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October 4, 2010

Donald Berwick, MD, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: OCIIO–9989–NC
P.O. Box 8010
Baltimore, MD 21244–8010.

Dear Dr. Berwick:

The National Kidney Foundation, a voluntary health agency with 50,000 members nationwide, serving the needs of kidney patients, organ transplant candidates, and organ transplant recipients for almost 60 years, appreciates the opportunity to comment on the planning and establishment of state-level exchanges authorized by Title 1 of the Patient Protection and Affordable Care Act. We are responding to the notice in the ***Federal Register*** for August 3, 2010, from the Office of Consumer Information and Insurance Oversight, file code OCIIO–9989–NC.

Our response relates to the invitation to comment on factors in establishing minimum requirements for level of coverage of qualified health plans in state exchanges, regional or intestate exchanges, or an exchange operated by the federal government on behalf of states that do not elect to establish an exchange. It is also relevant to "General Requirements for Exchanges," specifically the minimum functions that an Exchange must perform. We maintain that the needs of individuals with chronic kidney disease (CKD), including but not limited to those with kidney failure or End-Stage Renal Disease (ESRD), who require chronic dialysis or a kidney transplant to survive, must be considered in the planning and establishment of these exchanges.

It is estimated from NHANES data that 26 million adult Americans have CKD. Furthermore, NHANES data also indicate that the proportion of individuals who were aware that they had weak or failing kidneys was low. The increase in the prevalence of CKD is due in part to the growing burden of diabetes and hypertension in this country. Nevertheless, there is evidence from randomized controlled trials that interventions are effective in slowing the progression of CKD for adults at increased risk because of hypertension and/or diabetes. Exchange plans should cover preventive services which would (a) identify individuals at risk for CKD or in the early stages of CKD, and (b)
manage CKD, and the diseases that accompany it, to delay or prevent progression.

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For those individuals whose CKD has progressed to kidney failure, exchange plans should provide access to year-round dialysis treatments, and all modalities of dialysis therapy (including home dialysis alternatives), as well as the medications that are needed to manage CKD complications, and the option of a kidney transplantation, for medically- eligible individuals. Furthermore lifetime coverage of immunosuppressive medications needed by kidney transplant recipients to avoid rejection of their grafts should be required.

As the result of Social Security amendments in 1972, most dialysis patients and kidney transplant recipients are eligible for Medicare coverage, regardless of age. Transplant recipients receive Medicare benefits for post-transplant care, including prescription drugs. Similarly, Medicare covers up to 3 dialysis treatments per week, without a time limit, as well as the dialysis-related medications that are needed to manage the complications of chronic kidney disease. However, in order to qualify for Medicare ESRD benefits, one must contribute to the Social Security system for 40 quarters. Thus many individuals with kidney failure may not be eligible for Medicare and could be covered by exchange plans. Additionally, many individuals on dialysis prefer the comprehensive benefits available from private insurance to the Medicare ESRD program.

Conversely, Medicare benefits for kidney transplant recipients terminate three years after their receipt of a transplant, if they are not entitled to Medicare disability coverage or have not reached Medicare age, even though organ transplant recipients must take immunosuppressive drugs daily for the lifetime of their transplant to reduce the likelihood of organ rejection. After Medicare benefits terminate, transplant recipients face the challenge of securing affordable health insurance coverage and are often forced to rely on a patchwork of state and pharmaceutical company assistance programs to obtain their immunosuppressive drugs. Availability of lifetime coverage for immunosuppressive drugs in exchange plans would enable more kidney patients to consider the option of transplantation, which over the long term, and for appropriate candidates, is more cost-effective than dialysis. Availability of lifetime coverage for immunosuppressive drugs, and year-round coverage for dialysis services, in exchange plans, can contribute to the ability of many individuals with kidney failure to remain active in the work force as tax-paying citizens, and help them to avoid the need to spend down to qualify for Medicaid payment for dialysis or transplant-related care. Furthermore, lifetime coverage for immunosuppressive drugs in exchange plans would mitigate avoidable transplant rejection. With 86,000 Americans waiting for a kidney transplant and fewer than 17,000 kidney transplants performed in 2009, it is a tragedy to lose a

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single donated kidney because of inability to access coverage for immunosuppressive medications.

Finally, we believe that exchange plan coverage for year-round dialysis services and lifetime immunosuppressive drug benefits should be considered an essential health benefit as defined in Section 1302 of the Act. That section, "Essential Health Benefit Requirements," includes several considerations for defining essential health benefits. For example, essential health benefits should (1) take into account the health care needs of diverse segments of the population including women, children, persons with disabilities, and other groups; and (2) should not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life.

Sincerely,

Bryan Becker

Bryan N. Becker, MD
President
National Kidney Foundation, Inc.

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30 East 33rd Street ● New York, NY 10016 ● Tel 800.622-9010 or 212.889.2210 ● Fax 212.689.9261 ● www.kidney.org