HALL RENDER
KILLIAN HEATH & LYMAN

HEALTH LAW NEWS

DECEMBER 29, 2011

CMS ISSUES NEW AND REVISED GUIDANCE FOR CAHS

Effective December 2, 2011, the Centers for Medicare and Medicaid Services ("CMS") issued and implemented new and revised guidance in Appendix W of the Medicare State Operations Manual ("Interpretive Guidelines") related to the Medicare Conditions of Participation for Critical Access Hospitals ("CAHs"). Importantly, CMS issued new Interpretive Guidelines to 42 C.F.R. § 485.635(f) concerning CAH patient visitation rights. CMS also issued revised Interpretive Guidelines regarding standard 42 C.F.R. § 485.608(a) to clarify existing regulatory requirements concerning advance directives and required patient disclosures. This article will provide a summary of these important changes.

42 C.F.R. § 485.635(F) STANDARD: PATIENT VISITATION RIGHTS

In November 2010, CMS added a new standard at 42 C.F.R. § 485.635(f) addressing patient visitation rights to ensure that CAHs respect the right of patients to have and designate visitors. The new standard took effect on January 18, 2011 and stemmed from an April 15, 2010 Presidential Memorandum to the Secretary of the U.S. Department of Health and Human Services in which the President directed the Secretary to initiate rulemaking so that individuals would not be denied the most basic of human needs, that of having a loved one at their side during an important time, simply because the loved one does not fit into a traditional concept of "family."

As outlined in 42 C.F.R. § 485.635(f), CAHs must: (1) inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restrictions or limitations on such rights, in advance of furnishing patient care whenever possible; (2) inform each patient of the right, subject to his or her consent, to receive visitors whom he or she designates, including, but not limited to, a spouse, domestic partner (including same-sex partner), parent or other family member or friend and his or her right to withdraw or deny such consent at any time; (3) not restrict, limit or otherwise deny visitation on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation or disability; and (4) ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

In the new Interpretive Guidelines to 42 C.F.R. § 485.635(f), CMS indicates that, if the CAH's policies restrict or limit visitation in any way, such restrictions or limitations must be medically necessary or based on the health care professional's best clinical judgment, taking into consideration all aspects of the patient's health and safety, including the benefits of visitation on a patient's care, as well as potential negative impacts that visitors may have on other patients in the CAH. Some examples of reasonable bases for a CAH to impose restrictions or limitations on visitors include, but are not limited to, the following:

- When there may be infection control issues;
- When visitation may interfere with the care of other patients;
- When the CAH is aware that there is an existing court order restricting contact;
- When visitors engage in disruptive, threatening or violent behavior of any kind;
- When the patient or patient's roommate needs rest or privacy;
- When the patient is undergoing care interventions; and
- In the case of an inpatient substance abuse treatment program, when there are protocols limiting visitation.

The new Interpretive Guidelines also suggest that the CAH's visitation policies and procedures are expected to address how CAH staff who play a role in facilitating or controlling visitor access to patients will be trained so as to ensure appropriate implementation of the visitation policies and to avoid unnecessary restrictions and limitations on visitation.

Clearly, the regulation permits CAHs some flexibility regarding patient visitation and the associated policies and procedures addressing patient visitation. However, CAHs may wish to review and revise their policies on patient visitation to ensure compliance not only with the regulation but also with the related Interpretive Guidelines. Staff education, particularly as it relates to restrictions and limitations on

visitation, should also be a priority to ensure that restrictions and limitations on visitation are appropriately based on clinical rationale rather than impermissible discrimination.

42 C.F.R. § 485.608(A) STANDARD: COMPLIANCE WITH FEDERAL LAWS AND REGULATIONS

CMS has made extensive revisions to the Interpretive Guidelines for CAHs related to 42 C.F.R. § 485.608(a) by adding language requiring CAHs to follow a patient's advance directives and requiring CAHs to make specific disclosures to patients.

Advance Directives. As a condition of a CAH's Medicare provider agreement, a CAH must comply with the advance directive regulations at 42 C.F.R. § 489.102(a). This regulation specifies the rights of a patient (as permitted by state law) to make medical care decisions, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives. The revised Interpretive Guidelines now explicitly detail the requirements for CAHs to comply with the advance directive regulations.

An advance directive is defined at 42 C.F.R. § 489.100 as "a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated." In an advance directive, the patient may provide guidance surrounding his or her wishes for the provision of care and may delegate decision making authority to another individual, as permitted by state law. The revised Interpretive Guidelines surrounding advanced directives now indicate that CAHs should:

- Allow CAH inpatients and outpatients to create advance directives and have CAH staff implement and comply with the advance directive;
- Not condition the provision of care or otherwise discriminate against an individual based on whether the individual has executed an advance directive;
- Educate staff concerning CAH policies and procedures on advance directives; and
- Provide and document efforts towards community education regarding advance directives.

In addition to the traditional advance directive, CAHs must also honor a psychiatric advance directive, which is a type of advance directive that might be prepared by an individual who is concerned that at some time he or she may be subject to involuntary psychiatric commitment or treatment. Like an advance directive, a psychiatric advance directive may name another person who is authorized to make decisions for the individual and provide the patient's instructions about hospitalization and uses of medications or therapies. A psychiatric advance directive must be afforded the same respect and consideration as a traditional advance directive. In states that have not explicitly adopted the use of psychiatric advance directives, CMS has indicated that consideration should still be given to these advance directives as the preferences expressed in the document may offer critical insight to the CAH staff as they develop a plan of care and treatment for the patient.

Disclosures to Patients. The revised Interpretive Guidelines related to 42 C.F.R. § 485.608(a) offer more detailed guidance regarding required disclosures to patients related to physician ownership in the CAH and the CAH's capability of handling medical emergencies. Physician-owned CAHs must provide written notice to their patients at the beginning of each patient's CAH inpatient stay or outpatient visit stating that the CAH is physician-owned, and a list of owners must be available upon request. In addition, each physician owner who is a member of the CAH's hospital staff must agree, as a condition of obtaining CAH medical staff privileges, to disclose in writing to all patients they refer to the CAH their ownership interest in the CAH. CAHs that do not have at least one referring physician with an ownership interest must sign an attestation statement to that effect and are exempt, as are physician owners who do not refer any patients to the CAH.

CAHs must also disclose their abilities to handle medical emergencies by providing a written notice to all patients at the beginning of an inpatient stay or outpatient visit if the CAH does not have a physician present in the CAH 24 hours per day, 7 days per week. The notice must indicate how the CAH will meet the medical needs of any patient who develops an emergency medical condition at a time when there is no physician present in the CAH. CAHs that have a physician on-site 24 hours per day, 7 days per week do not need to issue such a disclosure notice.

In consideration of the revised Interpretive Guidelines, providers should assess how they handle patients' health care directives and disclosures to patients regarding physician ownership and emergency capabilities to ensure compliance with regulatory requirements and related guidelines. CAHs should review their disclosure policies to ensure compliance with the guidelines and educate physicians as well as staff on the requirements.

The new and revised Interpretive Guidelines can be accessed at:
http://www.cms.gov/transmittals/downloads/R75SOMA.pdf

If you would like additional information or assistance with policy/procedure preparation, please contact Katherine A. Kuchan at kkuchan@hallrender.com or (414) 721-0479, Rachel S. Delaney at rdelaney@hallrender.com or(414) 721-0448 or your regular Hall Render attorney.