



National
Kidney
Foundation™

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

December 18, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Patient Protection and Affordable Care Act; 2017 Notice of Benefit and Payment Parameters

Dear Acting Administrator Slavitt,

The National Kidney Foundation (NKF) appreciates the opportunity to comment on the Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters for 2017. NKF is America's largest and oldest health organization dedicated to the awareness, prevention, and treatment of kidney disease for hundreds of thousands of healthcare professionals, millions of patients and their families, and tens of millions of people at risk. In addition, NKF has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (NKF KDOQI). We also provide professional and patient education, patient support services, and community health programs. We work with volunteers to offer the scientific, clinical and kidney patient perspective on what needs to be done to prevent kidney disease, delay progression, and better treat kidney disease and kidney failure. NKF has local division and affiliate offices serving our constituents in all 50 states.

We appreciate the great progress HHS has made in issuing guidance to reduce discrimination against individuals with chronic conditions, including those with kidney disease. This proposal adds to this progress by calling for quantifiable network adequacy standards, developing a standard benefit option, and proposing standards to protect beneficiary's continuity of care. However, there remain a number of needed clarifications to better protect beneficiaries with kidney disease from practices that specifically impede their access to care and prescription medications. As a result NKF offers comments and recommendations on the following issues:

- Medicare eligibility and End-stage Renal Disease: NKF requests the final notice clarify that issuers are not able to terminate coverage, limit benefits, or use non-negotiated rates subjecting patients to balance billing charges that do not count towards the patient's out of pocket maximum based on a their eligibility for Medicare due to ESRD.

- **Access to Medications and the Standardized Option:** NKF recommends rather than encouraging the development of a standardized benefit option, that HHS go further to protect patients with chronic conditions from adverse selection and cost-shifting by requiring all plans to cover prescription drugs immediately, before deductibles are met, and to encourage copayments be used for all generic drugs. In addition, criteria should be established for the placement of drugs on a specialty tier and cost-sharing across all tiers should be capped at a reasonable amount.
- **Network Adequacy:** NKF strongly supports the proposal to require states to issue quantifiable network adequacy standards regarding time and distance and number of providers across provider types.
 - Drive time and distance standards: NKF supports HHS action to develop a minimum Federal network adequacy standard for drive time and distance to providers and that this standard is based on what is used for Medicare Advantage plans. Should HHS determine that state network adequacy geographical standards do not meet HHS criteria, we appreciate that the Federal standard would be used as the default for 2017.
 - Provider types and wait times: NKF urges HHS to finalize a quantifiable minimal standard that ensures an adequate number of nephrologists, dialysis facilities and transplant centers to ensure patients have options in where they receive care.
- **Continuity of Care:** NKF urges HHS to finalize its proposal to ensure that individuals undergoing active treatment maintain access to their provider for 90 days in situations where the provider is terminated by the plan or the contract with the provider is not renewed without cause, and that the provider still be considered an in-network provider in terms of cost-sharing for patients. In addition we request CMS specifically include ESRD patients on dialysis in the list of examples for “a serious acute condition as a disease or condition requiring complex on-going care which the covered person is currently receiving.”
- **Third Party Payments:** NKF urges HHS to notify issuers that plans must accept third party payments from non-profit charitable organizations that existed prior to the enactment of the ACA, have been reviewed favorably by the OIG, and offers assistance for the purchase of any coverage option, including the American Kidney Fund.

Medicare Eligibility and ESRD

Under the Medicare ESRD program, most individuals are eligible for Medicare when they are diagnosed with ESRD regardless of their age. However, they are not required to enroll in Medicare.¹ IRS Notice 2013-41 issued in June 2013 clarified that ESRD patients could keep tax credits and

¹ Sec. 226A of the Social Security Act; 42 U.S.C. 426-1; 42 C.F.R. § 406.13(c).

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

subsidies to maintain QHP coverage as long as the patient did not enroll in Medicare.² In addition, Section 226A of the Social Security Act gives eligible ESRD patients the option to enroll in Medicare, but does not require them to do so. Regardless, we have found that QHP issuers in several states have included language that discriminates against ESRD patients by basing coverage or benefits on eligibility rather than enrollment. Given this, **NKF requests the final notice clarify that issuers are not able to terminate coverage, limit benefits, or use non-negotiated rates subjecting patients to balance billing charges that do not count towards the patient's out of pocket maximum based on a patient's eligibility for Medicare due to ESRD. Doing so discriminates against a patient with ESRD and could cause them to feel they have no other option but to enroll in Medicare, even when that may not be in their best interest.**

While most individuals do choose Medicare coverage, there are patients who decide Marketplace coverage over Medicare better meets their financial, family and health needs. For example, patients who are not eligible under their state's Medicaid program, or for the Medicare Savings Program and who enroll in Medicare without access to secondary coverage, are subject to paying Medicare premiums in addition to a 20% coinsurance under Medicare Part B for each dialysis treatment, out-patient office visit, and non-ESRD related injectable medications. This is in addition to the premium and out-of-pocket costs they incur if they have prescription drug coverage under Medicare Part D. On average a dialysis patient can incur approximately \$7,188 or more annually in out-of-pocket expenses just on coinsurance alone for dialysis.³ While Medigap coverage is available in some states, 22 states do not allow ESRD patients under 65 to enroll in Medigap. Even in many of the states that do offer coverage to ESRD patients, the premiums are high and cost-prohibitive. In contrast, QHPs have a cap on total out-of-pocket costs for medical services and prescription drugs and for patients making 100-250% below FPL, that cap is lowered even more on Silver level plans. In addition, patients may wish to maintain Marketplace coverage because their family can also share in that plan, benefiting from family deductibles and out-of-pocket maximums.

Access to Medications and the Standardized Option

Affordability of medications and transparency of costs remains a problem for beneficiaries with chronic conditions as insurers continue to look for ways to cost-shift to patients through benefit designs and tier placement practices that are not and were not seen in employer plans pre-ACA. While we appreciate language in the 2016 Notice of Benefits and Payment Parameters that placement of all or nearly all drugs used to treat a chronic condition on the highest cost-sharing tier

² IRS Notice 2013-41 issued June 2013 states, *[T]his notice clarifies that, for purposes of the premium tax credit, an individual is eligible for minimum essential coverage under Medicaid or Medicare in the circumstances described below only upon a favorable determination of eligibility by the responsible agency:*

- 1. Medicaid coverage requiring a finding of disability or blindness.*
- 2. Medicare coverage based solely on a finding of disability or illness.*

³ Methodology: Assumes Medicare reimbursement rate of \$230.39 per dialysis treatment (2016 final unadjusted base rate) and that the patient receives 156 treatments per year in an out-patient dialysis facility.

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

could be discriminatory, NKF requests that HHS take an affirmative stance in final regulations that this is prohibited practice.

NKF commissioned a study by Avalere Health that shows while most Silver exchange plans use flat copayments for generic immunosuppressive medication, for any given drug 19-32% of exchange plans are using coinsurance. The average amount of patient coinsurance across generic and brand immunosuppressive drugs is 36% with three plans requiring coinsurance for immunosuppressive drugs up to 60%. The use of coinsurance typically results in patients paying more for their drugs. There is also a lack of transparency for the dollar amount they will have to pay to fill their prescriptions.

When coinsurance is used, the average patient cost-sharing across all Silver exchange plans is 36% of immunosuppressive medications. The portion patients are being required to pay can easily meet the annual out-of-pocket maximum.

PERCENT OF PLANS WITH COST-SHARING TYPE AND RANGE OF AMOUNT, FOR SELECTED IMMUNE SUPPRESSANTS, SILVER PLANS, 2015

	Coinsurance	Copayment
Percent of Plans Applying Cost Sharing Type	40%	60%
Average Cost Sharing Amount	36%	\$38
Min/Max Cost Sharing Amount	0% to 60%	\$0 to \$395

Source: Avalere Health PlanScape®, a proprietary analysis of exchange plan features, November 2015. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

NKF is encouraged by proposed patient protections in the development of the standardize benefit options. The proposal that prescription drugs not be subject to deductibles, the encouragement that copayments be used instead of coinsurance, and the limitation to four tiers for formularies are exactly the types of protections and the transparency that individuals with chronic conditions need to access their medications. However, NKF believes protections should be required across all plans in the exchanges rather solely used in an optional benefit design.

Additionally, NKF is concerned that under the standardized option, formularies may be more restrictive – listing fewer drug options and thus limiting their usefulness to some individuals with

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

chronic conditions. NKF has also identified some plans arbitrarily placing immunosuppressive drugs, including generics, on specialty tiers by classifying them as specialty pharmacy.

NKF recommends that rather than encouraging the development of a standardized benefit option, HHS go further to protect patients with chronic conditions from adverse selection and cost-shifting by requiring all plans to cover prescription drugs immediately, before deductibles are met, and to encourage copayments be used for all generic drugs. In addition, criteria should be established for the placement of drugs on a specialty tier and cost-sharing across all tiers should be capped at a reasonable amount.

Network Adequacy

NKF strongly supports the proposal to require states to issue quantifiable network adequacy standards regarding time and distance and number of providers across provider types. NKF has advocated for quantifiable standards with HHS and the National Association of Insurance Commissioners (NAIC).

NKF supports HHS action to develop a minimum Federal network adequacy standard for drive time and distance to providers and that this standard is based on what is used for Medicare Advantage plans. Should HHS determine that state network adequacy geographical standards do not meet HHS criteria, we appreciate that the Federal standard would be used as the default for 2017. We were disappointed that the NAIC Network Adequacy Model did not identify such quantifiable time and distance standards. Such a standard is vital for dialysis patients.

Given that dialysis patients typically receive treatment in an outpatient facility three times per week for four hours a day, it is important that patients not be required to commute a significant distance to obtain treatment. Shorter travel times and distance to dialysis clinics have been associated with improved patient outcomes and a higher health-related quality of life.⁴ 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.⁵ Additionally, patients who miss dialysis treatments may need to seek expensive care in hospital emergency departments. To help protect patients from having to commute further from their home or work to a dialysis facility, we strongly encourage HHS to finalize this quantifiable minimal time and distance standard.

NKF also supports the establishment of quantifiable metrics to assess sufficient access to provider types that take into account wait times. We appreciate the development of a tool that allows

⁴ 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.

⁵ J.E. Leggat, et al, Noncompliance in Hemodialysis: Predictors and Survival Analysis, *Am J. Kidney Dis.* 1998 Jul;32(1):139-45.

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

patients to search through plans to determine which plans have their providers in network. Given that kidney disease is a progressive disease, patients may need access to different services at different stages of disease. Kidney patients need to consider access to primary care practitioners, nephrologists, dialysis centers and transplant centers in addition to providers who take care of their other health needs. NKF [tailored a tool](#) to help kidney patients identify the provider types and services they may need now and in the future and the ability to search by provider and provider type in the federal market place helps make this process simpler for patients. We look forward to enhancements of the tool in the future. **However, without quantifiable metrics for number of nephrologists, dialysis facilities and transplant centers, patients will find their options for plans that encompass the health care services they need very limited. NKF urges HHS to finalize a minimal standard that ensures an adequate number of these types of providers so that patients have options.**

Continuity of Care

NKF appreciates HHS addressing the need for individuals with chronic conditions to maintain access to their healthcare providers when they are undergoing an active treatment. **We urge HHS to finalize its proposal to ensure that individuals undergoing active treatment maintain access to their provider for 90 days when the provider is terminated by the plan without cause and that the provider still be considered an in network provider in terms of cost-sharing to the patients. We also encourage HHS to extend this proposal to ensure patients undergoing active treatment, with a provider whose contract is non-renewed as termination without cause, are able to continue seeing that provider. While patients with ESRD meet the proposed definitions and criteria for “active treatment,” we request CMS specifically include ESRD patients on dialysis in the list of examples for “a serious acute condition as a disease or condition requiring complex on-going care which the covered person is currently receiving.”**

Third Party Payer

NKF appreciates HHS is considering requiring issuers to accept third party payments from non-profit charitable entities. The American Kidney Fund (AKF) has provided premium and cost-sharing assistance to dialysis patients for many years – affording them the option to maintain health insurance coverage of their choice. As highlighted above ESRD patients are not required to enroll in Medicare and while Medicare is considered credible coverage, there are certain circumstances where Medicare coverage is less affordable than Marketplace coverage and additional reasons some patients desire maintaining private coverage. The AKF program helps protect dialysis patients’ choice in insurance coverage and makes accessing healthcare services and dialysis services more affordable for patients whether they choose Medicare (with Medigap coverage), Medicaid, or private coverage. The HHS Office of the Inspector General has approved arrangements such as the American Kidney Fund’s Health Insurance Premium Program (HIPP) and stated that is a program that “will expand, rather than limit, beneficiaries’ freedom of choice.”⁶ **NKF urges HHS to notify issuers that plans must accept third party payments from non-profit charitable organizations that existed**

⁶ HHS OIG, Advisory Opinion No. 97-1, June 11, 1997.

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

prior to the enactment of the ACA, have been reviewed favorably by the OIG, and offers assistance for the purchase of any coverage option, including the AKF.

In sum, NKF appreciates the progress made over the years to protect individuals with kidney disease access to health care services and coverage of their choice. We look forward to partnering with HHS on strengthening these protections and ensuring that patients with kidney disease have affordable access to coverage and care. If you have any questions please contact Tonya Saffer, Senior Health Policy Director at tonya.saffer@kidney.org or at 202.244.7900 extension 717.

Sincerely,

Jeffrey Berns

Jeffrey Berns, MD
President