interest or whose immediate family member has an ownership or investment interest in the CAH. The CAH must maintain this attestation in its records.

- 42 CFR 489.20(u)(1) requires that all physician-owned CAHs 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, in order to assist the patient in making an informed decision
  about his or her care.
  - A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned CAH admission for inpatient care or for an outpatient service subject to notice. An unplanned inpatient stay or outpatient visit subject to the notice requirement begins at the earliest point at which the patient presents to the CAH.
- The notice must disclose, in a manner reasonably designed to be understood by all patients, that the CAH is physician-owned and that a list of owners or investors who are physicians or immediate family members of physicians is available upon request. If the patient (or someone on behalf of the patient) requests this list, the CAH must provide it at the time of the request.
- 42 CFR 489.20(u)(2) provides that physician-owned CAHs must require each physician owner who is a member of the hospital's medical staff to agree, as a condition of obtaining/retaining CAH medical staff membership or admitting privileges, to disclose in writing to all patients they refer to the CAH their ownership or investment interest or that of any immediate family member in the CAH. The CAH must require that this disclosure be made at the time of the referral and the requirement should be reflected in the hospital's policies and procedures governing privileges for physician owners.
  - The CAH may exempt from this disclosure requirement any physician owner who does not refer any patients to the CAH.
- 42 CFR 489.12 permits CMS to refuse to enter into a provider agreement with a physicianowned CAH applicant that does not have procedures in place to notify patients of physician ownership in the hospital, as required under §483.20(u).
- <u>42 CFR 489.53(c)</u> permits CMS to terminate the provider agreement of a physician-owned CAH if the CAH fails to comply with the requirements at <u>§489.20(u)</u>.

## **✗** MD/DO 24/7 On-Site Presence

42 CFR 489.20(w) mandates that if there is no doctor of medicine or osteopathy present in the CAH 24 hours per day, seven days per week the CAH must provide written notice to all impatients at the beginning of a planned or unplanned inpatient stay, and to outpatients for certain types of outpatient visits. The purpose of the requirement is to assist the patient in making an informed decision about his/her care. CAHs that have an MD/DO (including

residents who are MDs or DOs) on-site 24/7 do not need to issue any disclosure notice about emergency services capability.

- The notice must be provided to all inpatients and to those outpatients who are under observation or who are having surgery or any other procedure using anesthesia.
- The notice must be provided at the beginning of the planned or unplanned inpatient stay, or applicable outpatient visit.
  - A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned CAH admission for inpatient care or for an outpatient service subject to notice. An unplanned inpatient stay or outpatient visit subject to the notice requirement begins at the earliest point at which the patient presents to the CAH.
- Individual notices are not required in the CAH's dedicated emergency department (DED) (as that term is defined in 42 CFR 489.24(b)), but the DED must post a notice conspicuously, in a place or places likely to be noticed by all individuals entering the dedicated emergency department. The posted notice must state that the CAH does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the CAH will meet the medical needs of any patient with an emergency medical condition, as defined in 42 CFR 489.24(b) [the EMTALA definition], at a time when there is no doctor of medicine or doctor of osteopathy present in the CAH. If an emergency department patient is determined to require admission, then the individual notice provisions of 42 CFR 489.20(w) would apply to that patient.
- Before admitting an inpatient or providing outpatient services requiring notice, the CAH
  must obtain a signed acknowledgement from the patient stating that he/she understands that
  a doctor of medicine or doctor of osteopathy may not be present during all hours services are
  furnished to him/her.
  - In the event of an unplanned surgery or inpatient admission to treat an emergency medical condition, it may in some cases be necessary in the interest of the patient's safety to proceed with treatment before the required notice can be given and acknowledgement can be obtained. In such circumstances the CAH must provide notice and obtain acknowledgement as soon as possible after the patient's stay or visit begins.
- For a CAH that participates in Medicare with multiple campuses providing inpatient services (e.g., a main provider campus and a separate remote location for a psychiatric or rehabilitation distinct part unit (DPU)) under one CMS Certification Number) a separate determination is made for each campus/location with inpatient services as to whether the disclosure notice is required. For example, if a CAH has a main campus with 25 inpatient beds and a remote location with 10 psychiatric DPU beds and 10 rehabilitation DPU beds, and a physician is present 24/7 on the main campus, but not at the DPU remote location, the CAH is required to provide the disclosure notice at the DPU location. No notice is required

for patients coming to the main provider campus. In this same example, if the CAH also has a provider-based, off-campus ambulatory surgery department, no notice is required at that off-campus surgery site, since the CAH's main campus does have an MD/DO present 24/7.

• 42 CFR 489.53(c) permits CMS to terminate a provider agreement with a CAH if the CAH fails to comply with the requirements at §489.20(w) when it does not have an MD or DO onsite 24/7.

## **Other Federal Requirements**

Other Federal requirements also apply to patient health and safety in the CAH. For example, Federal laws and regulations govern both the disposal of medical waste and occupational health. However, surveyors are not expected to be knowledgeable about the requirements of other Federal agencies and therefore do not assess compliance with non-CMS regulations. A surveyor who suspects a CAH may not be in compliance with other Federal requirements may refer the matter to the appropriate Federal agency. If CMS is notified or becomes aware of another Federal agency's final enforcement action, action will be taken only if the final enforcement action remains in effect.

## Survey Procedures §485.608(a)

## Assessing Compliance with Advance Directives Requirements

- Review the CAH's advance directive notice. Does it advise inpatients or applicable
  outpatients, or their representatives, of the patient's right to formulate an advance directive
  and to have CAH staff comply with the advance directive (in accordance with State law)?
  Does it include a clear, precise, and valid statement of limitation if the CAH cannot
  implement an advance directive on the basis of conscience?
- Review the records of a sample of patients for evidence of CAH compliance with advance directive notice requirements. Does every inpatient or applicable outpatient record contain documentation that notice of the CAH's advance directives policy was provided at the time of admission or registration? Is there documentation of whether or not each patient has an advance directive? For those patients who have reported an advance directive, has a copy of the patient's advance directive been placed in the medical record?
- What mechanism does the CAH have in place to allow patients to formulate an advance directive or to update their current advance directive? Is there evidence that the CAH is promoting and protecting each patient's right to formulate an advance directive?
- Determine to what extent the CAH complies, as permitted under State law, with patient advance directives that delegate decisions about the patient's care to a designated individual.
- Determine to what extent the CAH educates its staff regarding advance directives.