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Dear Dr. McClellan:

The American College of Clinical Pharmacy (ACCP) appreciates the opportunity to provide comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease (ESRD) facilities as published in the *Federal Register* notice of February 4, 2005. **In particular, we are providing comments concerning Proposed § 494.140 ("Personnel Qualifications") with regard to the role of a pharmacist within the dialysis facility, as well as the facility's appropriate responsibility for pharmaceutical services and the efficient use of medications as a part of the revised conditions of coverage.**

ACCP is a national professional and scientific society representing almost 10,000 clinical pharmacist practitioners, researchers, and educators. Our members have been among the profession's leaders for almost three decades in developing and providing professional services, consultation, cutting-edge clinical research, and educational programs that improve the quality of medication use in the health care settings in which they practice.

Within ACCP's membership are approximately 200 members whose practice activities focus on nephrology, chronic kidney disease, and related medical conditions. These specialized practitioners are key thought leaders in the field who provide medication therapy management and pharmaceutical care services to dialysis patients as well as patients at earlier stages of chronic kidney disease. Many are actively involved within the clinical nephrology community, and have served on task forces such as the National Kidney Foundation's K/DOQI guidelines development groups. They have taken a leadership role in educating the pharmacy and medical communities about the growing prevalence of chronic kidney disease and the important role that pharmacists play in optimizing the quality of care of patients with mild, moderate, and severe kidney disease (references provided as Appendix A).

We are pleased to note the proposed rule's recognition of the contributions of pharmacists in improving the quality and cost-effectiveness of medication use in various patient populations. Patients served by ESRD facilities are a particularly relevant target population in which to assure the safe and appropriate use of medications due to:

- the severity of their medical condition(s);
- the prevalence of co-morbidities that frequently require complex drug therapy regimens; and
- the substantial clinical impact that dialysis procedures have on the pharmacodynamics and pharmacokinetics of the medications taken by ESRD patients.

Consequently, ACCP urges that the revised conditions of coverage provide for the inclusion of qualified pharmacists, in either an employed or consultative capacity, as integral members of the multidisciplinary teams within Medicare-approved dialysis facilities.

Among the reasons that ACCP believes pharmacists should be included as an integral member of the dialysis facility's multidisciplinary team are the following:

- Dialysis patients are prescribed medication regimens that are highly complex. Dialysis patients require an average of 10-12 prescribed medications and thus must take as many as 70 tablets or capsules daily. This represents more than twice the number of medications consumed by the typical non-ESRD Medicare patient. Several studies have documented non-adherence to prescribed medications in dialysis patients and the improvements in outcomes that have been associated with pharmacists' interventions to enhance medication adherence.
- Dialysis patients must have their dosage individualization based on the mode of dialysis they are receiving and the hemodialyzer being used, since both can significantly impact the dosage of and response to medications. Pharmacists have published a substantial body of original research in this area and have written many of the review articles that are utilized to guide drug dosing in such patients.
- Dialysis patients have multiple co-morbid conditions that increase the need for multi-drug regimens that increase the risk of clinically significant drug interactions. Dialysis patients also typically require frequent inpatient hospital admissions and have fluctuating biochemistry profiles that further complicate drug therapy regimens, placing them at increased risk for adverse medication outcomes. Pharmacists are uniquely qualified to provide the clinical review and consultation services that can promote safer and more effective medication use.
- Positive clinical and financial outcomes have been reported when pharmacists are involved in the management of conditions (including anemia, metabolic bone disease, and diabetes mellitus) that frequently occur in ESRD patients. The provision by pharmacists of effective medication therapy management, both for individual patients and those served by hospital-affiliated dialysis facilities has resulted in as much as $4 of health care cost savings for every $1 spent on pharmaceutical care.

- The role of pharmacists in providing medication therapy management services to at-risk Medicare beneficiaries is recognized within the scope of the new Part D drug benefit which begins in January 2006. This policy and benefit should logically be a part of the services provided to Medicare beneficiaries receiving services from ESRD facilities.

ACCP makes the following specific recommendations regarding the role of pharmacists as members of the dialysis facility multidisciplinary team:

1) A comprehensive medication review for each dialysis patient should be conducted by a pharmacist prior to or at the initiation of dialysis and at clinically appropriate intervals thereafter. Documentation of the review should include generation of an updated list of medications including drug name, dose, frequency, and special instructions. All medication-related problems should be documented and a plan of action to prevent or correct the problems should be recommended to the medical director of the facility. The pharmacist should provide counseling and education to patients to assure understanding of the proper use of their medications and to promote adherence with the medication regimen.

2) A regular review of laboratory studies should be conducted by a pharmacist to evaluate the appropriateness and effectiveness of prescribed medication regimens. A collaboratively-developed plan to modify the medication therapy as necessary should be developed and implemented based on the facility's policies and procedures. Examples of laboratory procedures that relate to medication therapy management protocols are provided in Appendix B.

3) The development of protocols and guidelines for the clinical use of medications should be managed by the pharmacist in collaboration with the medical director and other multidisciplinary team members in order to promote patient safety and high-quality, cost-effective drug use. In addition, a continuous quality improvement program should be implemented and administered by the pharmacist for such protocols, and guidelines to evaluate the outcomes of the protocols should be in place.

4) The development and implementation of policies and procedures for the control, preparation, administration, storage, and management of medications, including sterile products, should be managed by the pharmacist in consultation with the medical director and other team members.

5) The pharmacist should coordinate the medication management for dialysis patients that is delivered within the facility with other community-based providers of disease and medication management programs.

In addition to these specific recommendations concerning the role of the pharmacist, ACCP encourages CMS to evaluate and revise as necessary the payment policies affecting ESRD facilities to assure that payment levels are appropriate to support the activities of pharmacists described in these recommendations. Given the substantial body

of evidence demonstrating the effectiveness of pharmacists' interventions in promoting safer and more cost-effective medication use, such payment policy adjustments would likely produce net savings to Medicare as a result of reductions in rates of hospitalization and consumption of other health care services that are known to occur in patients whose medication regimens are ineffectively managed.

In summary, ACCP believes that an active clinical role for pharmacists as part of the multidisciplinary team within ESRD facilities will contribute substantially to the stated objectives of CMS for revising the conditions of coverage – namely that they:

- be founded on evidence;
- be patient-centered;
- promote outcomes desired for Medicare and Medicaid beneficiaries;
- establish a framework for the collection and reporting of consensus-driven performance standards;
- set clear expectations for dialysis facility accountability; and
- stimulate improvements in processes, outcomes of care, and beneficiary satisfaction.

ACCP and its members involved in caring for patients covered under the ESRD benefit would be pleased to work with the Centers for Medicare and Medicaid Services to further develop and refine the conditions of coverage in order to facilitate the active involvement of pharmacists as members of the ESRD facility's multidisciplinary team. Please feel free to follow up with us at any time.

Sincerely,

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Executive Director

C. Edwin Webb, Pharm.D., M.P.H.
Director, Government and Professional Affairs

Appendix A - Selected References in Nephrology Pharmacy Practice

Identification of drug-related problems in CKD/ESRD patients:

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Appendix B – Selected Laboratory Parameters for Medication Management

Laboratory Parameter	Indication for Monitoring	Pharmacist Role
Hemoglobin and Hematocrit Iron Indices	Anemia of Chronic Kidney Disease	• Foster achievement of K/DOQI guidelines by adjusting doses of EPO appropriately** • Evaluate for EPO resistance • Appropriately initiate and monitor IV iron therapy. Pharmacists are most able to interpret the current therapeutic controversies surrounding IV iron (e.g. dosing in hyperferritinemia and differentiation of the safety/toxicity profiles of the available agents. regarding
Calcium, phosphorus, parathyroid hormone (PTH), alkaline phosphatase, albumin	Renal Osteodystrophy	• Foster achievement of K/DOQI guidelines for calcium, phosphorus and PTH • Evaluate patients for best phosphate binder choice by evaluating data on risks, benefits, safety tolerability and cost • Optimize PTH suppression with vitamin D analogs and calcimimetic agents which require expertise in dosing and monitoring
Electrolytes (sodium, potassium, bicarbonate)	Hyperkalemia Metabolic acidosis	• Evaluate for drug-induced causes of hyperkalemia (e.g., ACE inhibitors, angiotensin receptor blockers)
Blood urea nitrogen, serum creatinine, albumin, transferrin	Dialysis Adequacy Malnutrition	• Evaluate for causes of suboptimal adequacy (e.g., heparin dose, access thrombosis) and adjust or initiate drug therapy where indicated. • Determine optimal pharmacologic interventions for malnutrition when indicated
Complete blood count	Thrombocytopenia Neutropenia Microcytosis Macrocytosis	• Evaluate for drug-induced causes (e.g., heparin-induced thrombocytopenia, vancomycin-induced neutropenia) • Evaluate for folate/B_{12} deficiency
Drug Concentrations (digoxin, phenytoin, gentamicin/vancomycin)	Therapeutic drug monitoring	• Pharmacists are extensively trained in pharmacokinetics of drugs that require dose modifications in CKD to optimize efficacy and minimize adverse events.