
September 8, 2015

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1631-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

**Re: CMS-1631-P: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016**

Dear Acting Administrator Slavitt:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments on its Proposed Rule updating payment policies and payment rates for services furnished under the Medicare Physician Fee Schedule (PFS) for calendar year 2016.

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 in dialysis care while addressing 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 10 percent of U.S. dialysis patients receive treatment at home.[1]

Although there has been substantial growth in home modalities, access has not kept up with patient eligibility and demand. More than 85 percent of patients with end-stage renal disease

[1] U.S. Renal Data System. USRDS 2013 Annual Data Report: atlas of chronic kidney disease and end stage renal disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, Maryland, USA; 2013.

(ESRD) are medically eligible for home dialysis[2], but home modalities are infrequently presented as an option. Between 25 to 40 percent of patients would choose a home dialysis modality if the option were presented to them. [3][4]

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;[5] improved cardiac status[6] and survival rates;[7] and increased likelihood for transplantation[8] and opportunity for rehabilitation.[9]

The Alliance believes that more patients are suitable for, and could benefit from, home dialysis. We believe that dialysis providers, health professionals (including physicians), and policymakers all play an integral role in ensuring that patients have access to the modality of their choice. Our comments identify opportunities for CMS to ensure that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation are able to make the choice and access this modality.

The Alliance offers the following comments to the Physician Fee Schedule Proposed Rule:

**Section II. E. Improving Payment Accuracy for Primary Care and Care Management Services**

The Alliance commends CMS for its recognition of the many and differing resources (particularly the cognitive work) involved in delivering broad-based, ongoing treatment to beneficiaries with chronic conditions. These resources far surpass those currently reflected in the codes describing the broader range of evaluation and management (E/M) services. The Alliance strongly supports efforts to more accurately capture the time and professional investment required to care for our nation's sickest patients, which include those managing Chronic Kidney Disease (CKD) and ESRD. These individuals, who typically manage many co-morbidities, benefit from physicians' thoughtful attention to strategizing how best to implement their care plan. This certainly includes the activities that CMS has listed in the Proposed Rule – including medication reconciliation, the assessment and integration of numerous data points, effective coordination of care among multiple other clinicians, collaboration with team members, continuous development and modification of care plans,

[2] Mendelssohn DC, Mujais SK, Soroka SD, et al. A prospective evaluation of renal replacement therapy modality eligibility. Nephrol Dial Transplant 2009; 24:555–561.
[3] Lacson E Jr, Wang W, DeVries C, et al. Effects of a nationwide predialysis educational program on modality choice, vascular access, and patient outcomes. Am J Kidney Dis 2011; 58:235–242.
[4] Maaroufi A, Fafin C, Mougel S, et al. Patients' preferences regarding choice of end-stage renal disease treatment options. Am J Nephrol 2013; 37:359–369.
[5] 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.
[6] Culleton, B et al. Effect of Frequent NHD vs. CHD on Left Ventricular Mass and Quality of Life. JAMA 2007;11
[7] 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.
[8] ibid
[9] 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.

patient or caregiver education, and the communication of test results. We encourage CMS to move forward with these specific proposals in the FY17 Proposed Rule.

**Section II.I. Valuation of Specific Codes / Advance Care Planning**

The Alliance strongly supports the proposed creation of two new codes addressing advance care planning services: CPT code 99497 *(Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health professional; first 30 minutes, face-to-face with the patient, family member(s) and/or surrogate)*; and an add-on CPT code 99498 *(Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health professional; each additional 30 minutes (List separately in addition to code for primary procedure))*. We are pleased that these codes do not exclude those practitioners who are paid under the monthly capitation payment (MCP) for ESRD. Many patients living with advanced chronic kidney conditions face difficult decisions when looking toward the future and planning for the end of life, often despite a long history of interaction with the health care system. We strongly support providers being reimbursed for the additional time spent consulting with patients and their loved ones around these challenging and important decisions.

**Section II.J. Medicare Telehealth Services**

The Alliance thanks CMS for its proposed addition of MCP services for the treatment of ESRD to the Medicare telehealth list: CPT codes 90963 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); 90964 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2–11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); 90965 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); and 90966 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older).

Although, as the agency recognizes, these services are related to home dialysis, and a patient's home is not yet an authorized originating site for telehealth, we agree that many components of these services would be furnished from a designated originating site and, therefore, can be furnished via telehealth. When the patient can substitute a telehealth visit for a face-to-face interaction, they are more likely to realize the benefits of home dialysis. Therefore, we fully support the addition of CPT codes 90963 – 90966 to the list of Medicare telehealth services.

We note that in order for the home dialysis community to further benefit from such additions to the telehealth list, Congress would have to act to make the home or non-hospital based dialysis facility an originating site for the provision of dialysis. The addition of the home as an

originating site should not incur any appreciable increase in program spending, as Medicare would be reimbursing for a telehealth visit that replaces an in-person visit with a physician. Originating sites are currently statutorily designated in section 1834(m)(4)(C) of the Social Security Act. To that end, a number of bills have been introduced this Congress that would make these changes, including the Medicare Telehealth Parity Act of 2015 (H.R. 2948),[10] which designates the home as an originating site, and the Chronic Kidney Disease Improvement in Research and Treatment Act of 2015 (H.R. 1130),[11] which designates the facility as an originating site. The Alliance is encouraged by lawmakers' interest in ensuring that home dialysis patients can reap the benefits of emerging telehealth technologies, and hopes that CMS will continue to work with us as these bills move forward to encourage this progression.

*Monthly Face-to-Face Requirement*

In addition, the Alliance respectfully requests that CMS consider revising the provision in the Medicare Claims Processing Manual (Manual) that requires a monthly face-to-face visit as a prerequisite for a physician or practitioner to receive the monthly capitated payment (MCP) with respect to a home dialysis patient. In Chapter 8, § 140.1.1 of the Manual, CMS states that the "MCP physician (or practitioner) must furnish at least one face-to-face patient visit per month for the home dialysis MCP service." The Manual goes on to provide that Medicare contractors "may waive the requirement for a monthly face-to-face visit for the home dialysis MCP service on a <u>case by case</u> basis, for example, when the nephrologist's notes indicate that the physician actively and adequately managed the care of the home dialysis patient throughout the month." *(Emphasis added)*. Although the Manual language allows a physician or practitioner to request a waiver for the monthly requirement, the current process is administratively burdensome and must be done for each patient, each month.

The statute governing ESRD payments does not require this monthly face-to-face visit, nor do CMS regulations. Rather, Section 1881(b)(3)(B) of the Social Security Act provides generally that the Medicare payment with respect to payments for physicians' services furnished to ESRD patients shall made:

> "on a comprehensive monthly fee or other basis (<u>which effectively encourages the efficient delivery of dialysis services and provides incentives for the increased use of home dialysis</u>) for an aggregate of services provided over a period of time (as defined in regulations)." *(Emphasis added)*.

The specific monthly face-to-face requirement was discussed and finalized, effective January 1, 2011, in CMS's CY 2011 Physician Fee Schedule Final Rule.[12] In the CY 2011 Final Rule, CMS stated that "we believe this [monthly face-to-face] requirement reflects appropriate, high quality medical care for ESRD patients being dialyzed at home and generally would be

[10] See Section 2(b)(2).
[11] See Section 203.
[12] 75 Fed. Reg. 73170, 73295 (Nov. 29, 2010).

consistent with the current standards of medical practice."[13] Almost five years have passed since CMS implemented this requirement. Given recent advances in home dialysis, as well as technological advances in the provision of remote monitoring services, practitioners can now effectively monitor stable home dialysis patients without the need for monthly face-to-face visits.

We propose that CMS allow for a physician, clinical nurse specialist, nurse practitioner, or physician's assistant to request, with respect to a patient who so chooses, a patient-specific waiver of periodic in-person visit requirements for a patient receiving home dialysis services. CMS could require the waiver to include documentation supporting active and adequate care of the specific patient and patient consent. We believe it would be appropriate for such a patient-specific waiver, once granted, to remain in effect until CMS withdraws the waiver approval. Furthermore, CMS should require, for patients with respect to whom a waiver applies, that the patient see their physician or practitioner at least once every three consecutive months, and to be assessed, via remote monitoring, at least once per month. These requirements would ensure that only patients who are stable and who do not require a monthly in-person examination would qualify for the waiver.

Lawmakers have shown an interest in expanding access to home dialysis and enhancing patient choice in this manner. The Medicare Telehealth Parity Act (H.R. 2948), referenced on the previous page, amends §1881(b)(3) of the Social Security Act to create a patient-specific waiver to allow eligible professionals to waive the monthly face-to-face requirement in favor of a monthly assessment performed via telehealth if the patient chooses, so long as a patient visits with his / her provider in-person at least once every three consecutive months.[14]

Regular interaction with a medical professional is critical for home dialysis patients. However, we believe that in certain circumstances, with respect to medically stable patients, requiring fewer in-person face-to-face encounters and allowing for the use of remote monitoring is medically appropriate and would reduce the administrative burden on practitioners and enable patients to avoid costly and time-consuming visits to hospitals and dialysis facilities. Finally, making such a change to the MCP requirements is consistent with the statutory language at section 1881(b)(3)(B) of the Act that states that the monthly payment should "encourage[] the efficient delivery of dialysis services and provide[] incentives for the increased use of home dialysis...."

As CMS remains apprised of advancements to improve care management for patients with chronic conditions, the Alliance encourages the agency to monitor the development and adoption of technologies that could improve care for patients on dialysis, including new technologies that link patients on dialysis with their practitioners to improve patient safety and treatment. Success in this area could form the basis for changes in dialysis care as well as Medicare policy.

[13] Id.
[14] See Section 2(e).

**Section III.I. Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System**

CMS proposes to remove "Hemodialysis Adequacy" and "Peritoneal Dialysis Adequacy" in the CY 2016 PFS proposed rule. In both cases, CMS indicates that each measure represents a clinical concept that does not add clinical value to PQRS, and that eligible professionals (EPs) consistently perform on this measure with performance rates close to 100 percent, suggesting no gap in care. The Alliance is concerned that the elimination of these measures will diminish accountability for providers caring for home patients. While the current rates of performance are encouraging, the existing measures of adequacy are not sufficiently defined to ensure that patients benefit, as they should, from the accountability demanded by the PQRS.

**Section III.M. Value Based Payment Modifier and Physician Feedback Program**

The Alliance supports CMS's efforts to implement the value-based payment modifier (VM) to increase the transparency of health care quality information and to assist providers and beneficiaries in improving medical decision-making and health care delivery. We also appreciate the acknowledgement that it is important to make adjustments for differences in beneficiary characteristics that impact health and cost outcomes and that are outside of the control of the provider, as is often the case in patients with CKD and ESRD. While CMS did not outline a specific proposal, we support any action that helps to establish empirical benchmarks that account for high quality care in extremely high risk populations. We would look forward to reviewing the option of stratifying cost measure benchmarks so that groups and solo practitioners are compared to other groups and individual practitioners treating beneficiaries with similar risk profiles.

**Conclusion**

The Alliance appreciates the opportunity to provide comments to the Proposed Rule. We look forward to continuing to work with CMS to advance policies that support appropriate utilization of home dialysis.

Please feel free to contact Elizabeth Brooks at 202-466-8700 if you have any questions or would like additional details.

Sincerely,

Stephanie Silverman
Executive Director


## Submitting Members

**American Association of Kidney Patients**

**American Nephrology Nurses Association**

**American Society of Nephrology**

**American Society of Pediatric Nephrology**

**Baxter**

**The Cleveland Clinic**

**DaVita HealthCare Partners Inc.**

**DEKA Research and Development**

**Dialysis Clinic, Inc.**

**Dialysis Patient Citizens**

**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.**