September 17, 1999

Nancy-Ann DeParle
Administrator
Health Care Financing Administration
Hubert Humphrey Building, Room 443-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: HCFA-3018-IFC, Medicare and Medicaid Hospital Conditions of Participation: Patients' Rights (64 *Federal Register* 36070), July 2, 1999

Dear Ms. DeParle:

On behalf of the American College of Physicians-American Society of Internal Medicine (ACP-ASIM), representing 115,000 physicians and medical students of internal medicine, I am writing to submit comments on the Health Care Financing Administration's (HCFA) July 2, 1999, interim final rule on Medicare and Medicaid hospital conditions of participation. This interim rule sets forth six standards that address the patient's physical and emotional health and safety while undergoing treatment at a hospital. We address two of these standards in our comments: 1) freedom from restraints used in the provision of acute medical and surgical care unless clinically necessary; and 2) freedom from seclusion and restraints used in behavior management unless clinically necessary.

ACP-ASIM is very concerned that the restraint and seclusion provisions of the interim final rule were developed without the appropriate consideration from the medical community—especially the physician one-hour face-to-face evaluation requirement. Thus, we are recommending that HCFA withdraw section 482.13(e) and (f) of the interim final rule and reissue the regulations in a notice of proposed rule making with at least a 60 day comment period.

It is ACP-ASIM's position that restraints and seclusion should be: (a) used only in accordance with the patient's care plan, (b) used only in the least restrictive manner possible, (c) used only to prevent immediate injury to the patient or to others, and (d) removed/ended at the earliest possible time. In general, restraints and seclusion should be utilized only upon the orders of a physician and carried out by staff properly trained in their use. However, restraints or seclusion should be allowed for use in emergencies without a physician's order as long as medical-staff-approved patient protocols are observed.

ACP-ASIM also strongly opposes the interim final rule's requirement for a face-to-face physician evaluation within one hour of the order to restrain or seclude a patient in the behavioral management setting. **This requirement is over-prescriptive, does not reflect the current nor best practice of medicine, and places an undue and unfair burden on all hospitals, especially psychiatric, small, and rural hospitals.** We do agree that a

timely evaluation is required when a patient is restrained or secluded, but HCFA has promulgated what amounts to the practice of medicine. A face-to-face evaluation within one hour by a physician is not clinically or medically necessary in every instance where a patient is restrained or secluded. Evaluations can routinely be made over the telephone by discussing the patient's condition with the nurse or other caregiver attending to the restrained or secluded patient. The physician, based on this discussion, can then make a professional medical decision as to whether a face-to-face evaluation is required.

HCFA has jeopardized the integrity of the rule-making process by promulgating the one-hour requirement in the interim final rule. This rule has been in effect since August 2, 1999, but HCFA has not completed the comment process on the effect of this rule. To our knowledge, HCFA did not make a serious attempt to evaluate the effect such a regulation would have on the institutions and physicians who are now subject to this rule.

Further, HCFA clearly states in the preamble that the revised Medicare hospital conditions of participation are in concert with the Reinventing Government (REGO) initiative that emphasizes reducing unnecessary structural and process requirements and allows more flexibility to hospitals and practitioners to meet quality standards. We believe that the one-hour rule is grossly inconsistent with HCFA's goal to comply with REGO.

ACP-ASIM believes that restraints and seclusion should not be "used only as a last resort" as HCFA originally proposed in the NPRM. This could lead to interventions that are potentially of greater harm to the patient (e.g., certain medications) or might prove ineffective in providing safety (e.g., a family member sitting with a highly suicidal patient). Restraints and seclusion should be used when they are medically indicated and offer the best balance of efficacy and safety for protecting the patient or others. HCFA amended the "last resort" language in the interim final rule to read, "when other less restrictive measures have been found to be ineffective." We believe that there is little distinction between these two phrases—both prevent physicians from utilizing their medical judgement and could result in harm to the patient or others. We maintain that the term "medically indicated" is the proper standard to apply.

In emergency situations, this amended language could result in the delay of medical treatment if a series of time consuming "less restrictive measures" are utilized before a patient can be safely restrained. Also, the "less restrictive measures" standard is ambiguous and could lead to confusion among hospital personnel in emergency situations. Further, by promulgating the "less restrictive measures" standard, HCFA has in effect usurped all existing medical-staff-approved patient restraint protocols without sufficient input from the medical community and without scientific study. **Thus, where an emergency situation exists and time is of the essence to treat the patient, physicians or other licensed independent practitioners should use reasonable clinical judgment and follow medical-staff-approved patient protocols when determining the method of restraint or seclusion.**

ACP-ASIM believes that the use of restraints, except in emergencies, should be implemented only upon the explicit order of a physician, in conformance with reasonable professional judgment. However, restraints or seclusion should be allowed for use in emergencies without a physician's order as long as the licensed independent practitioner follows medical-staff-approved patient protocols are observed. In this situation, the order to restrain or seclude should be reviewed by a physician (medical doctor or doctor of osteopathy). Allowing licensed independent practitioners to routinely issue orders to restrain or seclude may jeopardize the patient's health or cause undue harm if other medical symptoms are overlooked. In non-emergency situations, we do not think that this is too great a burden to assure that the patient receives the highest quality health care.

In the interim rule, HCFA distinguishes between situations where a restraint is used to provide acute-level medical and surgical care and those where restraints or seclusion are used to manage behavior. ACP-ASIM agrees that this differentiation is appropriate to reduce unnecessary regulatory burdens in situations that do not call for them. However, HCFA does not provide guidance in the interim final rule on when the behavior management standards would apply in acute-level medical and surgical care setting. We note that there was discussion on this matter in the preamble to the interim final rule, but further clarification should be provided in the regulatory language to guide the medical community on how to comply with this rule.

Under the standards for behavior management set forth in the interim final rule, hospitals are now required to report to HCFA any deaths that occur while a patient is restrained or secluded, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion. ACP-ASIM does not understand why HCFA is placing this regulatory burden on hospitals when the reporting of deaths or other sentinel events is already required by states, the Joint Commission, and the Food and Drug Administration. This information already exists. HCFA even cites in the preamble a report in which the FDA determined the number of deaths due to improper use of restraints.

HCFA clearly states in the preamble that the revised Medicare hospital conditions of participation are in concert the REGO initiative that emphasizes reducing unnecessary structural and process requirements and allows more flexibility to hospitals and practitioners to meet quality standards. As with the one-hour rule, we believe that this reporting requirement is inconsistent with HCFA's goal to comply with REGO.

The interim final rule does not specify the amount of detail HCFA would require hospitals to report concerning the death of a patient due to restraints or seclusion. ACP-ASIM is extremely concerned that if HCFA were to require the reporting of information pertaining to peer review activities, then current state laws that protect the confidentiality of this information would be seriously compromised. This would clearly have a chilling effect on peer review and quality improvement activities, as physicians and other health care providers would fear that their comments would be subject to public scrutiny—especially by lawyers. This could be extremely damaging to all patient safety and quality improvement initiatives.

ACP-ASIM appreciates the opportunity to comment on the interim final rule, and looks forward to working with you to further develop a reasonable and workable approach to achieve our mutual goal of protecting patients when extraordinary measures such as restraints or seclusion are necessary to safely deliver needed medical care.

Sincerely,

Alan R. Nelson, M.D.
Associate Executive Vice President