Members of the Kidney Affinity Group
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1654-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

Dear Members of the Kidney Affinity Group:

The Alliance for Home Dialysis appreciates the time the Kidney Affinity Group took to meet with our members on Monday, February 5, 2018. We found the conversation very productive and appreciate your willingness to continue to engage with us.

As follow-up to that meeting, we would like to provide you with an outline of our major advocacy priorities related to Kidney Disease Education (KDE). The Alliance strongly believes in the necessity of KDE in ensuring that patients are educated on all treatment options, but are concerned about the low uptake of the current benefit.

Home dialysis—peritoneal dialysis (PD) and home hemodialysis (HHD)—is an important treatment option that offers patients significant quality of life advantages, including clinically meaningful improvements in physical and mental health.

Home hemodialysis (HHD) is often performed on a more frequent treatment schedule than in-center hemodialysis. More frequent dialysis makes a significant tangible clinical difference for patients, and has been cited in clinical evidence as the cause for many health-related quality of life improvements. Studies have demonstrated that more frequent hemodialysis results in faster recovery time after treatment and fewer side effects[1]; improved cardiac status[2] and survival rates[3]; and increased opportunity for rehabilitation.[4] Importantly, these benefits are seen in ESRD patients with both acute and chronic conditions.

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[1] Heidenheim AP, Muirhead N, Moist L, et al. Patient Quality of Life on Quotidian Hemodialysis. *Am J Kidney Dis.* 2003 Jul; 42(1 Suppl):36-41.
[2] Culleton, B et al. Effect of Frequent NHD vs.CHD on Left Ventricular Mass and Quality of Life. *JAMA 2007;*11
[3] Foley, R.N, D.T. Gilbertson et al. Long interdialytic interval and mortality among patients receiving hemodialysis. *New England Journal of Medicine. 2011* 365, no.12:1099-1107
[4] Blagg, Christopher. "It's Time to Look at Home Hemodialysis in a New Light." Hemodialysis Horizons: Patient Safety & Approaches to Reducing Errors. (2006): 22- 28. Web. 12 Apr 2012. http://www.aami.org/publications/HH/Home.Blagg.pdf.

Peritoneal dialysis offers significant clinical benefits as well. Studies show that PD is associated with a slower decline in residual kidney function[5], as well as superior outcomes among patients with congestive heart failure.[6] Patients on PD are also more likely to be employed[7] and report a higher level of satisfaction with their care.[8] PD has a lower overall cost of care, given the decreased time necessary from staff and lower overhead. decreased staff-to-patient ratio, and lower overhead.[9] In addition to reduced cost to the health care system, community, and patient, due to high rates of employment, society experiences fewer productivity losses.

Unfortunately, despite these benefits, only 11.6 percent of dialysis patients receive treatment at home.[10] As we discussed during our meeting, studies have shown that unbiased ESRD modality education, when offered prior to dialysis initiation, results in up to 1/3 of patients choosing a home modality.

While Medicare offers access to modality education through its Kidney Disease Education benefit, current uptake of the benefit is quite low and continues to fall. According to the United States Renal Data System (USRDS), in 2011 and 2012, less than 2% of eligible Medicare beneficiaries used the KDE benefit. Further, MedPAC concluded that in the same years, Medicare only covered KDE for approximately 4,200 patients; in 2013 that number fell to 3,600.

We look forward to collaborating with the Kidney Affinity Group as your staff members continue to think about possible changes to increase the update of the KDE benefit and other innovative approaches to patient education. Given the Kidney Affinity Group's position as a cross-sectional group covering multiple federal agencies, we are excited be a resource to you and participate in your important work.

We have divided our priorities into area. First, we encourage CMS to take action through regulation to advance KDE. Second, we hope that CMS also will take recommended action to advise Congress on legislative changes to increase access to patient education.

I. Regulatory Priorities

The Alliance believes that there are three major areas ripe for regulatory examination and activity:

a. Designation of KDE as a Preventive Service

Currently, Medicare patients typically pay a co-pay, or coinsurance, when receiving KDE services. Alliance members, particularly our physician members, are concerned that this additional payment disincentivizes both providers and patients from taking advantage of KDE;

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[5] Misra M, Vonesh E, Van Stone JC, Moore HL, Prowant B, Nolph KD. Effect of cause and time of dropout on the residual GFR: a comparative analysis of the decline of GFR on dialysis. Kidney Int. 2001;59(2):754–763.
[6] François K, Bargman JM. Evaluating the benefits of home-based peritoneal dialysis. Int J Nephrol Renovasc Dis. 2014;7:447–455.
[7] Factors affecting employment at initiation of dialysis. Muehrer RJ, Schatell D, Witten B, Gangnon R, Becker BN, Hofmann RM Clin J Am Soc Nephrol. 2011 Mar; 6(3):489-96.
[8] Griva K, Kang AW, Yu ZL, et al. Quality of life and emotional distress between patients on peritoneal dialysis versus community-based hemodialysis. Qual Life Res. 2014;23(1):57–66.
[9] Berger A, Edelsberg J, Inglese GW, Bhattacharyya SK, Oster G. Cost comparison of peritoneal dialysis versus hemodialysis in end-stage renal disease. Am J Manag Care. 2009;15(8):509–518.
[10] United States Renal Data System (USRDS), 2016 Annual Data Report: Epidemiology of Kidney Disease in the United States.

providers are reluctant to bill patients for a service provided for free in the past, and patients may not have the financial means to pay the coinsurance fee. However, CMS has the authority to add full coverage of preventive services in Medicare through the National Coverage Determination process if the new service meets certain required criteria.[11] The Alliance encourages the Kidney Affinity Group to support inclusion of KDE as a preventive service.

b. KDE in Alternative Payment Models (APMs)

Currently, only certain patients are eligible to receive KDE services, namely patients in Stage 4 of Chronic Kidney Disease. However, research shows that when patients are educated earlier, especially prior to dialysis initiation, they are more likely to choose a home modality. Therefore, the Alliance strongly believes that patients in CKD Stages 1-3 and 5 should be eligible to receive KDE. The Alliance believes that APMs, such as the ACOs, are a natural place to begin allowing KDE services for these patients and urges the Kidney Affinity Group to consider advising CMS to allow this change.

c. Reduction of Administrative Burden on Providers

Many providers invest heavily in patient education, but rarely bill for it due to the burdensome compliance regime and administrative challenges. The Alliance urges the Kidney Affinity Group to consider reforms that would decrease the administrative burden on such providers, in order to increase uptake. As discussed in our meeting, if the administrative burden is a mistaken perception, we recommend additional proactive technical assistance to providers to educate around the requirements.

II. Legislative and Additional Priorities

In addition to regulatory action, we encourage CMS to fulfill the recommendation of the Government Accountability Office (GAO) in their 2015 report, *END-STAGE RENAL DISEASE: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis,* which stated that CMS should "examine and, if appropriate, seek legislation to revise the KDE benefit."[12]

a. Expansion of Patients Eligible to Receive KDE

Currently, only certain patients are eligible to receive KDE services, namely patients in Stage 4 of Chronic Kidney Disease. However, research shows that when patients are educated earlier, especially prior to dialysis initiation, are more likely to choose a home modality. Therefore, the Alliance strongly believes that legislation should be changed to allow patients in CKD Stages 1-3 and 5 to receive KDE.

b. Expansion of Providers Able to Bill for KDE

[11] https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html
[12] https://www.gao.gov/assets/680/673140.pdf

Under current law, the "qualified person[s]" who can provide KDE services are limited to a physician, physician's assistant, nurse practitioner, or clinical nurse specialist.[13] While these clinicians are valued members of the dialysis patient care team, the Alliance strongly believes that there is a need for a multidisciplinary team (including professionals like RNs, NPs, MDs, nutritionists, and others) to provide effective KDE. Currently, many of these important people are unable to bill for their services. The Alliance hopes that the Kidney Affinity Group, or individual agency staff members therein, will encourage Congress to rethink the current and much too narrow definition of "qualified person."

c. Addition of Curriculum Around Patient Emotional Needs During KDE

Many members of the Alliance work directly with dialysis patients and are able to advocate for policy changes based on these meaningful interactions. One observation that has come up time and again is the need for patient education to cover not only training and medical information, but also to address the new emotional needs that come along with an end stage renal disease diagnosis and the news that a patient needs dialysis. Patients may experience emotions such as anger, denial, depression, and anxiety following a kidney disease diagnosis,[14] which can negatively impact their ability to truly think about and understand their condition and options. KDE sessions present an ideal time to address these complicated feelings, and the Alliance urges CMS to consider developing curriculum around this important patient need.

As discussed during our meeting, the Alliance would like to serve as a resource for the Kidney Affinity Group, particularly on Kidney Disease Education issues, as you work to decrease patient progression to ESRD and increase modality choice. Please do not hesitate to reach out to Alliance members or staff to discuss how we can work together. Please contact Michelle Seger at michelle@homedialysisalliance.org or 202-466-8700 if you have any questions.

Sincerely,

Stephanie Silverman
Executive Director

[13] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r1876cp.pdf
[14] http://www.dciinc.org/emotions/

Alliance for Home Dialysis Endorsing Members

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