare and Medicaid Services (CMS) Review Board states that it is their belief 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.

Hospitals and physicians have now had over 15 years of experience in organizing themselves to comply with the provisions of EMTALA. In the May 9, 2002 proposed rule, they (the Review Board) specifically solicited comments on all of these proposed changes. In response to the proposed rule, they received approximately 600 pieces of correspondence, most of which contained multiple comments. What follows is a summary of the Review Board's current ruling on EMTALA.

The following abbreviations appear frequently in the report:

Conditions of participation (CoPs)
Advance beneficiary notices (ABNs)
Office of the Inspector General (OIG)
Quality Improvement Organizations (QIOs)
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
Social Security Act (the Act)
Critical access hospitals (CAHs)
Federally Qualified Health Centers (FQHCs)
Office of Management and Budget (OMB)
Paperwork Reduction Act (PRA)
Regulatory Flexibility Act (RFA)

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Dedicated Emergency Department:
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". 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. Note that this definition of dedicated emergency department' does not reference any special equipment or staffing requirements.

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 emergency care services. The Review Board notes that the 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, non-appointment basis*.

The Review Board specifies 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 [such as a "Minor Care Center"] 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 [by CMS], 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. By assessing a facility's performance over a calendar year, they believe that the effects of seasonal or other variations in utilization will be mitigated.

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.

They 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.

Bottom line: ``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;

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(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 by CMS 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

Clarification of “Come to the Emergency Department":

An individual can “come to the emergency department," creating an EMTALA obligation on the part of the hospital, in one of three ways:

(1) The individual can present at a hospital's dedicated emergency department and request examination or treatment for a medical condition; or

(2) 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; or

(3) Where there is no actual request because, for example, the individual is unaccompanied and physically incapable of making the request, the request may be inferred from what 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.

NOTE**:** 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.

“Hospital property" is, in part, defined as “the entire main hospital campus 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 or other entities that participate separately in Medicare, or restaurants, shops, or other non-medical facilities."

The Review Board believes 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.

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.''

EMTALA applies not only to dedicated emergency departments but also to presentations for emergency care *anywhere* on hospital property. An individual may not be denied emergency services simply because a person failed to actually enter a hospital's emergency department.

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Prudent Layperson:
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. The prudent layperson standard is necessary for both presentations inside the dedicated emergency department and elsewhere on hospital property. This has arisen as a result of concerns of circumstances where hospital staff has observed the appearance and/or behavior of an individual who clearly has an emergency medical condition, but does nothing to provide treatment for that individual.

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.

Medical Screening Exam:
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. Therefore, hospitals are not obligated to provide screening services beyond those needed to determine that there is no 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.

NOTE: An emergency medical condition does not actually have to exist upon examination of an individual in order for EMTALA obligations to apply. Instead, the individual presenting (or the prudent layperson observer) needs simply to believe he or she needs emergency care.

Triage 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 EMTALA.

The decision to take vital signs [during the medical screening exam] 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. The Review Board does not believe the taking of a patient's vital signs is required for every presentation to a hospital's dedicated emergency department. 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.

The Review Board noted that while EMTALA does not require all screenings to be performed by an M.D. or D.O., any non-physician (such as an emergency department registered nurse) who performs such screening should be an individual whom the hospital has designated as a

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``qualified medical person'' for purposes of appropriate transfer certification. While CMS refrains from dictating to hospitals standards for medical screening examinations, all EMTALA screenings must be equally extensive to each individual who presents to the dedicated emergency department.

If an individual presents to a dedicated emergency department and requests services that are not for an examination or treatment of a medical condition, such as preventive care services, the hospital is not obligated to provide a medical screening examination under EMTALA to this individual. This is not to imply that a hospital has no obligation under EMTALA to an individual who presents at a dedicated emergency department for ``non-emergency purposes'' [e.g. preventive care services, pharmaceutical services, or medical clearances for law enforcement purposes such as blood alcohol tests required by police] 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.
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.

Hospitals are 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.

Hospitals are not obligated to provide screening services beyond those needed to determine that there is no emergency medical condition. The necessary examination is generally within the judgment and discretion of the qualified medical personnel performing the examination. However, the Review Board stated 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. 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.

Registration:
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.*

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.

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Patient Transfers/Discharge:
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. 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. Once the individual has been stabilized, the EMTALA obligations end.

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, if 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.

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 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.

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, 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.

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. EMTALA 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.

The courts have given 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

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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. As a result of these court cases, and because existing hospital CoPs provide adequate, and in some cases, superior protection to patients, hospital obligations under EMTALA are considered as ended once the individuals are admitted to the hospital inpatient care. 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.

Since EMTALA is not triggered for admitted elective patients who experience an emergency during the inpatient admission the EMTALA transfer requirements would not apply to the transfer of such an individual to another hospital.

NOTE: Sanctions for inappropriate transfer during a national emergency do not apply to a hospital with a dedicated emergency department located within an emergency area.

Admitted Patients held in the Emergency Department:
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.

Patient Referrals:
If upon examination by a qualified medical person no emergency medical condition is found to exist, the patient may be referred to his or her physician's office for further treatment. An example sited by the Review Board is a patient coming to the emergency department for a suture removal. Nevertheless, they also stated 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*.

Outpatients, Visitors, and others:
EMTALA would not apply to an individual who experiences what may be an emergency medical condition if the individual is an outpatient. However, an outpatient experiencing 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. Hospitals that fail to provide treatment to these patients could face termination of their Medicare provider agreements for a violation of the CoPs.

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.

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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 family visitor of an admitted patient). Should such an individual experience an emergency medical condition while on hospital property, they are considered to have ``come to the emergency department'' and are protected by EMTALA. Hospitals must provide them with screening and necessary stabilizing treatment.

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, individuals who present with emergency conditions to a provider-based, off-campus department that is not a dedicated emergency department are not protected by EMTALA, but rather by the hospital CoPs as well as relevant State law.

NOTE: As mentioned previously, hospitals are not expected or required to 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.

Obviously, only if the hospital's staff is aware of an individual's presence in the department for examination or treatment for a medical condition is EMTALA triggered.

Off-Campus Facilities/Departments:
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. 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.

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.

On-call Physicians:
As a requirement for participation in the Medicare program, 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.

Physicians, including specialists and sub-specialists (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

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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.

CMS allows hospitals flexibility to comply with EMTALA obligations by maintaining a level of on-call coverage that is within their capability. If a hospital offers a service to the public, the service should be available through on-call coverage of the emergency department. CMS will investigate complaints of inadequate on-call coverage and will take appropriate action if the level of coverage is unacceptably low.

Ambulances (Ground and Air):
If an individual is in an ambulance (ground or air) 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 is necessary as some hospitals that owned and operated ambulances were transporting individuals who had called for an ambulance to other hospitals, thereby evading their EMTALA responsibilities to the individuals. However, 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 that hospital's property.

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.

Patient Refusal of Treatment:
If a hospital offers an individual further medical examination and treatment [beyond the initial medical screening exam] 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.

If the hospital offers to transfer the individual to another medical facility 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.

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