Supporting Statement – Part A

Examination and Treatment for Emergency Medical Conditions and Women in Labor (EMTALA), 42 CFR 482.12, 488.18, 489.20, and 489.24

A. Background

Congress was concerned about the increasing number of reports that hospital emergency rooms were refusing to accept or treat individuals with emergency conditions, including medically unstable individuals, if the individuals could not pay for the services or did not have medical insurance. Additionally, Congress had received reports that individuals in an unstable condition were transferred improperly, often without the consent of the receiving hospital. As a means to begin to address these concerns, Congress imposed new requirements, under the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 which became effective August 1, 1986, on hospitals that choose to participate in the Medicare program.

Therefore, since August 1, 1986, sections 1866(a)(1)(I) and 1867 of the Social Security Act (Act) mandate that Medicare-participating hospitals with emergency medical departments must perform medical screening examinations of any individual who comes to the emergency department, to determine whether or not the individual has an emergency medical condition or is a woman in labor. If an emergency medical condition is found, the hospital must then provide necessary stabilizing treatment within its capabilities. If the hospital does not have the capability to treat the individual's emergency medical condition, it must follow prescribed steps to provide for an appropriate transfer to another facility that has the capability (unless the individual or the individual's representative refuses treatment or transfer).

Subsequent to the COBRA, Congress added new provisions to sections 1866 and 1867 of the Act which strengthened and refined existing requirements through the Omnibus Budget Reconciliation Act of 1989 (OBRA '89, effective July 1, 1990) and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90, effective February 1, 1991). To begin, OBRA '89 added a new category of hospital provider known as a "rural primary care hospital" (as defined in section 1861(mm)(1) of the Act) and the Balanced Budget Act of 1997 redesignated this provider category as "critical access hospitals" (CAHs). Therefore, for purposes of the EMTALA statute, all further references to the term hospital will be assumed to include the term "critical access hospital."

OBRA '89 also amended section 1867 to protect the unborn children of women in labor and to protect pregnant women until their placentas are delivered. OBRA '89 and OBRA '90 further amended sections 1866 and 1867 to include many other additional requirements for Medicare participating hospitals with emergency departments, such as:

1. Maintaining a list of on-call physicians available for duty to provide stabilizing treatment for individuals with emergency conditions;

2. Requiring the capability of a facility's emergency department to include ancillary services customarily available to the emergency department;

3. Informing individuals (or persons acting on their behalf) of the risks and benefits to the individual of examination and treatment and/or transfer and to "take all reasonable steps to secure the individual's (or

person's) written informed consent to refuse such examination and treatment" and/or transfer, or to obtain a written request for a transfer;

4. Hospitals' transfer certifications must “include a summary of the risks and benefits upon which the certification is based”;

5. Specified certain information and records which must be included in the medical records of an individual with an emergency medical condition who is being transferred to another medical facility;

6. Medicare participating hospitals with special capabilities or facilities (such as burn units or shock trauma units) must “. . . accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual”; and

7. Participating hospitals may not delay the provision of medical screening examination and/or treatment "to inquire about the individual's method of payment or insurance status."

8. Section 1154 of the Act was also amended to require utilization and quality improvement organizations (QIOs) (with contracts under Part B of Title XI of the Act) to prepare a report, upon a request from CMS, assessing whether an individual had an emergency condition which was not stabilized.

The Notice of Proposed Rulemaking (NPRM) was published June 16, 1988. On June 22, 1994, we published an Interim Final Rule with a comment period (IFC). We had been operating through informal, interim instructions based on COBRA ‘85, OBRA ‘89 and OBRA ‘90, but the 1994 regulations clarified the procedures to promote uniform and thorough application of the requirements. On April 7, 2000, a Final Rule with comment period was published. That rule stated explicitly that the prohibitions on patient dumping also apply to hospital departments located off the hospital's main campus, and specified the obligations of hospitals with respect to individuals who come to such departments and request examination or treatment for a potential emergency medical condition. On May 9, 2002, a proposed rule to further clarify several situations on EMTALA applicability was published. On September 9, 2003, a Final Rule clarifying EMTALA applicability in those situations was published. The following is a summary of the provisions in that rule:

- The April 7, 2000 OPPS Final Rule clarified that EMTALA applies to all provider-based departments of a hospital, even those off the main campus. In the EMTALA Final Rule, CMS stated that EMTALA does not apply to emergency patients presenting at off-campus departments of hospitals that do not routinely provide emergency services. Instead, we provide that the hospital would have to adopt protocols for such departments under the Conditions of Participation to deal with emergencies.
- In late 1998, the United States Supreme Court considered a case (Roberts v. Galen of Virginia) that involved the question of whether EMTALA applies to inpatients in a hospital. In the context of that case, the United States Solicitor General told the Supreme Court that the Department of Health and Human Services (HHS) would develop a regulation clarifying its position on that issue. Pursuant to that commitment, CMS has provided that EMTALA does not apply to individuals who have been admitted as inpatients in a hospital, if the admission was undertaken in good faith and not as a pretext for avoiding EMTALA.

- CMS clarified the limits on hospital and physician responsibility in the circumstances in which physicians, particularly specialty physicians, must serve on hospital medical staff "on-call" lists.
- CMS clarified that hospital-owned ambulances can be more fully integrated with citywide and local community EMS procedures for responding to medical emergencies.
- CMS clarified that a participating hospital may not seek authorization from the individual's insurance company until after the hospital has provided the appropriate medical screening examination required by EMTALA, and any required stabilizing treatment has been initiated.
- CMS clarified that EMTALA does not apply to hospital outpatients who had begun to receive outpatient services before the emergency began.

On April 25, 2006, an NPRM to further clarify several situations on EMTALA applicability was published. On August 18, 2006, a Final Rule clarifying EMTALA applicability in those situations was published. That rule clarified the obligation of all participating hospitals with specialized capabilities to accept appropriate transfers, and revised the definition of "labor" to allow certain nonphysician qualified medical persons to determine whether a woman having contractions is in false labor.

On May 3, 2007, an NPRM to implement EMTALA provisions included in the Pandemic and All Hazards Preparedness Act (P.L. 109-417) enacted by Congress on December 19, 2006 was published. On August 22, 2007, a Final Rule implementing the NPRM was published. The rule made changes to section 489.24(a)(2) of the regulations to state that sanctions do not apply for an inappropriate transfer of an individual who has not been stabilized or for the redirection or relocation of an individual to receive medical screening at an alternate location under section 1135 if a waiver has been granted. The rule also stated that a waiver of sanctions is limited to 72 hours beginning with the implementation of a hospital disaster protocol, except if the public health emergency involves a pandemic infectious disease, the duration of the waiver is determined in accordance with section 1135(e) of the Act.

On April 30, 2008 an NPRM to clarify several aspects of EMTALA was published. Specifically, the NPRM addressed the applicability of EMTALA to hospital inpatients, the requirement to maintain an on-call list, community on-call, and the nonapplicability of EMTALA sanctions under a section 1135 waiver. The NPRM also included a brief description of the EMTALA Technical Advisory Group (TAG) and a summary of which of the TAG's recommendations had been addressed by CMS to date. On August 19, 2008, we published a Final Rule. In that Final Rule we clarified that if an individual is admitted in good faith, the admitting hospital has satisfied its EMTALA obligation with respect to that individual even if the individual continues to have an unstabilized emergency medical condition and a hospital with specialized capabilities does not have an EMTALA obligation to accept a transfer of that individual. We made this change by amending the regulations at 489.24(f) to include a paragraph (2). We finalized our proposed policy to move the language regarding maintaining an on-call list from section 489.24(j)(1) to 489.20(r)(2) and revised the language to make it consistent with our policy on community call. We finalized our policy on community call by stating that hospital can meet the on-call requirements at section 489.20(r)(2) by having a formal community call plan and we specified what elements a formal community call plan must include. We also finalized our technical change to the regulations at section 489.24(a)(2) regarding the nonapplicability of EMTALA sanctions as proposed.

On May 22, 2009, an NPRM to further refine the regulations at section 489.24(a)(2) to make them consistent with the statutory text at section 1135 of the Act was published. We proposed to amend the regulations to state that a waiver of EMTALA sanctions for an inappropriate transfer is only valid if the transfer arises out of the circumstances of the emergency. We proposed to clarify that the Secretary has the authority to apply the waiver of EMTALA sanctions to one or more hospitals in a portion of an emergency area or a portion of an emergency period. We proposed to clarify in the regulations that a waiver of EMTALA sanctions for an inappropriate transfer or for the redirection or relocation of an individual to receive a medical screening examination are only in effect if the hospital to which the waiver applies does not discriminate on the source of an individual's payment or ability to pay. On August 27, 2009, a Final Rule was published in which we clarified that a waiver of EMTALA sanctions for an inappropriate transfer is only valid if the transfer is necessitated by the circumstances of the declared emergency, we also finalized our other proposals regarding section 489.24(a)(2) of the regulations.

On December 23, 2010, an Advance Notice of Proposed Rulemaking with Comment (ANPRM) was published. The ANPRM, in addition to summarizing CMS' previously published proposed and final rules related to the applicability of EMTALA to hospital inpatients and the responsibilities of hospitals with specialized capabilities, requested commenters to provide specific examples to demonstrate whether CMS should revisit the policies articulated in the September 3, 2009 Final Rule and the August 19, 2008 Final Rule. In addition, we requested real world examples that would inform our understanding of the current policy's impact on patients' access to care for an emergency medical condition and that demonstrate whether it would be beneficial to revisit our existing policies. We also requested comments regarding the responsibilities of hospitals with specialized capabilities.

On February 2, 2012 we published a Notice with Comment. In that Notice with Comment we stated that in response to comments we received on the December 23, 2010 ANPRM, we were maintaining our current policy regarding the applicability of EMTALA to hospital inpatients. We also stated that we were making no proposals with respect to our policies regarding the applicability of EMTALA to hospitals with specialized capabilities, however, we would continue to monitor whether it may be appropriate to reconsider this issue in the future.

B. Justification

1. Need and Legal Basis

Pursuant to section 1866(a)(1)(I) of the Act, Congress has mandated that the Secretary enforce section 1867 of the Act. Under section 1867, effective August 1, 1986, hospitals may continue to participate in the Medicare program only if they are not out of compliance with its provisions. Continued Paper Work Reduction Act (PRA) approval of the regulation sections cited below will promote uniform and thorough application of the section 1866 and 1867 requirements. They will also provide information when requested by Congress and other interested parties regarding the implementation of the statute.

During 2004 through 2015, approximately 6,316 complaints were received, approximately 6,035 of those complaints were investigated, and approximately 8 condition-level deficiencies and 2,428 standard-level deficiencies were found. During Federal fiscal years 2001 through 2005 the Inspector General's Office

imposed civil money penalties on hospitals in 105 cases, for a total of $2,645,750 in penalties.

An audit completed by the Office of Inspector General (OIG) (entitled, Office of Inspector General: Implementation and Enforcement of the Examination and Treatment for Emergency Medical Conditions and Women in Labor by the Health Care Financing Administration, April 1995, A-06-93-00087) determined that CMS's implementation of the Act was generally effective, but Regional Offices (RO) were not consistent with conducting timely investigations, sending acknowledgments to complaints, ensuring that investigations were thorough, or ensuring that violations were referred to the OIG in accordance with CMS policy for possible civil monetary penalty action. OIG further concluded that without proper compliance, there is an increased risk that individuals with emergency medical conditions will not receive the treatment needed to stabilize their condition, which may place them in greater risk of death.

(a) Section 482.12(f)
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 collection requirement is subject to the PRA, we believe the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) & (b)(3).

(b) Section 488.18(d)
Pursuant to section 1867 of the Act, this regulation added a new paragraph (d) to 42 CFR 488.18, Documentation of Findings. This paragraph requires Medicare State Survey Agencies to promptly inform CMS, via the Associate Regional Administrators, of information they receive concerning possible violations of 42 CFR 489.24, Special responsibilities of Medicare hospitals in emergency cases (also based on section 1867 of the Act). This information is vital for CMS to meet its responsibility to assure that section 1867 violations cease promptly and Medicare State Survey Agencies are in an excellent position to determine when a violation of these provisions has occurred.

Medicare State Survey Agencies who are under contract with HHS receive complaints regarding alleged emergency services violations almost exclusively by telephone on an individual case basis. State agency staff, in turn, log in the information, call in the alleged violation reports to CMS RO staff and keep track of all actions resulting from the report. The written reports received are scanned and attached in the Automated Survey Processing Environment (ASPEN) Complaints/Incidents Tracking System (ACTS) for review by the CMS ROs. Some states, under their own initiative to meet their needs, have established "hot lines" which may be used by the public to report alleged dumping violations.

The actual CMS process is as follows: CMS RO staff receives the reports by telephone, by mail, by email message or via ACTS (if complaint submitted to the State Survey Agency first). CMS staff reviews, analyzes and log in the reports, and for those reports determined to warrant investigation, they complete a form in ACTS authorizing State Survey Agency investigation. Almost all reports received have been investigated.

As such, these Information Collection Requests (ICRs) are exempt for the following reasons: These are individually-identified complaints. State agencies are acting under contract, as agents of the Federal government during the conduct of an investigation or audit against specific individuals or entities. [5 CFR

1320.4(a)(2)]

(c) Section 489.20(m)
Based on sections 1861(e)(9) and 1866 of the Act, section 489.20, Basic commitments, requires a hospital to notify CMS or the State Survey Agency of any suspected incident in violation of 489.24(d). Section 489.24(e) restricts transfers of individuals in an unstable emergency medical condition until such individuals are stabilized and pregnant women until their placentas are delivered, or a transfer request is made by or on behalf of the individual, or the hospital certifies that the transfer is in the individual's best interests, and the transfer is effected through qualified personnel and transportation equipment.

An Office of Inspector General (OIG) study (Office of Inspector General, Patient Dumping After COBRA: Assessing the Incidences and Perspectives of Health Care Professionals, August 11, 1988), showed a marked reluctance on the part of hospitals to report suspected inappropriate transfers, that a number of individuals in unstable conditions have been transferred improperly, and that the cases are not reported to CMS. However, this may be the result of the absence of OMB approval at the time so hospitals were not obligated to file a report. Incidentally, OMB approval was published September 29, 1995 (60 FR 50443). Some hospitals did file reports anyway, however, an accurate number is not available at this time. Nonetheless, these reporting requirements are needed to assure that we are aware of such instances of improper transfers which may needlessly jeopardize people's lives so that specific action may be taken. When a hospital violates its duties under these provisions, CMS must take immediate and prescribed actions to prevent that hospital from jeopardizing the health and safety of the next person who may seek help in an emergency situation. Hospitals are in the best position to determine when an inappropriate transfer has taken place. Further, this provision should encourage hospitals to cooperate in planning for appropriate transfers. It is also important to note that the OIG study also identified incidents of improper transfers being reported to State Survey Agencies that were not then reported to CMS.

This requirement is also supported by two other current statutes. Section 1861(e)(9) of the Act permits the Secretary to impose on hospitals such other requirements as she/he finds necessary in the interests of the health and safety of individuals who are furnished services in the institution. It is under this authority that the Secretary has obligated hospitals that participate in Medicare to report when they receive patients that have been inappropriately transferred. Under sections 1866(b)(2)(A) and (B) of the Act, the Secretary may terminate the provider agreement of a hospital that is not complying substantially with the statute and regulations under title XVIII or that no longer substantially meets the provisions of section 1861 of the Act.

We estimate that close to half of the section 1867 violation reports we received were submitted (by telephone) by hospitals. The calls were usually made by physicians, who review pertinent records before making their calls, usually to the State, rarely to CMS. While the American Hospital Association (AHA) has noted that this requirement is the only significant reporting issue raised by their constituents, CMS believes that this requirement serves and protects the patient and is mandated by statute. As such, CMS does not believe this requirement can be altered without impacting negatively on the quality of the health care provided to the patient. These ICRs are exempt for the following reasons: The alleged complaints are received on an individual case-by-case basis, and are, therefore, not subject to the PRA as stipulated at 5 CFR 1320.3(c), and are pursuant to the conduct of an investigation or audit against specific individuals or entities. [5 CFR

1320.4(a)(2)]

(d) Section 489.20(r)(2)
Based upon section 1866(a)(1)(I)(iii) of the Act, both transferring and receiving hospitals must maintain a list of physicians who are on-call for duty after an initial examination to provide treatment needed to stabilize an individual with an emergency medical condition. Congress, under section 6018(a)(1) of OBRA '89, added this requirement to the original COBRA requirements in order to add the capabilities of such physicians to the emergency department staff. This is also an extension of the concept contained in the OBRA '89 requirement (section 6211(a)), which defines a hospital's emergency department capabilities to include "ancillary services routinely available to the emergency department." It is also an extension of a hospital's responsibility under 42 CFR 482.55 to provide adequate medical personnel to meet its anticipated emergency needs by using on-call physicians either to staff or to augment its emergency department. Section 42 CFR 489.20(r)(2) is also one of the requirements hospitals must meet to receive accreditation from the Joint Commission (previously known as the Joint Commission on Accreditation of Healthcare Organizations). In the August 19, 2008 Final Rule, we revised the regulation text at section 489.20(r)(2) by moving the language regarding maintaining an on-call list from the regulations at section 489.24(j)(1) to section 489.20(r)(2) and incorporating language pertaining to community call.

The burden associated with the list of on-call physicians is very limited. These lists are maintained routinely by hospitals. While these ICRs are subject to the PRA, the burden associated with these ICRs are exempt because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities (e.g., in compiling and maintaining business records). [5 CFR 1320.3(b)(2)]

(e) Section 489.20(r)(3)
Based upon sections 1861(e)(9) and 1866 of the Act, hospitals are required to maintain a central log on all individuals who come to their emergency departments seeking assistance. The log must indicate whether the individual refused treatment, was refused treatment, was transferred, admitted and treated, stabilized and transferred, or discharged. Such a record will permit CMS and Medicare State Survey Agencies to select and gain access to individual medical records for further inquiry and will help to determine whether the person was transferred appropriately under the statute. The log is one method of enforcing the intent of the Congress to protect individuals with emergency conditions and women in labor against possible erroneous transfers. It will also educate hospital personnel regarding the section 1867 requirements, will provide an audit trail to assist CMS in performing its monitoring and enforcement duties, in many cases will cause receiving hospital physicians to receive appropriate medical information for each individual, and will deter dumping. This central log requirement is also an accreditation requirement for Joint Commission hospitals.

The previously cited OIG study reported that lack of a central record on the disposition of persons seeking emergency services hinders CMS's ability to monitor compliance with the statute. Additionally, a report by the House Committee on Government Operations, March 25, 1988, report #100-531, recommended the establishment of such a central log.

Hospitals routinely maintain logs on individual patients receiving care in the emergency room setting. When

this rule was promulgated, hospitals were required to centralize the information in the logs. While this requirement may have imposed a one-time burden, the requirement improved the maintenance, retention, and ease of retrieval of existing hospital records. Therefore there is no burden associated with this requirement. [5 CFR 1320.3(b)(2)]

(f) Section 489.24(d)(2)
If a hospital admits an individual with an unstable emergency medical condition as an inpatient in good faith in order to stabilize the emergency medical condition, the admission must be documented in the individual's medical record, to show that the hospital has satisfied its special responsibilities under this section with respect to that individual. While this collection requirement is subject to the PRA, we believe the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) & (b)(3).

(g) Section 489.24(d)(3)
Based upon section 1867 of the Act, an individual's medical record must contain a description of the examination and/or treatment refused by or on behalf of an individual. The hospital must also try to obtain a written informed consent for such refusal which should indicate the person's knowledge of the risks and benefits of the examination or treatment. Congress believed that this decision must be an informed one and therefore, under section 6211(b) of OBRA '89, a hospital is required to inform an individual or their representative of the risks and benefits of the examination and treatment and to "take all reasonable steps to secure the individual's (or person's) written informed consent to refuse such examination and treatment." This helps prevent hospitals from coercing individuals into making judgments which may be against their best interests, helps ensure that the individual or the person acting on their behalf is aware of the hospital's obligations, and may reduce litigation concerning whether examination and/or treatment was refused or requested.

The recording in the patient's medical record of the description of the examination and/or treatment that was refused by or on behalf of an individual is standard industry practice. The information is recorded by either a physician or a nurse and signed or initialed by a physician if recorded by a nurse. The written informed consent to refuse the examination and/or treatment, including recording the risks and benefits of the examination and/or treatment, is usually written by either a physician or a nurse and signed by or on behalf of the individual. While this information collection is subject to the PRA, the burden associated with these ICRs are exempt because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities (e.g., in compiling and maintaining business records). [5 CFR 1320.3(b)(2)]

(h) Section 489.24(d)(5)
Under section 1867 of the Act, if a transfer is refused by or on behalf of an individual in an unstabilized emergency condition or a woman in labor, the individual's medical record must contain a description of the transfer that was refused. The hospital must also attempt to obtain the individual's (or person's) written informed consent to refuse such transfer and the refusal should indicate the person's knowledge of the risks and benefits of the transfer and the reasons for the refusal. This requirement will help prevent such a refusal from being obtained by coercion or by the hospital misrepresenting its obligations under the statute. This requirement will also help ensure that the refusal is informed, is not obtained under duress, is in the individual's best interests, and will help prevent the hospital from being subject to ambiguous requirements

for carrying out the statute's mandate. Further, this requirement closely parallels the statute, and as such, reflects Congressional intent. We expect this provision increases the incentives for hospitals to avoid improper transfers, thus improving emergency care for uninsured individuals. We also expect this provision makes emergency services available to more individuals.

The recording in a patient's medical record of the description of the transfer that was refused by or on behalf of a patient is standard industry practice. The information is recorded by either a physician or a nurse and signed or initialed by a physician if recorded by a nurse. The written informed consent to refuse the transfer, including a description of the risks and benefits of the transfer, is usually written by either a physician or a nurse and signed by or on behalf of an individual. While these ICRs are subject to the PRA, the burden associated with these ICRs are exempt because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities (e.g., in compiling and maintaining business records). [5 CFR 1320.3(b)(2)]

(i) Section 489.24(e)(1)(ii)(A)
Based on section 1867 of the Act, under this section of the regulation if an individual in an unstable emergency condition, or a woman in labor, or someone acting on their behalf requests a transfer, the request must be in writing, must indicate the reasons for the request and that the person making the request is aware of the risks and benefits of the transfer. These provisions will verify that the person has made an informed decision and will help ensure that the request is not coerced. Moreover, this requirement will reduce litigation regarding whether or not an individual requests transfer.

We believe that hospitals operating in a manner that potentially subjects individuals to the threat of summary transfer without treatment, poses an immediate and serious threat to individuals who may present themselves to the hospital for treatment of emergency conditions or labor, and these requirements will help to ensure that such individuals will be stabilized before transfer. This requirement will also educate hospital personnel to provide a record of enforcement of the statute, help assure that the receiving physicians receive appropriate medical information to treat each individual, will deter dumping, and will help to detect inappropriate transfers.

The recording of the request for a transfer by the patient (or the patient’s legal representative) whose condition has not been stabilized, including the reasons for the request and the risks and benefits of the transfer, is a standard industry practice. The request statement and information are usually written by either a physician or a nurse and signed by or on behalf of an individual. While these ICRs are subject to the PRA, the burden associated with these ICRs are exempt because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities (e.g., in compiling and maintaining business records). [5 CFR 1320.3(b)(2)]

(j) Sections 489.24(e)(1)(ii)(B) and (C)
Under section 1867 of the Act, before an individual in an unstabilized emergency condition or a woman in labor may be transferred in the absence of a request for transfer, a physician or other qualified medical personnel, in the absence of a physician, must sign a certification that based upon the information available at the time of transfer, the medical benefits expected from appropriate medical treatment at another facility outweigh the risks associated with transfer. The certification must contain a summary of the risks and benefits

upon which the certification is based. It is reasonable to conclude that Congress intended such documentation, based upon the specificity of the statutory language in sections 1867(c)(l)(A)(ii) and (iii).

This provision will help receiving hospitals make informed decisions concerning whether the transfers are appropriate. The statutory language is extremely specific because it was Congress' intent to protect emergency patients, women in labor and their unborn children against possible erroneous transfers and the certification cannot always be implied from the findings in the medical record and the fact that the individual was transferred.

The statute and current industry practices routinely require a physician, or when a physician is not available, other qualified medical personnel, to weigh the benefits and risks associated with the transfer and to determine whether the transfer should take place of an individual in an unstabilized condition or a woman in labor. While these ICRs are subject to the PRA, the burden associated with these ICRs are exempt because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities (e.g., in compiling and maintaining business records). [5 CFR 1320.3(b)(2)]

(k) Section 489.24(f)
In the August 18, 2009 Final Rule we addressed the applicability of EMTALA to hospital inpatients by stating that once an individual with an emergency medical condition has been admitted even if the individual continues to have an unstabilized emergency medical condition, the admitting hospital no longer has an EMTALA obligation and a hospital with specialized capabilities does not have an EMTALA obligation to accept an appropriate transfer of that individual. We made this change by amending the regulations at section 489.24(f) to include a paragraph (2).

(l) Section 489.24(h)(1)
Pursuant to a complaint investigation, there may be cases where a medical opinion is necessary to determine a physician's or hospital's liability under section 1867(d)(1). Therefore CMS requests the appropriate QIO (with a contract under Medicare Part B, Title XI of the Act) to determine if there should be further action. As such, these ICRs are exempt for the following reasons: These are individually-identified complaints. QIOs are acting under contract, as agents of the Federal government during the conduct of an investigation or audit against specific individuals or entities. [5 CFR 1320.4(a)(2)]

(m) Section 489.24(h)(2)
Based upon sections 1154, 1866 and 1867 of the Act, a civil monetary penalty (CMP) can be imposed against a hospital or a physician or a physician can be excluded from the Medicare program for violating any of these statutory requirements, and a QIO (with a contract under Part B of Title XI of the Act) must be asked to prepare a report assessing whether the individual involved had an emergency condition which had not been stabilized. The QIO must notify the physician and the hospital of the review and must provide the physician and the hospital a reasonable opportunity to discuss the matter and to submit additional information, before the QIO provides its report.

Congress enacted this provision as part of the OBRA '90 amendments (it became effective February 1, 1991) to safeguard physicians and hospitals from CMP or exclusion actions by the government without another

opinion and to offer physicians and hospitals a medical review of the alleged violation before such actions are taken.

(n) Section 489.24(j)(2)(iii)

In the August 19, 2008 Final Rule, we added the regulations at section 489.24(j)(2)(iii) to permit hospitals to participate in formal community call plans, we outline the specific requirements of a formal community call plan at section 489.24(j)(2)(iii)(A) – (F). We do not believe there is a burden associated with these provisions because participation in a formal community call plan is optional and is meant to afford additional flexibility to hospitals providing on-call services and improve access to specialty physician services for individuals in an emergency department.

(o) Removal of previous section 489.24(i) and addition of section 482.12(f)(3)

As discussed above, the April 7, 2000 Final Rule finalized the policy that the prohibitions on patient dumping would also apply to hospital departments located off the hospital's main campus. In the September 9, 2003 Final Rule, CMS eliminated the EMTALA requirements relating to emergency patients presenting at off-campus departments of hospitals that do not routinely provide emergency services. We deleted previous section 489.24(i) because its primary purpose was 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 Final Rule, 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 previous section 489.24(i). In the same September 9, 2003 Final Rule, we added a requirement, in section 482.12(f)(3), stating that if emergency services are provided at a hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital is required to assure that the medical staff has written policies and procedures for off-campus departments for appraisal of emergencies and referral when appropriate In general, we believe that the burden associated with the requirements at section 482.12(f)(3) will be significantly less than the burden under previous 489.24(i).

(p) Removal of sections 489.24(i)(2) and (i)(2)(i), (i)(2)(ii), and (i)(3)

As explained above, in the September 9, 2003 Final Rule we eliminated the EMTALA requirements relating to emergency patients presenting at off-campus departments of hospitals that do not routinely provide emergency services. We deleted previous section 489.24(i) because its primary purpose was 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 Final Rule, however, a hospital would have no EMTALA obligation with respect to individuals presenting to such departments.

(q) Removal of previous section 489.24(j)(1) and addition of section 489.24(j)(2)(iii)

As discussed above in the August 19, 2008 Final Rule, we moved the regulations regarding the requirement to maintain an on-call list from previous section 489.24(j)(1) to section 489.20(r)(2), since that requirement is found under section 1866 of the Social Security Act, which refers to provider agreements. We also revised the regulations at section 489.24(j) by including a provision at section 489.24(j)(2)(iii) which details the requirements of a formal community call plan. Participation in a formal community call arrangement is not a requirement. We believe that adding the community call provision affords additional flexibility to hospitals providing on-call services and improves access to specialty physician services for individuals in an emergency department. We do not believe the burden associated with participating in a formal community call plan (which is optional) will be significant.

2. Information Users

Pursuant to regulation sections 488.18, 489.20 and 489.24, during Medicare surveys of hospitals and State Agencies CMS will review hospital records for lists of on-call physicians, and will review and obtain the information which must be recorded on hospital medical records for individuals with emergency medical conditions and women in labor, and the emergency department reporting information Medicare participating hospitals and Medicare State survey agencies must pass on to CMS. Additionally, CMS will use the QIO Report assessing whether an individual had an emergency condition and whether the individual was stabilized to determine whether to impose a CMP or physician exclusion sanctions. Without such information, CMS will be unable to make the hospital emergency services compliance determinations that Congress expects CMS to make under sections 1154, 1866 and 1867 of the Act.

3. Use of Information Technology

EMTALA uses the Automated Survey Processing Environment (ASPEN) Complaints/Incidents Tracking System (ACTS). State Survey Agency and CMS Staff use ACTS for documentation of EMTALA complaint activity. EMTALA survey results and other EMTALA data is available from the ASPEN system.

Material collected during an EMTALA investigation is not collected electronically but is electronically entered into ACTS as part of the survey documentation.

ACTS is not available for use by hospitals or others submitting EMTALA complaints. The system is for the use of State Survey Agency and CMS staff members.

EMTALA complaints may be submitted via email as well as by phone and mail, but there is no other current electronic method available for submission of complaints. There are no plans at this time to give hospitals or other complainants' access to the surveyor documentation systems.

4. Duplication of Efforts

The ICRs contained in these regulations do not duplicate any other information collection system.

5. Small Businesses

These requirements do not affect small businesses.

6. Less Frequent Collection

This information is collected as needed. If it were collected on a less frequent basis, CMS would have greater difficulty ensuring compliance and protecting future emergency patients and women in labor from potential harm.

7. Special Circumstances

Absent a legislative amendment, we are unable to anticipate any circumstances that would change the requirements of this package. EMTALA is a complaint driven process.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice was published on June 13, 2016 (81 FR 38186). The 30-day Federal Register notice was published on September 2, 2016 (81 FR 60704). No comments were received.

History

The NPRM was published June 16, 1988 (53 FR 22513) and we received 68 letters containing comments. The Interim Final Rule with comment period was published June 22, 1994 (59 FR 32086) and we received 19 letters containing comments, including a few on ICRs. The notice of OMB approval of the regulatory sections contained in the original request was not published until September 29, 1995 (60 FR 50443). The NPRM specifying the obligations of hospitals with respect to individuals coming to off-campus departments was published on September 8, 1998 (63 FR 47552) and we received approximately 120 letters of comment, including approximately 10 letters that commented on the antidumping provisions. These comments were addressed in the Final Rule published on April 7, 2000 (65 FR 18434). On May 9, 2002 we published the NPRM (67 FR 31404) proposing several clarifications on the EMTALA applicability; in response, we received approximately 600 pieces of correspondence, most of which contained multiple comments. We responded to these comments in the preamble to the September 9, 2003 Final Rule. On April 25, 2006, we published an NPRM (71 FR 23996) to further clarify several situations on EMTALA applicability. We received approximately 50 letters of comment. We responded to those comments in the preamble to the August 18, 2006 Final Rule (71 FR 47870). On May 3, 2007, we published an NPRM (72 FR 24815) to implement changes made by the Pandemic and All-Hazards Preparedness Act (P.L. 109 – 417). We proposed to implement these changes by amending the regulations at section 489.24(a)(2). We received several letters of comment on the proposals and responded to them in the preamble to the August 22, 2007 Final Rule (72 FR 47384). On April 30, 2008, we published an NPRM (73 FR 23668), in which we proposed to clarify the applicability of EMTALA to hospital inpatients, move the requirement to maintain an on-call list from the regulations at section 489.24(j)(1) to the regulations at section 489.20(r)(2), allow hospitals to participate in formal community call arrangements, and revise the regulations regarding the nonapplicability of EMTALA sanctions at section 489.24(a)(2). We received approximately 86 letters of comment on the proposed provisions. We responded to comments received on these proposals in the preamble to the August 19, 2008 Final Rule (73 FR 48654). On May 22, 2009, we published an NPRM (74 FR 24193), in which we proposed to make further changes to the regulations governing the nonapplicability of EMTALA sanctions at section 489.24(a)(2) of the regulations and we received approximately 15 comments on our proposed changes. We responded to comments received on the proposed changes in the preamble to the August 27, 2009 Final Rule (74 FR 43919). On December 23, 2010 we published an ANPRM (75 FR 80762) in which we requested comments on the applicability of EMTALA to hospital inpatients and hospitals with specialized capabilities. We received approximately 72 comments on the issues discussed in the ANPRM. In response to comments received on the ANPRM, we published a Notice with Comment on February 2, 2012 (77 FR 5213) in which we stated that we were maintaining our current policy regarding the applicability of EMTALA to hospital inpatients and making no proposals with respect to our policies regarding the applicability of EMTALA to hospitals with specialized capabilities but that we would continue to monitor if whether in the future it would

be appropriate to reconsider the issue. We received approximately 20 comments in response to the Notice with Comment.

9. Payments/Gifts to Respondents

We do not plan to provide any payment or gift to respondents other than remuneration of contractors or grantees.

10. Confidentiality

We do not pledge confidentiality because the information collected under these provisions are available to the public and not subject to confidentiality.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimates (Hours & Wages)

EMTALA is a complaint driven process, the number of respondents is approximately 4,872. This estimate is based on the approximate number of hospitals (including critical access hospitals) required to comply with the EMTALA requirements as summarized in this supporting statement. Since most of the requirements would be incurred by persons in the normal course of their activities, we estimate an additional hour would be required for maintenance of these requirements.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

Central Office staff spends approximately two days (16 hrs.) a month compiling/reporting investigation information received from the regions, at a salary of approximately $51.43/hr. Total approximate cost per year $9,874.56 is expended at the Central Office level.

RO staff time varies by state assignments. For instance, the regional representative for a state with a high volume of complaints could spend up to 25 hours a week in processing time. Cost estimates for a GS-13, step 1, salary of about $43.52/hr. times 25 hours a week equals $1,088.00 or about $56,576.00 a year (1,088.00 x 52). The regional representative for a state with a low volume of complaints could spend as little as 8 hours a week in processing time. Cost estimates for a GS-13, step 1, salary of about $43.52/hr. times 8 hours a week equals $348.16 or about $18,104.32 a year. Using the higher volume annual cost estimate of $56,576.00 and an average of 4 regional reps per region times 10 regions, the annual cost estimate for RO staff is $2,263,040.00

Central Office = $9,874.56
RO Estimate = $2,263,040.00
Total Annual Cost Estimate = $2,272,914.56

15. Changes to Burden

This reinstatement includes a change in the agency estimate resulting in a decrease of 1,277 burden hours. Historically our analysis has included all Medicare-participating hospitals (including critical access hospitals). However, we believe the specific requirements discussed in this supporting statement apply to approximately 4,872 Medicare-participating hospitals.

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	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses for this IC	4,872	0	0	-1,277		0
Annual IC Time Burden (Hours)	4,872	0	0	4,872	1	0
Annual IC Cost Burden (Dollars)	0	0	0	0	0	0

16. Publication/Tabulation Dates

We do not plan to publish any of the information collected under these provisions for statistical use.

17. Expiration Date

Upon receiving OMB approval, CMS will publish a notice in the Federal Register to inform the public of both the approval as well as the expiration date.

18. Certification Statement

There are no exceptions to the certification statement contained in item 19.