ALERTS AND UPDATES

New Medicare Building Code Requirements Raise Concerns for Hospital Provider-based Facilities

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With little fanfare, the U.S. Department of Health and Human Services' Centers for Medicare and Medicaid Services ("CMS") recently issued a letter to state survey directors (the "Guidance") on how to survey a hospital, including its components, for Medicare purposes.[1] The Guidance also amends the Medicare State Operations Manual's ("SOM") Appendix A, "Survey Protocol, Regulations and Interpretive Guidelines for Hospitals," and Appendix I, "Survey Procedures and Interpretive Guidelines for Life Safety Code Surveys."[2] The Guidance and the SOM amendments may raise significant issues for hospitals that include or are seeking to develop provider-based facilities.

Over the last several years, the hospital footprint has expanded beyond a single building or set of connected buildings located on one campus. Many hospitals include noncontiguous or off-site facilities that provide outpatient services, such as ambulatory surgery, general and specialty physician services, physical therapy, urgent care and others. These "component facilities" (the term used in the Guidance) are encouraged for a number of reasons. They offer hospital-level services to patients in the community; they promote efficiencies in the healthcare system by integrating the delivery of care under the hospital; and they extend and solidify the hospital's brand in an increasingly competitive healthcare marketplace. Recognizing the hospital's costs in supporting a component facility, CMS permits the hospital to bill Medicare for the technical portion for certain services offered at the facility if the hospital satisfies the rigorous "provider-based" rules with respect to the facility. CMS has been intently following the proliferation of provider-based facilities, and has expressed concern that some provider-based facilities may not satisfy appropriate fire codes, which could endanger some patients. The Guidance and the amendments to the SOM address this concern.

The Medicare provider-based rules require significant integration between a hospital and a component facility, as demonstrated by joint licensure (except in states where joint licensure is prohibited, in which case an exception may be granted), a shared medical staff, financial integration and significant clinical and administrative oversight of the facility, among other conditions. In effect, the provider-based facility is like any another department or clinic of the hospital, except that it is not located within the hospital's four walls. Medicare's Conditions of Participation[3] require that a hospital must satisfy the 2000 edition of the National Fire Protection Association's Life Safety Code ("LSC") or equivalent standards imposed under state law. Prior to the Guidance, states and providers did not have sufficient clarity on which LSC standards to apply to which hospital facilities. The Guidance seeks to "assure alignment" between hospitals and hospital component facilities and the LSC occupancy classification provisions so that there is an adequate level of fire protection for patients and others using the facilities.

The Guidance and the SOM amendments describe three main LSC classifications: Health Care Occupancy, Ambulatory Health Care, and Business.[4] They also indicate which chapters of the LSC apply and summarize the features of each as follows:

- A Health Care Occupancy–level facility: (1) provides sleeping accommodations, (2) provides medical treatment or services on a 24-hour basis, *and* (3) has patients who are *mostly* incapable of self-preservation during an emergency.

- An Ambulatory Health Care Occupancy–level facility: (1) does not provide sleeping accommodations, (2) does not provide medical treatment or services on a 24-hour basis, (3) provides anesthesia services *and* (4) has patients who are *mostly* incapable of self-preservation during an emergency.
- A Business Occupancy–level facility: (1) does not provide sleeping accommodations, (2) does not provide medical treatment or services on a 24-hour basis, (3) does not provide anesthesia services *and* (4) has patients who are *mostly* capable of self-preservation during an emergency.

Applying these conditions, Health Care Occupancy appears to be the most stringent classification and would be appropriate for a general inpatient hospital, regardless of the number of patients receiving treatment. The Ambulatory Health Care Occupancy–level facility treats outpatients only, but its patients are mostly incapable of taking action for self-preservation "without the assistance of others"—such as patients who are under anesthesia or on account of their medical condition. The most common example of Ambulatory Health Care Occupancy is an ambulatory surgical facility. However, this classification could also cover a facility that mostly treats disabled patients. A Business Occupancy–level may apply to the remainder of facilities treating patients, such as a wellness clinic. The Guidance and the SOM amendments also address hospital component facilities located in a building with more than one occupancy classification; for example, a building that includes a provider-based ambulatory surgical facility on one floor and a physician clinic on a separate floor. In these mixed-occupancy buildings, the entire building must satisfy the most stringent occupancy classification, unless there is adequate separation between the facilities based on the LSC standards.

Perhaps the most challenging feature of these classifications is understanding when patients are "mostly" capable or incapable of self-preservation. CMS instructs:

A patient may be incapable of self-preservation due to many factors, including, but not limited to, age, physical or mental disability, medical or therapeutic interventions, medication reactions, etc. . . . In addition, when determining the ability for self-preservation, consideration should be given to both the characteristics of current patients and the characteristics of patients the facility is likely to provide medical treatment or services to in the future, as evidenced by the provider's own advertisement and clientele to which the provider holds itself out to serve.

Although CMS offers no insight on how a surveyor should assess whether patients are "mostly" capable or incapable of self-preservation, the modifier "mostly" was specifically added in the February revisions to the Guidance and suggests some discretion. Regarding the direction for the surveyor to consider both the current and future patients based on the provider's "own advertisement and clientele to which the provider holds itself out to serve," it is not known at this time how a surveyor would use a hospital's ads and patient base in making a building clarification determination. At a minimum, this language permits the surveyor to undertake more due diligence about the ultimate purpose of a facility before approving or denying a particular classification.

The Guidance is already raising the following significant questions for hospitals that have or seek provider-based status for certain facilities.

- Does a 24/7 walk-in clinic require Ambulatory Health Care Occupancy classification?
- What if the 24/7 clinic maintains a few beds for observation purposes?
- What if the 24/7 clinic is considering offering wound care and minor surgery?

- Can a provider-based outpatient radiology center that also provides select services to hospital inpatients maintain a Business Occupancy classification?
- What if the radiology center is provided to inpatients only on an infrequent basis, and the closest hospital facility offering those same services is twice as far away?
- How will surveyors enforce these requirements, particularly with existing facilities?

States have already begun to incorporate the classification requirements under the Guidance and the SOM amendments into hospital licensure requirements. On December 17, 2010, Colorado issued an answer to a frequently asked question on off-campus locations that tracked the changes under the Guidance. Over the last month, Pennsylvania has issued form letters to hospitals requesting licensure exceptions for provider-based activities, stating that the hospitals must first comply with the Guidance. Therefore, hospitals (and their architects and contractors) developing provider-based projects may want to thoroughly familiarize themselves with the Guidance and consider any potential survey issues.

As a final matter, a hospital that disputes a surveyor's classification has some recourse. Under the Medicare regulations:

CMS may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of the patients.[5]

The SOM's Appendix A Interpretive Guidelines[6] note that the hospital may request a waiver *after* it has been cited for a deficiency—which is likely to be small consolation for a hospital that has developed or operates a provider-based facility on the reasonable assumption that it satisfies the appropriate LSC requirements. However, by its terms, the waiver provision is not limited to post-deficiency challenges. Hospitals should consider requesting a hardship waiver where an overly rigid classification may be unnecessary and costly, and where another classification might still assure an adequate level of fire protection for the building—and ultimately, patients' health and safety. However, while Medicare regulations mandate the availability of hardship waivers, it is unknown how generous CMS is in granting them.

For Further Information

If you have any questions about this *Alert* or would like more information, please contact Lisa W. Clark, any of the attorneys in our Health Law Practice Group or the attorney in the firm with whom you are regularly in contact.

Notes

1. Letter from Center for Medicaid, CHIP, and Survey & Certification to State Survey Agency Directors, Hospital and Critical Access Hospital (CAH) Facility Life Safety Code (LSC) Occupancy Classification Update, Ref. S&C-11-05-LSC, issued Dec. 17, 2010, as amended Feb. 18, 2011 (the "Guidance").
2. The Guidance also describes and amends the survey guidelines for critical access hospitals ("CAHs"). This article focuses on the hospital amendments only.
3. 42 C.F.R. § 482.41(b).
4. The Guidance recognizes other LSC occupancy classifications, such as for Day Care and Storage Occupancies. This article does not address those other classifications.
5. 42 C.F.R. § 482.41(b)(2).
6. 42 C.F.R. § 482.41(b)(3).