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September 27th 2011

Lisa J. Wilson
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-9989-P
P.O. Box 8010,
Baltimore, MD 21244-8010.

Dear Ms. Wilson:

The National Kidney Foundation (NKF), the nation's oldest and largest organization advocating on behalf of kidney patients, appreciates the opportunity to comment on the Proposed Rule, "Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans" that was published in the Federal Register for July 15, 2011 [Attention: CMS-9989-P]. As stated in our letter to Dr. Berwick dated October 4, 2010, 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 maintenance dialysis treatments or a kidney transplant to survive, must be considered in the planning and establishment of these exchanges. Our recommendations for the Final Rule follow.

1. **Definitions** (Section 155.201) (Qualified Individual): Health insurance coverage offered through an exchange should be available to individuals who are eligible to enroll in Medicare (say, for example, because of End Stage Renal Disease) but have not yet done so. An individual who qualifies for Medicare on the basis of ESRD but is not enrolled in the program is not "eligible for coverage" but simply "eligible to enroll." See, for example, section 1836 of the Social Security Act which reads: "Every individual who... (1) is entitled to hospital insurance benefits under Part A, or (2) has attained age 65 and is a resident of the United States... is *eligible to enroll* (for Part B Benefits)..." (Emphasis added.) Many individuals on dialysis prefer the comprehensive benefits available from private insurance to those provided pursuant to the Medicare ESRD program.
2. **Functions of an Exchange** (Section 155.200): In response to the request for comments regarding other functions that should be required of an Exchange, Exchanges should be charged with ensuring that insurers participating in the exchanges do not discriminate against individuals with certain chronic diseases, such as CKD or ESRD. Section 1302 of the Affordable Care Act provides that coverage decisions, and/or design benefits should not discriminate against individuals because of their age, disability, or expected length of life. Some examples of discriminatory practices that should be precluded follow.

- a) Utilization control strategies may discriminate against individuals with kidney failure or end-stage renal disease. Individuals who have experienced kidney failure require dialysis treatments at least three times per week, 52 weeks per year, or a kidney transplant to survive. Limiting the number of covered dialysis treatments per week or per year would be a discriminatory practice. Individuals with End Stage Renal Disease who have received a kidney transplant need coverage for the drugs that prevent the rejection of their kidneys and often must rely upon a combination of pharmacologic agents to keep their transplanted kidneys functioning. Medicare recognized the need to assure access to all the various anti-rejection medications in the Part D program by including them among the list of protected drug classes. Insurance that limits the type of immunosuppressive drugs covered or the period of time during which they are covered would be discriminatory against individuals with ESRD.
- b) Exchanges should evaluate the adequacy of provider networks in exchange-based health insurance since this could also be a form of discrimination. (Please see section 6, below.)
- c) Exchanges should ensure that services will be covered when the insured has to travel to different parts of the country on business or to take care of family responsibilities. Since dialysis is a life-preserving service, failure to cover “transient dialysis” would be a discriminatory practice.
3. Termination of Coverage (Section 155.430) The ability of an Exchange to terminate coverage (or a Qualified Health Plan issuer to terminate coverage) when the enrollee has other minimum essential coverage should not be exercised when the insured becomes eligible to enroll in Medicare if the insured has not actually enrolled in Medicare. (Please see paragraph #1, above.)
4. Subpart H - Small Business Health Options Program (SHOP).
To maintain parity between coverage inside and outside of the exchanges, there should be consistent application of the Medicare Secondary Payer (MSP) law. Since members of private health plans often have lower out-of-pocket costs and wider choice in providers than Medicare beneficiaries, an employee with ESRD enrolled in a QHP through the SHOP should have the right to keep the health plan of their choice for 30 months before switching to Medicare.

5. Certification Standards for Qualified Health Plans (Section 155.1000)
Exchanges should not certify health plans with design benefits that discriminate against individuals with certain chronic diseases, such as CKD or ESRD.

6. Network Adequacy Standards (Section 156.230). Since most dialysis patients require dialysis treatments three times a week (and each treatment lasts three to four hours), there should be a sufficient choice of hemodialysis providers within a reasonable transit time from the patient's home (e.g. 30 minutes). Shorter travel times and distance to dialysis clinics have been associated with improved patient outcomes and a higher health-related quality of life. M. J. Diamant, et al. A Comparison of Quality of Life and Travel-Related Factors between In-center and Satellite-Based Hemodialysis Patients *Clin J Am Soc Nephrol* 5: 268–274, 2010. If dialysis patients encounter problems keeping appointments because of transit demands, missed or shortened treatments may result. Compared with other dialysis patients, those who missed one or more dialysis sessions in a month had a 25% higher risk of death. Patients who shortened three or more dialysis treatments in a month had a 20% higher risk of death than those who received the prescribed treatment. J.E. Leggat, et al, Noncompliance in Hemodialysis: Predictors and Survival Analysis, *Am J. Kidney Dis.* 1998 Jul;32(1):139-45. Additionally, patients who miss dialysis treatments may need to seek expensive care in hospital emergency departments.

Thank you very much for your consideration of these comments.

Sincerely,

Lynda A Szczech

Lynda A Szczech, MD

President

National Kidney Foundation, Inc.