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Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-08-08

DATE: January 11, 2008

TO: State Survey Agency Directors

FROM: Director

Survey and Certification Group

SUBJECT: Requirements for Provider-based Off-campus Emergency Departments and

Hospitals that Specialize in the Provision of Emergency Services

Memorandum Summary

- Growth in the demand for hospital emergency services has resulted in a number of
 hospitals seeking to expand their emergency department (ED) services to off-site
 locations.
- Provider-based off-site hospital EDs are permitted, and must demonstrate compliance with the hospital Conditions of Participation (CoPs). They must also be in compliance with the provider-based regulations at 42 CFR 413.65.
- In rare cases, new providers are seeking certification as a hospital specializing in the provision of emergency services. Such providers have the burden of proof to demonstrate that they meet the statutory definition of a hospital for Medicare purposes, and their applications require detailed, case-specific analysis. Regional Offices (ROs) are to consult with Centers for Medicare & Medicaid Services (CMS) Central Office survey and certification staff before processing such applications.

Background

CMS is encountering increasing interest in so-called "freestanding¹" emergency departments (EDs) from providers and communities around the country, who point to the continued growth over the past decade in the demand for ED services and crowding in existing EDs.

¹ We are using the term "freestanding" in a colloquial sense here, and not as the term is used in the definition of a free-standing facility found at 42 CFR 413.65(a)(2).

A variety of arrangements have been proposed under the rubric of a "freestanding" ED. In most cases, the ED would be owned and operated by a Medicare-participating hospital as a provider-based ED. In rare cases, the provider seeks to participate in Medicare as a stand-alone hospital, with its own provider agreement, and specializing in the provision of emergency services. In terms of operations, some EDs would be open 24 hours/day, 7 days/week, while others would operate only part-time. This memorandum contains guidance on the applicable regulatory standards that govern the circumstances under which provider-based EDs and so-called "emergency services hospitals" meet the CMS CoPs that qualify them to participate in Medicare as a hospital or part of a hospital.

Hospital Provider-based ED

The most common scenario occurs when a Medicare-participating hospital that offers emergency services seeks to establish an ED located away from the main campus and to have that ED operate as a provider-based department of the hospital. Services of the provider-based ED would be included under the hospital's Medicare Provider Agreement. Such arrangements are acceptable, so long as the off-campus ED complies with:

- Hospital CoPs found in 42 CFR 482.1 through 482.45. The expectation here is the same as for any department on the hospital's campus. This includes, but is not limited to, the following requirements:
 - Medical staff practicing at the off-campus ED must be part of the hospital's single organized medical staff as required by the Medical Staff CoP at 42 CFR 482.22.
 - The responsibilities of the hospital's Governing Body, as specified in the Governing Body CoP at 42 CFR 482.12, apply to the services and activities of the off-campus ED.
 - Nursing personnel at the off-campus ED must be part of the hospital's single organized nursing service and all nursing services must be provided in accordance with the Nursing CoP at 42 CFR 482.23.
 - Emergency laboratory services must be available to the off-campus ED during all
 of its operating hours, in accordance with the Laboratory Services CoP at 42 CFR
 482.27(b)(1).
 - The off-campus ED must be integrated into the hospital's quality assessment/performance improvement (QAPI) program, as specified under the QAPI CoP at 42 CFR 482.21.
 - The medical records of patients seen at the off-campus ED must be part of the hospital's single medical record system and must satisfy the standards for the Medical Records Services CoP at 42 CFR 482.24.
 - Infection control practices at the off-campus ED must meet the requirements of the Infection Control CoP at 42 CFR 482.42.

- Requirements pertaining to the Hospital CoP governing emergency services found at 42 CFR 482.55. In particular:
 - The provider must demonstrate how the off-campus ED meets the emergency needs of its patients in accordance with accepted standards of practice for hospital emergency departments.
 - + Neither the hospital CoP for emergency services nor the EMTALA definition of a dedicated emergency department (noted below) specifically addresses part-time versus full-time operation of an ED. Medicare payment rules include codes for both full- and part-time EDs.
 - + All hospital EDs, including off-campus EDs, must comply with all applicable State requirements, including any requirements related to hours of operation.
 - + Providers operating part-time provider-based EDs as permitted under State law are expected by CMS to document how the needs of patients will be addressed when they present at the off-site ED during hours when it is not in operation.
 - The provider must demonstrate how the off-campus ED satisfies the requirement at 42 CFR 482.55(a)(2) for its services to be integrated with the other departments of the hospital. This includes documenting how inpatient admissions and intrahospital transport of patients from the off-site ED to the main campus would be handled in a manner that is also consistent with the requirement at 42 CFR 482.13(c)(2) for patients to receive care in a safe setting.
 - The organization and direction of the emergency services at the off-campus location must be by a qualified member of the hospital's medical staff. In view of the provider-based requirement (see below) for integration of services between the off-campus ED and the main campus, CMS expects the hospital's main and off-campus EDs to be under the same overall medical staff direction.
 - The policies and procedures governing medical care provided at the off-campus location must be established by, and remain an ongoing responsibility of the hospital's medical staff. In view of the provider-based requirement (see below) for integration of services between the off-campus ED and the main campus, CMS expects the off-campus ED to operate under the same general policies and procedures as the ED at the hospital's main campus, taking into account pertinent differences in the scope of their operations.
- Hospital CoPs found in 42 CFR 482.51 through 42 CFR 482.57 governing other optional services the hospital chooses to offer at the off-campus location. If any of these optional services, such as surgery, anesthesia, rehabilitation, or respiratory services, is offered at the off-campus ED location, that service must be provided in accordance with the applicable CoP. For example, if respiratory services are offered, those services must comply with the requirements of the Respiratory Services CoP at 42 CFR 482.57.

• EMTALA requirements at 42 CFR 489.20 and 489.24. The off-campus ED would be considered a "dedicated emergency department," as defined at 42 CFR 489.24(b):

"Dedicated emergency department means any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:

- 1. It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department;
- 2. It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or
- 3. During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment."

The EMTALA-related provisions include the requirement at 42 CFR 489.24(d) to provide individuals determined to have an emergency medical condition with either stabilizing treatment or an appropriate transfer to another hospital. In the case of an investigation of an EMTALA complaint alleging failure to provide a medical screening examination, stabilizing treatment, or an appropriate transfer from the off-campus ED, SAs and ROs should consider the capabilities and capacity of the hospital's main campus, not just the off-campus ED, when determining whether there has been an EMTALA violation.

- Requirements found in 42 CFR 413.65 for a provider-based off-campus department of the main hospital. SAs do not survey for compliance with the provider-based requirements per se, but the hospital would be expected to document its compliance. Among the clinical services requirements at 42 CFR 413.65(d)(2) are the following:
 - Professional staff of the off-campus ED have clinical privileges at the main campus of the hospital.
 - The hospital maintains the same monitoring and oversight of the off-campus
 ED as it does for any other of its departments.
 - The medical director of the off-campus ED maintains a reporting relationship to the hospital's chief medical officer (or similar position) that is similar to that of a department medical director.
 - Medical staff committees of the hospital are responsible for medical activities in the off-campus ED.
 - Medical records are integrated into a unified retrieval system.
 - The services of the off-campus ED are integrated into those of the hospital's main campus, and patients of the off-campus ED who require further care have access to all services of the main campus.

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CMS encourages hospitals with off-campus EDs to educate communities and EMS agencies in their service area about the operating hours and capabilities available at the off-campus ED, as well as the hospital's capabilities for rapid transport of patients from the off-campus ED to the main campus for further treatment. This is particularly desirable in the case of off-site EDs that are closer to another hospital than to their own main campus, as a way to facilitate informed decision-making by patients choosing where to seek emergency medical care and by EMS providers transporting patients in need of emergency medical care.

Each request for provider-based status for an off-campus ED submitted to a Regional Office (RO) must be reviewed by RO survey and certification staff in addition to the standard review of provider-based requests.

SAs must tailor surveys of a hospital facility that includes an off-campus ED to the nature of all the services provided at the site.

Hospitals Specializing in Emergency Services

CMS has occasionally encountered interest from providers who seek participation in Medicare as a hospital that specializes in emergency services. However, "emergency services hospital" is not a recognized separate category of Medicare-participating hospital. Such an applicant must demonstrate that it satisfies the statutory definition of a hospital at Section 1861(e) of the Social Security Act, including the requirement that the provider is primarily engaged in the provision of services to inpatients. In the case of an applicant specializing in emergency services, CMS would pay particular attention to the size of the applicant's ED compared to its inpatient capacity. A detailed analysis of the facts of the applicant's operations would be required.

We interpret the statutory requirement that a hospital be primarily engaged in the provision of inpatient services to mean that the provider devotes 51% or more of its beds to inpatient care. In the absence of other clearly persuasive data, CMS renders a determination regarding hospital status based on the proportion of inpatient beds to all other beds. At the request of the applicant CMS may examine other factors in addition to bed ratio. The agency recognizes that the "51%" test may not be dispositive in all cases. However, we consider the burden of proof (to demonstrate that inpatient care is the primary health care service) to reside with the applicant, and consider the burden to increase substantially as the ratio of inpatient to other beds decreases.

Regional Offices that receive applications from facilities seeking first-time participation in Medicare as a hospital specializing in emergency services must consult with the Central Office Survey and Certification Group, Division of Acute Care Services on the review of the application.

If you have additional questions or concerns, please contact David Eddinger at 410-786-3429 or via email at david.eddinger@cms.hhs.gov.

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Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

/s/ Thomas E. Hamilton

cc: Survey and Certification Regional Office Management