June 22, 2015

The Honorable Johnny Isakson
United States Senate
131 Russell Building
Washington, DC 20510

The Honorable Mark Warner
United States Senate
475 Russell Building
Washington, DC 20510

Dear Senators Isakson and Warner:

The Alliance for Home Dialysis ("the Alliance") commends your leadership of the Finance Committee's working group to improve the delivery and coordination of care for Medicare patients with chronic conditions, and appreciates the request for recommendations for thoughtful policies to advance your mission.

Chronic kidney disease (CKD) takes a tremendous toll on patients, providers, and payers, as it requires ongoing intensive treatment. Today, over 26 million American adults are living with CKD, all of whom are at risk for eventual kidney failure or End Stage Renal Disease (ESRD). Currently, more than 636,000 Americans suffer from ESRD – an irreversible condition that is fatal without a kidney transplant or life-sustaining dialysis treatments. Of these, 430,000 are on dialysis, and that number is expected to double over the next decade.

The Alliance is a coalition of kidney dialysis stakeholders, representing patients, clinicians, providers, and industry. We have come together to promote activities and policies to facilitate treatment choice for individuals in need of dialysis and to address systemic barriers that limit access for patients and their families to the many benefits of home dialysis.

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. Currently, about 11.5% of U.S. dialysis patients receive treatment at home. However, access to treatment in the home can significantly improve patients' clinical outcomes and facilitate care coordination. Studies have demonstrated that more frequent hemodialysis, which occurs when dialysis is delivered in the home, results in faster recovery time after

treatment, with fewer side effects;[1] improved cardiac status[2] and survival rates;[3] and increased likelihood for transplantation[4] and opportunity for rehabilitation.[5]

The Alliance respectfully requests your consideration of policy changes in two areas that would improve access to home dialysis, thereby improving the care available to patients with CKD and ESRD.

1. **The Prospective Payment System (PPS) should include an appropriate and routine update of the self- and home dialysis training add-on adjustment.**

The Alliance supports a strong, stable Medicare payment system for dialysis to ensure that patients have access to all treatment modalities. Congress articulated in the creation of the Medicare ESRD benefit that "the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated."[6] In its final rule implementing the new ESRD prospective payment system (PPS), CMS echoed this commitment, stating that the new bundled payment would "encourage patient access to home dialysis"[7] and "make home dialysis economically feasible and available to the ESRD patient population."[8] Indeed, data show that the ESRD PPS—which pays for home dialysis at the same rate as it does dialysis provided in a facility—has led to an increase in the utilization of home dialysis.[9] According to the Medicare Payment Advisory Commission's (MedPAC) 2014 Report to Congress on Medicare Payment Policy, "under the new PPS, use of home dialysis, which is associated with improved patient satisfaction and quality of life, has increased modestly from 8 percent of beneficiaries to 10 percent" between January 2010 and June 2013.[10] This increase is significant, especially given that in prior years there was little growth in home dialysis, a modality that has been available to patients for many decades. The Alliance believes that payment parity in the ESRD bundled payment has had and will continue to have a demonstrable effect on the growth of home dialysis.

However, one persistent barrier to home dialysis – particularly HHD – is the cost associated with training a dialysis patient to dialyze at home. A recent paper published in the *Clinical Journal of the American Society of Nephrology* identified inadequate payment for training as a potential barrier to the expansion of HHD,[11] as the average training cost for HHD significantly exceeds the incremental CY 2014 training payment ($50.16). The ESRD Conditions of Coverage, set forth by CMS, require that home training services be provided by an experienced registered nurse (RN). This one-on-one training service can be

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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] Pauley, R.P. Survival comparison between intensive hemodialysis and transplantation in the context of the existing literature surrounding nocturnal and short-daily hemodialysis. Nephrol Dial Transplant. 2013 28: 44-47.

[4] ibid

[5] 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.

[6] Section 1881(c)(6) of the Social Security Act.

[7] 75 Fed. Reg. 49,030, 49,058 (Aug. 12, 2010).

[8] *Id*. at 49,060.

[9] Allan J. Collins, MD, FACP, "ESRD Payment Policy Changes: The New 'Bundled' Dialysis Prospective Payment System (PPS) in the United States", National Kidney Foundation Spring Clinical Meeting Presentation (Mar. 2012), *available at* http://www.usrds.org/2012/pres/USDialysisBundle_impact_NKFCM2012.pdf.

[10] Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, March 2014.

[11] Young BA, Chan C, Blagg C, Lockridge R, Golper T, Finkelstein F, Shaffer R, Mehrotra R; ASN Dialysis Advisory Group. Clin J Am Soc Nephrol. 2012 Dec;7(12):2023-32

essential to supporting beneficiaries; however, it is very time and resource intensive. Additionally, during self- and home training, the RN is responsible for teaching both the training patient and a care partner in each session.

To enable better access to the benefits of home dialysis for CKD and ESRD patients, the Alliance recommends that Congress direct CMS to use the best available information to update the dialysis training add-on payment in a way that reflects the actual costs of providing this service, and to refine this methodology over time. Any update to the training add-on should be made in a manner that avoids disparate impact on other treatment modalities. Congress should also direct CMS to allow for an inflationary adjustment to the payment. This is necessary because the payment is outside the bundled base rate, and is not adjusted by the annual market basket update. Because the "training add-on adjustment is directly related to nursing salaries,"[12] and those salaries and staffing costs increase over time, the training add-on payment should be adjusted accordingly.

2. Telehealth services should be expanded to improve access to home dialysis for ESRD patients.

The Alliance recommends that the Committee improve the current system for reimbursing providers for services provided through new technologies designed to more efficiently connect ESRD patients with the care they need. These technologies, commonly referred to under the collective term "telehealth," stand to improve care coordination, as well as create significant savings for the healthcare system. As a result, they are beginning to gain traction among private payers. However, Medicare's inadequate reimbursement of these technologies creates significant barriers for adoption throughout most of the country, and this gap is particularly impactful where ESRD patients are concerned.

The current system for telemedicine reimbursement, created in Section 1834(m) of the Social Security Act, creates a series of hurdles for practitioners wishing to incorporate these technologies into their practices. To qualify for reimbursement for visits by video conference, each interaction must meet a series of requirements. First, the patient must be located at a statutorily defined "originating" site, which does not include either the patient's home or the dialysis facility. Second, the services must be provided within a rural Health Professional Shortage Area (HPSA), a county outside a Metropolitan Statistical Area (MSA), or to be part of a federal telemedicine demonstration project. Finally, the services can only be provided by a statutorily defined list of approved practitioners.

These restrictions create a system that disincentivizes providers from adopting new technologies, and discourage innovators from developing new access and outcome bolstering technologies because they worry that they will never be reimbursed. Additionally, the statute categorically prevents the reimbursement of "store and forward" technologies, such as remote patient monitoring devices, that would allow providers to more closely track their patients' conditions.

The Alliance urges the Committee to adopt what we consider to be common-sense reforms that would allow dialysis patients to access telehealth services that could provide improved outcomes and lower costs. As an initial step, we recommend that the Committee:

1. Include the home and the dialysis facility as eligible "originating" sites for the purposes of home dialysis services;
2. Allow CMS to reimburse telehealth services throughout the country, regardless of an area's health shortage status;
3. Allow greater flexibility in which providers can bill for telehealth services;

[12] 75 Fed. Reg. at 49,063.

4. Allow for standing waivers of the monthly Medicare face-to-face requirement for physicians billing for care management of dialysis patients in the home when appropriate conditions are met, including the use of remote monitoring technologies; and
5. Create a reimbursement mechanism for remote patient monitoring technologies.

While the Alliance believes that these reforms would provide a significant improvement over the current system, we are also open to working with Members to develop new reimbursement schemes outside of the current 1834(m) rubric, or to remove the barriers to expanded use of telehealth and remote monitoring to care for dialysis patients. We recognize the potential that telehealth presents to create real savings to the healthcare system, and are dedicated to working with Congress to develop a reimbursement system that will allow for the flexibility necessary to adapt to new technologies, while also ensuring improved patient outcomes.

As you are aware, efforts have already begun in the House to reform this system. A bipartisan working group of Energy and Commerce Committee members has been working with a broad group of stakeholders to develop innovative ways to modernize the reimbursement scheme surrounding telehealth services. Chairman Upton and Ranking Member Pallone, along with Representatives Harper, Matsui, Welch, Latta, Walden, and Johnson, have already released one round of proposals for stakeholder feedback, and are working through the comments they received in developing their next draft. Given the breadth of policy issues on this topic that fall within the purview of the Senate Finance Committee, we hope the Committee will engage these Members in their process in an effort to develop consensus-based solutions.

Finally, throughout efforts to expand telemedicine, the Alliance recognizes the importance of protecting the security of personal patient information. We strongly support current HIPAA requirements, and hope that any proposal presented by the Committee will also include strong protections of patient privacy.

We greatly appreciate the opportunity to provide this feedback, and would be glad to discuss further if it would be helpful. If you have any questions, please contact Elizabeth Brooks at ebrooks@vennstrategies.com or 202-466-8700.

Sincerely,

Stephanie Silverman
Executive Director

Cc: The Honorable Orrin Hatch, Chairman
The Honorable Ron Wyden, Ranking Member

Submitting Members

American Association of Kidney Patients

American Kidney Fund

American Nephrology Nurses Association

American Society of Nephrology

American Society of Pediatric Nephrology

Baxter

The Cleveland Clinic

DEKA Research and Development

Dialysis Clinic, Inc.

Greenfield Health Systems

Home Dialyzors United

Hortense and Louis Rubin Dialysis Center, Inc.

Medical Education Institute

N.A. Chapter International Society for Peritoneal Dialysis

National Kidney Foundation

National Renal Administrators Association

Northwest Kidney Centers

NxStage Medical

Outset Medical

Renal Physicians Association

Satellite Healthcare

Southwest Kidney Institute

TNT Moborg International Ltd.