2. Patient Safety Measures

In the DRA Report to Congress (page 67), we stated that it was appropriate to issue further guidance on what we expect of all hospitals with respect to the appraisal, initial treatment, and referral, when appropriate, of patients with medical emergencies. The Medicare hospital CoP regulations at 42 CFR Part 482 impose requirements on hospitals that have emergency departments, as well as requirements on hospitals without emergency departments. We believe that hospitals should be required to disclose to patients at the time of inpatient admission or registration for an outpatient service information concerning whether a physician is available on the premises 24 hours per day, 7 days per week. In the FY 2008 IPPS proposed rule (72 FR 24817), under the authority at sections 1861(e)(9), 1820(e)(3), 1866, 1871, and 1102 of the Act (described previously), we proposed to add a new provision at §489.20(v) to require that hospitals furnish all patients notice at the beginning of their hospital stay or outpatient service if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week, and to describe how the hospital will meet the medical needs of any patient who develops an emergency medical condition, at a time when no physician is present in the hospital. We sought comment as to whether this change would be best effectuated through changes to the Medicare provider agreement regulations or whether it would be more appropriate to include this change in the CoP requirements applicable to acute care hospitals and CAHs.

It has also come to our attention that some hospitals have called 9-1-1 when a patient has gone into respiratory arrest, a physician has not been on the premises, and the onsite clinical personnel have lacked the requisite equipment or training to provide the required assessment, initial treatment, and referrals that are required of all hospitals. In some cases, required interventions to initiate emergency treatment may be outside the scope of practice of the clinical personnel onsite. This has occurred even in hospitals that operate emergency departments. Therefore, in the FY 2008 IPPS proposed rule (72 FR 24817), we solicited comments on whether current requirements for emergency service capability in hospitals with or without emergency departments should be strengthened in certain areas. Specifically, we sought feedback on whether present regulatory provisions should be expanded with respect to the type of clinical personnel that must be present at all times in hospitals with and without emergency departments; the competencies that such personnel must demonstrate, such as training in Advanced Cardiac Life Support, or successful completion of specified professional training programs; the type of emergency response equipment that must be available and the manner in which it must be available, such as in each emergency department, or inpatient unit, among others; and whether emergency departments must be operated 24 hours per day, 7 days per week. We indicated that after evaluating the comments we received, we would consider whether we should amend the Medicare hospital CoPs related to the provision of emergency services in hospitals with and without emergency departments.

We received a number of public comments on our proposal. Our response follows each comment summary below.

Comment: Most of the commenters stated that only physician-owned specialty hospitals should be required to disclose to patients whether or not a physician is on site at all times and how emergencies are handled when a physician is not on-site. The commenters stated that physician-owned specialty hospitals are generally not part of a larger system of care, most often have no transfer agreements with other hospitals, and tend to specialize in one type of care delivery, and that these factors create challenges to their ability to treat the unexpected emergency. The commenters also stated that "full-service community" hospitals are part of a network of care in their community that involves referrals from local physician practices, reliance on local trauma support networks, participation in local emergency medical transport systems, and transfer agreements among facilities. The commenters stated that applying additional requirements to full-service community hospitals is unnecessary and costly. However, they stated that applying them to physician-owned specialty hospitals could be used to assure that such hospitals, in the absence of being part of the broader care network, meet minimum standards for patient safety.

In contrast, several other commenters stated that they supported a requirement to disclose onsite physician coverage, so long at it applies to all hospitals, regardless of whether they are physician-owned. Another commenter supported extending the physician onsite disclosure requirement to all hospitals and CAHs, stating

that ideally all patients should be informed regarding the level of physician staffing present in the hospital. This commenter stated that patients should know, for example, whether a physician will remain in the hospital until all patients have recovered from anesthesia and are fully conscious. The commenter also stated that patients should be informed of the hospital's emergency response plan when a physician is not on the premises 24 hours per day, 7 days per week.

Response: Fully informed consumers of hospital and CAH services play an essential role in assuring the quality of health care services. It is important to provide patients information about whether a hospital or CAH has a physician on site at all times, and the provisions for handling emergencies when a physician is not on site. Consumers may have an expectation that a hospital or CAH, as a health care facility that operates 24 hours per day, 7 days per week, always has a physician on site. Therefore, it is important to ensure that consumers are provided accurate information on the availability of physician services at the point when they are about to become patients of a hospital or CAH. All hospitals and CAHs are required to have the basic capabilities to address medical emergencies within their facilities, regardless of whether a physician is always on-site and, in the case of hospitals, regardless of whether or not the hospital offers an emergency department or service. (All CAHs are required to offer emergency services.)

In order to be fully informed, consumers also should be made aware of the hospital's or CAH's process for addressing medical emergencies that may occur when a physician is not on-site. Therefore, we have not adopted the suggestion of those commenters who would condition consumers" access to this information on the basis of the ownership structure of the hospital or CAH. Medicare hospital health and safety regulations are the same for all participating hospitals, regardless of their type of ownership. The same is true for the Medicare CAH health and safety regulations. For example, all hospitals are expected to have the capability to assess a medical emergency, provide initial treatment, and refer, or transfer, a patient to another hospital when appropriate. Given the uniform applicability of hospital and CAH requirements to all hospitals or CAHs, there is no basis for requiring only those hospitals or CAHs that are physician-owned to make the proposed physician availability-related disclosures. The disclosure requirement is appropriately triggered when a hospital or CAH does not have a physician on-site 24 hours per day, 7 days per week.

As discussed in the regulatory impact statement, this final rule with comment period change will not have any significant economic impact on hospitals or CAHs. Therefore, we disagree with those commenters who stated that the physician-availability disclosure requirement would be costly for hospitals and CAHs.

Comment: Several commenters addressed whether the physician-availability disclosure requirement should apply to CAHs as well as hospitals. One commenter stated that the problem of hospitals ill-prepared to handle patient emergencies seems confined to specialty hospitals. This commenter stated that the physician-availability disclosure requirement would affect numerous rural hospitals and CAHs, which often do not have physicians on site, and often utilize physician assistants or nurse practitioners, or both, with a supervising physician available by telephone. The commenter stated that, because these hospitals have established referral systems and often serve as staging areas where patients are stabilized for transport, additional requirements would be unnecessary and costly. The commenter also stated that limiting rural hospitals' and CAHs' ability to utilize physician assistants and nurse practitioners would create substantial access problems.

Similarly, another commenter stated that the proposed change would be a particular problem for CAHs. This commenter stated that the CAH CoPs have been written expressly to provide flexibility for CAHs so they can meet the needs of patients in isolated, rural communities without having a physician in the building at all times.

In contrast, another commenter stated that the physician-availability disclosure requirement should include CAHs because there is no clear distinction between the services offered by physician-owned specialty hospitals and CAHs. This commenter stated that, while most CAHs are nonprofit hospitals that provide a range of services to small rural communities, some CAHs are for-profit hospitals and some offer specialty services. The commenter stated he was aware of one CAH with a hand surgery focus and another with a cardiac catheterization laboratory. The commenter stated that, because CAHs are not restricted in the services they offer, they should have the

same physician-availability disclosure requirements as other hospitals.

Response: We agree that the physician-availability disclosure requirement should apply equally to hospitals and CAHs. Although we agree with those commenters who stated that many CAHs do not have physicians on-site at all times, and thus would be required to disclose this information to patients, we do not agree that this alone is sufficient reason to exempt CAHs from the physician-availability disclosure requirement. It would not be appropriate to condition patients' access to information on physician availability on whether or not the patients reside in a rural area. Because we do not require either hospitals or CAHs to have a physician on-site at all times, there is no basis to require only hospitals, but not CAHs, to disclose this information. As one commenter stated, the CAH CoPs provide greater flexibility in many areas when compared to the hospital CoPs. However, this is not the case in all areas. CAHs, for example, must provide emergency services to the public 24 hours per day, while hospitals have the option of operating an emergency department or not. Furthermore, as one commenter stated, there is no restriction on the types of services a CAH may offer. Thus, it may be difficult for consumers to distinguish whether a given provider is a hospital or a CAH. Consumers may not be aware that there are different requirements for CAHs than for facilities participating in Medicare as hospitals. Consumers may make assumptions about physician availability in any "hospital," because the facility provides services 24 hours per day, 7 days per week, regardless of whether that facility is a CAH or hospital for Medicare purposes. Therefore, it is important for consumers to be informed whether a physician is always on site, and how emergencies will be handled when no physician is available. We do not agree that this requirement limits the ability of rural hospitals or CAHs to utilize physician assistants and nurse practitioners. There is no change to the current requirements in the CoPs for hospitals or CAHs regarding utilization of physician assistants and nurse practitioners.

Comment: One commenter stated a physician-availability disclosure requirement should apply only to facilities that provide inpatient care 24 hours per day, 7 days per week. The commenter stated that CMS should clarify in the FY 2008 IPPS final rule that the requirement does not apply to provider-based settings that are not open at all times and/or are not providing inpatient services. The commenter stated that disclosure of emergency services capabilities in the registration process will create greater confusion for patients.

Response: Because the requirement in this final rule with comment period applies to hospitals and CAHs, and because both hospitals and CAHs are required to make inpatient care available on a 24 hours per day, 7 days per week basis, we do not agree that the requirement would be narrowed to fewer facilities by applying it only to facilities providing inpatient care. We do not agree that provider-based locations are subject to a separate standard because they do not participate separately in Medicare. The health and safety standards apply to provider-based locations of hospitals or CAHs. All provider-based locations of a hospital or CAH are considered part of the hospital or CAH, and the provider-based location's clinical services, including the provision of emergency services, must be integrated into those of the hospital or CAH.

Comment: One commenter stated that the proposed requirement fails to provide timely or useful information to the patient, indicating that the physician-availability disclosure occurs post-admission. The commenter stated that CMS should undertake a comprehensive consumer education initiative prior to imposing this requirement, so that the patient could make an informed choice about any particular facility.

Response: We do not agree that the patient would, in every instance, already have been admitted before the required physician-availability disclosure would take place. We proposed that, for purposes of this disclosure requirement, the hospital stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or the provision of a package of information regarding an outpatient service. It is our intent that this information be provided by the hospital to the consumer at the first point of contact related to a particular admission or episode of care, in order to enhance its usefulness.

CMS strives, as part of its overall commitment to increasing the transparency of the health care system to consumers, to equip consumers with information that enables them to make informed choices about their care. Education and outreach about our efforts are ongoing. We do not agree that implementation of the physician-

availability disclosure requirement should be delayed until a specific educational campaign is concluded.

Comment: One commenter stated that hospitals are currently required to have a plan in place for how they will provide care, including emergency care. The commenter stated that the physician-availability disclosure requirement is therefore redundant and places an unnecessary burden on the facility.

Response: We do not agree that having a plan in place for providing emergency care is the same as informing consumers about the availability of physician services and how emergency care will be provided to them when a physician is not on the premises. The physician-availability disclosure required by this final rule with comment period is intended to assure provision of important information to consumers making healthcare decisions. This requirement is separate and distinct from any requirements contained in the hospital and CAH CoPs regarding the provision of emergency services and the care planning for each patient, among others.

Comment: One commenter stated that the required disclosure "arguably" should be extended to cover the presence or absence of particular equipment, or the level of expertise of the facility's staff, so the patient can understand what to expect depending on the nature of the emergency and the capabilities of the facility, and the likelihood of transfer to another hospital for any particular medical emergency.

Response: Ideally, an informed consumer would have a comprehensive understanding of the capabilities of any hospital and/or CAH, in terms of both specialized equipment and staff, that the consumer considers using. However, the commenter's suggestion would greatly expand the impact of the physician-availability disclosure requirement. Instead of affecting only those hospitals and CAHs that do not have a physician present 24 hours per day, 7 days per week, the commenter's suggested approach would affect all hospitals and CAHs. It would not only increase the number of hospitals and CAHs affected by the requirement, but would also require them to provide a much more detailed and lengthy disclosure. Therefore, at this time, we will not be mandating an expanded disclosure requirement. Hospitals have the flexibility to provide such additional information to consumers, either as a general policy or in response to questions from consumers.

Comment: One commenter did not object to informing patients when a physician is not always in the facility. However, the commenter hoped that the required notice of how emergency services would be provided would not imply that patients are receiving less than competent care. The commenter stated that a hospital could make an affirmative statement, such as the following: "This facility provides competent, fully trained staff who are available 24 hours per day. At times when there is no physician present, patients with health care emergencies will be assessed and treated by qualified medical personnel, with physician support available via telephone or pager, and will be transferred to another hospital, when necessary."

Response: We are requiring hospitals and CAHs that do not have a physician on site at all times to state this in the notice, as well as how the hospital will meet the needs of any patient who develops an emergency medical condition at a time when there is no physician present. We are not prescribing specific wording for the notice, since the content must be tailored to the circumstances of the individual hospital or CAH, but we note that the commenter's suggested wording lacks explicit notice that the hospital does not provide on-site availability of a physician 24 hours per day, 7 days per week. Adoption of this disclosure requirement does not imply anything about the competency of care provided by other types of practitioners.

Comment: One commenter stated that many long term care hospitals do not provide on-site, 24-hour physician coverage and asked whether such hospitals are expected to have such on-site physician services. The commenter stated that if this is CMS's interpretation, then this interpretation should be translated into the CoPs.

Response: In this final rule with comment period, we are requiring hospitals and CAHs that do not have a physician on-site 24 hours per day, 7 days per week to disclose this information to patients, along with information about how they would handle an emergency when no physician is on-site. We are not making any changes to the

hospital or CAH CoPs in this final rule with comment period. The current hospital and CAH CoPs do not include a requirement for a physician to be on site at all times.

Comment: One commenter stated that CMS should clarify whether the disclosure would be required only on those days when a physician is not on-site, or at all times if there is a possibility that a physician might not be on-site. The commenter also stated that CMS should indicate whether it expects a separate, signed notice to be provided to patients or a general notice to be included with other registration/admission documents outlining basic provisions for unexpected emergency care.

Response: This final rule with comment period requires any hospital or CAH that does not provide for a physician to be on-site 24 hours per day, 7 days per week to disclose this to patients, regardless of whether or not it happens to have 24-hour on-site coverage at the beginning of the patient's hospital or CAH inpatient stay or outpatient visit. A hospital or CAH that is required under this final rule with comment period to make a physician-availability disclosure must do so via a written notice provided to each patient. The required notice must indicate that a physician is not on-site 24 hours per day, 7 days per week, and how the hospital or CAH handles medical emergencies that arise when a physician is not on-site. This final rule with comment period does not require that the hospital have the patient sign the notice.

Comment: Most of the commenters stated that they supported strengthening requirements concerning emergency services capabilities only for physician-owned specialty hospitals. The commenters stated that applying additional requirements for "full-service community hospitals" is unnecessary and costly, but that applying them to physician-owned facilities could be used to assure that such hospitals, in the absence of being part of the broader care network, meet minimum standards for patient safety.

Another commenter also stated that any additional measures should be applied only to physician-owned facilities and not to "full-service community hospitals." This commenter also stated that State and Federal rules for CAHs already delineate in detail the emergency equipment that must be provided on site, mechanisms to contact on-call practitioners, timeframes within which these practitioners must be available, and written agreements and protocols for transferring patients for further treatment when indicated.

In contrast, several other commenters stated that, in the interest of patient safety, they would support a requirement that standardized the type and training of clinical personnel available in any Medicare-certified hospital. These commenters also stated that they endorse setting minimum requirements for equipment.

Another commenter stated that the condition of participation for emergency services in both hospitals and CAHs should be strengthened, stating that a hospital should be capable of handling any situation that can reasonably be expected to occur. This commenter also stated that, to develop the precise regulatory provisions in the revised CoPs, CMS should convene an expert panel or, at a minimum, consult with the State agencies and recognized national accrediting bodies, as required by section 1863 of the Act.

Finally, one commenter, while stating support for CMS setting minimum emergency service standards, also stated concern that such standards might conflict with, duplicate, or exceed current State requirements. The commenter stated CMS should coordinate development of minimum emergency medical response standards with interested professional organizations as well as State authorities overseeing medical emergency response.

Response: We disagree with those commenters who supported expanded regulatory requirements for emergency services capabilities only for physician-owned facilities, because Medicare hospital health and safety standards apply to all participating hospitals, regardless of their type of ownership. The same is true for the Medicare CAH health and safety standards. We are not aware of any evidence to support the view that patient safety concerns arise only in physician-owned facilities, and that what the commenters call "full-service community hospitals" always assure that care is provided to patients in the right time and setting, due to these

hospitals' participation in a community network of care. Our oversight experience suggests that patient safety problems can occur in hospitals with any type of ownership structure, or any type of service mix, whether general or specialized. For this reason, any changes to the hospital CoPs that we might propose would apply to all hospitals, and likewise any changes to the CAH CoPs that we might propose would apply to all CAHs.

We also note the support of several commenters for a requirement that would standardize the type and training of clinical personnel, as well as minimum requirements for equipment that must be available in any Medicare-certified hospital. With respect to whether strengthening the minimum Medicare requirements related to emergency services would raise issues of conflict with or exceeding State requirements, this potential situation is not unique to emergency services standards. Medicare health and safety standards, unless the regulations specifically state to the contrary, preempt conflicting State requirements. We will consider the commenters' views, including the suggestions about consultation, in undertaking any future rulemaking to strengthen emergency services minimum requirements.

We agree with the commenter who pointed out that the existing emergency services requirements for CAHs are detailed. For example, our current regulations at 42 CFR 485.618(a) require CAHs to make emergency services available on a 24-hour per day basis. Section 485.618(b) establishes the standard regarding availability of equipment, supplies, and medication used in treating emergency cases. Our regulations at §485.618(d) are specific as to the required CAH emergency services clinical personnel, including the types of personnel, as well as the mode and timeframe for their availability. These regulatory standards are more detailed than those found in the comparable hospital emergency services CoP (42 CFR 482.55), or in the applicable hospital standard at 42 CFR 482.12(f)(2) for hospitals that do not have emergency departments. Because hospitals tend to be larger health care facilities than CAHs, it might be reasonable to provide a comparable degree of specificity, appropriate to the hospital setting, in the hospital CoPs. We will consider the commenters' views in undertaking any future rulemaking on this issue.

Comment: One commenter stated that, if CMS chooses to expand the existing regulatory provisions for clinical personnel that must be present at all times, CMS should use broad terminology. The commenter provided the following examples: "qualified medical personnel," or "practitioners with appropriate privileges," or "licensed practitioners," including the phrase "with/and physician supervision to the extent required by state law." The commenter also stated CMS should drop its current usage of the term "licensed independent practitioner" in its regulations, stating that this causes "endless headaches" for hospitals that wish to utilize physician assistants.

Response: We note that the terminology suggested by the commenter is very broad and would not significantly expand upon existing requirements. We will consider these comments in undertaking any future rulemaking on this issue.

Comment: Two commenters specifically addressed our request for comments on whether we should require hospitals with emergency departments to provide these emergency services 24 hours per day, 7 days per week. They stated that such a requirement would best come from the State or EMS district in which the hospital is located, because these authorities would be in the best position to judge the need for emergency care.

Response: CAHs are currently required, under the provisions at 42 CFR 485.618(a), to make emergency services available on a 24 hours per day basis. Because hospitals with emergency departments tend to be larger health care facilities than CAHs, it might be reasonable to require hospital emergency departments to also be available to the public on a 24 hour per day basis. We will consider these comments in any future rulemaking on this issue.

Comment: Two commenters addressed the issue of locating the physician-availability disclosure requirement in the provider agreement rules rather than in the CoPs. One commenter stated it would be more appropriate to include the requirement in the provider agreement rules. The other commenter stated that it would be easier to ensure compliance if CMS implemented the physician-availability disclosure requirement through the CoPs rather

than the provider agreement regulations. This commenter further stated that, unlike the CoPs referenced regularly, the provider agreement rules are only referenced when a health care facility initially enrolls [in Medicare], with no subsequent review of compliance. The commenter also stated that placement of the requirement in the CoPs would facilitate the commenter's consultation with Medicare requirements when developing its own practices and policies.

Response: We agree that the physician-availability disclosure requirement should be included in the provider agreement regulations. We do not agree that the provider agreement regulations are referenced only when a facility initially enrolls in Medicare. Each participating provider must comply with all applicable provisions of the provider agreement regulations found in 42 CFR Part 489, and CMS may terminate its provider agreement if the provider is not in substantial compliance with these requirements. A provider's compliance with applicable provider agreement regulations is reviewed through a variety of means, including on-site investigation of complaints. An example of this mode of compliance review is our enforcement of the special responsibilities of Medicare hospitals in emergency cases, commonly known as EMTALA (EMTALA requirements are addressed in §489.24, with certain related provisions found in §489.20). Therefore, we do not agree that the regulatory language we proposed concerning disclosure of physician on-site availability should be moved to the CoPs in order to permit compliance reviews. We do not consider the ease of referencing the regulations containing the CoPs, versus that of referencing those containing the provider agreement regulations, a compelling reason to move the regulatory language from the provider agreement regulations to the CoPs.

After consideration of the public comments we received, we are adopting as final, with one technical correction, the addition of a provision at §489.20(v) to require that hospitals and CAHs furnish all patients written notice at the beginning of their hospital stay or outpatient service if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week, and to describe how the hospital or CAH will meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present in the hospital. We are correcting a typographical error that appeared in the proposed rule. The proposed regulatory text stated that the required notice must indicate "* * *how the hospital will meet the medical needs of any inpatient who develops an emergency medical condition* * *" We intended to say "patient" instead of "inpatient," as is clear from the references to outpatient visits in two other places within the regulatory text we originally proposed.