

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-08-07

DATE: December 14, 2007

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Enforcement of Requirements for Certain Hospital and Critical Access Hospital (CAH) Disclosures to Patients

Memorandum Summary

- The final inpatient prospective payment regulation requires, beginning October 1, 2007, certain disclosures to patients by physician-owned hospitals and CAHs and by hospitals and CAHs that do not have a physician on site 24 hours/day, seven days/week.
- For hospitals, enforcement of the new notice requirements falls under the Patients' Rights Condition of Participation (CoP) at 42 CFR 482.13.
- For CAHs, enforcement of the new notice requirements falls under the Compliance with Federal, State, and local laws and regulations CoP at 42 CFR 485.608(a).

The final rule governing the hospital inpatient prospective payment system was published on August 22, 2007 (See Federal Register, 72 FR 47130). Under the final rule:

- 42 CFR 489.3 was amended to add a definition of a "physician-owned hospital" as any participating hospital (which, as defined in §489.24 includes any CAH) in which a physician or physicians have an ownership or investment interest, except for those satisfying exception criteria found at 42 CFR 411.356(a) or (b).
- 42 CFR 489.20(u) was added to the provider agreement requirements, mandating that all physician-owned hospitals and CAHs provide written notice to a patient at the beginning of an inpatient stay or outpatient visit that the hospital or CAH is physician-owned, in order to assist the patient in making an informed decision about his/her care, in accordance with 42 CFR 482.13(b)(2). The notice is required to disclose, in a manner reasonably designed to be understood by all patients, that the hospital is physician-owned and that the list of physician owners or investors is available upon request. The regulation provides clarification about when an inpatient stay or

outpatient visit “begins,” i.e., 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. In other words, the written notice must be provided to the patient at the time of the earliest contact from the hospital or CAH to the patient where the hospital provides the patient written materials concerning a specific hospital stay or visit.

- 42 CFR 489.12 was amended to permit the Centers for Medicare & Medicaid Services (CMS) to deny a provider agreement to a hospital or CAH applicant that does not have procedures in place to notify patients of physician ownership in the hospital.
- 42 CFR 489.53 was amended to permit CMS to terminate a provider agreement with a physician-owned hospital if the hospital fails to comply with the requirements of §489.20(u).
- 42 CFR 489.20(v) was added to the provider agreement requirements, mandating that all hospitals and CAHs provide written notice to all patients at the beginning of an inpatient stay or outpatient visit if there is no doctor of medicine or doctor of osteopathy present in the hospital 24 hours per day, seven days per week, in order to assist the patient in making an informed decision about his/her care, in accordance with 42 CFR 482.13(b)(2). The notice must also indicate how the hospital or CAH will meet the medical needs of any patient who develops an emergency medical condition, as defined in 42 CFR 489.24(b) [the EMTALA definition], at a time when no physician is present in the hospital or CAH. The regulation provides the same clarification about when a hospital/CAH stay or outpatient visit “begins” as in the regulation concerning physician-owned hospital disclosures.

In the case of a hospital that participates in Medicare with multiple campuses, satellites, remote, and/or provider-based locations all covered under one CMS Certification Number, presence of a physician 24 hours per day, seven days per week in any portion of the hospital means that there is no requirement to make this disclosure. For example, if a hospital has three campuses, only two of which have a physician present 24/7, there is no requirement for the third campus to make a disclosure that there is no physician present 24/7 at that campus. Likewise, if a hospital’s main campus has a physician present 24/7, there is no requirement for a disclosure by any of its provider-based locations that do not have a physician at that location 24/7.

Enforcement of the mandatory disclosure requirements is linked to the Patients’ Rights CoP for hospitals and the Compliance with Federal, State, and local laws and regulations CoP for CAHs. The Patient’s Rights CoP for hospitals at 42 CFR 482.13(b)(2) states that a patient has the right to make informed decisions regarding his or her care. The CoP at 42 CFR 485.608 requires that the CAH and its staff be in compliance with applicable Federal, State, and local laws and regulations.

Beginning October 1, 2007, the compliance of hospitals and CAHs with the disclosure requirements is to be assessed when surveying hospitals for compliance with the Patients Rights CoP and CAHs for the Compliance with Federal, State, and local laws and regulations CoP. The interpretive guidelines in the State Operations Manual (SOM) for the Patients' Rights CoP for hospitals and the Compliance with Federal, State, and local laws and regulations CoP for CAHs are being amended to reflect the regulatory requirements governing these mandatory disclosures.

Surveyors are not required to make an independent determination regarding whether a hospital or CAH meets the Medicare definition of a physician-owned hospital. Surveyors are required, however, to ask the hospital or CAH whether it is a physician-owned hospital under the Medicare definition. If a hospital/CAH indicates that it is physician-owned, surveyors must then verify that the hospital/CAH has appropriate policies and procedures in place to ensure that written notice is provided to all patients at the beginning of an inpatient stay or outpatient visit that the hospital is physician-owned and that a list of the physician owners or investors is available. Surveyors are expected to review the notice that the hospital issues in order to verify that it is reasonably designed to be understood by all patients. Surveyors must verify that the hospital/CAH, upon a patient's request, makes available in a timely manner a list of physician owners or investors. In addition, surveyors may also interview hospital/CAH staff to assess their knowledge and understanding of the physician ownership notice requirements, including the hospital's/CAH's process for delivering the notice and responding to requests for the list of physician owners or investors. Surveyors may also interview patients to verify that the hospital/CAH is providing them with the written notice in compliance with the regulatory requirements.

For all hospitals and CAHs, surveyors are expected to determine whether a doctor of medicine or a doctor of osteopathy is on-site 24 hours/day, seven days/week. If a doctor of medicine or osteopathy is not on-site at a hospital or CAH at all times, surveyors must then verify that the hospital/CAH has appropriate policies and procedures in place to ensure that written notice of this is provided to all patients at the beginning of an inpatient stay or outpatient visit. The notice must also indicate how the hospital/CAH will meet the medical needs of a patient who develops an emergency medical condition when there is no doctor of medicine or osteopathy on site. Surveyors may also interview hospital/CAH staff to assess their knowledge and understanding of the notice requirements when a physician is not on site 24/7. If appropriate in terms of the scope of the survey underway at the facility, surveyors may also survey the hospital or CAH for its compliance with the applicable requirements concerning provision of emergency services. (See 42 CFR 482.55 and S&C-07-19 for hospitals and 42 CFR 485.618 for CAHs.)

For questions regarding enforcement of the requirements for hospitals under the Patients' Rights CoP, please contact David Eddinger at 410-786-3429 or David.Eddinger@cms.hhs.gov.
For questions regarding enforcement of the requirements for CAHs under the Compliance with Federal, State, and local laws and regulations CoP, please contact Cindy Melanson at 410-786-0310 or Cindy.Melanson@cms.hhs.gov.

Effective Date: The effective date of the change in regulation was October 1, 2007, 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

cc: Survey and Certification Regional Office Management