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Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-25

DATE: February 13, 2009

TO: State Survey Agency Directors

FROM: Director

Survey and Certification Group

SUBJECT: Enforcement of Amended Requirements for Certain Hospital and Critical Access

Hospital (CAH) Disclosures to Patients

Memorandum Summary

- Revision to Physician-owned Hospital Disclosure Requirements. 42 CFR 489.3 and \$489.20(u) and (v) were amended, effective October 1, 2008, to:
 - Expand the definition of "physician-owned hospital" to include a participating
 hospital in which a physician or immediate family member of a physician has an
 ownership interest in the hospital;
 - Require hospitals/CAHs to provide a list of physician owners at the time a patient requests it;
 - Require hospitals/CAHs to make disclosure at the time of referral a condition of medical staff membership for referring physician owners; and
 - Exempt from the disclosure requirements hospitals whose physician owners do not refer patients.
- Clarification of Termination Basis. 42 CFR 489.53 was also amended as of October 1, 2008, to clarify that the Centers for Medicare & Medicaid Services (CMS) may terminate the provider agreement of hospitals or CAHs that fail to make required disclosures, including disclosures when a hospital does not have a physician on site 24/7.

On December 14, 2007, we issued S&C-08-07, which discussed enforcement of the requirement for certain hospital and Critical Access Hospital (CAH) disclosures to patients. The final rule governing the hospital inpatient prospective payment system, published on August 19, 2008 and effective October 1, 2008, amended these Medicare provider agreement requirements. (73 FR 48434, 48757) Under the final rule:

• 42 CFR 489.3 was amended to include in the definition of a "physician-owned hospital" (which includes CAHs for this purpose) an owner who is *an immediate family member of a physician* (as defined in 42 CFR 411.351).

- 42 CFR 489.20(u) of the provider agreement requirements was revised and renumbered to:
 - Mandate not only that all physician-owned hospitals/CAHs advise all patients that a
 list of physician owners is available upon request, but also that they furnish that list
 at the time a patient or patient's representative requests it.
 - Mandate that each physician-owned hospital/CAH require, as a condition for continued membership on the medical staff and/or admitting privileges at the hospital, that their referring physician owners disclose, in writing, any ownership or investment interest held by the physician or an immediate family member to all patients that the physician refers to that hospital.
- A requirement at 42 CFR 489.20(v) was added to clarify that the disclosure requirements do not apply to any physician-owned hospital/CAH that does not have at least one referring physician owner, provided that such hospital signs an attestation statement to that effect and maintains such attestation in its records.
- 42 CFR 489.20(v) and (w) were re-designated as (w) and (x) respectively but there were no changes to the regulatory text itself.
- CFR 489.53(c) was amended to clarify that CMS may terminate a provider agreement with a hospital or CAH that fails to make the required disclosures, including when the hospital or CAH does not have a physician on site 24 hours per day/7 days per week.

The complete text of the revised regulations is attached.

The enforcement of these provider agreement requirements for disclosures by certain hospitals or CAHs will continue to use the general process described in S&C-08-07, relying upon the Patients' Rights Condition of Participation standard at 42 CFR 482.13(b)(2) for hospitals and the Compliance with Federal, State and local laws regulation at 42 CFR 485.608 for CAHs. For the new requirements related to physician-owned hospital disclosures:

- Surveyors must ask to see the hospital's/CAH's signed attestation that it does not have any referring owners when the hospital or CAH indicates that it is physician-owned, but exempt from the disclosure requirement. Creation of an attestation at the time of survey does not satisfy the regulatory requirement.
- Surveyors will determine, through staff interviews, observation when possible, and review of facility policies and procedures, whether physician-owned hospitals/CAHs furnish their list of physician owners at the time a patient, or a patient's representative has requested it.
- Surveyors will determine, through staff interviews and review of policies and procedures and medical staff records, whether physician-owned hospitals/CAHs

Page 3 - State Survey Agency Directors

include in their requirements for retaining medical staff membership or admitting privileges the requirement that a physician owner make a written disclosure of the ownership interest of the physician, or an immediate family member, to all patients at the time of referral to the hospital.

For questions regarding enforcement of these requirements for hospitals or CAHs please contact David Eddinger at 410-786-3429 or <u>David.Eddinger@cms.hhs.gov</u>.

Effective Date: The effective date of the change in regulation was October 1, 2008, and should be implemented immediately.

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

Enclosure

cc: Survey and Certification Regional Office Management

Regulations Governing Required Disclosures by Certain Hospitals or CAHs

42 CFR 489.3 Definitions.

* * *

Physician-owned hospital means any participating hospital (as defined in §489.24) in which a physician, or an immediate family member of a physician (as defined in §411.351 of this chapter), has an ownership or investment interest in the hospital. The ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in the hospital. This definition does not include a hospital with physician ownership or investment interests that satisfy the requirements at §411.356(a) or (b) of this chapter.

§ 489.20 Basic commitments.

* * *

- (u) Except as provided in paragraph (v) of this section, in the case of a physician-owned hospital as defined at §489.3—
 - (1) To furnish written notice to each patient at the beginning of the patient's hospital stay or outpatient visit that the hospital is a physician-owned hospital, in order to assist the patient in making an informed decision regarding his or her care, in accordance with §482.13(b)(2) of this subchapter. The notice should disclose, in a manner reasonably designed to be understood by all patients, the fact that the hospital meets the Federal definition of a physician-owned hospital specified in §489.3 and that the list of the hospital's owners or investors who are physicians or immediate family members (as defined at §411.351 of this chapter) of physicians is available upon request and must be provided to the patient at the time the request for the list is made by or on behalf of the patient. For purposes of this paragraph (u)(1), 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 an outpatient service.
 - (2) To require each physician who is a member of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to disclose, in writing, to all patients the physician refers to the hospital any ownership or investment interest in the hospital that is held by the physician or by an immediate family member (as defined at §411.351 of this chapter) of the physician. Disclosure must be required at the time the referral is made.
- (v) The requirements of paragraph (u) of this section do not apply to any physician-owned hospital that does not have at least one referring physician (as defined at §411.351 of this chapter) who has an ownership or investment interest in the hospital or who has an immediate family member who has an ownership or investment interest in the hospital, provided that such hospital signs an attestation statement to that effect and maintains such attestation in its records.

Page 5 - State Survey Agency Directors

(w) In the case of a hospital as defined in §489.24(b), to furnish written notice to all patients at the beginning of their hospital stay or outpatient visit if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week, in order to assist the patients in making informed decisions regarding their care, in accordance with §482.13(b)(2) of this subchapter. The notice must indicate how the hospital will meet the medical needs of any patient who develops an emergency medical condition, as defined in §489.24(b), at a time when there is no physician present in the hospital. For purposes of this paragraph, 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 outpatient service.

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§ 489.53 Termination by CMS.

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(c) Termination of agreements with hospitals that fail to make required disclosures. In the case of a physician-owned hospital, as defined at §489.3, CMS may terminate the provider agreement if the hospital failed to comply with the requirements of §489.20(u) or (w). In the case of other participating hospitals, as defined at §489.24, CMS may terminate the provider agreement if the participating hospital failed to comply with the requirements of §489.20(w).