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January 11, 2017

Mr. Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard,
Baltimore, MD 21244-1850

Re: CMS-3337-IFC: Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities--Third Party Payment

Dear Acting Administrator Slavitt,

The National Kidney Foundation (NKF) appreciates the opportunity to comment on the interim final rule Medicare Program; Conditions for Coverage for End-Stage Renal Disease (ESRD) Facilities--Third Party Payment. NKF is pleased the agency has taken steps to require patients to be thoroughly educated on their insurance options as we recommended in our September 22, 2016 comments on the Centers for Medicare & Medicaid Services (CMS) Request for Information (RFI): Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans [CMS-6074-NC]. We agree that patients want and need better education to help them understand their insurance options and the short-term and long-term coverage and cost implications of those options. However, CMS should not place barriers to kidney patients accessing charitable, third party premium assistance for the insurance coverage of their choice. In addition, we have many concerns with this interim final rule and its impact on patient care, lifestyle, and finances. We strongly encourage the agency to withhold implementation of the rule and instead issue a proposed rule, with revised content, and at least a 30-day public comment period. In addition, we offer the following recommendations and comments on this interim final rule:

1. CMS, not dialysis facilities, should develop the required education in consultation with kidney patients, patient advocates, dialysis facility staff and transplant center staff. This education should

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not be limited to Marketplace plans, but should be comprehensive of all insurance options available to ESRD patients.

2. Require all dialysis facilities, not just those that contribute to third party premium assistance programs, to have an appropriately trained person on staff to educate patients on their insurance options or ensure patients receive education by a knowledgeable third party

3. Remove any assumption or reference to social workers being responsible for implementing the new educational requirements in the calculation of time and costs for implementing this final rule. Many dialysis facilities employ insurance counselors and time and cost assumptions for education and counseling should be attributed to this role rather than setting up the expectation that this will become an additional responsibility for social workers. While we recognize social workers currently provide information on insurance options to patients and help answer their questions, this new detailed level of information is an additive responsibility that should not fall on social workers and would be best provided by someone with specialized insurance training.

4. Require dialysis facility staff functioning as insurance counselors to undergo the CMS Certified Application Counselor Program training. The time involved in the training and the associated costs of the training should also be factored in total budget impact. Consider the same requirement of transplant centers who have staff that counsel patients on insurance.

5. Remove the requirement that dialysis facilities contact the Marketplace issuers to obtain permission for patients receiving third party premium assistance to enroll in their plans. Instead, require insurers who do not accept third party premium payments to alert CMS and the dialysis facilities each year.

6. Do not remove the ability of patients to receive premium assistance to enroll in the coverage option of their choice, including Marketplace plans – patients should not have limited options because of perceived or actual bad actors.

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1. **Development of Educational Materials**

NKF supports the development of educational materials that disclose to ESRD patients their insurance options, the cost of those options and the implications of those options as it relates to transplantation. This will help patients and their families better understand and consider their options in the context of their short-term and long-term health care needs. However, to ensure educational materials are transparent, consistent, and at an appropriate literacy level, NKF recommends that CMS, not dialysis facilities, develop the required materials.

In addition, NKF has concerns with the assumptions made that dialysis facility administrative assistants and managers universally have the training and skills necessary to conduct research and develop the required educational tools needed to meet the new requirements. The development of these materials and the ability to identify the required information on coverage and cost for each individual Marketplace health plan offered in the facility's geographic location and compare it to public coverage options including Medicare and Medicaid requires familiarity with insurance products and terminology. In addition, allowing each facility or provider to develop this material on their own is likely to result in differences in the quality and consistency of the information provided to patients, leaving them continually vulnerable to misinformation and potential steering.

For these reasons, we recommend that CMS develop the required educational materials and do so in consultation with kidney patients, patient advocates, dialysis facility staff and transplant center staff. The materials should be factual, unbiased and empower patients to make decisions based on their individual healthcare and financial needs. The should also include information on all patients' options including availability and cost of Medigap plans in their area. We also strongly recommend that CMS include both dialysis and transplant social workers in the development of insurance educational materials and that these materials be used in both dialysis facilities and kidney transplant centers. This will help to ensure patients receive consistent education about choosing coverage that meets their dialysis and transplant needs.

2. **Educating all ESRD patients**

In our comments on the CMS RFI, we noted in our national online survey results that 60% of patients felt knowledgeable about all their insurance options – leaving substantial room for improvement in education. Many patients have substantial difficulty understanding their options and even understanding their coverage once they select an option; therefore, having materials to help with decision making and refer back to is crucial. This is true for private insurance plans as well as for Medicare, Medicaid and Medigap. We do not believe the requirement of education should be unique only to providers who contribute to third party premium assistance programs. All ESRD patients should have the opportunity to receive education about their insurance options. Most ESRD patients are counseled about insurance decisions by their dialysis clinic staff and transplant center staff regardless of whether that facility contributes to and/or enrolls patients in third party

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premium assistance. Therefore, if CMS advances these new requirements, NKF recommends they be extended to all dialysis facilities that engage in counseling or advising patients about their insurance options. We also encourage CMS to consider similar requirements for transplant centers that have staff who advise or counsel patients on insurance options.

We recognize this requirement is likely to impose a significant time and cost burden, particularly on small facilities and providers. Therefore, we suggest that CMS consider alternatives to allow all ESRD patients, regardless of where they receive dialysis, to have the opportunity to receive the same quality of education on all their insurance options. For example, CMS could consider allowing dialysis facilities to refer patients for insurance education to a knowledgeable third-party entity to meet the education requirements of this rule. This third-party entity should understand ESRD patients' healthcare needs, the ESRD Medicare program, and all coverage options available to ESRD patients, and have undergone CMS certified marketplace navigator or application counselor training programs. To ensure that these third parties are well versed in the insurance options available to ESRD patients and their unique healthcare needs, CMS could integrate this information into the Marketplace certified navigator and counselor training programs.

3. **Assumption of additional responsibilities on dialysis social workers**
As we stated in our September 22, 2016 comments on the CMS RFI, Nephrology social workers are not trained as insurance counselors. The time it would take them to navigate insurance options and assist patients in applying for coverage would take away from their current responsibilities. While currently many nephrology social workers do discuss patients' insurance options and help patients navigate public options like applying for social security benefits, enrolling in Medicare, and Medicaid, this interim final rule poses significant additional educational responsibilities that nephrology social workers believe will take away from their core responsibilities and are beyond the scope of their license and training. Additionally, to really ensure patients understand the education that is to be received under this rule would take considerably more time than CMS has estimated. Proper education and understanding results from repetition and assessment of comprehension.

More insurance options are available to dialysis patients as a result of the Affordable Care Act (ACA) and more will be coming, with Medicare Advantage plans universally available to dialysis patients beginning in 2021. The educational needs of ESRD patients about their insurance options will continue to increase. Nephrology social workers with their current caseloads and responsibilities cannot be expected to continue to have a large role in educating on and navigating health insurance options and still meet the health and social welfare needs of their patients.

In April 2015, NKF submitted comments on the ESRD Conditions for Coverage (CfC) and provided data highlighting that nephrology social workers across the country have experienced notable increases in their caseloads (> 40%) and required job tasks (> 80%) since the implementation of the

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2008 CfCs.[1] High nephrology social work caseloads have been linked to decreased patient satisfaction and less successful patient rehabilitation outcomes.[2] In addition, dialysis survey citations for V552 ("The interdisciplinary team must provide the necessary monitoring and social work interventions") have risen in the list of the top 25 citations among all U.S. dialysis facilities; specifically, from 21st place in fiscal year 2010 to 11th place in fiscal year 2011.

Thus, we strongly urge CMS to remove any reference in the updated CfCs to nephrology social workers having responsibility for delivering insurance education. However, we recognize the substantial need for ESRD patients to have access to a qualified professional that can help educate patients on their insurance options and help answer their insurance questions. Therefore, we recommend this responsibility be assigned to insurance counselors. For facilities that do not employ insurance counselors, we reiterate our above recommendation that allows facilities to refer patients to a knowledgeable third-party entity.

NKF also encourages CMS to take this opportunity to also update the CfCs (or the interpretive guidance) to include our prior recommendations related to sufficient staffing is as intended in all dialysis units. Specifying the responsibilities of nursing staff, dietitians, and social workers, as is done for the Medical Director, so that facilities are not assigning inappropriate tasks to these professionals, may improve these highly skilled and trained professionals' abilities to perform the clinical responsibilities that are central to maintaining and improving patient care.

4. **Insurance Counselor Training**
As a result of this new requirement for dialysis facilities to specifically educate on Marketplace options, staff functioning as insurance counselors should be required to undergo the certified marketplace navigator or application counselor training programs. This will help to ensure they have the appropriate knowledge to assist patients and deliver information to patients consistently across the country. CMS should consider a similar requirement of staff counseling patients on insurance in kidney transplant centers as there continues to be confusion among

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[1] Merighi, J. R., Browne, T., & Bruder, K., Caseloads and salaries of nephrology social workers by state, ESRD Network, and National Kidney Foundation region: Summary findings for 2007 and 2010, Journal of Nephrology Social Work, 2010: 34; 9-51.

[2] Callahan, M. B., Moncrief, M., Wittman, J., & Maceda, M. Nephrology social work interventions and the effect of caseload size on patient satisfaction and rehabilitation interventions. Journal of Nephrology Social Work, 1998: 18; 66–79.

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patients who receive different advice from their dialysis facility than they do from the staff at the transplant center.

Many transplant centers begin the process of intake with a financial evaluation by phone so that no initial appointment or evaluation will be scheduled without passing the first financial assessment hurdle. This emphasizes how important the insurance aspects are for patients. From the perspective of the transplant center, they do not wish to allocate a scarce kidney to a patient who cannot afford the immunosuppressive therapy. Misinformation about options and drug coverage has considerable importance in this space. NKF appreciates that CMS recognizes this, but it should not be used as rationale to limit patients access to premium assistance and insurance coverage that they determine will best meet their health and financial needs... Consistency in the education delivered to the patients will ensure that patients are empowered to make independent, but informed decisions about their insurance coverage options.

For example, one patient whose kidneys failed while he was self-employed and enrolled in a Platinum level Marketplace plan was advised by his dialysis facility to maintain his coverage because it was more comprehensive (90% actuarial value with out-of-pocket caps) than what Medicare could provide. This individual was happy to keep his Marketplace plan and grateful for the charitable assistance he received to pay his premiums when he could no longer work, but when he went to be evaluated for a kidney transplant he was told to drop his Marketplace coverage and enroll in Medicare right away – even though the transplant was not imminent for him. He followed the advice of his transplant center, believing this would be a better option because Medicare covered the costs of a living donor. However, since enrolling in Medicare he's had substantially higher out of pocket costs because he has been unable to obtain a supplemental policy and he still has not received a transplant.

This anecdote and many others reinforce the National Kidney Foundation's position that anyone counseling or advising kidney patients on whether to keep or forgo Marketplace coverage should be required to receive the same level of training so they can best help their patients make informed decisions.

5. **Obtaining Permission from Insurance Companies to Accept Third Party Premium Payments**
NKF disagrees with the requirement that dialysis facilities that contribute to third party premium programs be required to contact the insurance company to obtain permission from the issuer that they will accept third-party premium assistance. This will lead to patients not being able to access the insurance coverage of their choice and puts inappropriate regulations on access to non-profit charitable assistance. Rather, to improve transparency, prevent delays in coverage, and ensure all patients are protected from adverse selection, the plan issuers should provide annual written

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notification to dialysis facilities and to CMS on their policies regarding third party premium assistance for dialysis patients and not be permitted to change those policies mid-year.

6. **Maintaining ESRD Patients Right and Access to their Choice of Coverage**
While NKF does not provide third party premium assistance, we believe the existence of these programs help people with chronic illnesses, including dialysis patients, obtain the most comprehensive insurance coverage that best allows them to receive and afford all the essential health care services based on their individual health and financial needs. NKF, along with many kidney patients, continues to urge CMS to require all insurers accept third-party premium assistance for any coverage option a patient chooses, so long as the premium assistance is provided by a non-profit charitable organization that adheres to appropriate firewalls to prevent misuse of funds as the American Kidney Fund Health Insurance Premium Program is required to do under the Office of Inspector General (OIG) Advisory Opinion. We note that some patients have been surprised to learn that charitable third-party premium assistance provided by the American Kidney Fund ends in the next payment period following transplant. NKF believes patients also need to receive better education on this, prior to enrollment in the program, to understand the cost implications post transplant.

   As we have pointed out and CMS has noted in this interim final rule, options other than Medicare, including the Marketplace plans, are available to ESRD patients. However, this interim final rule makes it much less likely that patients who choose and truly may benefit from a Marketplace plan could get one or keep their current policy. While NKF is very concerned about the alleged inappropriate practices of some providers steering patients, we believe the answer is to ensure ESRD patients receive better education that empowers them to make informed decisions, not prohibitions against charitable assistance. Therefore, we strongly urge CMS not to move forward with an alternative proposal to ban charitable assistance offered to dialysis patients enrolling in the Marketplace.

   While most patients depend on Medicare and are extremely grateful for the opportunity to enroll when their kidneys have failed, many strongly believe they should have the same rights as other patients with chronic illnesses to choose the insurance option that they feel best serves their health and financial needs. Patients also believe they should be able to receive charitable assistance to support their choice in coverage. The ESRD program was intended to help patients access and afford dialysis and transplantation, but it was not intended to require patients to enroll or limit their options.

NKF urges, CMS to not allow this rule to go into effect and instead replace it by issuing a proposed rule, with revised content, and at least a 30-day public comment period with thoughtful consideration of those comments, particularly those made by kidney patients and kidney patient advocacy organizations.

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We appreciate the opportunity to comment on the interim final rule before it's effective date. NKF hopes our recommendations will be considered and included in the issuing of a new proposed rule. We would be happy to further discuss our recommendations and offer our assistance as CMS on moving forward in a way that best protects patients' interests.

Sincerely,

Kevin Longino
Kevin Longino
Chief Executive Officer
Kidney Transplant Recipient

Joseph Vassalotti
Joseph Vassalotti, MD
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