aakp

The Voice of All Kidney Patients

October 4, 2004

BY ELECTRONIC SUBMISSION

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Baltimore, MD 21244–8012

Subject: CMS CMS–4068–P, Comments Regarding Proposed Rule, Medicare Prescription Drug Benefit—EXTENDED COMMENTS

Dear Dr. McClellan:

On behalf of the American Association of Kidney Patients ("AAKP"), I am writing to comment on the proposed rule for the Medicare prescription drug benefit, published in the *Federal Register* on August 3, 2004. This letter incorporates and extends comments AAKP submitted on September 28, 2004.

About AAKP. 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. Each year AAKP serves over 12,000 members and, through its programs, hundreds of thousands of other Americans who have either lost kidney function (and live with dialysis or transplant) or have chronic kidney disease (CKD). The *average* life expectancy for individuals following initiation of dialysis therapy is short, about 5 years. But AAKP's membership includes many long-term dialysis survivors, who live full and productive lives only by aggressive attention to their health care, a core mission of AAKP. Indeed, most kidney patients face not only the challenge of kidney disease, but other medical conditions as well, such as diabetes and hypertension.

General Principles. AAKP reviews proposed government policies with respect to several core principles: Will the proposed policy improve access to, and quality of, care, and does the proposed policy respect the principle that *the physician and patient make a joint determination of the care plan best suited for that patient*?

Comments. AAKP submits the following comments:

American Association of Kidney Patients
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1. General Provisions—Access to Covered Part D Drugs (§ 423.120)—b. Formulary Requirements (FR 46659)—Medicare Members with Kidney Disease Should Be Considered a "Special Population" and Provided "Open Formulary" with Access to All Needed Medications on a Preferred Basis. Medicare drug plans (Part D) can establish formularies that limit the drugs that they will cover. If a sponsor uses a formulary, the formulary must include drugs within each therapeutic category and class of covered Part D drugs, although not necessarily all drugs within such categories or classes.

However, the proposed rule recognizes that special populations may require special treatment:

> We request comments regarding any special treatment (for example, offering certain classes of enrollees an alternative or open formulary that accounts for their unique medical needs, and/or special rules with respect to access to dosage forms that may be needed by these populations but not by other Part D enrollees), we should consider requiring of plans with respect to special populations, as well as suggestions regarding the particular special populations for whom we may want to make allowances.

FR 46661

In this regard, AAKP respectfully requests that Medicare members with impaired kidney function (chronic kidney disease and end-stage renal disease) be considered a "special population" and that Medicare members with kidney disease should have access to an "open formulary", with all prescribed drugs covered on a preferred basis, for several reasons:

- **Pharmaceuticals Can Have Nephrotoxic Effects.** The kidneys are the primary organs of the urinary system, which purifies the blood by removing wastes and excreting in urine. Accordingly, the kidneys are a major pathway for excretion of pharmaceuticals and pharmaceutical metabolites. However, a wide variety of pharmaceuticals can damage the kidneys (nephrotoxic effects), and accelerate damage to the kidneys. In the worse case, an individual with impaired but functional kidneys will graduate to end-stage renal disease, and require a life-sustaining but expensive and demanding renal replacement therapy (e.g., dialysis or transplant). To avoid or minimize nephrotoxic pharmaceutical effects on individuals with already impaired kidneys, physicians must have the flexibility to prescribe appropriately, and that (at a minimum) any proposed substitution be approved by the patient's physician.

- **Kidney Patients Have Many Co-Morbid Conditions, and Multiple Medications Raise the Risk of Adverse Events.** Kidney patients have high rates of co-morbid conditions, including primary causes of kidney disease such as diabetes and hypertension, and common concomitants to kidney disease, including cardiovascular and other vascular diseases (see 2004 Annual Data Report of the U.S. Renal Data System, at www.usrds.org). Physicians prescribe both to treat a clinical condition and to avoid

adverse interactions. Again, it is imperative that physicians have maximum prescribing flexibility to minimize adverse events.

- **Kidney Disease Patients Require Medications to Treat Ancillary Conditions.** Kidney disease patients frequently require medications to prevent or manage conditions secondary to kidney disease such as cardiovascular disease, anemia (treated with erythropoietin), and secondary hyperparathyroidism (treated with active forms of Vitamin D). It is essential that all medications needed by a kidney patient are covered by a prescription drug plan.

- **Transplant Patients Require Carefully Selected Immunosuppressive Medications.** For individuals who have lost effective use of an organ (such as a kidney or liver), transplantation can be a highly effective form of replacement therapy. AAKP believes strongly that transplant patients should have access to an "open formulary", and that all immunosuppressive drugs should be covered on a preferred basis. The number of Medicare beneficiaries with a kidney transplant is small (about 60,000), and the number of immunosuppressive medications is very limited. Physicians should be able to prescribe the clinically indicated immunosuppressive drug.

Perhaps for certain other medical conditions a trial of a replacement or substitution medication may have few consequences, but for a transplant patient any untoward reaction could lead to catastrophic loss of the organ transplant. The principle of "open formulary" for immunosuppressive drugs for transplant recipients, and the risks of drug substitution (including generics), has been recognized by State pharmaceutical programs (including Medicaid).

2. General Provisions—D. Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans—1. Overview (§ 423.150)—c. Medication Therapy Management Programs (FR 46668). Medication therapy management is intended to optimize therapeutic outcomes, and includes programs to educate patients on the use of medications, increase adherence to prescription medication regimens, and detection of adverse drug events. AAKP urges CMS to include chronic kidney disease and end-stage renal disease patients for such programs. Kidney patients have high rates of diabetes, hypertension, and cardiovascular and other vascular diseases, among other conditions – and frequently are prescribed medications for each of these diseases. Ensuring that kidney patients understand the need and use of medications, take medications properly, and are informed about adverse events (including drug interactions) would be of immense value.

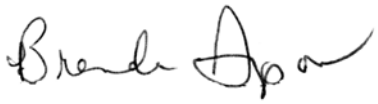
3. Section 101(c) (c), "Study On Transitioning Part B Prescription Drug Coverage". Although this matter is not raised in the proposed rule, the Medicare Modernization Act (MMA) requires the Secretary to submit a report to Congress that makes recommendations regarding methods for providing benefits under Part D currently provided under Part B, no later than January 1, 2005. AAKP believes this report should not be submitted to Congress without opportunity for public comment on a draft, and that no recommendations regarding transitioning Part B covered drugs used by kidney

patients be made until a thorough, independent study is made, including consideration of the financial costs to kidney patients and the impact on access and compliance with medication.

AAKP appreciates the hard work of CMS personnel involved in improving the lives of kidney patients. If you require further information regarding this letter, please contact Kris Robinson, AAKP's Executive Director, at (800) 749-2257.

Thank you in advance for considering AAKP's comments.

Sincerely,



Brenda Dyson
President

cc: Brady Augustine
Barry Straub, M.D.