

**Written Testimony to the House Ways and Means Committee Regarding
Patient Safety and Quality Issues in End Stage Renal Disease Treatment**

Submitted by

The American Association of Kidney Patients (AAKP)

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The American Association of Kidney Patients (AAKP) (www.aakp.org), founded in 1969, is the nation's only kidney patient-led and managed education and advocacy organization for people with kidney disease. AAKP serves over one million Americans annually who have either lost kidney function (and live with dialysis or transplant) or have chronic kidney disease (CKD). As you may know, the *average* life expectancy for individuals following initiation of dialysis therapy is short, less than 5 years. As patients ourselves, we realize the important need to ensure quality of care and access for all dialysis and potential dialysis patients.

AAKP was instrumental in the fight for the enactment of the Medicare ESRD Program. In 1972, Shep Glazer, the Vice President of our forerunner organization, testified before the House Ways and Means Committee while being dialyzed. This effort was crowned with success in 1972 when Congress enacted the program that continues to provide Medicare funding for dialysis and kidney transplantation.

AAKP appreciates the opportunity to provide written testimony to the House Ways and Means Committee. We are available to assist the Committee with needed information as it continues to review quality of care issues for today's dialysis patients. AAKP's written testimony will provide patients' views on safety and efficacy in healthcare and provide insight into what patients need to ensure a high quality of life and health.

AAKP commends the Committee for assessing and reviewing patient safety and quality issues for care received by dialysis patients. AAKP's mission has always been to help all kidney patients achieve the best possible quality of life and longevity.

Regarding specific issues under review by the Committee, AAKP has developed and distributed position papers on the following topics in recent years: 1). Support for the continuation of the patient and physician relationship in medical care; 2). Support for continuous quality care and improvement and 3). Support for continuous safety monitoring. The content of these positions is summarized below:

Patient/Physician Relationship – AAKP strongly believes the principle that *a physician and patient must be permitted to decide a care plan best suited for that patient*. Averages and other statistics are fine for certain purposes, but medicine is fundamentally about the treatment of a unique individual. In this light, we worry that any legislation that mandates particular treatment options may impede the doctor/patient decision-making relationship.

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ESRD Continuous Quality Improvement – AAKP supports legislation to provide data on outcomes and quality of care for kidney patients. We worry that piecemeal approaches to improving quality may not offer the best health outcomes for patients and is why we have continuously asked Congress to establish a “National Commission on Improved Kidney Patient Outcomes.”

Safety Monitoring – AAKP supports legislation to ensure safety in healthcare settings. We applaud Congress, the Centers for Medicare and Medicaid Services (CMS) and the renal community as a whole for developing programs to ensure safety for all patients. However, we wish to encourage Congress to look at the major safety issues that impact all patients.

With regard specifically to the administration of erythropoietin (EPO) to patients, AAKP has previously addressed CMS with comments and questions regarding dosing policies. Though recent clinical studies such as CHOIR have demonstrated mortality in non-dialysis patients, we have asked CMS “Is there any clinical data that demonstrates that dialysis patients – either nationally or regionally -- are in fact receiving more EPO than necessary to maintain an appropriate hematocrit level, or that inappropriate EPO prescribing by physicians is the driver for increased EPO spending?” We are awaiting a response.

Furthermore, AAKP is also interested in how the issues currently being discussed about EPO will be affected by the “Medicare Prescription Drug, Improvement, and Modernization Act of 2003” (DIMA) (P.L. 108-173). In particular, section 623 of DIMA instructs CMS to implement effective January 1, 2005, a new “basic case-mix adjusted composite rate”, which would, *inter alia*, transfer the dollar difference (the “spread”) between acquisition and Medicare payment rates for separately billed drugs and biologicals (including erythropoietin) to the per-session composite rate for dialysis treatment. Even if there is some current law financial incentive for overutilization of EPO, would not that incentive be eliminated by section 623? We are concerned that section 623 has not occurred as scheduled.

National Commission on Improved Kidney Patient Outcomes - AAKP previously wrote to the House Ways and Means Committee calling for a “National Commission on Improved Kidney Patient Outcomes.” We believe a global perspective – rather than a piecemeal approach – is needed to improve quality and coordination of medical care for dialysis patients, and perhaps even create savings to Medicare. Indeed, as payor for the medical care of about 75 percent of all kidney patients receiving dialysis in the United States, CMS bears a special responsibility to ensure that dialysis patients not only receive quality medical care -- but that care is provided in a manner that maximizes positive *outcomes*. We would note the November 21 report by the HHS Inspector General calling for more collection of quality of care data in the ESRD program. AAKP believes these issues will become even more urgent as the nation’s dialysis population is expected to grow three-fold over the next decade.

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Moreover, in the kidney community today, there is a vigorous debate about the adequacy of medical care of dialysis patients, prompted by apparently higher U.S. dialysis patient disability, morbidity, and mortality in cross-national studies. Some have argued that it is a “national disgrace that the death rate now solidly stays in the region of 24% every year and has more than doubled over the last 30 years” (Kjellstrand, CM, Blagg, CR, “Differences in dialysis practice are the main reasons for the high mortality rate in the United States compared to Japan,” *Hemodial Int.* 2003; 7(1): 70). Others believe that cross-national comparisons are flawed for selection reasons (i.e., sicker, older patients are denied dialysis in comparison countries) and that the U.S. should take pride in the unique availability of dialysis here (*see, e.g.,* Friedman, EA, “International comparisons of survival on dialysis: Are they reliable?” *Hemodial Int.* 2003; 7(1):59-66). In any case, with the U.S. ranking last among industrialized countries in mortality for kidney patients, there is a clear need to take a close look at the adequacy of medical care for U.S. dialysis patients.

Charged with a comprehensive program review, the agenda for such a National Commission might also include patient access to other important renal replacement treatments, such as home dialysis and transplantation; nephrologists’ residency training; and reimbursement of rural facilities. There are also many other opportunities to improve care and reduce costs to Medicare, including slowing the progression to ESRD among chronic kidney disease patients (CKD), better chronic disease management, advances in new technology and biomedical solutions, more transplantation, and improved patient education. AAKP stands ready to assist the Committee on ways to implement such a Commission.

AAKP commends the Committee for addressing the issues of quality of care as currently delivered to the over 300,000 dialysis patients. We appreciate the opportunity to provide input into your efforts and look forward to working with you to provide continuous quality improvement to all patients.

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