



June 14, 2013

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Tavenner:

As you develop the annual rule to update the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) for fiscal year (FY) 2014, the Alliance for Home Dialysis encourages the Agency to ensure continued access to home dialysis by providing an appropriate update to the training add-on payment for home hemodialysis (HHD) that reflects the actual nursing and facility costs to provide the service.

The Alliance for Home Dialysis is a coalition of kidney dialysis stakeholders, representing patients, clinicians, providers and industry, that 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.

As you know, Congress and the Centers for Medicare and Medicaid Services (CMS) have consistently acknowledged the importance of ensuring beneficiaries with access to home dialysis. In fact, one of the Agency's stated goals in the implementation of the new ESRD payment system was to "encourage patient access to home dialysis"¹ and to "make home dialysis economically feasible and available to the ESRD patient population."²

HHD is an important treatment option that offers significant clinical benefits because it allows for more frequent and/or longer lasting dialysis sessions. For instance, studies have demonstrated that more frequent hemodialysis results in quicker recovery time after treatment and fewer side effects³; improved cardiac status⁴ and survival rates⁵; and increased opportunity for rehabilitation.⁶ Additionally, HHD offers significant quality of life advantages, including greater autonomy and flexibility in dialysis scheduling, and reduced dependence on transportation. However, today, only 10% of U.S. dialysis

¹ 75 Fed. Reg. 49,030, 49,058 (Aug. 12, 2010).

² *Id.* at 49,060.

³ 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.

⁴ Culleton, B et al. Effect of Frequent NHD vs. CHD on Left Ventricular Mass and Quality of Life. *JAMA* 2007;11

⁵ 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

⁶ 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>.

patients receive treatment at home, with less than 2% of patients receiving HHD.⁷ Additionally, less than a quarter of dialysis centers are certified to offer HHD.⁸

The Alliance believes that one of the barriers to achieving appropriate utilization of HHD is the up-front investment in nursing and other resources that are necessary to create and nurture a HHD program for Medicare beneficiaries. In fact, a recent paper published in the Clinical Journal of the American Society of Nephrology identified inadequate payment for training as a barrier to centers providing greater access to HHD.⁹

Significant training is involved in preparing a HHD patient to dialyze at home and the ESRD Conditions of Coverage require that home training services must be provided by an experienced registered nurse (RN). The one-on-one HHD training service performed by RNs is essential to supporting beneficiaries; however, it is very time- and resource intensive. Additionally, during HHD training the RN is responsible for teaching both the training patient and a care-partner during each session.

The Alliance believes that there is significant disparity between the reimbursement that the facility receives for HHD training and the actual cost to provide a HHD training session. By way of example, according to a 2012 NxStage Survey of 13 large home training programs representing 170 HHD patients trained in 2011, HHD training required, on average, 103 nursing hours per patient (averaging 18.7 training days at 5.6 hours per session.) Under the ESRD PPS for FY2013, the per-training session add-on payment is approximately \$33.44,¹⁰ which represents one hour of nursing time.¹¹ In practice, given the 5.6 hours of RN labor required to provide a patient and care-partner training for HHD, the current training add-on results in a grossly inadequate \$6.00 hourly wage rate.

The Alliance is concerned that without an appropriate update to the add-on training payment for HHD, combined with reductions to the base payment required under ATRA, facilities may not be able to invest in the development and ongoing management of home dialysis programs, and therefore patients will face even greater challenges accessing this important treatment option.

The Alliance believes that an update to the training-add on should be made in a manner as to not impact patients on other treatment modalities. To that end, it is our understanding that current law does not require an adjustment to the home dialysis training add-on to be accomplished in a budget neutral way. The Medicare statute (SSA § 1881(b)(14)(D)) mandates certain adjustments to the ESRD PPS and provides CMS with the discretion to create other adjustments. The statute is silent as to whether adjustments to the ESRD PPS after the program has been implemented must be budget neutral, which is in contrast to the statutorily established budget neutrality for the initial establishment and phase-in to the ESRD PPS. Read as a whole, we believe that the statute does not require a new or augmented home dialysis training add-on adjustment to be accomplished in a budget neutral fashion.

⁷ U S Renal Data System, USRDS 2012 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, MD, 2012.

⁸ Dialysis Facility Compare <http://www.medicare.gov/Download/DownloaddbInterim.asp>

⁹ 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

¹⁰ CMS Publication 100-04, Medicare Claims Processing Manual, Chapter 20.1 (*Calculation of the Basic Case-Mix Adjusted Composite Rate and the ESRD Prospective Payment System Rate*), p. 29. <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf>

¹¹ 75 Fed. Reg. at 49,063.

We understand that this is a fiscally challenging environment, but the Alliance believes that in order to meet the Congressional intent of providing and encouraging access to home dialysis an update to the add-on training payment is necessary and we encourage CMS to use its current authority to do so.

Thank you for your consideration of this request. We look forward to working with you to advance policies that support appropriate utilization of home dialysis. Please do not hesitate to contact Amy Redl at amy@homedialysisalliance.org with any questions.

Sincerely,

A handwritten signature in black ink that reads "Stephanie Silverman". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Stephanie Silverman
Executive Director

cc. Laurence Wilson, Director, Chronic Care Policy Group



Signing Alliance Members

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