American College of Clinical Pharmacy

3101 Broadway, Suite 380
Kansas City, Missouri 64111
(816) 531-2177
(816) 531-4990 Fax
http://www.accp.com

April 15, 1998

Health Care Financing Administration
Room 309-G
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: HCFA Proposed Rule: Medicare/Medicaid Hospital Conditions of Participation
HCFA-3745-P

Dear Sir or Madam:

I am writing on behalf of the more than 4,400 members of the American College of Clinical Pharmacy (ACCP) to provide comments regarding the revisions proposed by the Health Care Financing Administration to the Pharmaceutical Services sections of its "Hospital Conditions of Participation" (§ 482.35).

Most ACCP members are Pharm.D.-educated and residency trained pharmacists who practice clinical pharmacy in university hospitals, community hospitals, or managed care organizations. Approximately 25% are board certified Pharmacotherapy Specialists, Nutrition Support Specialists, or Psychiatric Pharmacy Specialists. A recent survey found that 87% regularly educate physicians regarding appropriate drug therapy through activities like participation in medical rounds, medical inservice education, and continuing medical education; 34% participate in these activities on a daily basis. Further, 42% either serve as members of, or provide input to the decision making process of, their institution's Pharmacy and Therapeutics Committee. Corresponding participation in other committees includes: Medication Use Evaluation—25%; Critical Pathways—21%; Quality Assurance—16%; and Antibiotic Use—13%.

ACCP supports HCFA's overall goals in proposing its revised Conditions of Participation: to focus on patient care and the outcomes of that care, reflect a cross-functional view of patient treatment, encourage flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. Further, we support HCFA's efforts to "require the hospital

to provide needed medication therapy through a safe, accurate, and effective system that minimizes adverse drug events and evaluates the patient's response to therapy " and to "adopt requirements that integrate drug therapy services and support a coordination of services by the various disciplines that provide them (medicine, nursing, and pharmacy)." However, ACCP believes that some of the specific conditions proposed by HCFA contradict these stated goals and may not be in the best interest of the patients we serve.

As stated, ACCP supports HCFA's goal to promote an interdisciplinary approach to drug therapy management. However, we believe that the proposed rules do not appropriately recognize the importance of the pharmacist in the drug use process. ACCP has published two comprehensive reviews of the economic evaluations of clinical pharmacy services (*Pharmacotherapy* 1996;16:1188-1208; *Pharmacotherapy* 1989;9:45-56) (copies enclosed). The extensive literature summarized in these reviews attests to the value of clinical pharmacy services in improving patient care and its outcomes. Among those studies published since 1988 where it is possible to determine a benefit-to-cost ratio, this ratio ranged from 1.08:1 to 75.84:1 (mean 16.7:1). In other words, for every dollar invested in clinical pharmacy services, $16.70 were returned to the health system in benefits.

HCFA appears to have relied heavily on the work of Bates et al (*JAMA* 1995;274:29-34) and Leape et al (*JAMA* 1995;274:35-43) in developing its proposed rules concerning drug management procedures (§ 482.35 (b)). As noted by Bates (page 30), "better systems should promote fewer errors and include effective mechanisms for catching those that do occur." As noted by Leape (page 38), "pharmacists [in the study hospitals] sometimes lacked information about clinical characteristics of patients and results of laboratory tests that would have enabled them to intercept an improper order." Within the four stages of the drug therapy process described by Leape et al, it was found that 89% of medication errors occurred at the stages of physician ordering, transcription and verification, and nurse administration; 11% occurred at the stage of pharmacy dispensing. In addition to decreasing errors related to pharmacy dispensing, ACCP believes that a drug therapy system that fully incorporates the pharmacist at all stages—from ordering to administration—will have the best likelihood of decreasing medication errors and adverse drug events to the lowest level possible, while maximizing the desired outcomes of pharmacotherapy.

HCFA has proposed that "before medications are administered, a licensed nurse (that is, a registered nurse, licensed practical nurse, or licensed vocational nurse) or a doctor of medicine or osteopathy must review the individual patient's information, and the orders of the practitioner who prescribed the medication."

ACCP strongly encourages HCFA to amend this proposed rule to state either:

(1) "Before medications are administered, a licensed nurse..., *pharmacist,* or doctor of medicine or osteopathy must review the individual patient's information..." or to state,

(2) "Before medications are administered, an *appropriate health professional* must review..."

The former recommendation would better align the language of this proposed rule with one of HCFA's stated goals, that is to "integrate drug therapy services and support a coordination of services by the various disciplines that provide them (medicine, nursing, and pharmacy)." The latter recommendation recognizes that health professionals other than nurses, for example respiratory therapists, also administer medications to patients.

We believe that, in most hospitals, it is unrealistic or unproductive to have a physician review the orders of the practitioner who prescribed the medication before its administration. Few, if any, hospitals could afford to have physicians routinely reviewing each others orders prior to drug administration. Although each physician should "review" his/her own medication orders prior to their transmittal, such a review would likely catch only those caused by a mental lapse on the part of that physician. Leape et al found that "physicians made many prescribing errors that appeared to be due to deficiencies of knowledge of the drug and how it should be used," including incorrect doses, dosage forms, frequencies of administration, and routes of administration. Although the availability of a "comprehensive drug information resource" as recommended by HCFA would probably help to prevent medication errors due to a lack of drug knowledge on the part of the prescriber, ACCP believes this is not sufficient. Having the information available, and knowing that one needs to access the information, are two very different things. We believe that the contemporary pharmacist, with his/her broad-based knowledge in pharmacology, pharmacokinetics, and pharmacotherapy, is ideally suited to assist the physician in making the most appropriate prescribing decisions.

HCFA also has proposed that "the hospital must ensure that its overall medication error rate is no higher than 2.0 percent," and that "its patients experience no significant medication errors," defined as those that actually jeopardize or cause serious potential for jeopardizing the health and safety of the patient (§ 482.35 (a)(2) and § 482.35 (a)(3)). ACCP appreciates and supports the need to decrease the frequency of medication errors as one means to decrease the occurrence of adverse drug events, and agrees that we should strive to completely eliminate significant errors that jeopardize patient safety. However, we feel that additional clarification of this proposed rule is required.

> **We could not find how HCFA defines an error rate of 2.0%, but presume it would mean 2 medication errors per 100 patient admissions (as opposed to 2 errors per 100 doses administered). This should be clarified.**
>
> **We interpret HCFA's discussion to mean that it intends this maximum allowable error rate to apply to those related to transcription, dispensing, and administration, but not to those related to ordering (i.e., prescribing). This should be clarified.**

In the studies by Bates and Leape, for example, the total medication error rate (per 100 admissions) was 7.3%, and adverse drug events attributable to medication errors occurred in 1.8% of patients. Errors related to transcription, dispensing, and administration accounted for 61% of the total, or 4.5 errors per 100 admissions. HCFA proposes to include errors related to the timing of drug administration in the calculation of its overall error rate. However, the

findings of Leape suggest that errors related to the timing or frequency of drug administration seldom resulted in a adverse drug event, while those related to wrong drug choice or wrong dose (i.e., ordering) accounted for 42% or all adverse drug events. We presume that the reason for focusing on the occurrence of medication errors is to reduce the number of adverse drug events.

> **It may not be sufficient simply to reduce the overall number of medication errors, we must prevent those errors most likely to result in an important adverse event. We therefore question whether setting an overall medication error rate of no more than 2.0% is the best way to reduce the frequency of adverse drug events, and suggest that HCFA reexamine this issue.**

In summary, the American College of Clinical Pharmacy supports HCFA's efforts to promote an interdisciplinary approach to medication therapy and to enhance the safety of that therapy. We strongly encourage HCFA to recognize the important roles and responsibilities of pharmacists in helping to assure cost-effective drug therapy as the agency continues to develop its revised Conditions of Participation. We find it inconsistent with HCFA's stated goals to eliminate all reference to the pharmacist's responsibilities within the proposed rules. We also strongly encourage HCFA to reexamine the issue of medication error rates, focusing on the prevention of adverse drug events. We would be pleased to work with the agency as this important activity continues.

Sincerely,

Robert M. Elenbaas, Pharm.D., FCCP
Executive Director