

April 20, 1998

Nancy-Ann Min DeParle, Administrator
Health Care Financing Administration
Department of Health and Human Services
Hubert H. Humphrey Building, Room 309-G
200 Independence Avenue, SW
Washington, DC 20201

Attention: 3745-P -- Hospital Conditions of Participation, Proposed Rule

Dear Ms. DeParle:

I am writing on behalf of the American Society of Internal Medicine (ASIM), representing the nation's largest medical specialty, to express our concern with certain aspects of the Health Care Financing Administration's (HCFA) proposed rule on hospital conditions of participation, as published in the December 19, 1997 *Federal Register*. Our primary concern with this proposed rule is that HCFA consistently replaces the requirements of professional competency and responsibility in a wide variety of areas subject to hospital conditions of participation with the Medicare program by substituting the hospital as the responsible party instead of the medical staff. This change may serve to compromise the quality of patient care provided in the Medicare program.

ASIM supports HCFA's focus on patient care and outcomes of care, increased flexibility in meeting quality standards, and elimination of unnecessary procedural requirements, but believes that it is essential to maintain the function of the independent medical staff. The medical staff is referred to throughout the proposed rule, but the existing medical staff conditions (42 code of federal regulation (CFR) section 482.22) are eliminated in the rule. The hospital medical staff serves a critical role in ensuring high quality patient care, therefore the existing medical staff regulations should be maintained, not eliminated. Practicing physicians must be involved in patient assessment, care planning, service delivery, quality assessment and performance improvement--the medical staff traditionally provides the organizational structure for physicians to provide these critically important services.

ASIM does not understand why HCFA would propose to eliminate the medical staff section of federal regulations when in the proposed rule HCFA states:

We do not intend to discount the value of a hospital of having a carefully selected and well-organized medical staff. On the contrary, we believe it is self-evident that the medical staff has a critical role in ensuring that high quality care is delivered consistently and that any hazards to patients are promptly detected and eliminated (FR, page 66749).

ASIM supports the elimination of section 482.12(a)(7) from the code of federal regulations to allow the medical staff and the hospital greater flexibility in determining whether requiring Board certification, fellowship, or membership in a specialty society would enhance the quality of care for the hospital's patients.

ASIM strongly opposes incorporating the medical staff into the new human resource section of the regulations (42 CFR section 482.125) because it can be interpreted that this change equates independent physicians to employed physicians and equates medical staff to other hospital departments. The proposed human resource section of regulations fails to recognize that most physicians are not employees of the hospital.

ASIM understands the provision in the provider agreement section (42 CFR section 489.53(6)) that requires physicians and other providers to provide records to HCFA or its designees to verify compliance with Medicare law. However, assurances must be incorporated into the regulation that specify that this

information would not be demanded in an unreasonable manner. As drafted, refusal to reply to any request for information would be a basis for termination of a provider agreement with the Medicare program. Such a response appears to be excessive and is contrary to Medicare's focus on quality because such an action could be detrimental to patient access to care. This section of the proposed rule should be revised to indicate that a provider agreement may be terminated in an instance where there is an unreasonable refusal to allow access to physician and other provider records.

ASIM suggests increased flexibility regarding authentication of verbal orders in the proposed CFR section 482.120(a)(c). The proposed change will increase the hassle factor for physicians asked to authenticate orders after the fact and increase unnecessary costs to the physician and hospital to provide authentication services. We agree with the American Medical Association that Joint Commission Hospital Standard IM.7.8 is a more reasonable substitute for the proposed regulation. The Joint Commission standard states that "every medical record is dated, its author identified, and, when necessary authenticated. The hospital must ensure that, at a minimum, entries of history and physical examinations, operative procedures, consultations, and discharge summaries are authenticated. Other entries are authenticated as specified by the hospital policy or medical staff bylaws or as required by state law and regulations."

ASIM believes that the proposed hospital conditions of participation regulations will be much stronger and realistic if the current medical staff section is maintained, and the provider agreement and verbal order sections are modified as suggested above. Thank you for full consideration of these comments.

Sincerely,

Alan Nelson, MD
Executive Vice President