

Response: We understand that PACE organizations operate under separate statutory authority and have a different model of care and provide a varied range of benefits to its enrolled population. However, we also recognize that PACE programs are paid for Medicare Part A and Part B services under section 1853 of the Act, along with MA plans, and we are required under section 1853(a)(3)(D) of the Act to apply risk adjustment uniformly. We are committed to working with all stakeholders to discuss and clarify how any changes in the methodology for calibrating the risk adjustment model will affect their organization.

After consideration of the public comments received, we are finalizing the proposed changes in policies under §422.310, with one modification. Under §422.310(f), we are identifying the uses of the encounter data that we will collect. Specifically, we will use the encounter data for calculating risk factors, updating risk adjustment models, calculating Medicare DSH percentages, conducting quality review and improvement activities, and for Medicare coverage purposes.

I. Hospital Emergency Services under EMTALA (§489.24)

1. Background

Sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867 of the Act impose specific obligations on certain Medicare-participating hospitals and CAHs. (Throughout this section of this final rule, when we reference the obligation of a "hospital" under these sections of the Act and in our regulations, we mean to include CAHs as well.) These obligations concern individuals who come to a hospital emergency department and

request examination or treatment for a medical condition, and apply to all of these individuals, regardless of whether they are beneficiaries of any program under the Act.

The statutory provisions cited above are frequently referred to as the Emergency Medical Treatment and Labor Act (EMTALA), also known as the patient antidumping statute. EMTALA was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Pub. L. 99-272. Congress incorporated these antidumping provisions within the Social Security Act to ensure that individuals with emergency medical conditions are not denied essential lifesaving services. Under section 1866(a)(1)(I)(i) of the Act, a hospital that fails to fulfill its EMTALA obligations under these provisions may be subject to termination of its Medicare provider agreement, which would result in loss of all Medicare and Medicaid payments.

Section 1867 of the Act sets forth requirements for medical screening examinations for individuals who come to the hospital and request examination or treatment for a medical condition. The section further provides that if a hospital finds that such an individual has an emergency medical condition, it is obligated to provide that individual with either necessary stabilizing treatment or an appropriate transfer to another medical facility where stabilization can occur.

The EMTALA statute also outlines the obligation of hospitals to receive appropriate transfers from other hospitals. Section 1867(g) of the Act states that a participating hospital that has specialized capabilities or facilities (such as burn units, shock-trauma units, neonatal intensive care units, or, with respect to rural areas, regional referral centers as identified by the Secretary in regulation) shall not refuse to accept an

appropriate transfer of an individual who requires these specialized capabilities or facilities if the hospital has the capacity to treat the individual. The regulations implementing section 1867 of the Act are found at 42 CFR 489.24. The regulations at 42 CFR 489.20(l), (m), (q), and (r) also refer to certain EMTALA requirements outlined in section 1866 of the Act. The Interpretive Guidelines concerning EMTALA are found at Appendix V of the CMS State Operations Manual.

2. EMTALA Technical Advisory Group (TAG) Recommendations

Section 945 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108-173, required the Secretary to establish a Technical Advisory Group (TAG) to advise the Secretary on issues related to the regulations and implementation of EMTALA. The MMA specified that the EMTALA TAG be composed of 19 members, including the Administrator of CMS, the Inspector General of HHS, hospital representatives and physicians representing specific specialties, patient representatives, and representatives of organizations involved in EMTALA enforcement.

The EMTALA TAG's functions, as identified in the charter for the EMTALA TAG, were as follows: (1) review EMTALA regulations; (2) provide advice and recommendations to the Secretary concerning these regulations and their application to hospitals and physicians; (3) solicit comments and recommendations from hospitals, physicians, and the public regarding the implementation of such regulations; and (4) disseminate information concerning the application of these regulations to hospitals, physicians, and the public. The TAG met 7 times during its 30-month term, which ended on September 30, 2007. At its meetings, the TAG heard testimony from representatives

of physician groups, hospital associations, and others regarding EMTALA issues and concerns. During each meeting, the three subcommittees established by the TAG (the On-Call Subcommittee, the Action Subcommittee, and the Framework Subcommittee) developed recommendations, which were then discussed and voted on by members of the TAG. In total, the TAG submitted 55 recommendations to the Secretary. If implemented, some of the recommendations would require regulatory changes. Of the 55 recommendations developed by the TAG, 5 have already been implemented by CMS. A complete list of TAG recommendations is available in the Emergency Medical Treatment and Labor Act Technical Advisory Group final report available at the Web site:

http://www.cms.hhs.gov/FACA/07_emtalatag.asp. The following recommendations have already been implemented by CMS:

- That CMS revise, in the EMTALA regulations [42 CFR 489.24(b)], the following sentence contained in the definition of "labor": "A woman experiencing contractions is in true labor unless a physician certifies that, after a reasonable time of observation, the woman is in false labor."

We revised the definition of "labor" in the regulations at §489.24(b) to permit a physician, certified nurse-midwife, or other qualified medical person, acting within his or her scope of practice in accordance with State law and hospital bylaws, to certify that a woman is experiencing false labor. This recommendation was adopted with modification in the FY 2007 IPPS final rule (71 FR 48143). We issued Survey and Certification Letter S&C-06-32 on September 29, 2006, to clarify the regulation change. (The Survey and

Certification Letter can be found at the following Web site:

<http://www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp>).

- That hospitals with specialized capabilities (as defined in the EMTALA regulations) that do not have a dedicated emergency department be bound by the same responsibilities under EMTALA to accept appropriate transfers as hospitals with specialized capabilities that do have a dedicated emergency department.

This recommendation was adopted in the FY 2007 IPPS final rule (71 FR 48143). We added language at §489.24(f) that makes explicit the current policy that all Medicare-participating providers with specialized capabilities are required to accept an appropriate transfer if they have the capacity to treat an individual in need of specialized care. We issued Survey and Certification Letter S&C-06-32 on September 29, 2006, to further clarify the regulation change. (The Survey and Certification Letter can be found at the following Web site:

<http://www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp>).

- That CMS clarify the intent of regulations regarding hospital obligations under EMTALA to receive individuals who arrive by ambulance. Specifically, the TAG recommended that CMS revise a letter of guidance that had been issued by the agency to clarify its position on the practice of delaying the transfer of an individual from an emergency medical service provider's stretcher to a bed in a hospital's emergency department.

This recommendation was adopted with modification by CMS in Survey and Certification Letter S&C-07-20, which was released on April 27, 2007. (The Survey and

Certification Letter can be found at the following Web site:

<http://www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp>).

- That CMS clarify that a hospital may not refuse to accept an individual appropriately transferred under EMTALA on the grounds that it (the receiving hospital) does not approve the method of transfer arranged by the attending physician at the sending hospital (for example, a receiving hospital may not require the sending hospital to use an ambulance transport designated by the receiving hospital). In addition, CMS should improve its communication of such clarifications with its regional offices.

This recommendation was adopted and implemented by CMS in Survey and Certification Letter S&C-07-20, which was released on April 27, 2007. (The Survey and Certification Letter can be found at the following Web site:

<http://www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp>).

- That CMS strike the language in the Interpretive Guidelines (CMS State Operations Manual, Appendix V) that addresses telehealth/telemedicine (relating to the regulations at §489.24(j)(1)) and replace it with language that clarifies that the treating physician ultimately determines whether an on-call physician should come to the emergency department and that the treating physician may use a variety of methods to communicate with the on-call physician. A potential violation occurs only if the treating physician requests that the on-call physician come to the emergency department and the on-call physician refuses.

This recommendation was adopted and implemented by CMS in Survey and Certification Letter S&C-07-23, which was released on June 22, 2007. (The Survey and

Certification Letter can be found at the following Web site:

<http://www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp>).

We are considering the remaining recommendations of the EMTALA TAG and may address them through future changes to or clarifications of the existing regulations or the Interpretive Guidelines, or both.

At the end of its term, the EMTALA TAG compiled a final report to the Secretary. This report includes, among other materials, minutes from each TAG meeting as well as a comprehensive list of all of the TAG's recommendations. The final report is available at the following Web site: http://www.cms.hhs.gov/FACA/07_emptalatag.asp.

3. Changes Relating to Applicability of EMTALA Requirements to Hospital Inpatients

While many issues pertaining to EMTALA involve individuals presenting to a hospital's dedicated emergency department, questions have been raised regarding the applicability of the EMTALA requirements to inpatients. We have previously discussed the applicability of the EMTALA requirements to hospital inpatients in both the May 9, 2002 IPPS proposed rule (67 FR 31475) and the September 9, 2003 stand alone final rule on EMTALA (68 FR 53243). As we stated in both of the aforementioned rules, in 1999, the United States Supreme Court considered a case (Roberts v. Galen of Virginia, 525 U.S. 249 (1999)) that involved, in part, the question of whether EMTALA applies to inpatients in a hospital. In the context of that case, the United States Solicitor General advised the Court that HHS would develop a regulation clarifying its position on that issue. In the 2003 final rule, CMS took the position that a hospital's obligation under EMTALA ends when that hospital, in good faith, admits an individual with an unstable

emergency medical condition as an inpatient to that hospital. In that rule, CMS noted that other patient safeguards protected inpatients, including the CoPs as well as State malpractice law. However, in the 2003 final rule, CMS did not directly address the question of whether EMTALA's "specialized care" requirements (section 1867(g) of the Act) applied to inpatients.

As noted in section IV.I.2. of this preamble, the EMTALA TAG has developed a set of recommendations to the Secretary. One of those recommendations calls for CMS to revise its regulations to address the situation of an individual who: (1) presents to a hospital that has a dedicated emergency department and is determined to have an unstabilized emergency medical condition; (2) is admitted to the hospital as an inpatient; and (3) the hospital subsequently determines that stabilizing the individual's emergency medical condition requires specialized care only available at another hospital.

We stated in the proposed rule that we believed that the obligation of EMTALA did not end for all hospitals once an individual had been admitted as an inpatient to the hospital where the individual first presented with a medical condition that was determined to be an emergency medical condition. Rather, once the individual was admitted, admission only impacted the EMTALA obligation of the hospital where the individual first presented. (Throughout this section of the preamble of this final rule, we refer to the hospital where the individual first presented as the "admitting hospital.") Section 1867(g) of the Act states: "Nondiscrimination – A participating hospital that has specialized capabilities or facilities (such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers as identified

by the Secretary in regulation) shall not refuse to accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual.” In the proposed rule we suggested that section 1867(g) of the Act requires a receiving hospital with specialized capabilities to accept a request to transfer an individual with an unstable emergency medical condition as long as the hospital has the capacity to treat that individual, regardless of whether the individual had been an inpatient at the admitting hospital. Our suggestion was supported by the September 9, 2003 final rule (68 FR 53263), in which we amended the regulations at §489.24(d)(2)(i) to state that: “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 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*” (emphasis added). In the proposed rule we stated that we believed that permitting inpatient admission at the *admitting* hospital to end EMTALA obligations for *another* hospital to which an unstabilized individual was being appropriately transferred to receive specialized care would seemingly contradict the intent of section 1867(g) of the Act to ensure that hospitals with specialized capabilities provide medical treatment to individuals with emergency medical conditions in order to stabilize those conditions.

We also noted in the proposed rule, that as discussed in the preamble of the September 9, 2003 stand alone final rule, notwithstanding any EMTALA protections, a hospital inpatient is protected under the Medicare CoPs and may also have additional protections under State law. A hospital that fails to provide necessary treatment to such

individuals could face termination of its Medicare provider agreement for a violation of the CoPs. We stated in the proposed rule that we believe it is consistent with the intent of EMTALA to limit its protections to individuals who need them most; for example, individuals who present to a hospital but may not have been formally admitted as patients and thus are not covered by other protections applicable to patients of the hospital. We believe that, in the case of inpatients, there is no need or requirement to also supplement the hospital's obligation to its patients under the CoPs in order to further the objectives of EMTALA. However, the obligations of a hospital under the CoPs apply only to that hospital's patients; they do not apply to individuals who are not patients. Further, there is no CoP that requires a hospital to accept the transfer of a patient from another facility. Thus, a hospital with specialized capabilities has no obligations under the CoPs to any nonpatients. On the other hand, the EMTALA statute, in section 1867(g) of the Act, does create an obligation for such hospitals to accept appropriate transfers of nonpatient individuals if it has the capacity to treat the individuals. Therefore, in our proposal, in order to ensure an individual the protections intended by the EMTALA statute, we indicated in the FY 2009 IPPS proposed rule (73 FR 23669) that we believed it was appropriate to propose to clarify that section 1867(g) of the Act (obligating a hospital with specialized capabilities to accept an appropriate transferred individual if it has the capacity to treat the individual) continues to apply so as to protect even an individual who has been admitted as an inpatient to an admitting hospital despite not being stabilized since becoming an inpatient. We stated that we believed that this clarification was necessary to ensure that EMTALA protections are continued for individuals who were

not otherwise protected by the hospital CoPs (with respect to the obligation of other hospitals to those individuals). (We noted that this proposed clarification was consistent with the EMATLA TAG's recommendation that EMTALA does not apply when an individual is admitted to the hospital for an elective procedure and subsequently develops an emergency medical condition.)

We recognized that the proposed clarification that the obligation to accept an appropriate transfer under EMTALA applied to a hospital with specialized capabilities when an inpatient (who presented to the admitting hospital under EMTALA) was in need of specialized care to stabilize his or her emergency medical condition may have raised concerns among the provider community that such a clarification in policy could hypothetically result in an increase in the number of transfers. However, we stated that the intention of this proposed clarification was not to encourage patient dumping to hospitals with specialized capabilities. Rather, even if the hospital with specialized capabilities had an EMTALA obligation to accept an individual who was an inpatient at the admitting hospital, the admitting hospital transferring the individual should take all steps necessary to ensure that it is provided needed treatment within its capabilities prior to transferring the individual. This meant that an individual with an unstabilized emergency medical condition should only be transferred when the capabilities of the admitting hospital were exceeded.

Accordingly, we proposed to revise §489.24(f) by adding to the existing text a provision that specifies that paragraph (f) also applies to an individual who has been admitted under paragraph (d)(2)(i) of the section and who has not been stabilized.

While we did not include the following in our proposed clarification, we sought public comments on whether the EMTALA obligation imposed on hospitals with specialized capabilities to accept appropriate transfers should apply to a hospital with specialized capabilities in the case of an individual who had a period of stability during his or her stay at the admitting hospital and is in need of specialized care available at the hospital with specialized capabilities. CMS takes seriously its duty to protect patients with emergency medical conditions as required by EMTALA. Thus, we sought public comments as to whether, with respect to the EMTALA obligation on the hospital with specialized capabilities, it should or should not matter if an individual who currently has an unstabilized emergency medical condition (which is beyond the capability of the admitting hospital) (1) remained unstable after coming to the hospital emergency department or (2) subsequently had a period of stability after coming to the hospital emergency department.

In summary, to implement the recommendation by the EMTALA TAG and clarify our policy regarding the applicability of EMTALA to hospital inpatients, we proposed to amend §489.24(f) to add a provision to state that when an individual covered by EMTALA was admitted as an inpatient and remains unstabilized with an emergency medical condition, a receiving hospital with specialized capabilities has an EMTALA obligation to accept that individual, assuming that the transfer of the individual is an appropriate transfer and the participating hospital with specialized capabilities has the capacity to treat the individual.

Comment: Numerous commenters opposed the proposal in the FY 2009 proposed rule regarding the applicability of EMTALA to hospital inpatients. Many commenters asserted that, rather than being a clarification of current regulations, CMS' proposal represents a significant change in policy which runs counter to CMS' policy expressed in the September 9, 2003 Federal Register (68 FR 53222). Commenters stated that the current regulations at §489.24(d)(2)(i) provide a "bright-line" test for EMTALA, which "...clearly states that once an individual presenting to the hospital's emergency department has been screened and admitted as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its EMTALA obligations for that individual, and EMTALA no longer applies to a subsequent transfer." Commenters stated they believe the proposed rule re-opens EMTALA for the admitting hospital. They noted the admitting hospital, after it has admitted the individual, would then be required to abide by the regulations governing an appropriate transfer when it transfers the inpatient to the hospital with specialized capabilities.

Many commenters questioned whether such a change in policy was necessary since it is unlikely that a hospital would knowingly admit an individual with an unstabilized emergency medical condition who they did not have the capability or capacity to stabilize. One commenter noted that all hospitals which have emergency departments should be capable of evaluating an individual who presents to the emergency department and if the hospital does not have the capability to appropriately care for the individual, the hospital should transfer, rather than admit the individual. Another commenter stated it was not the intent of EMTALA for a hospital to be able to transfer

any individual whose condition worsens after admission. Commenters asserted that the proposed rule is unnecessary because current statutory and regulatory requirements provide extensive legal protections separate and apart from EMTALA. One commenter stated that, in addition to hospital CoPs, the Arkansas Rules and Regulations for Hospitals and Related Institutions as well as the Rules and Regulations for Critical Access Hospitals contain hundreds of pages of requirements concerning hospitals' care and treatment for all patients.

Commenters asserted that CMS is relying on a recommendation of the EMTALA TAG to make its policy change and the actions of the TAG do not justify a need for a change in policy. One commenter noted that the TAG vote in favor of the recommendation to apply EMTALA to hospital inpatients was 10 to 8 and that 5 of the votes in favor of the recommendation came from the U.S. Department of Health and Human Services. The commenter also noted that the vote was taken twice and that the recommendation was voted as a "low" priority by the TAG. Commenters stated that a discussion of the contentious nature of the TAG's recommendation was not included in the preamble to the proposed rule. Specifically, the commenters noted that CMS failed to state that the recommendation was only passed by a slim majority with most of the physician and hospital representatives opposing the recommendation. Commenters noted that after the TAG meeting, members of the TAG sent the TAG chairman letters indicating their concern that if implemented, the recommendation would adversely affect patient care and could increase the number of unnecessary patient transfers. Furthermore, the commenters stated that two physicians who had voted in favor of the recommendation

subsequently sent a letter expressing their concern that the recommendation could have a potential for abuse, namely patient dumping, and that they “...fear that the potentially unintended consequence may be the transfer of EMTALA patients for reasons other than those related to emergency care of the problem for which the patient was originally admitted when these services could have been provided at the sending hospital.”

Many commenters were concerned that the proposed rule would facilitate patient dumping at hospitals with specialized capabilities. Commenters were concerned the admitting hospital would not initially pay sufficient attention to the EMTALA requirements by not adequately assessing whether it actually has the capabilities necessary to treat an individual who presents under EMTALA. The commenter stated that there is no clear mechanism outlined in the proposed rule for reporting a hospital that fails to treat individuals adequately or fails to utilize all available resources before transferring an individual. One commenter suggested that CMS require admitting hospitals, which are part of a larger hospital system, to look to other system hospitals within the geographic area for specialized capabilities before transferring an individual to a hospital located outside of the system (assuming it is in the best interests for the patient to be transferred). The commenter stated such a policy would dissuade hospitals from making transfers for financial rather than patient care. One commenter asked CMS to clarify whether it intends for the proposed rule to apply to any individual with an emergency medical condition, regardless of whether or not the individual actually goes to the emergency department. The commenter stated “Some patients with an emergency medical condition may have been a direct admission to the hospital by a local physician

but never cared for initially by the ER; the patient simply came through the ER as a direct admission. We request CMS clarify whether these patients also will be covered by EMTALA.” Another commenter stated that in addition to being overwhelmed by transfer requests, a receiving hospital will have to determine: (1) whether the inpatient originally presented to the requesting hospital’s emergency department; (2) whether the patient has ever been stable; and (3) whether the patient requires specialized services not offered at the requesting hospital.

Commenters expressed their concern that tertiary care hospitals, urban safety net, and teaching hospitals that are already providing care to the indigent and uninsured patients, may become further overburdened by the proposed rule. Commenters stated that a sending hospital, acting in bad faith, could choose to only transfer medically complex patients requiring extensive lengths of stay, patients who are uninsured, and patients who have been subject to a medical error. One commenter stated that physicians expect that transfer requests of unresolved emergency medical conditions will come on weekends and holidays as a convenience measure and not a necessity. Another commenter stated that it treats more than 80,000 patients annually at its facility, which is the region’s only Level I trauma center. The commenter stated it will always accept critically ill patients who are unable to be stabilized at another facility. The commenter stated that, under the proposed rule, it would now be obligated to accept the patient even though it has no ability to weigh in on the appropriateness of the transfer, which may not be in the best interest of the patient.

Commenters also expressed their concern on how the proposed rule would affect the care and treatment of patients. Commenters were especially concerned about the consequences to patient health (both physical and psychological) and safety due to a potential increase in inappropriate/unnecessary transfers and over-triaging. One commenter asserted that the proposed policy will worsen the increase of inappropriate transfers and that already too few seriously ill patients are receiving appropriate initial evaluations at Level I and II trauma centers, while too many patients with non serious injuries, are presenting to or being transferred to those centers. One commenter noted that if the policy is finalized as proposed, the referring hospital may transfer patients who deteriorate following admission, thereby risking the life of the patient. The commenter further noted that patients without health insurance may be given an incentive to bypass their closest emergency department and go to larger medical centers offering indigent care. The commenter noted that the proposed rule would discourage “savvy” patients from seeking care at the nearest available emergency department and encourage them to go to the most sophisticated emergency department to avoid the possibility of being admitted to a hospital lacking the necessary capabilities and the possibility of eventually being transferred. The commenter noted “Unless and until CMS recognizes the magnitude of the problem of some hospitals avoiding their EMTALA obligations, no EMTALA policy can ever be adequate to the task of protecting the interests of patients.”

Commenters expressed their concern with the definition of “stable” and “unstable” and how the interpretation of these terms could be affected by the proposed rule. One commenter highlighted the applicability of the proposed rule to the state of

Idaho, stating that Idaho contains many small hospitals that may only employ one general surgeon or orthopedic surgeon. The commenter noted that, when individuals require transfer, often what makes the receiving hospital “the hospital with specialized capabilities” is that it has an on-call specialist. One commenter stated that hospitals will have the incentive to stretch the definition of “specialized” to make the determination that some component of care for a particular patient is beyond its capability.

One commenter stated that CMS lacks the legal authority to apply EMTALA to an inpatient who presented to the admitting hospital under EMTALA. The commenter stated that the 2003 rule established a “bright line” for EMTALA, which also made a distinction between “individuals” and “patients,” (the primary distinction being that individuals, not patients, are protected by EMTALA.) The commenter recommended CMS withdraw the proposed rule as not authorized under the limited scope of the EMTALA statute. Additionally, the commenter stated that the preamble to the proposed rule does not provide sufficient reason as to why EMTALA should be expanded to apply to inpatients. The commenter stated that both the EMTALA interpretive guidelines and judicial decisions emphasize that EMTALA is anti-discrimination and designed to ensure that all patients with similar signs and symptoms are treated the same as recipients of emergency care services. The commenter argued that the proposed rule is the antithesis of the intent of the EMTALA statute and creates a dual standard of care for patients who require the same level of care by permitting inpatients who present to the hospital under EMTALA special privileges. The commenter stated it would be difficult for a hospital to determine what type of inpatient it is dealing with, one with or without residual

EMTALA rights. The commenter noted that hospitals and physicians are already puzzled by the inexact language of EMTALA, including the terms “stabilization,” “resolved” (as used in the IGs), “stable,” and what is meant by a higher level of care. The commenter recommended CMS provide greater “specificity” and “clarity” as to when a patient’s condition is considered stabilized. The commenter further stated “...there is no guidance as to what is an ‘appropriate transfer’ of an inpatient with residual EMTALA rights that triggers the obligation of a receiving hospital to accept the inpatient transfer.” The commenter stated EMTALA is only triggered for the accepting hospital, if the transferring hospital participates in an “appropriate transfer” of an individual.

Another commenter recommended that the rule address requirements for the admitting hospital to take all steps necessary to ensure that it is providing required treatment within its capabilities prior to engaging in a transfer. The commenter stated that the proposed rule treats hospitals unequally because it does not impose sanctions on the transferring hospital for making an inappropriate transfer of an individual with residual EMTALA rights. The commenter stated that “If receiving hospitals are subject to EMTALA sanctions for refusing an appropriate transfer of an inpatient with residual EMTALA rights, then sending hospitals and physicians should have the equivalent exposure to sanctions for making an improper transfer of an inpatient with residual EMTALA rights.”

Response: We thank the commenters for expressing their concerns regarding our proposal. We agree with the commenters that finalizing the proposed rule may result in hospitals with specialized capabilities experiencing an increase in inappropriate transfers.

We understand that medical institutions such as academic medical centers, tertiary care centers, and public safety net hospitals are already facing significant and growing challenges in providing emergency services. After consideration of the comments, we believe that finalizing the policy as proposed may negatively impact patient care, due to an increase in inappropriate transfers which could be detrimental to the physical and psychological health and well-being of patients. We are concerned that finalizing our proposed rule could further burden the emergency services system and may force hospitals providing emergency care to limit their services or close, reducing access to emergency care.

We agree with the commenters' concerns that some hospitals might abuse the proposed policy by not providing patients with the necessary screening examination required under EMTALA to determine the nature and extent of their emergency medical condition. We believe that, in the case where an individual is admitted and later found to be in need of specialized care not available at the admitting hospital, hospitals with specialized capabilities generally do accept the transfer, even in the absence of a legal requirement to do so. Furthermore, as one commenter pointed out by referencing the Arkansas Rules and Regulations for Hospitals and Related Institutions as well as the Rules and Regulations for Critical Access Hospitals, some States have requirements in addition to the hospital CoPs that provide for further protections for patients.

We are very concerned about the possible disparate treatment of inpatients under the proposed policy. Specifically, under the proposed policy, an individual who presented to the hospital under EMTALA may have different transfer rights than an

inpatient who was admitted for an elective procedure. This situation also creates operational challenges for hospital staff to differentiate which inpatient is afforded which transfer rights. Determining which individuals are covered by transfer rights under EMTALA may tie up a hospital's already strained resources. Furthermore, we believe that if we finalized the proposed rule, the admitting hospital may encounter challenges in determining whether or not an individual has ever been stable, as that term is defined in the EMTALA statute, because if the individual had any period of stability, EMTALA would not require acceptance of the transfer by the hospital with specialized capabilities. We recognize that the EMTALA definition of "stable" differs from clinical usage of this term.

We support in principle the commenter's suggestion that hospitals that are part of a larger hospital system should transfer an individual to a system hospital with the required specialized capabilities within the same geographic area, so long as doing so would not result in a significantly longer transport for the individual than would transfer to a nonsystem hospital. However, we cannot mandate that individuals only be transferred to certain hospitals within a specific geographic region. In response to the commenter who asked that we clarify (in the context of the proposed rule) whether EMTALA would apply to an individual with an emergency medical condition, regardless of whether or not the individual went to the emergency department, we would like to clarify when EMTALA applies. In addition to EMTALA applying when an individual presents to a hospital emergency department and requests examination or treatment for a medical condition, or has a request made on his or her behalf, EMTALA applies when an

individual presents on hospital property (as defined at §489.24(b)) and requests examination or treatment for an emergency medical condition, or has a request made on his or her behalf.

We recognize the concern of the commenters that the recommendation provided by the TAG to apply EMTALA to hospital inpatients was accepted by the TAG on the narrowest of margins and that the majority of hospital representatives serving on the TAG were opposed to the recommendation. The discussion of the TAG's recommendation is provided on the CMS Web site under the meeting reports link, or link to the EMTALA TAG final report at : http://www.cms.hhs.gov/FACA/07_emptalatag.asp. Therefore, in this final rule, due to the concerns noted above, we are clarifying our policy on the EMTALA obligation of a hospital with specialized capabilities, by stating that if an individual presents to the admitting hospital that has a dedicated emergency department, is provided an appropriate medical screening examination and is found to have an emergency medical condition, and is admitted as an inpatient in good faith for stabilizing treatment of an emergency medical condition, then the admitting hospital has met its EMTALA obligation to that individual, even if the individual remains unstable. Furthermore, in such a case, a hospital with specialized capabilities does not have an obligation under EMTALA to accept a transfer of that individual from the referring hospital. Accordingly, we have revised the regulation at §489.24(f) to state that it does not apply to an individual who has been admitted under §489.24 (d)(2)(i).

Due to the many concerns that the commenters raised which are noted above, we believe it is appropriate to finalize a policy to state that if an individual with an unstable

emergency medical condition is admitted, the EMTALA obligation has ended for the admitting hospital and even if the individual's emergency medical condition remains unstabilized and the individual requires special services only available at another hospital, the hospital with specialized capabilities does not have an EMTALA obligation to accept an appropriate transfer of that individual. However, we would like to emphasize that if an individual presents to a hospital with a dedicated emergency department and is found to have an emergency medical condition that requires stabilizing treatment which requires specialized treatment not available at the hospital where the individual presented, and has not been admitted as an inpatient, then another Medicare-participating hospital with the requisite specialized capabilities is obligated under EMTALA to accept the appropriate transfer of this individual so long as it has the capacity to treat the individual.

Comment: Several commenters supported the proposal to apply EMTALA to hospital inpatients who present under EMTALA, continue to have an unstable emergency medical condition, and are found to require treatment or services only available at another hospital with specialized capabilities. Commenters stated the proposed policy is necessary to protect individuals who are not otherwise protected by hospital CoPs. One commenter stated that hospitals with specialized capabilities should not be exempt from accepting the transfer of an unstable patient from a hospital that lacks the specialized capabilities to treat that patient. However, the commenter stated that the regulation needs to be specific in order to minimize the potential for multiple interpretations and the actual process should be monitored for abuse, for example, excessive transfers from a hospital.

One commenter believed hospitals are already routinely following the policy expressed in the proposed rule. Therefore, the commenter believed the proposed requirement will only formalize existing practice. Another commenter stated that the proposal was especially important for individuals living in rural areas because those individuals are routinely denied transfer to a regional facility for definitive care based on the conclusion that the individuals are already at a “hospital.” The commenter noted this scenario has been experienced multiple times by CAHs.

Commenters stated that the proposal would effectively treat the hospitalized inpatient as an individual who comes to the hospital with specialized capabilities seeking emergency care, when the hospital with specialized capabilities falls within the conditions described under section 1867(g) of the Act. The commenter took issue with CMS’ 2003 final rule and stated that the proposed policy corrects the problem introduced by CMS’ 2003 final rule, when the agency decided that inpatient admission would end EMTALA unless a subterfuge can be proven. One commenter asserted that the fact of whether or not an individual was admitted is irrelevant in determining whether the individual has an emergency medical condition or whether the admitting hospital has the capability to provide the necessary care. Instead, the commenter mentioned the aforementioned criteria are “...the only operative criteria to whether the transfer is justified under EMTALA.” The commenter stated that EMTALA was conceived because Congress recognized that patients needing transfers were being denied access to higher levels of care. The commenter urged CMS to go forward with the proposed changes and requested that clarifying language be included to establish that “...CMS recognizes no

provisions in paragraph G anti-discrimination provisions that would allow a receiving hospital to deny any patient on the basis of their admission status or physical location at the sending facility.”

Another commenter stated that CMS’ proposal is in the best interests of patient care and should be implemented. The commenter claimed that without clarification, a hospital with specialized capabilities could legitimately decline a transfer, asserting that hospitals’ EMTALA obligations and rights end upon admission of an individual to a hospital. The commenter stated that “CMS should monitor closely the actual experience of inpatient emergency transfer to specialized care facilities for the first two years and then, if warranted, consider an appropriate DRG reimbursement adjustment for the initial admitting hospital’s abbreviated admission that resulted in an emergent transfer to a specialized acute care facility.”

Response: We appreciate the commenters’ emphasis on patient care and would like to reinforce that the intent of EMTALA was not to provide hospitals with a clear indication of the point at which their legal responsibility towards an individual ends, but rather the intent of EMTALA was to provide access to emergency care to all individuals who present to an emergency department and are determined to have an emergency medical condition, including the uninsured. In response to the commenter who believed that the policy expressed in the proposed rule is already routine practice, we also agree, as stated previously, that generally hospitals with specialized capabilities would accept the transfer of an inpatient with an unstable emergency medical condition, even if there was no legal requirement under EMTALA to do so. In response to the commenter who

suggested that CMS monitor inpatient transfers to hospitals with specialized capabilities for the first 2 years and consider appropriate DRG reimbursement for the initial hospital's admission, EMTALA requirements are separate from Medicare payment policy for covered services provided to Medicare beneficiaries. Existing policy already addresses payment in cases of transfer of a beneficiary who is an inpatient to another hospital. In addition, although commenters expressed concerns regarding hospitals experiencing difficulties transferring patients (which we believe may exist), we are concerned with the potential for overcrowding that could result at academic medical centers, tertiary care centers, and public safety net hospitals if we were to finalize the proposed policy.

Furthermore, we would like to emphasize that it is essential that the hospital to which the individual originally presents employ all available resources in its attempts to either stabilize the individual or transfer him/her, under an appropriate transfer. Not only is it a potential EMTALA violation for a hospital to provide an individual with insufficient medical screening or an inappropriate transfer when the hospital actually has the capability to treat the individual a potential EMTALA violation, it may prove to be more costly to society because the individual's emergency medical condition was not initially treated to the extent that it could have been, potentially risking the life of the individual. We would also like to make sure that individuals are aware of their resources if they believe they have been witness to an EMTALA violation. In addition to the investigation of EMTALA complaints conducted by CMS, individuals should be aware that the OIG also enforces EMTALA and may levy civil and monetary penalties against a physician and/or hospital for an EMTALA violation. The law also permits individuals to file a

private right of action. Furthermore, the Act provides for whistleblower protection for hospital personnel. Section 1867(i) of the Act states “A participating hospital may not penalize or take adverse action against a qualified medical person described in subsection (c)(1)(A)(iii) or a physician because the person or physician 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 the requirement of this section.”

Finally, as stated previously, due to the concerns that commenters raised, we are not finalizing the proposed policy. Rather, we are finalizing a policy that a hospital with specialized capabilities is not required under EMTALA to accept the transfer of a hospital inpatient. Although we believe that the language of section 1867(g) of the Act can be interpreted as either applying or not applying to inpatients, after reviewing the comments raised by many commenters, we have serious concerns about the impact the proposed policy would have had on patient care and the possibility that it may overburden many hospitals that are currently having difficulties providing sufficient emergency care.

Comment: We did not receive any public comments in support of our request in the proposed rule for comment on whether the EMTALA obligation imposed on hospitals with specialized capabilities to accept appropriate transfers should apply to a hospital with specialized capabilities in the case of an individual who had a period of stability during his or her stay at the admitting hospital and is in need of specialized care available at the hospital with specialized capabilities. Commenters were concerned that such an

application would provide for further potential for abuse. One commenter stated that a period of stability followed by instability should not be a reason to impose EMTALA obligations on a hospital with specialized capabilities. Another commenter stated that CMS' request for comment was based on a concept not even contemplated by the TAG's controversial comment. One commenter stated that such a policy may encourage hospitals to dump patients when they receive an especially difficult case study.

Response: We thank the commenters for their responses to our question on whether EMTALA should apply when an individual had a period of stability.

Comment: Commenters included information regarding recent publications which communicate the dire circumstances facing emergency care. Several commenters mentioned the 2006 Institute of Medicine (IOM) reports focused on the future of emergency care. One commenter mentioned a report recently issued by the House Oversight and Government Reform Committee titled: "Hospital Emergency Surge Capacity: Not Ready for the Predictable Surprise." The commenter also cited a testimony made before the Committee by J. Wayne Meredith, MD, Professor and Chairman of General Surgery, Wake Forest University Baptist Hospital. One commenter stated that it wished to commend the work of the EMTALA TAG and stated that most of the TAG's recommendations will help clarify current interpretations of EMTALA and help improve the delivery of emergency medical services. The commenter wished to take the opportunity to highlight several of the TAG's recommendations, and urged CMS to adopt the following recommendations as soon as possible: 1, 8, 9, 11, 13, 14, 19, 27, 52, and 53. (Note: the number of the recommendation refers to the corresponding number

found in final report of the EMTALA TAG. The final report can be found at the following website: http://www.cms.hhs.gov/FACA/07_emptalatag.asp). The commenter also discussed a survey of neurosurgeons conducted by the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) in 2004, which concluded that 45 percent of neurosurgeons practicing at either an academic health center or Level I or II trauma center, experienced an increase in the number of neurosurgical emergency cases in the previous 2 years. Another commenter stated that it supported number 53 of the TAG's recommendation, which recommends the statute be modified to create a funding mechanism for EMTALA.

Response: We thank the commenters for the information on the IOM reports and testimony which address the current crisis in emergency care as well as their support of the TAG and several of its recommendations. Although these comments pertain to EMTALA, they do not directly address the proposed rule. Therefore, we are not responding to them at this time.

As stated previously, in this final rule, rather than adopting the proposed regulation language, we are clarifying the EMTALA regulations at §489.24(f) with respect to hospital inpatients by stating that once an individual is admitted in good faith by the admitting hospital, the admitting hospital has satisfied its EMTALA obligation with respect to that individual even if the individual remains unstabilized and a hospital with specialized capabilities does not have an EMTALA obligation to accept an appropriate transfer of that individual. We encourage the public to make CMS aware if this interpretation of section 1867(g) of the Act should result in harmful refusals by

hospitals with specialized capabilities to accept the transfer of inpatients whose emergency medical condition remains unstabilized, or any other unintended consequences.

4. Changes to the EMTALA Physician On-Call Requirements

a. Relocation of Regulatory Provisions

During its term, the EMTALA TAG dedicated a significant portion of its discussion to a hospital's physician on-call obligations under EMTALA and made several recommendations to the Secretary regarding physician on-call requirements that are included in its final report (available at the Web site:

http://www.cms.hhs.gov/FACA/07_emptalatag.asp). As one recommendation, the TAG recommended that CMS move the regulation discussing the obligation to maintain an on-call list from the EMTALA regulations at §489.24(j)(1) to the regulations implementing provider agreements at §489.20(r)(2). As we stated in the proposed rule, we agree with the TAG's recommendation. The requirement to maintain an on-call list is found at section 1866(a)(1)(I)(iii) of the Act, the section of the Act that refers to provider agreements. Section 1867 of the Act, which outlines the EMTALA requirements, makes no mention of the requirement to maintain an on-call list.

To implement the EMTALA TAG's recommendation, in the FY 2009 IPPS proposed rule, we proposed to delete the provision relating to maintaining a list of on-call physicians from §489.24(j)(1). We noted that a provision for an on-call physician list is already included in the regulations as a hospital provider agreement requirement at §489.20(r)(2). We proposed to incorporate the language of §489.24(j)(1) as replacement

language for the existing §489.20(r)(2) and amend the regulatory language to make it more consistent with the statutory language found at section 1866(a)(1)(I)(iii) of the Act. We proposed that revised §489.20(r)(2) would read: "An on-call list of physicians on its medical staff available to provide treatment necessary after the initial examination to stabilize individuals with emergency medical conditions who are receiving services required under §489.24 in accordance with the resources available to the hospital.

The EMTALA TAG made additional recommendations regarding how a hospital would satisfy its on-call list obligations, including calling for an annual plan by the hospital and medical staff for on-call coverage that would include an assessment of factors such as the hospital's capabilities and services, community need for emergency department services as indicated by emergency department visits, emergent transfers, physician resources, and past performance of previous on-call plans. The TAG also recommended that a hospital have a backup plan for viable patient care options when an on-call physician is not available, including such factors as telemedicine, other staff physicians, transfer agreements, and regional or community call arrangements. While community call arrangements are discussed below, we intend to address the remainder of the TAG recommendations at a later date.

Comment: Several commenters supported our proposal to move and amend the regulations text relating to maintaining a list of on-call physicians. However, the commenters requested that CMS explain why the language "in a manner that best meets the needs of the hospital's patients" was deleted. The commenters stated that this explanation is important so that "... the change is not misconstrued as undermining the

ability of hospitals to set expectations for physicians agreeing to serve on-call to the hospital emergency department.” Two commenters suggested that the entire language of §489.24(j) be moved to §489.20(r) of the regulations. One commenter stated that moving the entire language of §489.24(j) would conform the regulations to the statute and that consolidating all of the on-call requirements under a single regulation, would help hospitals more easily identify and comply with all applicable EMTALA on-call requirements.

Response: We proposed moving the regulatory text because we believe the change would make the regulations consistent with the statutory language. Furthermore, we deleted the "best meets the needs" language because we believe that the phrase has caused confusion among the provider community as to its meaning. We believe the language "in accordance with the resources available to the hospital" provides clarification that the hospital should provide on-call services based on the resources it has available, including the availability of specialists. We did not intend to suggest that removing the “best meets the needs” language would limit, in any way, a hospital’s ability to set expectations that physicians be on call. It is crucial that hospitals are aware of their responsibility to ensure that they are providing sufficient on-call services to meet the needs of their community in accordance with the resources they have available. A hospital should strive to provide adequate specialty on-call coverage consistent with the services provided at the hospital and the resources the hospital has available. We are aware that providing specialty on-call coverage can be challenging for a hospital because of the limited availability of specialty physicians who are willing or able to take call.

Physicians should not perceive the change in regulations text as confirmation that they should limit their on-call availability. In addition, we believe the community call provision discussed below will help hospitals diversify their on-call coverage and ease the burden on those physicians who are providing continuous on-call coverage. Finally, we note that the TAG made additional recommendations related to on-call coverage that remain under consideration by CMS. We may, in the future, in response to these recommendations, engage in additional rulemaking or revise our interpretative guidelines to the EMTALA and related regulations in 42 CFR Part 489.

In response to the commenters who suggested moving all of the language currently at §489.24(j) to §489.20(r), the proposed regulations regarding community call and the existing regulations that permit on-call physicians to serve simultaneous call and schedule elective surgery while on-call provide hospitals and physicians flexibility in meeting the requirement that when an emergency room physician requests the appearance of an on-call physician, that on-call physician is required to appear under EMTALA. We believe that the provisions included under §489.24(j) should continue to be included under the EMTALA regulations and should not be moved to the provider agreement regulations at §489.20(r).

We are adding the phrase "who are on the hospital's medical staff, or who have privileges at the hospital, or who are on staff or have privileges at another hospital participating in a formal community call plan in accordance with §489.24(j)(2)(iii)" to the regulation text to make the regulation text consistent with our policy on community call plans. The finalized regulation text at §489.20(r)(2) reads: "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 staff or have privileges at another hospital participating in a formal community call plan in accordance with §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 §489.24 in accordance with the resources available to the hospital.

b. Shared/Community Call

As noted in the previous section, section 1866(a)(1)(I)(iii) of the Act states, as a requirement for participation in the Medicare program, that a hospital must keep a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition. If a physician on the list is called by a hospital to provide stabilizing treatment and either fails or refuses to appear within a reasonable period of time, the hospital and that physician may be in violation of EMTALA as provided for under section 1867(d)(1)(C) of the Act. Thus, hospitals are required to maintain a list of on-call physicians, and physicians or hospitals, or both, may be held responsible under the EMTALA statute if a physician who is on call fails or refuses to appear within a reasonable period of time.

In the May 9, 2002 proposed rule (67 FR 31471), we stated that we were aware of hospitals' increasing concerns regarding their physician on-call requirements. Specifically, we noted that we were aware of reports of physicians, particularly specialty physicians, severing their relationships with hospitals because of on-call obligations, especially when those physicians belong to more than one hospital medical staff. We

further noted that physician attrition from these medical staffs could result in hospitals having no specialty physician service coverage for their patients. In the September 9, 2003 final rule (68 FR 53264), we clarified the regulations at §489.24(j) to permit on-call physicians to schedule elective surgery during the time that they are on call and to permit on-call physicians to have simultaneous on-call duties. We also specified that physicians, including specialists and subspecialists, are not required to be on call at all times, and that the hospital must have policies and procedures to be followed when a particular specialty is not available or the on-call physician cannot respond because of situations beyond his or her control. We expected these clarifications to help improve access to physician services for all hospital patients by permitting hospitals flexibility to determine how best to maximize their available physician resources. Furthermore, we expected that these clarifications would permit hospitals to continue to attract physicians to serve on their medical staffs, thereby continuing to provide services to all patients, including those individuals who are covered by EMTALA.

As part of its recommendations concerning physician on-call requirements, the EMTALA TAG recommended that hospitals be permitted to participate in "community call." Specifically, the language of the recommendation states: "The TAG recommends that CMS clarify its position regarding shared or community call: that such community call arrangements are acceptable if the hospitals involved have formal agreements recognized in their policies and procedures, as well as backup plans. It should also be clarified that a community call arrangement does not remove a hospital's obligation to perform an MSE [medical screening examination]." The TAG also recommended in a

subsequent recommendation that "A hospital may satisfy its on-call coverage obligation by participation in an approved community/regional call coverage program (CMS to determine appropriate approval process)."

We believe that community call (as described below) would afford additional flexibility to hospitals providing on-call services and improve access to specialty physician services for individuals in an emergency department. Therefore, in the FY 2009 IPPS proposed rule, we proposed to amend our regulations at §489.24(j) to provide that hospitals may comply with the on-call list requirement specified at §489.20(r)(2) (under our proposed revision), by participating in a formal community call plan so long as the plan meets the elements outlined below. We further proposed to revise the regulations to state that, notwithstanding participation in a community call plan, hospitals are still required to perform medical screening examinations on individuals who present seeking treatment and to provide for an appropriate transfer when appropriate.

We proposed "community call," to be a formal on-call plan that permits a specific hospital in a region to be designated as the on-call facility for a specific time period, or for a specific service, or both. For example, if there are two hospitals that choose to participate in community call, Hospital A could be designated as the on-call facility for the first 15 days of each month and Hospital B could be designated as the on-call facility for the remaining days of each month. Alternatively, Hospital A could be designated as on-call for cases requiring specialized interventional cardiac care, while Hospital B could be designated as on-call for neurosurgical cases. Based on the proposal, we anticipated

that hospitals and their communities would have the flexibility to develop a plan that reflects their local resources and needs. Such a community on-call plan would allow various physicians in a certain specialty in the aggregate to be on continuous call (24 hours a day, 7 days a week), without putting a continuous call obligation on any one physician. We note that, generally, if an individual arrives at a hospital other than the designated on-call facility, is determined to have an unstabilized emergency medical condition, and requires the services of an on-call specialist, the individual would be transferred to the designated on-call facility in accordance with the community call plan.

As noted above, we proposed that a community call plan must be a formal plan among the participating hospitals. While we do not believe it is necessary for the formal community call plan to be subject to preapproval by CMS, if an EMTALA complaint investigation is initiated, the plan will be subject to review by CMS. We proposed that, at a minimum, hospitals must include the following elements when devising a formal community call plan:

- The community call plan would include a clear delineation of on-call coverage responsibilities, that is, when each hospital participating in the plan is responsible for on-call coverage.
- The community call plan would define the specific geographic area to which the plan applies.
- The community call plan would be signed by an appropriate representative of each hospital participating in the plan.

- The community call plan would ensure that any local and regional EMS system protocol formally includes information on community on-call arrangements.
- Hospitals participating in the community call plan would engage in an analysis of the specialty on-call needs of the community for which the plan is effective.
- The community call plan would include a statement specifying that even if an individual arrives at the hospital that is not designated as the on-call hospital, that hospital still has an EMTALA obligation to provide a medical screening examination and stabilizing treatment within its capability, and hospitals participating in community call must abide by the EMTALA regulations governing appropriate transfers.
- There would be an annual reassessment of the community call plan by the participating hospitals.

We proposed that revised §489.24(j) would read “Availability of on-call physicians. In accordance with the on-call list requirements specified in §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 call plan must include the following elements: [proposed elements noted above in the bullets are included in regulations text].”

We welcomed public comments on the proposed elements of the formal community call plan noted above. We also solicited public comments on whether individuals believe it is important that, in situations where there is a governing State or local agency that would have authority over the development of a formal community call plan, the plan be approved by that agency. In summary, we proposed that, as part of the obligation to have an on-call list, hospitals may choose to participate in community call, provided that the formal community call plan includes, at a minimum, the elements noted in bullets above. In addition, we proposed that each hospital participating in the community call plan must have written policies and procedures in place to respond to situations in which the on-call physician is unable to respond due to situations beyond his or her control. We further proposed that a hospital would still be responsible for performing medical screening examinations on individuals who present to the hospital seeking treatment and conducting appropriate transfers, regardless of which hospital has on-call responsibilities on a particular day.

Comment: The majority of commenters supported our proposal to permit hospitals to use participation in a community call plan as a means of meeting their on-call obligation. The commenters stated that such an approach would allow communities to provide for access to specialty care in a more reasoned, expedited and efficient manner as well as relieve specialists from on-call 24 hours a day, 7 days a week, eliminate the need

for duplicative coverage of nearby hospitals, increase physician retention of specialists, and regionalize scarce resources. Another commenter stated that community call, along with telemedicine, is one of the few ways limited resources can be used efficiently. The commenter noted that participation in community call is a necessary response to the workforce crisis in the emergency department.

In addition, some commenters stated that the community call proposal would be particularly important to rural areas where physicians are in short supply. One commenter specifically addressed concerns about on-call coverage for the field of neurosurgery. The commenter stated that there are approximately 3,100 board certified neurosurgeons actively practicing in the country and about 5,000 hospitals with emergency departments. The commenter stated it is, therefore, impossible to have neurosurgical on-call coverage for every emergency department 24 hours a day, 7 days a week, 365 days a year. The commenter noted that, in an effort to provide as much on-call coverage as possible, more than half of the country's neurosurgeons take simultaneous call at more than 1 hospital, 28 percent of neurosurgeons cover 2 hospitals, 13 percent cover 3 hospitals, and 10 percent cover 4 or more hospitals. The commenter stated that the Institute of Medicine's (IOM's) series of reports on the future of emergency care addressed the shortage of on-call specialists. The commenter noted that an IOM committee studying the issue of on-call specialists identified regionalization of specialty services as an approach that warrants special consideration. The commenter included in its comment some language from the IOM committee and stated that while not exactly the same as regionalization, the idea of community call addresses a number of the same

challenges that hospitals and on-call specialists face in their attempt to provide on-call coverage. The commenter stated that the IOM committee also noted that current EMTALA rules may be hampering the adoption of regional or community call; the commenter included language from the IOM committee which stated "uncertainty surrounding the interpretation and enforcement of EMTALA remains a damper to the development of coordinated, integrated emergency care systems." The commenter noted that the IOM recommended "that the Department of Health and Human Services adopt regulatory changes to the Emergency Medical Treatment and Active Labor Act (EMTALA)...so that the original goals of the law are preserved but integrated systems may further develop." The commenter stated that [they] are hopeful that because CMS has embraced the concept of community call and in essence removed the EMTALA barrier to organize such plans, patient access to timely emergency neurosurgical care will improve.

The commenters cautioned CMS against being too prescriptive in the requirements imposed on hospitals that choose to participate in a community call arrangement. In particular, the commenters recommended that CMS delete the requirement in the proposed §489.24(j)(2)(iii)(E) requiring "evidence of engagement of the hospitals participating in the community call plan in an analysis of the specialty on-call needs of the community for which the plan is effective." One commenter encouraged CMS to work with other Federal agencies to remove legal and financial barriers to facilitate the proposed rule. The commenter noted that recent efforts to develop a community call plan in one county in Florida have been promising, although

complex. The commenter urged CMS to provide for as much flexibility as possible to “...support models for other communities to emulate.”

Several commenters stated that CMS should not require approval of community call plans by public agencies. Another commenter stated that while the development of a community call plan is a worthwhile goal, developing that plan may be challenging, especially in communities where there is competition between hospitals and hospital systems. The commenter supported the proposal that the community call remain voluntary. Another commenter believed that the use of community call plans will provide relief to hospitals that are struggling to meet their EMTALA obligations. The commenter suggested CMS consider requiring medical staff to take call as a condition of holding privileges at a hospital. The commenter stated that legally requiring hospitals to maintain a call schedule, but placing no legal obligation on medical staff to participate in on-call, has led to staff members refusing to participate, participating only if paid, or changing their status from “active” to “courtesy” or “consulting” (categories which the commenter noted, traditionally, do not require a physician to take call).

One commenter supported the proposal to formalize in regulation previous subregulatory guidance related to unavailability of certain specialists, scheduling elective surgery while taking call, and simultaneous on-call duties. In addition, the commenter “...enthusiastically supports any initiative that fosters communication and cooperation among the hospitals in a community.” The commenter stated that while the proposed regulations on community call fall under the EMTALA regulations, they are in line with The Joint Commission standards for emergency management that involve community

partners in the development of emergency management plans as well as communication with community emergency response agencies and directives for timely communication with other hospitals during an emergency.

One commenter stated the preamble indicated that a community call plan, which would qualify under the proposed rule, should have in the aggregate physicians on continuous call (24 hours a day, 7 days a week) and that this requirement is too restrictive and should be made more flexible. The commenter stated that this requirement does not appear to be consistent with the current regulatory standard that allows hospitals to maintain an on-call list in accordance with the hospital's resources.

Response: We appreciate the commenters' support of the proposal to allow hospitals to participate in community call arrangements in order to meet their on-call obligations. We believe that providing hospitals with flexibility in maintaining on-call will allow for, as well as encourage, more specialists to participate in on-call for hospitals. We agree with the commenters that this proposal is especially important to rural hospitals that may have previously had difficulty obtaining specialty coverage for their emergency departments. We also appreciate the commenter's shared concerns regarding the field of neurosurgery and believe that community call plans will provide individuals with greater access to many specialties, such as neurosurgery.

In response to the commenter who requested CMS provide models of community call plans for other communities to emulate, we stated in the proposed rule that we do not believe a community call plan needs preapproval from CMS. We continue to believe that a community call plan does not require authorization from CMS prior to taking effect.

However, we encourage hospitals that believe they have an effective community call plan to communicate such a plan to other hospitals that are interested in developing such a plan. We also emphasize that participation in a community call plan is strictly voluntary because the proposed regulations at §489.24(j)(2)(iii) do not require hospitals to participate in a community call arrangement. Rather, our proposal was intended to provide hospitals with a tool to use to promote an increase in the availability of specialty on-call physicians.

In response to the commenter who suggested CMS require medical staff to take call as a condition of holding privileges at a hospital, we believe that would be an overly broad and inflexible approach to developing specific on-call arrangements for each hospital. Hospitals can, if they choose, make taking a call a requirement for physicians granted privileges at their hospital. In response to the commenter who supported “the proposal” to formalize the subregulatory guidance permitting simultaneous call and scheduling of elective surgery while on-call, we are clarifying that CMS previously finalized these regulations in the September 9, 2003 final rule (68 FR 53264). We did not propose any changes to those provisions in the FY 2009 IPPS proposed rule. We stated in the proposed rule that we believe a community call plan will allow various physicians in a certain specialty, in the aggregate, to be on continuous call (24 hours a day, 7 days a week,) without putting a continuous call obligation on any one physician. While we are not at this time mandating that hospitals maintain 24/7 on-call coverage, hospitals should carefully consider whether they are providing sufficient on-call services in line with their available resources. In the event of an investigation related to the compliance of a

hospital with regard to an on-call list, whether accomplished through a community call plan or not, the determination, as at present, will be based on the specific circumstances of that hospital and, if applicable, the community call plan. We also note that the TAG made additional recommendations on the topic of on-call requirements which remain under consideration by CMS, and which may be the subject of future rulemaking or revisions of interpretative guidelines.

With regard to the elements that we proposed that must be included in a formal community call plan, we agree with the commenters that it is not necessary for a community call plan to include the following proposed requirement in proposed §489.24(j)(2)(iii)(E): “Evidence of engagement of the hospitals participating in the community call plan in an analysis of the specialty on-call needs of the community for which the plan is effective.” We believe this requirement is covered under proposed paragraph (G) of §489.24(j)(2)(iii), which requires: “An annual reassessment of the community call plan by the participating hospitals.” Therefore, we are finalizing the community call regulation as proposed, with one modification. We are deleting the requirement under paragraph (E) of the proposed §489.24(j)(2)(iii).

Comment: Several commenters were concerned with potential liabilities under the Sherman Anti-Trust Act if they were to engage in a multihospital community call plan. Two commenters stated “If a group of hospitals were to jointly formulate a community call plan, it is conceivable that the hospitals may, as a group, choose to contract with a physician group for coverage of certain emergency services. This could be regarded as collusion under certain interpretations of Sherman.” One commenter stated that hospitals

are presently reluctant to establish community call arrangements due to “...potential Federal or State antitrust liability related to unlawful market division.” The commenter recommended CMS support efforts to establish antitrust exemptions for community call arrangements. Another commenter expressed concern that, without an arrangement that is approved by the Antitrust Division of the Department of Justice, competitor hospitals could be investigated for anticompetitive activities related to the division of markets, resulting from either a timeframe or service-line division of responsibility. The commenter recommended that CMS obtain guidance from Justice on the additional checks and balances that might be needed to ensure hospitals can safely avail themselves of this added flexibility.

Another commenter requested clarification of the application of the HIPAA to the proposed policy. The commenter asked whether, because protected health information of patients who may need the services of on-call physicians would not be in existence at the time of the community call agreement, the community call agreement would be classified under health care operations, an organized health care organization, or a business relationship. The commenters also requested clarification of the proposed policy if one or several hospitals that were part of a proposed community call plan decided not to participate in the plan. The commenters requested that CMS respond to the following questions regarding hospital participation: (1) Does nonparticipation of all providers invalidate the plans? (2) Is there a threshold for participation that must be met? (3) Does the presence of a community call plan in an area with nonparticipating providers partially or fully meet the nonparticipating hospital’s EMTALA obligation?

Response: In response to commenters' concerns pertaining to potential antitrust liabilities, we suggest that antitrust concerns be directed to the U.S. Department of Justice Antitrust Division for further review under the business review process. As mentioned previously, participation in a community call plan is strictly voluntary. Therefore, there is no threshold for participation in a community call plan, nor does nonparticipation of one or more hospitals invalidate the plan. In the event of an investigation related to the compliance of a hospital with the on-call requirements outlined in §489.20(r)(2), the determination, as at present, will be based on a review of the specific circumstances of that hospital, including, as applicable, the provisions of any community call plan in which it participates.

In response to the commenter who expressed concerns about the applicability of the HIPAA Privacy Rule to the proposed community call provisions, the Office for Civil Rights (OCR) in the U.S. Department of Health and Human Services provides technical guidance and enforces the HIPAA Privacy Rule. OCR has explained that hospitals and other covered health care providers with a direct treatment relationship with individuals are not required to provide their notices to patients at the time they are providing emergency treatment. In these situations, the HIPAA Privacy Rule requires only that providers give patients a notice when it is practical to do so after the emergency situation has ended. In addition, where notice is delayed by an emergency treatment situation, the Privacy Rule does not require that providers make a good faith effort to obtain the patient's written acknowledgment of receipt of the notice. Any questions concerning the

application of the HIPAA Privacy Rule to patients with emergency medical conditions should be directed to OCR.

Comment: Several commenters expressed specific concerns regarding CMS' community call proposal. A few commenters were concerned that a community call plan could actually reduce the amount of specialty services provided by a hospital, if hospitals were to contract with each other and transfer the burden of providing specialty on-call services to public safety net hospitals. One commenter urged CMS to closely monitor the implementation of community call plans as well as changes in patterns of on-call coverage. The commenter expressed concern that "...groups of hospitals may misuse community call by improperly decreasing their community's access to specialty on-call coverage." The commenter provided an example in which two private hospitals that currently provide specialty on-call services would enter into a community call plan and decrease the amount of coverage so that the amount of coverage they provide together to the community is less than the coverage that was provided prior to the plan being in effect. The commenter stated that, in this case, the community call plan would become a tool whereby private and other nonprofit hospitals coordinate decreasing their on-call coverage at the expense of safety net hospitals.

One commenter requested further research on the impact of the proposed rule and suggested pilot testing in representative communities to determine the impact. Another commenter stated that while it does appear that community call arrangements would encourage physicians to take call at specific hospitals, in most cases there are not enough tertiary care hospitals with specialized capabilities to manage all of the transfer requests.

The commenter stated that from her experience, a community call plan does not stop abuse of EMTALA and stated “It should not surprise CMS, and it is an unspoken truth, that specialty physicians prefer insured patients.” The commenter noted a difference in the treatment of individuals who are uninsured versus those who are insured and stated that if an individual is uninsured a specialty physician may refuse to see that individual. The commenter asserted that, in such a case, the hospital would need to transfer the individual because no physician will see him or her and the hospital would not be paid for admitting the individual. The commenter stated that it is very difficult for a receiving hospital to charge the transferring hospital with an EMTALA violation because “...we must take them at their professional word that the hospital does not have a physician on call for the needs of the patient.” The commenter provided several examples that illustrate abuse of EMTALA requirements and recommended that, to avoid abuse of the community call plan, hospitals be “...required to report the results of the on-call annual plan and the patients that the on-call physician accepts on subsequent days, but was not on call or available for the day the patient came to the ER.” In addition, the commenter requested that CMS address that commenter's suggestion that local emergency rooms should make every effort to arrange the transportation of an individual to a nearby facility before turning to tertiary and quaternary care centers. One commenter stated that hospitals’ annual on-call plans should be made available to the public and should include an assessment of whether the plan was adequate. The commenter also suggested the hospitals’ backup plans be made available.

Another commenter stated that the proposed policies would have a negative impact on patients. The commenter stated that a community call arrangement, such as the one outlined in the proposed rule could "...erode an emergency department physician's ability to consult a specialist and may require a patient transfer to the hospital that the on-call specialist is covering." The commenter stated that it is unfair and unsafe to transport an individual only for the convenience of the on-call specialist. The commenter also noted that moving the individual to the on-call specialist could delay treatment and increase the staffing burden on an already-taxed emergency care system because it is likely that advanced life support as well as a registered nurse would be required to accompany the individual. Instead of the proposal, the commenter urged CMS to adopt the recommendation provided by the IOM (included in *Hospital-Based Emergency Care at the Breaking Point 2006*), which reads: "The Department of Health and Human Services and the National Highway Traffic Safety Administration, in partnership with professional organizations, convene a panel of individuals with multidisciplinary expertise to develop evidence-based categorization systems for emergency medical services, emergency departments, and trauma centers based on adult and pediatric services capabilities."

Response: We agree with the commenters that a community call plan should improve patient care by providing greater access to specialists rather than potentially risking an individual's life by engaging in an unnecessary transfer. Furthermore, we agree that a hospital that makes an appropriate transfer in accordance with EMTALA requirements should attempt to avoid transporting individuals long distances when a

shorter transport to a hospital with the appropriate specialized capabilities and capacity is possible. We also remind hospitals and medical staff that EMTALA requires a hospital to treat an individual regardless of his or her insurance status. Therefore, if there is evidence of disparate treatment based on an individual's insurance coverage, the hospital or physician, or both, may be subject to penalties for an EMTALA violation. Moreover, a hospital that believes it has been the recipient of an inappropriate transfer of an individual with an unstable emergency medical condition who is protected under EMTALA is obligated to report this to CMS. In response to the commenters who suggested the effect of community call will be to allow certain hospitals to get together to reduce their on-call capacity and in effect dump individuals on other hospitals in their area, we remind hospitals that CMS will continue to investigate complaints about hospitals' compliance with EMTALA and related requirements, including compliance with on-call requirements.

In response to the commenter who suggested that hospitals be "...required to report the results of the on-call annual plan and the patients that the on-call physician accepts on subsequent days, but was not on call or available for the day the patient came to the ER," we stated in the regulations proposed at §489.24(j)(2)(iii)(G) that there must be an "Annual assessment of the community call plan by the participating hospitals." However, we believe that a requirement for hospitals to report the results of their community call plans on an annual basis to CMS may be too burdensome. Therefore, we are not instituting a mandatory reporting requirement at this time.

In response to the commenters who suggested further research and adoption of the IOM recommendation, we anticipate that we will continue to present proposals concerning various on-call issues in future rulemaking and will consider the commenters' suggestions at that time.

Comment: One commenter stated that the health care district of its county has been working for several years with the hospital and physician community to address the shortage of specialty physicians providing on-call coverage in the county's hospital emergency departments. The commenter requested that CMS consider the following comments and questions:

(1) Will the final regulation address whether the shared/community call plan can contain a financial arrangement to address how participating physicians and/or hospitals can be compensated for serving as the designated on-call facility during an established period of time?

(2) What parameters will be allowed to define the specific geographic area? For example, does it have to be set up to include an entire county, or could it be as small as a city or sub-county region?

(3) Do all hospitals within the defined geographic area have to participate in the community call plan?

(4) Will CMS place any safeguards into the regulation to prevent hospitals from other counties or areas outside the defined geographic area from taking advantage of the new community call plan by transporting patients to the designated on-call facility absent a transfer agreement?

(5) Will any entity grant authority to community call plans?

(6) Will the community call plan regulation provide any guidance on the financial/payer arrangements for patients outside the Medicare and Medicaid system and the implication of patients being transferred to a hospital that may not accept their insurance?

(7) The development of community call plans should not impose a disproportionate and uncompensated obligation on tertiary hospitals that have a broader representation of medical specialties in limited supply on their medical staffs.

Response: We appreciate the commenter's questions and comments regarding the community call plan. In response to the question regarding compensation for serving as the designated on-call facility during an established period of time, the financial arrangements made between an on-call physician and a hospital are between that physician and that hospital. CMS is not in a position to participate in any sort of contractual relationship between a physician and a hospital. We do not believe any sort of financial agreement needs to be included in the community call plan. However, if hospitals choose to, they are welcome to include this information in their community call plans.

In response to the commenters request for clarification on defining the geographic boundaries of a community call plan, we did not specify in the proposed rule any geographic parameters that a community call plan must adhere to; that is, we did not specify whether a community call plan must cover a city, region, or State, or other area because we intended to promote flexibility for hospitals in the development of

community call plans. Therefore, we would like to clarify that there are no geographic rules that hospitals must follow as participants of a community call plan. Similarly, not all hospitals within a defined geographic area need to participate in the community call plan. For example, if four hospitals are located in a specific county and only three of those hospitals choose to participate in the community call plan, the plan will not be invalidated due to lack of participation of the fourth hospital in the community call plan.

In response to the commenter's question as to whether CMS will place any safeguards into the regulation to prevent hospitals not participating in the plan from transporting individuals to the on-call facility without a transfer agreement, we specified in the proposed regulation text at §489.24(j)(2)(iii) that: "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*" (emphasis added). Therefore, if an individual presents to a hospital and requests treatment for a medical condition and it is determined the individual has an emergency medical condition, the hospital must provide stabilizing treatment within its capability and capacity, and may make an appropriate transfer, consistent with the EMTALA regulations governing transfer. This obligation remains, regardless of whether or not the hospital to which the individual presented is either participating in the community call plan or is designated as the on-call facility. If CMS determines through an investigation that a hospital, whether or not it is participating in a community call plan, engaged in an inappropriate transfer of an individual with an unstable emergency medical condition who was protected under EMTALA, that hospital would be in

violation of EMTALA and subject to enforcement action. All Medicare-participating hospitals with dedicated emergency departments, including hospitals that are outside a particular geographic region or not participating in a formal community call plan, can still seek to transfer individuals to hospitals that are participating in a formal community call plan, via an appropriate transfer, notwithstanding the absence or presence of a transfer agreement and regardless of whether the transferring hospital is participating in a formal community call plan. Neither the current EMTALA regulations nor the proposed regulations require a hospital to have a transfer agreement in place prior to seeking to transfer an individual to another hospital that is capable of providing stabilizing care.

In the proposed rule, we did not propose, but solicited comment, on whether community call plans should be approved by State or local agencies. We did not receive any comments supporting preapproval of a community call plan by a local or State agency, or both. Therefore, at this time, we are not requiring local, State, or Federal agencies to approve a community call plan.

In response to the commenter's request for guidance as to whether the regulations would give guidance on financial/payer arrangements to provide for individuals not covered by Medicare or Medicaid and the implication of individuals being transferred to a hospital that may not accept their insurance, we note that the intent of EMTALA is to ensure that an individual presenting to a hospital with a dedicated emergency department receives an appropriate medical screening examination to determine whether the individual has an emergency medical condition and, if necessary, receives stabilizing treatment or providing for an appropriate transfer to another facility, regardless of the

individual's method of payment or insurance status. Thus, we do not see the relevance of providing any guidance on financial/payer arrangements outside of the EMTALA context. Together with the OIG, we issued a Special Advisory Bulletin on the Patient Anti-Dumping Statute that addresses hospital obligations toward individuals under EMTALA, including individuals covered under managed care plans (64 FR 61353). We continue to stand by that guidance.

In summary, after consideration of the public comments we received, we are finalizing the community call provision at §489.24(j)(2)(iii) as proposed, with one modification. We are deleting the requirement at proposed paragraph (j)(2)(iii)(E) "Evidence of engagement of the hospitals participating in the community call plan in an analysis of the specialty on-call needs of the community for which the plan is effective."

5. Technical Change to Regulations

In the FY 2008 IPPS final rule with comment period (72 FR 47413), we revised §489.24(a)(2) (which refers to the nonapplicability of certain EMTALA provisions in an emergency area during an emergency period) to conform it to the changes made to section 1135 of the Act by the Pandemic and All-Hazards Preparedness Act. When we made the change to the regulations, we inadvertently left out language consistent with the following statutory language found in section 1135: “pursuant to an appropriate State emergency preparedness plan; or in the case of a public health emergency described in subsection (g)(1)(B) that involves a pandemic infectious disease, pursuant to a State pandemic preparedness plan or a plan referred to in clause (i), whichever is applicable in the State.” We also inadvertently left out the phrase in section 1135 “during an emergency period” when we state the nonapplicability of the sanctions in an emergency area. As we proposed, we are revising the language at §489.24(a)(2) to include the aforementioned language to conform the regulation text to the statutory language. Proposed revised §489.24(a)(2) would read as follows: "Nonapplicability of provisions of this section. Sanctions under this section for an inappropriate transfer during a national emergency or for the direction or relocation of an individual to receive medical screening at an alternate location 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 do not apply to a hospital with a dedicated emergency department located in an emergency area during an emergency period, as specified in section 1135(g)(1) of the Act. 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 for by section 1135(e)(1)(B) of the Act."

Comment: Several commenters addressed our proposal to amend the regulations at §489.24(r)(2) so that the regulations conform to the statute and to the changes made to section 1135 of the Act by the Pandemic and All-Hazards Preparedness Act. The commenters supported the change because it makes the regulations consistent with the requirements of the statute and allows hospitals to provide appropriate care in a timely manner during a disaster without fear of EMTALA sanctions.

Response: We appreciate the commenters' support of our proposed technical change. We are finalizing the technical change to §489.24(a)(2) as proposed.

J. Application of Incentives to Reduce Avoidable Readmissions to Hospitals

1. Overview

In the FY 2009 IPPS proposed rule (73 FR 23673), we discussed the development and application of evidence-based best practices meant to reduce the incidence of avoidable hospital readmissions. We note that we are not adopting policy in this final rule. Rather, we are providing a summary of the public comments received on this topic.

A significant portion of Medicare spending—\$15 billion each year—is related to hospital readmissions. According to a 2005 MedPAC report,²⁴ nearly 18 percent of

²⁴ Medicare Payment Advisory Commission: Report to Congress: Promoting Greater Efficiency in Medicare. June 2007, Chapter 5, p. 103.